

Aquablation versus TURP: 5-year outcomes of the WATER randomized clinical trial for prostate volumes 50-80 mL

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Introduction: To report the 5-year efficacy and safety of Aquablation compared with transurethral resection of the prostate for the management of lower urinary tract symptoms secondary to benign prostatic hyperplasia in men with prostate volumes 50-80 mL.

Materials and methods: In a large double-blinded, multicenter, and prospective randomized controlled trial, 96 randomized men with 50-80 mL prostates who underwent Aquablation or transurethral prostate resection were prospectively identified for subgroup analysis. Follow up was performed for up to 5 years. The primary efficacy endpoint was the reduction in International Prostate Symptom Score (IPSS) at 6

months. The primary safety endpoint was the occurrence of Clavien-Dindo (CD) postoperative complications grade 1 persistent and grade 2 or higher at 3 months.

Results: Both groups had comparable baseline characteristics. Reduction in IPSS score was significantly higher in the Aquablation group across 5 years of follow up (-14.1 vs. -10.8, $p = 0.02$). The Aquablation group achieved a significantly lower rate of CD1P and CD2 or higher events at 3 months follow up (risk difference of -23.1%). Among recorded adverse events, de novo postoperative ejaculatory dysfunction was notably lower in Aquablation (risk difference of -21.9%), while the risk of bleeding remained similar after 6 months. The surgical and medical retreatment rate at 6 months was also lower in Aquablation (risk difference of -14.4%).

Conclusions: In the 50-80 mL prostate volume subgroup, Aquablation yields superior long-term symptom relief and lower complication rates than standard transurethral resection, with notably lower rates of ejaculatory dysfunction. This further supports the adoption of Aquablation for men with medium-sized prostates.

Key Words: prostatic hyperplasia, LUTS, TURP

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Introduction

While transurethral resection of the prostate (TURP) remains the gold standard treatment modality used by urologists for the management of lower urinary tract symptoms (LUTS) in men with prostate volumes < 80 mL,^{1,2} it can sometimes be associated with complications such as bleeding, clot retention, and postoperative ejaculatory dysfunction.^{3,4} Specifically, retrograde ejaculation is quite common following TURP, with reported rates up to and beyond 60%.⁵

Recently, alternatives to TURP as the reference standard of treatment have gained popularity. These range from non-ablative to ablative surgical modalities, such as laser enucleation, photovaporization, and robotic waterjet ablation therapy.⁶

The recent addition of robotic waterjet ablation therapy (RWT/Aquablation) provides a surgical modality with a low risk of sexual side effects and a short learning curve.⁷ The double-blind, randomized controlled trial comparing Aquablation versus TURP (WATER)⁸ solidified Aquablation's position in the American Urological Association's benign prostatic hyperplasia (BPH) surgical guidelines.^{1,9} The WATER trial demonstrated Aquablation to be a safe and effective alternative to TURP, with non-inferior outcomes maintained across 5 years of follow up.¹⁰ However, a persistent limitation from prospective Aquablation data is the lack of long-term outcomes on symptom improvement durability.

To date, no long-term superiority efficacy endpoints (≥ 5 years) have been reported for Aquablation in studies focusing specifically on medium-sized (50-80 mL) prostates. In this pre-specified subgroup analysis of the WATER cohort, we sought to further describe the 5-year efficacy and safety of Aquablation compared to standard treatment (TURP) in medium-sized prostates.

Materials and methods

Study design and participants

Our study is a pre-specified subgroup analysis of the WATER trial (Waterjet Ablation Therapy for Endoscopic Resection of prostate tissue; NCT02505919), which is an FDA-approved, double-blinded, multicenter, international, and prospective randomized controlled trial comparing the safety and efficacy outcomes of Aquablation therapy and TURP for the management of symptomatic BPH. Ethics board approval was obtained at each participating site and informed patient consent was obtained for enrollment.

In the WATER trial, the inclusion criteria were: ages 45-80, prostate volume 30-80 mL as evidenced by transrectal ultrasound, and moderate-to-severe symptoms as indicated by an IPSS ≥ 12 and a Qmax of < 15 mL/s. Exclusion criteria were: history of prostate or bladder cancer, neurogenic bladder, bladder calculus, clinically significant bladder diverticulum, active infection, treatment for chronic prostatitis, previous prostate surgery, severe cardiovascular disease, diagnosis of urethral stricture, bladder neck contracture or meatal stenosis, damaged external urinary sphincter, stress incontinence, post-void residual > 300 mL or urinary retention, or use of self-catheters. Patients treated with anticoagulant or anti-platelet medication who could not suspend the medication before surgery were excluded as well.

Randomization and intervention

This is a subgroup analysis of the 5-year outcomes from the WATER cohort, in which 181 patients with prostate sizes 30-80 mL were randomly assigned to surgical treatment with Aquablation or TURP in a 2:1 fashion (as illustrated in Figure 1). Randomization was stratified by site and baseline IPSS. Monopolar or bipolar TURP was performed according to current standards of care. Aquablation was performed using the AquaBeam Robotic System (PROCEPT BioRobotics, Redwood City, CA, USA) as previously described by experts.^{8,11} Patients underwent the procedure under general or spinal anesthesia in the operating theatre. Real-time visualization of prostate anatomy was achieved via transrectal ultrasound, which allowed surgeons to segment the targeted prostatic tissue's contour on the operating console. Surgical ablation of prostatic adenoma was executed endoscopically using a high-pressure water jet by a robotic system under the surgeon's guidance. Hemostasis was achieved at the surgeon's discretion with either electrocautery (n = 24) or low-pressure inflation of a Foley catheter balloon in the prostate fossa (n = 38). Postoperative management was similar across groups and all patients received bladder irrigation.

Data collection

Both study participants and follow up investigators were blinded to the assigned treatment for up to 3 years. Patients were followed up at 1 week (phone call), 1, 3, 6, and 12 months, then annually for up to 5 years. Functional outcomes were compared between both groups using subjective voiding parameters, including the IPSS and QoL questionnaires. Objective voiding parameters, such as Qmax and PVR, were measured via uroflowmetry. Sexual and ejaculatory function was assessed using the MSHQ-Ejd short

form and IIEF-5 questionnaire. The analysis for sexual and ejaculatory function via MSHQ-EjD was only completed for men who were sexually active at baseline. Other measures included prostatic specific antigen (PSA) serum levels and prostate volume in mL as evidenced by transrectal ultrasound. Adverse events were investigated at every follow up using the Clavien-Dindo Classification system for postoperative complications. Retreatment rates were likewise recorded and defined as needing subsequent BPH medication (alpha-blockers, 5 α -reductase inhibitors, or a combination of both) or surgical reintervention.

Clinical endpoints and subgroup analysis

The initial study sample was calculated to achieve 80% power for establishing superiority in safety and non-inferiority in efficacy. Differences in clinical outcomes at every follow up were tested for statistical significance using Student's t-test. Overall changes in outcome measurements across 5 years of follow up were tested for significance using repeated measures ANOVA. Differences in risk of complications were tested for significance using Fisher's exact test. A p < 0.05 was considered statistically significant.

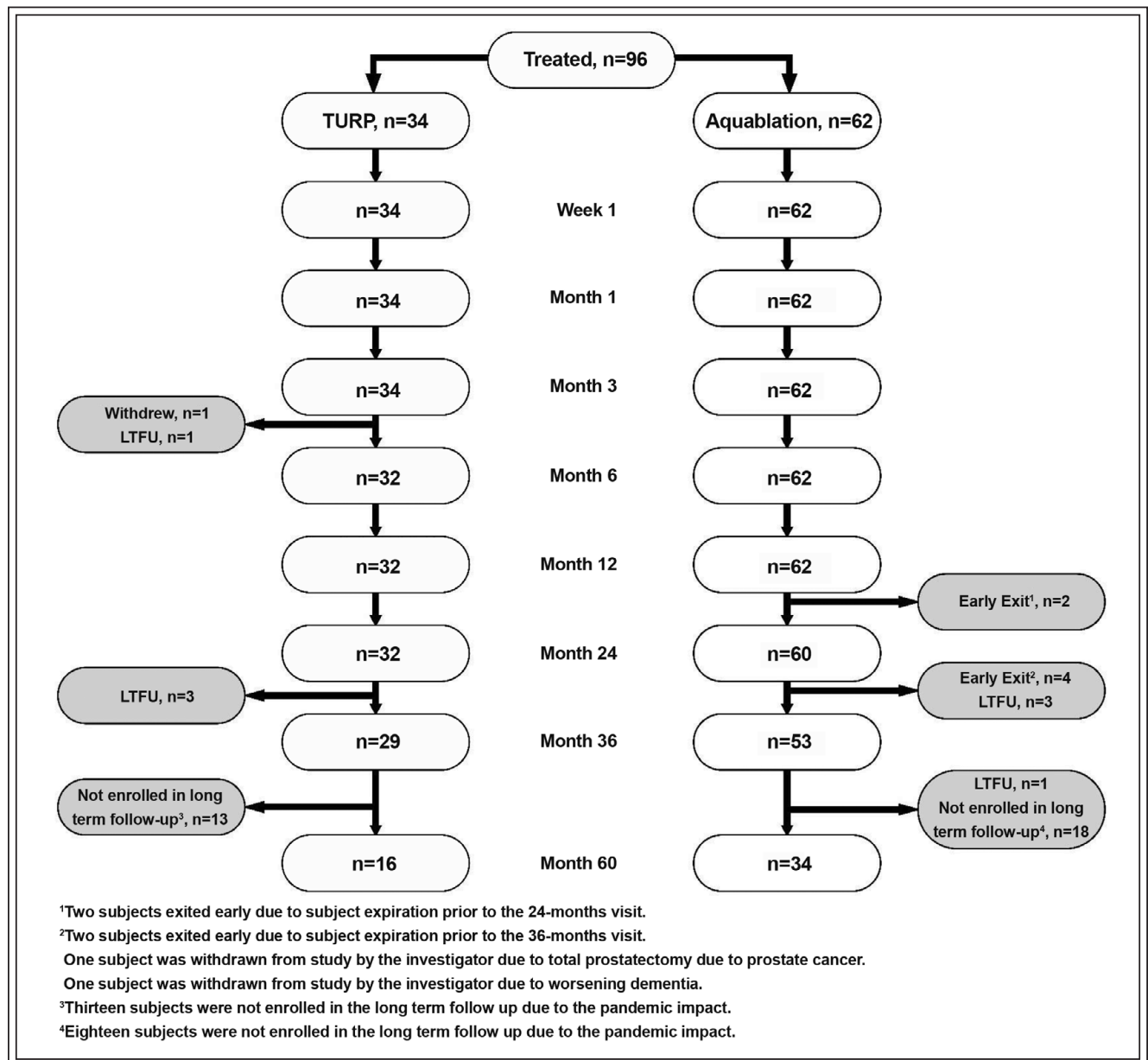


Figure 1. CONSORT diagram (randomized patients and follow up). LTFU = lost to follow up.

TABLE 1a. **Baseline and operative characteristics. Study groups showed similar baseline demographics and clinical presentation. Operative times were similar in both groups**

Visit		Aquablation n = 62	TURP n = 34	p value
Demographics and clinical presentation				
Age (years)	Mean ± SD	67.9 ± 6.8	66.4 ± 7.2	0.2893
	Median	68.5	66.3	
	Min, Max	53, 80	50, 82	
Body mass index	Mean ± SD	28.5 ± 3.9	28.2 ± 4.5	0.7181
	Median	27.9	27.2	
	Min, Max	21, 40	19, 41	
Prostate size TRUS (mL)	Mean ± SD	66.4 ± 9.2	61.7 ± 8.8	0.0181
	Median	67.0	57.9	
	Min, Max	51, 80	50, 78	
Obstructive median lobe		67.7%	70.6%	0.8216
PSA (ng/mL)	Mean ± SD	4.5 ± 3.1	3.9 ± 2.5	0.3709
	Median	4.0	3.5	
	Min, Max	0, 15	1, 10	
Baseline questionnaires				
IPSS score	Mean ± SD	23.3 ± 6.0	20.9 ± 6.2	0.0667
	Median	24.0	20.5	
	Min, Max	12, 35	12, 32	
IPSS QoL	Mean ± SD	4.8 ± 1.0	4.9 ± 0.9	0.8330
	Median	5.0	5.0	
	Min, Max	2, 6	2, 6	
Sexually active		80.6% (50/62)	85.3% (29/34)	0.7807
MSHQ-EjD	Mean ± SD	8.2 ± 3.8	8.1 ± 4.0	0.9102
	Median	9.0	8.0	
	Min, Max	1, 15	1, 15	
IIEF-5	Mean ± SD	16.1 ± 7.0	13.3 ± 9.1	0.1325
	Median	18.0	13.0	
	Min, Max	4, 25	1, 25	
Antithrombotic use				
	Anticoagulant	3.2% (2/62)	2.9% (1/34)	1.0000
	Antiplatelet/NSAID including high dose Aspirin	14.5% (9/62)	8.8% (3/34)	0.5299
	Aspirin	19.4% (12/62)	14.7% (5/34)	0.7807
	Any of above	37.1% (23/62)	26.5% (9/34)	0.3674
BPH medication use				
	Alpha blocker	66.1% (41/62)	61.8% (21/34)	0.8237
	5-ARI	21.0% (13/62)	29.4% (10/34)	0.4540
	Alpha blocker/5-ARI	17.7% (11/62)	26.5% (9/34)	0.4309
	Any of above	69.4% (43/62)	64.7% (22/34)	0.6547
Operative characteristics				
Procedure time (minutes)	Mean ± SD	42.0 ± 18.9	37.8 ± 14.5	0.2604
	Median	36.0	34.0	
	Min, Max	18, 96	19, 71	

The primary efficacy endpoint was the reduction of the IPSS at 6 months. Secondary efficacy endpoints were defined as changes in the IPSS, IPSS QoL, MSHQ-EjD, and IIEF-5 scores, as well as Qmax and PVR across 5 years of follow up. The primary safety endpoint was the occurrence of Clavien-Dindo postoperative complications grade 1 persistent (CD1P) and grade 2 (CD2) or higher at 3 months. The distribution of adverse events for up to 6 months was also recorded as additional data.

Results

Study groups and baseline characteristics

Ninety-six men from the 50-80 mL subgroup were included in the statistical analysis: 62 participants in the Aquablation group and 34 participants in the TURP group. The randomization and follow up process is illustrated in Figure 1. Baseline and preoperative characteristics between both groups are presented in Table 1a. There was a statistically significant but non-clinically meaningful difference between groups in terms of baseline prostate size, with the Aquablation group having larger baseline prostate volumes (66.4 ± 9.2 vs. 61.7 ± 8.8 mL, $p = 0.018$).

Operative time

Intraoperatively, there was no significant difference between the Aquablation and TURP groups for mean operative time (42.0 ± 18.9 vs. 37.8 ± 14.5 minutes, $p = 0.26$; Table 1a).

Functional outcomes

Functional outcomes are illustrated in Figure 2. The IPSS score significantly improved 1 month after surgery for patients treated with Aquablation compared to TURP (-13.1 ± 8.1 vs. -9.3 ± 7.9 , $p = 0.028$). Repeated measures ANOVA revealed that this difference was maintained across 5 years of follow up (-14.1 ± 8.5 vs. -10.8 ± 9.0 , $p = 0.020$). Likewise, there was a significant improvement in terms of Qmax for patients treated with Aquablation at the 36-month visit when compared with TURP (13.9 ± 16.2 vs. 7.3 ± 6.2 mL/sec, $p = 0.015$), as well as in QoL at 3 months (-3.4 ± 1.8 vs. -2.3 ± 1.8 , $p = 0.0040$). However, these findings were not consistent across 5 years of follow up. Moreover, there were no significant differences between both groups in terms of PVR throughout the entire follow up period, ($p > 0.050$).

Ejaculatory and erectile function

There was no significant difference in the frequency of men who were sexually active at baseline between

the two surgical groups (80.6% in Aquablation vs. 85.3% in TURP, $p = 0.78$). There were no significant changes in ejaculatory function, as assessed by the MSHQ-EjD, in the Aquablation group, while the TURP group reported an average decline in MSHQ-EjD scores across all follow up time points as shown in Figure 2 (0.6 ± 4.8 vs. -2.1 ± 5.0 , $p = 0.0095$). There was no significant difference between both groups in terms of erectile function at different follow up visits, as measured by changes in the IIEF-5 score ($p = 0.10$).

PSA and prostate volume

Postoperative measurements of serum PSA levels showed no significant difference between the Aquablation and TURP groups across 5 years of follow up ($p > 0.05$). Aquablation patients had slightly larger prostates at baseline, Table 1a, and at 3-month follow up (43.0 ± 15.9 vs. 30.5 ± 10.6 , $p < 0.0001$). However, comparing pre and postoperative volumes shows that prostate volume reduction in Aquablation patients was lower than TURP (-23.9 ± 15.2 vs. -31.3 ± 15.4 , $p = 0.0278$), as seen in Table 1b. The average prostate volume reduction in the Aquablation group was -35.2%, compared to -49.1% in the TURP group.

Surgical and medical retreatment rates

The risk of patients needing a secondary BPH therapy for up to 5 years due to recurrent LUTS, defined as needing subsequent BPH medication or surgical intervention, was 3.2% and 17.6% for Aquablation and TURP respectively, with a risk difference of -14.4% (95% CI [-2.29, -30.4]). To further breakdown, the surgical re-intervention for Aquablation and TURP was 1.6% and 3.1%, respectively. The return to BPH medical therapy (alpha-blockers, 5 α -reductase inhibitors, or a combination of both) for Aquablation and TURP was 1.6% and 15.6%.

Adverse events

Aquablation patients displayed lower occurrences of CD1P and CD2 or higher postoperative complications at 6 months compared to TURP (21.0% vs. 44.1%, risk difference = -23.1%; 95% CI [-28.9, -15.5]). The distribution of adverse events is characterized in Table 2. When looking at CD1P events, 1.6% ($n = 1$) of men in the Aquablation group had ejaculatory dysfunction, compared to 23.5% ($n = 8$) in the TURP group (risk difference = -21.9%; 95% CI [-32.5, -10.7]). No patient suffered from de novo erectile dysfunction or urinary incontinence in either group. We found no significant differences between both groups when isolating the occurrence of CD2, CD3a, CD3b, and CD4 adverse events ($p > 0.05$). Among serious complications, one patient (1.6%) from the Aquablation group had urinary retention

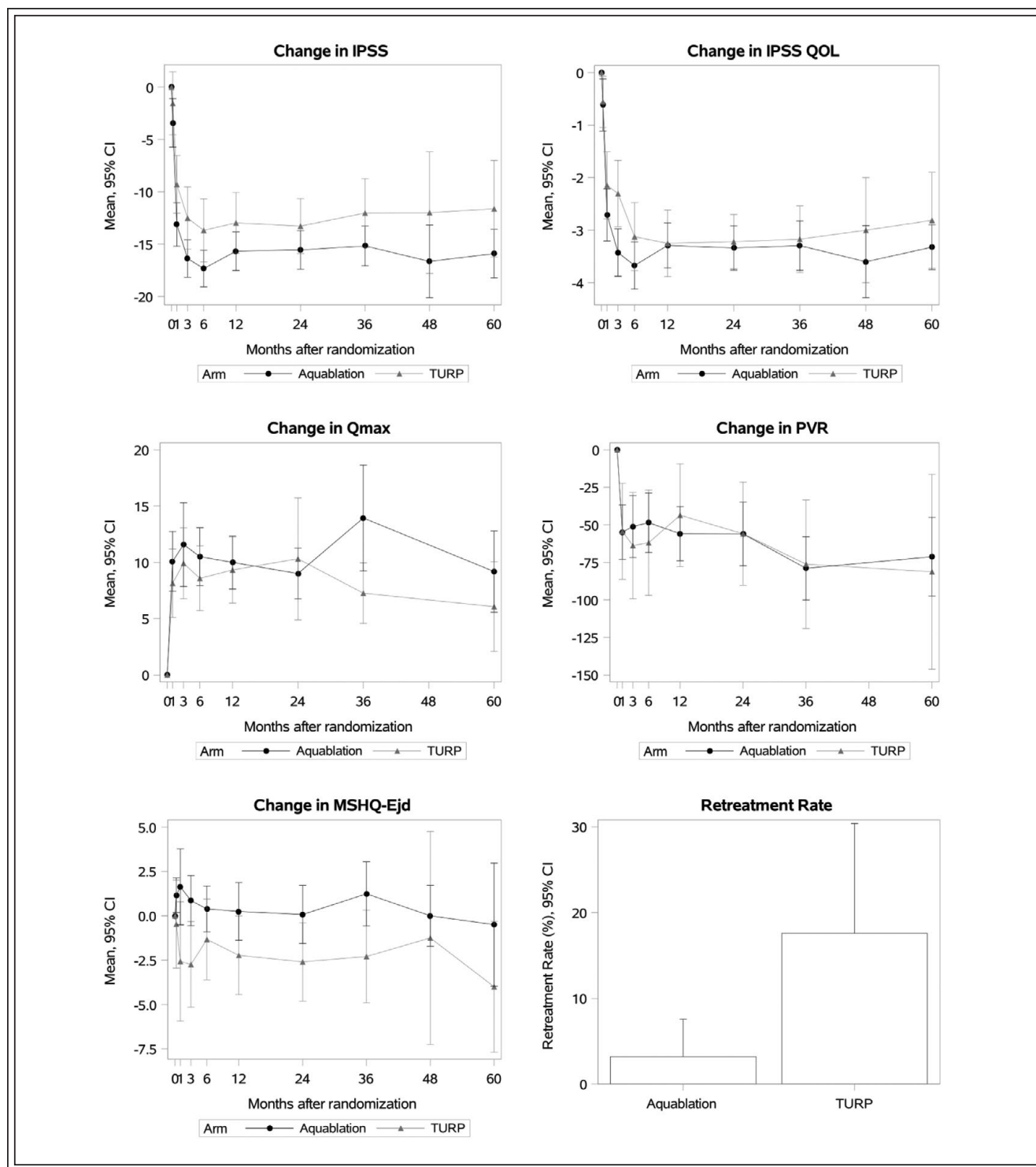


Figure 2. Changes in IPSS total score, IPSS QoL, Qmax, PVR, MSHQ-EjD, and retreatment rates over 5 years of follow up for men undergoing Aquablation therapy vs. TURP for LUTS related to BPH. Aquablation patients showed better IPSS reduction and no decline in MSHQ-EjD. Statistical significance was tested using Student’s T-test at each timepoint and using repeated measures ANOVA to assess overall differences in functional symptom scores across 5 years. Retreatments were defined as needing further BPH medication (alpha-blockers, 5 α -reductase inhibitors, or both) or surgical reintervention postoperatively.

TABLE 1b. Prostate size reduction. Aquablation patients had a mean prostate size difference of -35.2% postoperatively compared to -49.1% for TURP patients. This further characterizes Aquablation as a tissue-conservative treatment despite its superior functional outcomes

Visit	Aquablation n = 62	TURP n = 34	p value
Prostate size TRUS (mL)			0.0181
Mean \pm SD	66.4 \pm 9.2	61.7 \pm 8.8	
Median	67.0	57.9	
Min, Max	51, 80	50, 78	
Prostate size change (mL) at 3 months			0.0278
Mean \pm SD	-23.9 \pm 15.2	-31.3 \pm 15.4	
Median	-23.8	-31.9	
Min, Max	-73, 30	-59, -2	
Prostate size change (%) at 3 months			-
Mean \pm SD	-35.2 \pm 21	-49.1 \pm 20.7	

TABLE 2a. Distribution of events at 6 months of follow up categorized by Clavien-Dindo grades (possibly, probably, or definitely related)

	AQUA (#AE)	AQUA (#Pts)	TURP (#AE)	TURP (#Pts)	p value (Fisher's exact test)
Distribution of events					
Clavien-Dindo Grade 2	13	16.1% (10/62)	8	20.6% (7/34)	0.5878
Bladder pain/spasm	3		2		
Non-urologic	2		1		
Pain	1		1		
Urinary tract infection	5		2		
Urinary urgency/ frequency/difficulty/ leakage	2		2		
Clavien-Dindo Grade 3a	2	3.2% (2/62)	2	5.9% (2/34)	0.6129
Bleeding	1		1		
Stricture or adhesions	1		1		
Clavien-Dindo Grade 3b	1	1.6% (1/62)	2	5.9% (2/34)	0.2853
Bleeding	0		1		
Stricture or adhesions	0		1		
Urinary retention	1		0		
Clavien-Dindo Grade 4	0		0		

TABLE 2b. Distribution of Clavien-Dindo grade 1 persistent events at 6 months of follow up (possibly, probably, or definitely related)

Endpoint	Aquablation n = 62	TURP n = 34	Rate difference (95% CI)
Ejaculatory dysfunction rate	1.6% (1/62)	23.5% (8/34)	-21.9% (-32.5 to -10.7%)
Erectile dysfunction rate	0	0	---

(CD3b), which was managed according to standard treatment. Two patients (5.9%) from the TURP group had urethral strictures or significant postoperative bleeding (CD3b) requiring a return to the OR for cauterization. No patient suffered from CD4 complications.

Discussion

In the original double-blind trial, Aquablation led to substantial improvements in BPH-related symptoms against the reference standard surgical treatment (TURP). Although the safety and efficacy of Aquablation have been demonstrated through several well-designed RCTs and meta-analyses, no study has specifically performed an in-depth look into the durability of Aquablation outcomes for medium-sized prostates up to 5 years. Our updated analysis at 5 years provides compelling evidence of the effectiveness of Aquablation compared to TURP in men with prostate volumes 50-80 mL. Aquablation led to significantly larger improvements in IPSS, lower surgical and medical retreatment rates, and no decline in MSHQ-EjD.

Our results are coherent with previous literature hinting at the higher consistency of outcomes provided by Aquablation in cases of medium-sized prostates and complex anatomy. A double-blinded randomized controlled trial demonstrated superior 6-month efficacy for Aquablation Therapy compared to TURP in patients presenting with a median lobe and prostate size 50-80 mL.¹² Our study also supplements previous evidence demonstrating the durability of Aquablation. However, international and multicentric studies only report consistent IPSS reduction after Aquablation up to 3 years of follow up, which further highlights the importance of our results.¹³⁻¹⁵

In the present analysis, men in the TURP arm reported a decline in postoperative MSHQ-EjD scores over 5 years of follow up. In comparison, Aquablation patients maintained their baseline ejaculatory function (Figure 2, change in MSHQ-EjD), further supporting current knowledge that an important advantage of Aquablation is its ability to preserve ejaculatory function after surgery.^{12,16} Indeed, anatomical studies demonstrated the involvement of critical landmarks (i.e., bladder neck, prostate tissue surrounding the verumontanum, ejaculatory ducts) in the preservation of antegrade ejaculation.^{17,18} TURP may target these structures more aggressively and indiscriminately during resection.¹⁹ We theorize that this partly explains the superiority of the Aquablation technology on 50-80 mL prostates, as past experiences of Aquablation in the clinical setting indicate its superiority at conserving

specific anatomical landmarks.^{6,20} Combining the benefits of real-time ultrasound imaging and robotic execution, the Aquablation system allows for better delineation of resection margins and more precise tissue removal. On a similar note, Table 1b shows that a lower prostate volume reduction was required in the Aquablation arm to achieve better functional outcomes. This may suggest its ability to target obstructive tissue without harming structures that are non-contributory to voiding and/or involved in ejaculation.

According to our analysis, the overall rates of adverse events up to 3 months postoperatively are lower with Aquablation compared to TURP. This is consistent with previous findings, which define Aquablation as having a better overall safety profile.^{8,21} Apart from being superior at preserving ejaculatory function, it is theorized that the safety benefits of Aquablation stem from the heat-free resection it provides. This sets it apart from traditional resective techniques by reducing thermal injury in the prostatic fossa. However, we cannot comment on the difference in safety endpoints between both groups with regard to specific Clavien-Dindo grades of complications because of the low overall occurrence of complications.

Weighing risks versus benefits, the present study demonstrates the superiority of Aquablation technology compared with TURP for prostates 50-80 mL. Conservation of ejaculatory function after Aquablation surgery is a significant finding of the present report. Our analysis has the merit of using international and multicentric data from a well-designed and powered, blinded, randomized controlled trial. Nevertheless, some limitations found within its design must be noted. First, the randomization yielded a statistically significant difference between both groups in baseline prostate size. A sensitivity analysis was performed using repeated measures ANOVA for the IPSS change endpoint at all follow ups while controlling for baseline prostate volume. The resulting outcome showed that baseline prostate volume had no impact on the validity of our conclusions. Additionally, the not insignificant loss to follow up at 5 years limits the generalizability of our findings. We acknowledge that the Covid-19 pandemic impacted the follow up numbers during years 4 and 5 of data collection. However, the follow up loss does not appear to disproportionately favor one surgical group or another. Additionally, the trial possessed a reasonable cohort at 5 years in comparison to other contemporary BPH studies.²² Nonetheless, the present study is to the best of our knowledge the first report demonstrating the superiority of the Aquablation technology in long-term efficacy endpoints in a targeted analysis for men presenting with prostate sizes 50-80

mL. Ultimately, further prospective, studies with even larger series of patients treated with Aquablation, with beyond 5 years of follow up, are warranted.

Conclusion

Both Aquablation and TURP are effective surgical treatments for symptomatic BPH in men presenting with prostate sizes 50-80 mL. Our subgroup analysis of the WATER trial showed that Aquablation Therapy yields better long-term efficacy and safety outcomes than TURP. Most notably, Aquablation is an effective intervention to improve LUTS while preserving ejaculatory function. This further supports the adoption of Aquablation over TURP for men with medium-sized prostates desiring preserved sexual function.

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Disclosures

Kussil Oumedjbeur and Kevin C. Zorn took the lead in analyzing the results and writing the manuscript. Data was provided by PROCEPT BioRobotics. All other authors provided critical feedback and helped shape the manuscript.

Naeem Bhojani, Dean Elterman, Brian T. Helfand, Vincent Misrai, Peter Gilling, Neil Barber, Mihir Desai, Alexis E. Te, Claus G. Roehrborn, and Kevin C. Zorn have or have had in the past a consulting agreement with PROCEPT BioRobotics. The remaining authors have no conflicts of interest to declare.

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