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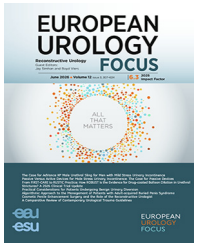

Benign Prostatic Obstruction

Water Vapor Thermal Therapy with Rezūm Versus Combination Pharmacotherapy for Male Lower Urinary Tract Symptoms due to Benign Prostatic Obstruction: 1-Yr Results From a Prospective, Multicenter, Pragmatic Randomized Controlled Trial (VAPEUR-RCT)

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Abstract

Background and objective: The VAPEUR randomized controlled trial compared Rezūm water vapor thermal therapy (WVTT) with combination pharmacotherapy (CP; alpha-blockers plus 5-alpha-reductase inhibitors) in sexually active men with symptomatic benign prostatic obstruction (BPO).

Methods: Overall, 151 men were randomized to WVTT (n = 75) or CP (n = 76). Primary endpoints changed from baseline to 1 yr in the International Prostate Symptom Score (IPSS) and Male Sexual Health Questionnaire (MSHQ) score. Secondary endpoints included surgical/medical treatment for recurring symptoms, ≥4 points IPSS worsening (ΔIPSS ≥4), and catheterization beyond 90 d post-procedure.

Key findings and limitations: At 1 yr, IPSS improvement was greater with WVTT than CP (mean difference −4.6 points; 97.5% confidence interval [CI] −7.6 to −1.6; p < 0.001), with mean improvements of 10.8 ± 6.8 versus 6.2 ± 7.7 points, respectively. MSHQ scores remained stable with WVTT (+1.1 ± 16.9) and CP (−5.2 ± 16.4). Superiority in preserving sexual function was not demonstrated with multiple imputation. Quality of life (QoL) improvement was greater with WVTT (−2.7 ± 1.8 vs −1.8 ± 2.0; p = 0.01). WVTT resulted in lower rates of surgical retreatment (1.3% vs 9.2%), ΔIPSS ≥4, (2.7% vs 13%) and post-

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90 d catheterization (0% vs 1.3%), but higher pharmacological retreatment (12% vs 1.3%; combined: hazard ratio = 0.52, CI 0.25–1.1, p = 0.08). Treatment related adverse events (AEs) were more frequent with WVTT (40% vs 28%; serious AEs, 12% vs 1.3%), largely procedure related; at 1 yr, 93% were resolved in WVTT versus 60% (25/42) in CP.

Conclusions and Clinical Implications: At 1 yr, WVTT provides superior symptom relief and greater QoL improvement versus CP, while preserving sexual function. These findings support WVTT as an effective alternative to CP.

ADVANCING PRACTICE

What does this study add?

This study is the first randomized clinical trial to compare water vapor thermal therapy (WVTT) to combination pharmacotherapy (CP) for the treatment of symptomatic benign prostatic obstruction in sexually active men. WVTT resulted in symptom relief superior to CP, with greater improvement in International Prostate Symptom Score-Quality of Life. Sexual function was preserved with WVTT, and surgical retreatment rates at 1 yr were low; however, transient procedural adverse events need to be weighed against lingering medication side effects. This trial provides crucial evidence to inform the consideration of a clinical practice shift from pharmacotherapy to WVTT.

Clinical Relevance

Combination pharmacotherapy (CP) is standard first-line management for bothersome LUTS due to benign prostatic obstruction, yet real-world adherence is poor and sexual side effects are common. Minimally invasive water vapour thermal therapy (WVTT) has never before been studied against CP head-to-head in a randomized trial. In this pragmatic multicentre trial, Rezūm WVTT nearly doubled the symptomatic improvement seen with combination pharmacotherapy at 1 year and produced greater gains in quality of life, alongside substantially lower rates of surgical re-treatment and better preservation of erectile and ejaculatory function. This symptomatic and functional advantage came with a higher burden of treatment-related adverse events, though these were largely procedural, transient, and resolved within the first year, in contrast to the more persistent sexual and general side effects associated with continued medication use. Notably, WVTT was not free of medication dependence. Roughly one in eight patients still required pharmacological re-treatment, indicating that thermal therapy does not eliminate the need for adjunctive drug therapy in all men. These results give clinicians randomized-trial evidence to reframe WVTT as potentially a first-line alternative to medication, not merely a bridge to surgery, for men who want to avoid the cumulative burden of long-term pharmacotherapy, provided they are counselled on the short-term risk of a procedural complication in exchange for durable symptom control. Given the 1-year follow-up and a CP re-treatment rate higher than historical trials would predict, longer-term follow-up is needed to determine whether the early advantages of WVTT are sustained and whether it meaningfully alters the trajectory of disease progression compared with medical therapy. Associate Editor: Dean S. Elterman.

Patient Summary

In this study we looked at two treatments of benign prostatic obstruction: a minimally invasive procedure called WVTT and CP (medications). One year after treatment, men who had the procedure felt much better and reported better quality of life than those taking medications. Their sexual function was also preserved. This suggests WVTT is a good option for men who prefer a treatment option other than medications.

1. Introduction

Benign prostatic obstruction (BPO) may result in bothersome lower urinary tract symptoms (LUTS) that impair quality of life (QoL). Current European guidelines recommend lifestyle modifications and alpha blockers (ABs) for mild to moderate LUTS, with addition of 5 alpha reductase inhibitors (5 ARIs) as combination pharmacotherapy (CP) when symptoms persist [1]. Although CP improves LUTS, peak flow rate (Qmax), and clinical progression, it comes with higher rates of adverse events (AEs) [2] and poor treatment adherence (<30% at 1 yr) [3]. For men dissatisfied with medications but wary of invasive surgeries such as transurethral resection of the prostate (TURP), minimally-invasive Rezūm water vapor thermal therapy (WVTT) provides effective symptom relief while preserving sexual function [4,5]. While WVTT and CP have been retrospectively compared in a propensity score analysis of two separate trials [6], they have not previously been evaluated in a randomized trial.

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The VAPEUR randomized controlled trial (RCT) compares WVTT to standard CP for treating BPO symptoms in sexually active men refractory to AB monotherapy. This pragmatic trial examines whether WVTT treatment can provide symptomatic relief superior to CP, while preserving sexual function. Surgical retreatment, worsening in International Prostate Symptom Score (IPSS) by 4 points, need for LUTS/BPO medications and catheterization beyond 90 d post-procedure were also evaluated.

2. Patients and methods

2.1. Design

VAPEUR RCT is a post market, multicenter, prospective, open label randomized trial comparing WVTT with standard CP in sexually active men with BPO refractory to alpha blocker monotherapy (Clinicaltrials.gov NCT04838769). The study was conducted with ethics approval, informed consent, and in accordance with the Declaration of Helsinki, ISO 14155, and local regulations.

2.2. Participants

Sexually active men aged ≥45 yr refractory to AB therapy were included if they had documented IPSS score ≥13, Qmax ≤15 ml/sec (minimum voided volume: ≥150 ml), post-void residual (PVR) ≤250 ml within 6 mo prior to enrollment, and prostate volume (PVol) ≥30 ml within 3 mo prior to enrollment; and if they were willing and able to answer all Male Sexual Health Questionnaire (MSHQ) questions; sexual activity status at enrollment was self-reported. Patients were excluded if they had prior surgical treatment for BPO; increased risk of bleeding; genitourinary or other pelvic cancer; neurogenic lower urinary tract dysfunction, neurologic conditions affecting bladder function, or presence of implantable neuromodulator or transcutaneous electrical nerve stimulation device for bladder overactivity; active urinary tract infection (UTI); structural or anatomic issues of the genitourinary system preventing surgery; high risk for general anesthesia, or comorbidities that would increase their risk of participating; ongoing use of 5-ARIs; unstable dosage of beta-blockers, anticonvulsants, antispasmodics, or antihistamines (unless 6-mo stable dosage was documented). Anticholinergic or cholinergic medication, estrogen, drug-producing androgen suppression, or anabolic steroids, and beta-3 adrenergic agonists were allowed up to 2 mo prior to enrollment.

2.3. Interventions

Patients were randomized 1:1 (block sizes: 2 and 4), stratified by site and baseline PVol (<40 vs ≥40 ml), with allocation concealed until randomization across 21 centers (20 in France, one in Australia). Standard WVTT procedure was performed within 45 d (up to 90 d) from randomization under ambulatory general anesthesia. Patients received prophylactic antibiotics based on personal risk factors and local microbiological guidance. All patients were discharged the same day with an in-dwelling urinary catheter (dwell time, 5.8 ± 2.20 d, mean ± SD). Catheter removal was performed per each center's standard of care. Alpha-blocker use was allowed up to 34 d post-procedure. Patients randomized to CP continued their AB and added a 5-ARI within 7 d post-randomization. This comparator was chosen as it reflects real-world clinical practice. Medication adherence was self-reported, defined as having taken at least 85% of doses since the previous follow-up visit.

2.4. Primary and secondary endpoints

The three primary endpoints were change in IPSS from baseline to 12 mo assessed for non-inferiority (Endpoint 1) and superiority (Endpoint 2a), and change in MSHQ total score assessed for superiority (Endpoint 2b).

The secondary endpoint was a composite defined by the occurrence of the following: surgical treatment of BPO symptoms; introduction of new medication to treat BPO symptoms; urinary retention requiring urinary catheterization after 90 d post-treatment; and IPSS worsening from baseline by ≥4 points. Components from the secondary endpoint were derived from the Medical Therapy of Prostatic Symptoms (MTOPS) study [7] (IPSS increase from baseline by ≥4 points) and outcomes clinically relevant to WVTT treatment (surgical or medical retreatment, need for extended catheterization). Survival time for subjects without an endpoint event was censored at the last study visit with available IPSS data.

Uroflowmetry outcomes (Qmax and PVR) were evaluated at baseline, 3-, 6- and 12-mo post-procedure. PVol, measured by transrectal ultrasound or magnetic resonance imaging (MRI) and prostate-specific antigen (PSA) levels at baseline and 12 mo were also collected. AEs and device-related serious AEs were reported.

2.5. Sample size and statistical analysis

Non-inferiority for Endpoint 1 was assessed using a one-sided two-sample t test (α = 2.5%; margin = 3 points). Endpoints 2a and 2b were tested for superiority using one-sided two-sample t tests (α = 1.25%), and the secondary endpoint using a one-sided log-rank test (α = 1.25%). Familywise error (2.5%) was controlled through hierarchical gatekeeping with Bonferroni adjustment; testing of Endpoints 2a and 2b was contingent on demonstrating Endpoint 1. No further multiplicity adjustments were made for other endpoints.

The sample size was determined based on IPSS change, with 150 subjects (75 per arm) providing 90% power to demonstrate non-inferiority at a 2.5% one-sided α, assuming a 7.5 standard deviation and a 1-point treatment difference in favor of WVTT.

All study endpoints were analyzed using available cases. For the primary endpoints, last observation carried forward (LOCF) and multiple imputation by chained equations (MICE) were applied for missing data. MICE was performed separately for each treatment arm and included arm-specific variables to account for therapy differences; imputed values outside IPSS or MSHQ permissible ranges were Winsorized to the scale limits (20 imputations). Additional pre-specified analyses used t tests for continuous endpoints without formal hypothesis testing. Changes described occurred at 12 mo unless noted. Results are reported for intent-to-treat patients, which includes all randomized subjects.

Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. Patient's demographics and treatment details

Between September 2021 and December 2024, 151 patients were randomized (75 WVTT, 76 CP), with 68 and 65 patients, respectively, completing 1 yr follow-up (Supplementary Fig. 1). Mean age was 64 ± 8 yr, PVol ranged from 27–150 ml. Median lobe was treated in 63% of WVTT patients (Table 1). Total treatment number per prostate was 5.1 ± 2.1 (mean ± SD; Supplementary Table 1). Most CP patients received dutasteride with similar distribution across alpha-blockers. A 1 yr, 75% of CP patients reported ≥85% medication adherence.

3.2. Primary endpoints

International Prostate Symptom Score. IPSS scores improved at 3 mo, with greater improvement after WVTT

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Table 1 – Patient demographics and procedural characteristics

Variables	WVTT (*n* = 75)	CP (*n* = 76)
Age (yr)	64.6 ± 7.7 (75) (45.0, 65.0, 78.0)	63.8 ± 8.9 (76) (45.0, 64.0, 84.0)
BMI (kg/m^2)	26.7 ± 3.7 (74) (18.1, 26.3, 37.3)	26.5 ± 3.5 (75) (19.4, 26.1, 37.0)
Prostate volume	62.1 ± 24.3 (75) (27.6, 59.4, 126.4)	62.4 ± 24.0 (76) (26.6, 57.0, 149.5)
Prostate volume distribution		
<40 ml	19% (14/75)	13% (10/76)
40–80 ml	61% (46/75)	67% (51/76)
>80 ml	20% (15/75)	20% (15/76)
PSA (ng/dL)	3.5 ± 2.4 (*n* = 75) (0.3, 2.9, 9.4)	3.3 ± 2.5 (*n* = 76) (0.4, 2.8, 9.2)
Combination pharmacotherapy post-randomization		
Tamsulosin + Dutasteride	NA	34% (25/73)
Silodosin + Dutasteride	NA	33% (24/73)
Alfuzosin + Dutasteride	NA	26% (19/73)
Doxazosin + Dutasteride	NA	1.4% (1/73)
Silodosin + Tamsulosin + Dutasteride[a]	NA	2.7% (2/73)
Alfuzosin + Tamsulosin + Dutasteride[a]	NA	1.4% (1/73)
Alfuzosin[b]	NA	1.4% (1/73)
Procedural characteristics		
Treatments per ml of prostate volume	0.09 ± 0.03 (72) (0.03, 0.08, 0.16)	N/A
Average procedure length (in min)	13.8 ± 16.6 (72) (2.0, 10.0, 121.0)	N/A
Median lobe treated	63% (45/72)	N/A

5-ARI = 5-alpha-reductase inhibitor; BMI = body mass index; CP = combination therapy; PSA = prostate-specific antigen; NA = not applicable; SD = standard deviation; WVTT = water vapor thermal therapy.
* Data provided as mean ± SD (*n*), (min, median, max).
[a] Patients received Combodart as 5-ARI.
[b] One patient did not tolerate the addition of a 5-ARI due to allergy and remained on alpha-blocker only.

maintained through 12 mo (−10.8 ± 6.8 vs −6.2 ± 7.7, WVTT vs CP; Fig. 1A, Supplementary Table 8). IPSS improvement was superior after WVTT compared to CP in both LOCF and MICE analysis (MICE mean difference, −6.5 points, 97.5% confidence interval [CI]: −9.8 to −3.2, $p < 0.0001$; Supplementary Table 3). At 12 mo, more patients achieved "mild symptoms" (IPSS score 0–7) in WVTT versus CP (33/63 vs 8/57, Fig. 2).

Male Sexual Health Questionnaire. MSHQ scores were maintained from baseline through 12 mo after WVTT (mean increase: 1.1 ± 16.9 points) and CP (−5.2 ± 16.4 at 1 yr; Fig. 1B). Results were sensitive to the missing-data handling approach, with superiority being shown with LOCF (mean difference, 6.5 points, 97.5% CI: 0.7–12.3, $p = 0.006$), but not MICE (mean difference, 7.0 points, 97.5% CI: −0.8 to 14.7, $p = 0.022$; Supplementary Table 4).

3.3. Secondary endpoints

At 12 mo, surgical treatment for BPO symptoms occurred in 1 WVTT and 7 CP patients (one photolaser vaporization of the prostate [PVP] in WVTT; four Rezūm-WVTT, two PVPs, and one bipolar transurethral vaporization in CP; Table 2). One CP patient required catheterization beyond 90 d. Nine WVTT patients required LUTS/BPO medications (six AB, two anticholinergic, and one CP; Supplementary Table 5). IPSS worsening (≥4 points) was less frequent with WVTT than CP (two vs 10 patients). The two cases of worsening IPSS in WVTT had 5-point increases at 3 mo, but a 6- and 8-point decrease from baseline to 6 mo. The hazard ratio was 0.52 (CI: 0.25 to 1.1; $p = 0.08$) for the composite secondary endpoint.

3.4. Other endpoints

PVol decreased similarly in both groups (WVTT −12.4 ± 15.6 ml; CP −10.1 ± 19.5 ml; Table 2). PSA changes after WVTT and CP were +0.1 ± 1.9 and −0.9 ± 1.9 ng/ml, respectively.

IPSS-QoL. IPSS-QoL improvement was greater in WVTT versus CP at all time points (−2.7 ± 1.8 vs −1.8 ± 2.0 at 1 yr, $p = 0.01$; Fig. 1C).

Uroflowmetry. Qmax showed greater improvement after WVTT at 3 mo (+5.8 ± 7.0 ml/s in WVTT vs +1.3 ± 4.5 in CP; $p < 0.0001$). Improvement was maintained through 12 mo in WVTT and improved gradually in CP (Fig. 1D). PVR decreased significantly more with WVTT than CP at 12 mo (−33.2 ± 71.7 ml vs 1.5 ± 70.2 ml, respectively; $p = 0.018$; Fig. 1E).

AEs. Treatment-related AEs occurred more frequently with WVTT than CP (30/75 vs 21/76; Table 3), including six serious procedure related events in WVTT, namely: urinary retention (2), bacterial prostatitis (1), prostatic obstruction (1), persistent LUTS (1) (all within 3 mo post-procedure), and anejaculation (1), which occurred 135 d post-procedure. All but one (anejaculation) resolved by 1 yr. In WVTT, most AEs occurred within 90 d post-procedure (44/50 events). The most frequent events were urinary retention, LUTS symptoms and hematuria (20/75 patients), infections (14/75), and erectile dysfunction (2/75). Six patients had bacterial prostatitis (one serious and five non-serious; Supplementary Table 6). All but one patients received prophylactic antibiotics on surgery day. In five cases, prostatitis occurred in the few days post-procedure (1–9 d later) and resolved rapidly with antibi-

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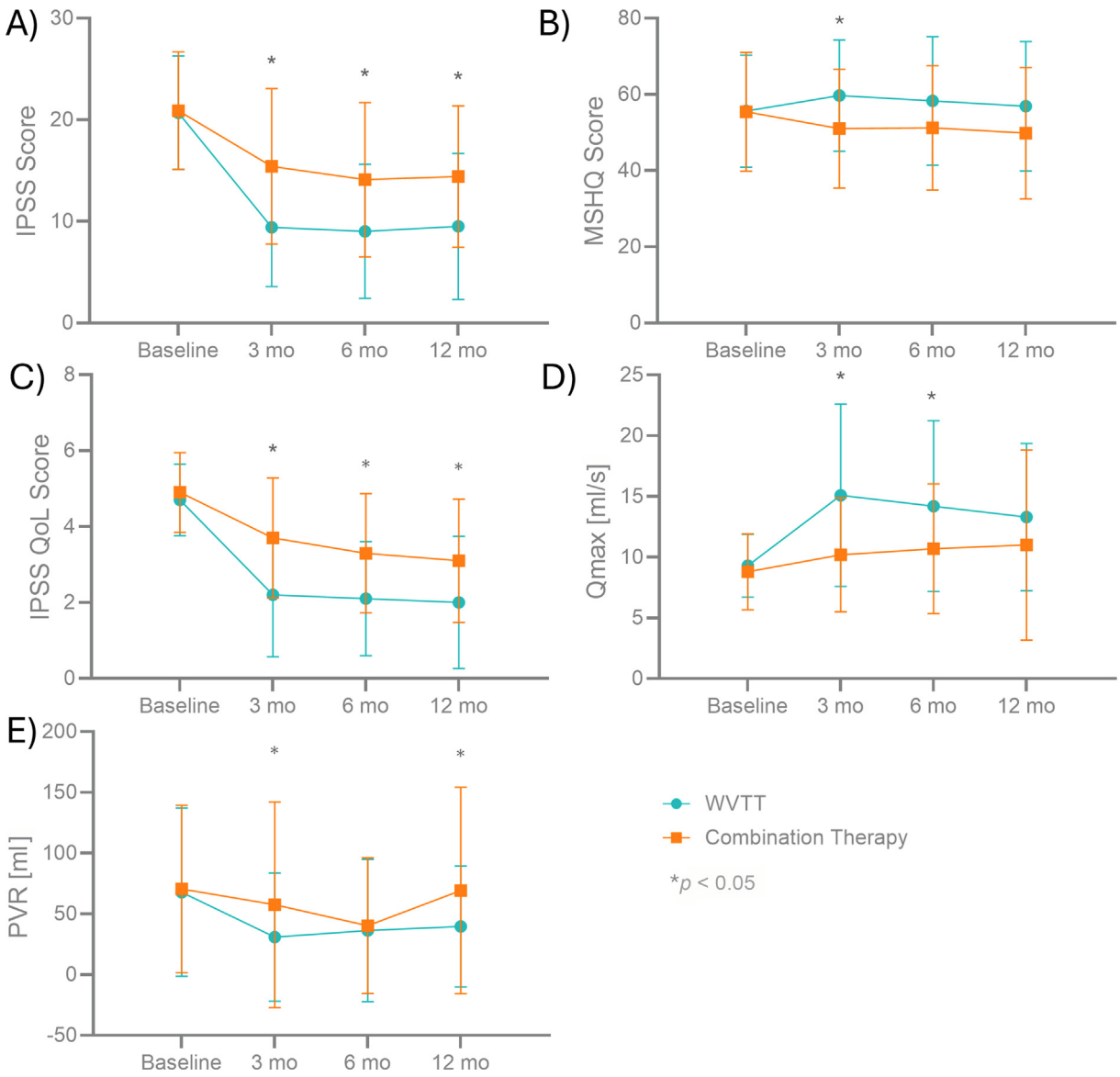

Fig. 1 – Changes over time in IPSS (A), MSHQ (B), IPSS-QoL (C), Qmax (D), and post-void residual (PVR) (E). Results are presented as mean ± SD. IPSS = International Prostate Symptom Score; MSHQ = Male Sexual Health Questionnaire; QoL = Quality of life; Qmax = peak flow rate; SD = standard deviation; WVTT = water vapor thermal therapy.

otics administration without additional intervention or longer hospitalization. Despite antibiotic prophylaxis, one patient presented with a UTI 10 d post-procedure treated with levofloxacin. Thirty-nine days post-procedure, the patient was hospitalized for severe prostatitis, treated with ceftriaxone, and ciprofloxacin. The patient was discharged 5 d later with no further complications. Supplementary Table 7 shows treatment details for infections (all Clavien-Dindo II).

In the CP group, 27/42 events occurred within 3 mo after starting treatment and included erectile dysfunction (10), loss/decreased libido (8), ejaculation failure (1), hyperplasia progression (1), gynecomastia (2), testicular and scrotal pain (1 each), dysuria (1), pollakiuria (1), urinary flow decrease (1) (Supplementary Table 5). General AEs were also reported, including asthenia (3), fatigue (1), dizziness (3), headaches (1), abdominal pain (1), palpitations (1), increased weight (1), and pruritus (1).

4. Discussion

The VAPEUR results show that Rezūm-WVTT yields superior IPSS improvements compared to CP and preserves sexual function, with low surgical retreatment rates at 1 yr.

IPSS. IPSS decreased by about 54% 1 yr after WVTT (from 20.7 to 9.5 points), consistent with previously-reported IPSS improvements (37–59% [5,8–11]). In CP, IPSS improved by 6.2 points (from 20.9 at baseline to 14.4), consistent with

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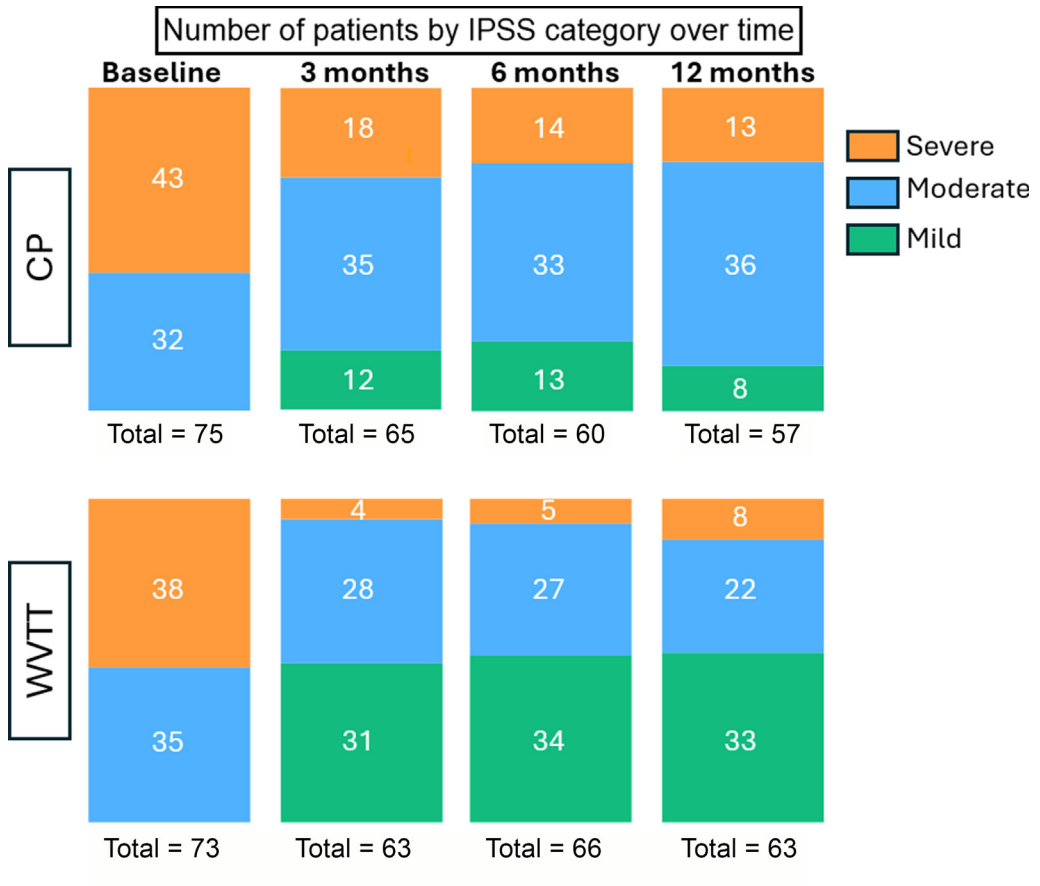

Fig. 2 – Patient distribution by IPSS symptoms categories at baseline, 3, 6, and 12 mo. CP = Combination pharmacotherapy; IPSS = International Prostate Symptom Score; WVTT = Water vapor thermal therapy. Symptom categories are as follows: IPSS score 0–7, mild symptoms; 8–19, moderate symptoms; 20–35, severe symptoms.

Table 2 – Components of secondary endpoint and prostate volume change at 12 mo

Component	WVTT (*n* = 75)	CP (*n* = 76)
Surgical retreatment for LUTS/BPH	1.3% (1/75)[a]	9.2% (7/76)[b]
Urinary retention requiring urinary catheterization after 90 d post-treatment	0.0% (0/75)	1.3% (1/76)
IPSS increase from baseline by ≥4 points	2.7% (2/75)	13% (10/76)
Introduction of a new drug agent to treat LUTS/BPH	12% (9/75)	1.3% (1/76)
Prostate volume change from baseline to 12 mo (ml)	−12.9 ± 15.1 (*n* = 61) (−56.8, −10.8, 28.8)	−10.3 ± 19.8 (*n* = 56) (−62.5, −9.3, 33.6)
PSA change from baseline to 12 mo	0.1 ± 1.9 (*n* = 63) (−5.0, −0.1, 5.6)	−0.9 ± 1.9 (*n* = 59) (−6.2, −0.8, 7.1)

BPH = benign prostatic hyperplasia; CP = combination therapy; IPSS = International Prostate Symptom Score; LUTS = lower urinary tract symptoms; PSA = prostate-specific antigen; PVP = photolaser vaporization of the prostate; SD = standard deviation; WVTT = water vapor thermal therapy.
* Data presented mean ± SD; (min, median, max).
Surgical retreatment type:
[a] One PVP.
[b] Four Rezūm-WVTT, two PVPs, and one bipolar transurethral vaporization of the prostate.

the 5.6-point decrease reported in the CombAT study; in CombAT, patients had lower baseline IPSS (16.6 points) compared to patients in VAPEUR, resulting in greater relative improvement than observed here [2]. In the MTOPS study, patients taking a doxazosin/finasteride combination experienced a 9.9-point decrease; IPSS for the matched WVTT cohort decreased by 11.2 points at 1 yr [6]. The VAPEUR results are consistent with these previous observations, directly demonstrating WVTT superiority in symptom improvements compared to CP. Both groups experienced improvement in IPSS-QoL, with greater improvement in WVTT versus CP (−2.7 vs −1.8 points, $p = 0.01$).

Sexual function. While 1-yr MSHQ scores were not statistically different between groups, sexual function side effects were more common with CP. Libido was affected in 11% of CP patients, and none with WVTT. Nine cases of de novo erectile dysfunction occurred in CP versus two in WVTT. Prior studies confirmed ejaculatory function preser-

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Table 3 – Adverse events summary

	WVTT (*N* = 75)		CP (*N* = 76)		*p* value
	Number of events	Subjects with event	Number of events	Subjects with event	
Adverse event	53	43% (32)	42	29% (22)	0.08
Serious adverse event	9	12% (9)	2	1.3% (1)	0.008
Led to death	0	0% (0)	0	0.0% (0)	NA
Treatment-related	50	40% (30)	40	28% (21)	0.11
Action taken	39	35% (26)	21	16% (12)	0.008
Medication	30	31% (23)	11	7.9% (6)	<.001
In-patient hospitalization	8	11% (8)	1	1.3% (1)	0.015
Catheterization	9	12% (9)	1	1.3% (1)	0.008
Procedure to treat benign prostatic obstruction	5	6.7% (5)	3	2.6% (2)	0.24
Other action taken	1	1.3% (1)	10	9.2% (7)	0.03
Outcome					
Not recovered/Not resolved	4	4.0% (3)	13	11% (8)	0.12
Recovering/resolving	0	0% (0)	2	1.3% (1)	0.3
Resolved	48	41% (31)	25	20% (15)	0.004
Resolved with sequelae	1	1.3% (1)	0	0.0% (0)	0.3
Death	0	0% (0)	0	0.0% (0)	NA
Unknown	0	0% (0)	2	1.3% (1)	0.3

CP = combination therapy; NA = not applicable; WVTT = water vapor thermal therapy.
*Adverse events are considered treatment-related if they are reported as possibly, probably, or causally related to treatment. For the WVTT treatment arm, adverse events can be related to the delivery device, generator, or procedure.

vation after WVTT, making it advantageous over TURP [10,12]. Results from VAPEUR support a favorable sexual function profile with WVTT than CP in sexually active men.

Urodynamics (uroflowmetry). Qmax improved in both groups, with greater early improvement after WVTT narrowing over time as CP continued to improve, consistent with MTOPS findings [6]. Meanwhile, PVR improved with WVTT, remaining stable with CP. In MTOPS versus Rezūm [6], doxazosin resulted in PVR's greatest improvement; finasteride alone had limited impact on PVR, and combining doxazosin+finasteride did not yield greater PVR improvement than doxazosin alone. While men in VAPEUR take different ABs and 5-ARIs than in MTOPS, the results are consistent with this prior observation [6]. Modest changes in uroflowmetry and PVol, with clear symptom improvements after WVTT raise questions about its mechanism of action. Lack of pressure flow studies limits interpretation, since bladder outlet obstruction and detrusor underactivity were not directly quantified. Elastography or diffusion-based MRI could further clarify tissue elasticity changes.

Medication usage post-WVTT. Overall, 88% of patients were medication-free at 12 mo; 12% resumed mainly alpha-blockers (Supplementary Table 4). Although the pivotal trial reported 1.5% medical retreatment at 1 yr [5], real-world rates are higher (17.4–31%), consistent with VAPEUR [13,14]. Medical retreatment is reported across benign prostatic hyperplasia procedures, including TURP [15]. Although surgeries should ideally not result in medication usage, the clinical reality is that some patients still need them for symptom management, even after TURP [16].

Surgical treatment after CP. Surgical treatment rate at 1 yr after CP observed here (9.2%) largely exceeds historical data from MTOPS (1% at 4 yr) [7]. Because patients in VAPEUR are more inclined toward intervention at enrollment and minimally-invasive therapies integrate into patient care, retreatment threshold may be lower than in the early 2000's, when MTOPS results were published.

AEs. WVTT was associated with more AEs than CP, most occurring within 3 mo and largely resolved by 1 yr (49/53 events: 92%). In contrast, CP-related events occurred throughout treatment, with fewer resolved at 1 yr (23/42: 55%). WVTT events were primarily procedure related, whereas CP events mainly affected sexual function and general wellbeing. Serious AEs and infection rates were high (12% and 19%, respectively); whereas most infections were easily treated with antibiotics (Supplementary Table 7), risks associated with the procedure are not negligible. Patient counseling should address the tradeoff between transient, potentially serious procedural AEs with greater symptoms and QoL improvement versus milder, persistent medication-related effects.

This study has limitations. Sources of bias include open-label design, which may have influenced subjective outcome and AE reporting, and self-reported medication adherence, as perceived adherence bias may have affected reported outcomes, IPSS in particular. Reduced enrollment following Rezūm reimbursement during the COVID pandemic prompted a redesign to an IPSS noninferiority study to preserve statistical power; this occurred after 148 patients were enrolled but before any outcomes review or comparative analyses. Comparing device and pharmacologic therapies was challenging because medication-derived endpoint (IPSS worsening $\geq$4 points) did not reflect WVTT recovery; indeed, two patients with IPSS worsening at 3 mo experienced sustained symptom relief by 6 mo. European guidelines recommend CP for prostate size $\geq$40 ml; however, there was no association between <40 ml prostate sizes and primary endpoint results (Supplementary Table 9). Finally, the follow-up duration is short (1 yr).

5. Conclusion

In conclusion, 1-yr results from this study support WVTT as an alternative to CP. Longer-term data is needed to confirm the benefits of WVTT in reducing disease progression.

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The principal and co-principal investigators, Romain Mathieu and Evanguelos Xylinas, and the corresponding author, Jean-Nicolas Cornu, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Appendix A. Supplementary data

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