Three-year outcomes after Aquablation therapy compared to TURP: results from a blinded randomized trial

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Introduction: *To compare 3-year efficacy and safety after prostate resection with Aquablation therapy or transurethral resection of the prostate (TURP) for the treatment of lower urinary tract symptoms related to benign prostate hyperplasia (BPH).*

Materials and methods: *One hundred and eighty-one patients assigned to either Aquablation therapy or TURP were followed for 3 years postoperatively. Patients and follow up assessors were blinded to treatment. Assessments included International Prostate Symptom Score (IPSS), Male Sexual Health Questionnaire (MSHQ-EjD), International Index of Erectile Function (IIEF) and uroflow.*

Results: *Over 3 years of treatment, improvements in IPSS scores were statistically similar across groups. Mean 3-year improvements were 14.4 and 13.9 points in the Aquablation and TURP groups, respectively (difference of 0.6 points, 95% CI -3.3–2.2, p = .6848). Similarly, 3-year improvements in Qmax were 11.6 and 8.2 cc/sec (difference of 3.3 [95% CI -0.5-7.1] cc/sec, p = .0848). At 3 years, PSA was reduced significantly in both groups by 0.9 and 1.1 ng/mL, respectively; the reduction was similar across groups (p = .5983). There were no surgical retreatments for BPH beyond 20 months for either Aquablation or TURP.*

Conclusions: *Three-year BPH symptom reduction and urinary flow rate improvement were similar after TURP and Aquablation therapy. No subjects required surgical retreatment beyond 20 months postoperatively. (ClinicalTrials.gov number, NCT02505919).*

Key Words: Aquablation, BPH, TURP

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Introduction

Benign prostatic hyperplasia (BPH) commonly results in lower urinary tract symptoms (LUTS) related to bladder outlet obstruction. The prevalence of symptoms is high (42% of men over age 50) and increases with age.[1,2] If medical treatment fails to provide sufficient relief, many men seek surgical treatments.

Several options are available for the surgical treatment of BPH, ranging from non-ablative techniques to ablative (resective) techniques such as laser enucleation, photovaporization and standard electrocautery (TURP). Although resective procedures have high rates of symptom relief, they commonly cause sexual dysfunction.[3-7] Retrograde ejaculation after TURP may occur in over 2/3 of men.[8]

Aquablation therapy is a surgeon-planned, image-guided and robotically executed technique to resect prostate tissue using a high-velocity waterjet. Previously we reported 6-month results of a double-blinded prospective randomized controlled trial comparing outcomes after either Aquablation therapy or TURP.[9] Herein we report safety and efficacy at 3 years.

Materials and methods

WATER (NCT02505919) is a prospective double-blinded multicenter international randomized trial, as previously described.[9] Seventeen sites participated, 12 in the United States, 3 in the United Kingdom and 2 in Australia/New Zealand. The study, which enrolled subjects between October 2015 and December 2016, included men age 45-80 years with a prostate size between 30-80cc (measured with transrectal ultrasound), moderate-to severe LUTS as indicated by an International Prostate Symptom Score (IPSS[10]) ≥ 12, and a maximum urinary flow rate (Qmax) < 15 mL/s. Men were excluded if they had a history of prostate or bladder cancer, neurogenic bladder, bladder calculus or clinically significant bladder diverticulum, active infection, treatment for chronic prostatitis, diagnosis of urethral stricture, meatal stenosis or bladder neck contracture, damaged external urinary sphincter, stress urinary incontinence, post void residual > 300 mL or urinary retention, use of self-catheterization, or prior prostate surgery. Men taking anticoagulants or on bladder anticholinergics or with severe cardiovascular disease were also excluded. The control group, TURP using electrocautery, represents the gold standard for the surgical treatment of moderate-to-severe BPH for patients within this volume range. All participants provided informed consent prior to participating.

Subjects were assigned at random (2:1 ratio) to Aquablation therapy or TURP. Assignments, stratified by study site and baseline IPSS score category with random block sizes, were obtained prior to treatment using a web-based system.

Aquablation therapy was performed using the AquaBeam Robotic System (PROCEPT BioRobotics, Redwood Shores, California, USA).[11] Post-Aquablation hemostasis was achieved using either low-pressure inflation of a Foley balloon catheter in the prostatic fossa or focal, non-resective, electrocautery.[12] All subjects received post-procedure bladder irrigation per standard institutional practice. TURP was performed according to standard practice.

All follow up assessments were administered by a blinded research team (physician and coordinator). Visits included IPSS, uroflow measurements, quality of life, adverse events and blinding assessment. The latter asked subjects to guess (at each visit) which treatment was received. Reasons for perceived unblinding were collected.

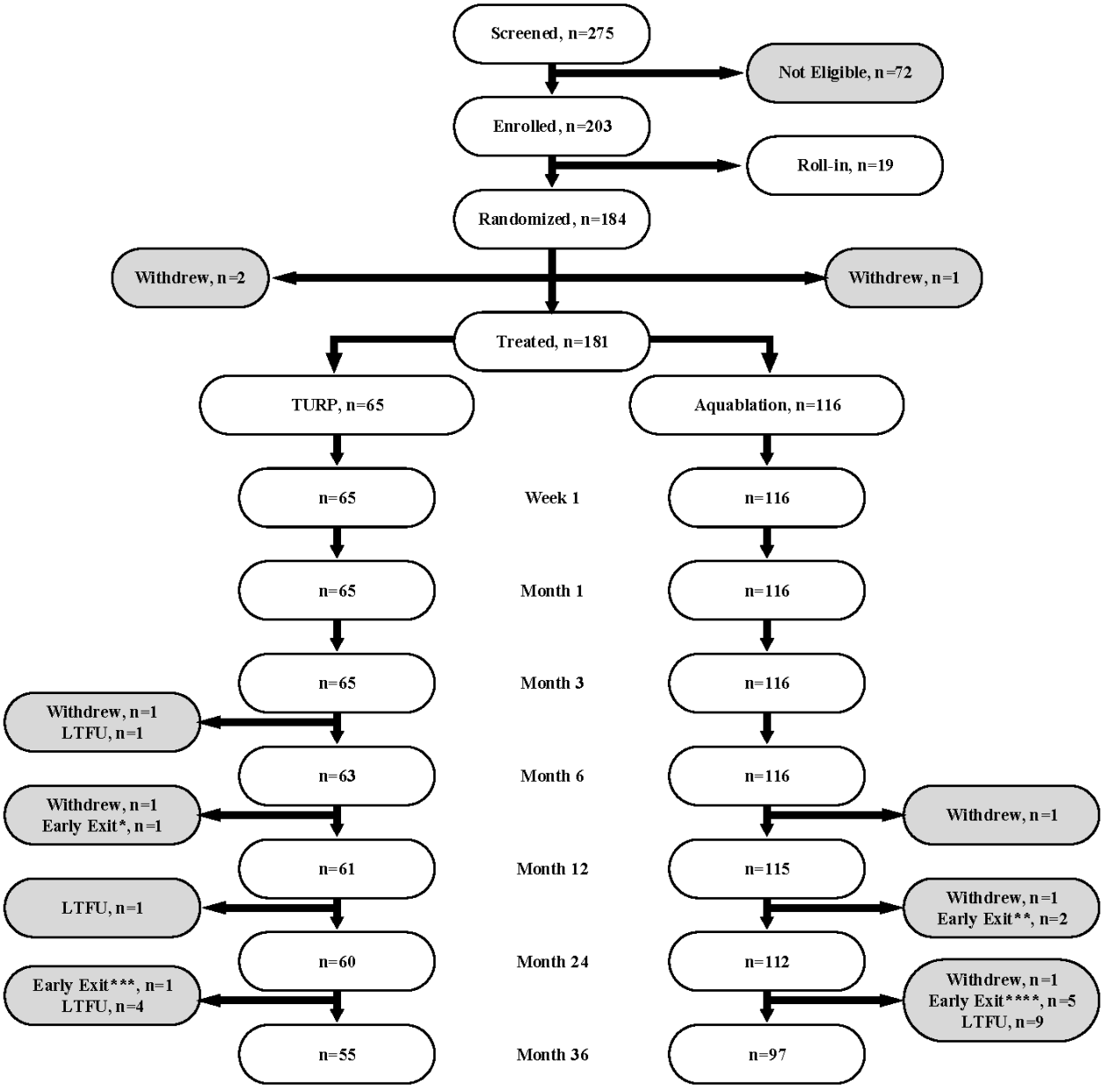
The study's primary efficacy endpoint, non-inferiority for the 6-month change in IPSS, was considered a success, as previously reported.[9] The focus herein is 3-year efficacy outcomes. For continuous outcomes, changes at postoperative time points were compared at once using repeated measures analysis of variance. The primary safety endpoint, the occurrence of procedure-related complications rated as Clavien-Dindo[13] grade 1 persistent or higher, showed superiority as reported previously. Events to month 12 were also reported previously. The focus of analysis herein is events occurring between months 24 and 36; differences in event rates were compared using Fisher's test. Note that per the study protocol, adverse events occurring after month 12 were not adjudicated by the CEC. All analysis uses events as reported by the site.

Study data were 100% verified by independent study monitors.

Results

Baseline characteristics of the 184 randomized subjects were balanced across treatment assignment, Table 1. Three subjects (2 TURP, 1 Aquablation) voluntarily withdrew prior to treatment, leaving a safety and efficacy cohort of 181. Mean prostate size was 53 cc and 81% were sexually active. Three-year follow up was obtained in 97 (84%) Aquablation subjects and 55 (85%) TURP subjects, Figure 1.

Mean (SD) IPSS reduction at 3 years was 14.4 (6.8) in the Aquablation group and 13.9 (8.6) in the TURP group (p = .6848 for difference, Figure 2. The mean percent reduction in IPSS score was 64% and 61% in Aquablation and TURP groups, respectively. Seventy-eight percent and 82% of subjects in the Aquablation and TURP groups had improvements of at least 5 points from baseline. Repeated measures analysis showed no statistically significant difference in postoperative change scores across groups nor any



*One subject exited early due to prostate cancer.
**Two subjects exited early due to subject expiration prior to the 24-months visit.
*** One subject exited early due to subject expiration prior to the 36-months visit.
****Two subjects exited early due to subject expiration prior to the 36-months visit.
One subject was withdrawn from study by the investigator due to total prostatectomy due to prostate cancer.
One subject was withdrawn from study by the investigator due to retreatment for BPH.
One subject was withdrawn from study by the investigator due to worsening dementia.

Figure 1. CONSORT diagram for the WATER trial.

TABLE 1. **Baseline characteristics**

Characteristic	**Aquablation n = 117**	**TURP n = 67**
Age, years, mean (SD)	66.0 (7.3)	65.8 (7.2)
Body mass index, mean (SD)	28.4 (4.1)	28.2 (4.5)
Prostate size (TRUS)*, gm; mean (SD)	54.1 (16.2)	51.8 (13.8)
Prostate specific antigen, g/dL; mean (SD)	3.7 (3.0)	3.3 (2.3)
Cystoscopy findings		
Lobes present		
Lateral lobe only	50 (42.7%)	31 (46.3%)
Middle lobe only	9 (7.7%)	3 (4.5%)
Both lateral and middle	55 (47.0%)	88 (47.8%)
Degree of middle lobe obstruction		
None	23 (19.7%)	15 (22.4%)
Mild	25 (21.4%)	15 (22.4%)
Moderate	35 (29.9%)	22 (32.8%)
Severe	14 (12.0%)	7 (10.4%)
Bladder neck obstruction	30 (25.6%)	24 (35.8%)
Baseline questionnaires		
IPSS score, mean (SD)	22.9 (6.0)	22.2 (6.1)
IPSS QoL, mean (SD)	4.8 (1.1)	4.8 (1.0)
Sexually active, n (%) [MSHQ-EjD]	93 (80.2%)	54 (83.1%)
MSHQ-EjD mean (SD)**	8.1 (3.7)	8.8 (3.6)
IIEF-5, mean (SD)**	17.2 (6.5)	18.2 (7.0)

*volume = prostate length × width × height × π/6
**sexually active men only

statistical interaction between time and treatment. However, for men with larger prostates (≥ 50 cc), IPSS reduction over 3-year follow up averaged 3.5 points larger in the Aquablation group compared to the TURP group (p = .0125, repeated measures analysis of variance). Mean 3-year IPSS quality of life score improvement was also similar in both groups (3.2 (1.8) versus 3.2 (1.7), p = .7845).

At all postoperative time points, changes in ejaculatory function, as measured by MSHQ-EjD, were close to 0 for the Aquablation group, Figure 3. Changes in in MSHQ-EjD score at all follow up visits averaged 2.8 points lower for the TURP group compared to the Aquablation group (repeated measures analysis of variance, p = .0008). Similarly, at all postoperative time points MSHQ bother score averaged 0.6 points higher in the TURP group (p = .0411). Erectile function, as measured by IIEF-15, showed no statistically significant changes in either group and no differences across groups.

In both groups, maximum 3-year urinary flow rates increased markedly within 1 month after surgery and were maintained at 3 years. Mean (SD) 3-year improvements in Qmax were 11.6 (14) cc/sec for the Aquablation group versus 8.2 (8) cc/sec for TURP (Figure 4 p = .0848). The mean 3-year reduction in post-void residual (PVR) was 52 (163) and 53 (224) cc (p = .9801). Most of the decrease in PVR occurred in men with elevated (> 100 cc) baseline PVR (127 and 135 cc, respectively). At 3 years, PSA was reduced significantly compared to baseline (by 0.9 [p = .0018] and 1.1 [p = .0002] ng/dL in the Aquablation and TURP groups, respectively); the difference in PSA reduction was not statistically significant (p = .5983).

Seventy-four (64%) Aquablation subjects were taking alpha blockers preoperatively. By year 3, only 10 of these men were taking alpha blockers. Eight men assigned to Aquablation started alpha blockers anew between surgery and year 3 follow up. Thirty-seven (57%) TURP subjects were taking alpha blockers preoperatively; of these only 5 were continuing at year 3. Seven men assigned to TURP started alpha blockers anew between surgery and year 3 follow

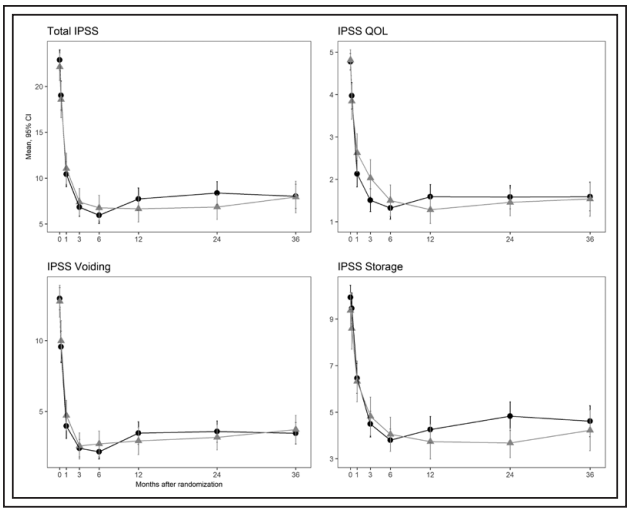


Figure 2. Change in International Prostate Symptom Score (IPSS, top left), IPSS quality of life (top right), and IPSS voiding (bottom left) and storage (bottom right) scores. Black circles = Aquablation; gray triangles = TURP.

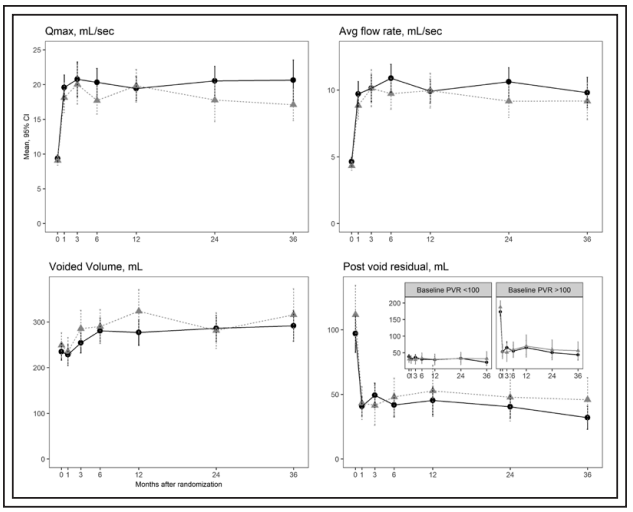


Figure 4. Uroflow measures by treatment and time. For PVR, inset graph shows subgroup analysis of those with elevated (> 100 cc) and not elevated (< 100 cc) baseline PVR. Black circles = Aquablation; gray triangles = TURP.

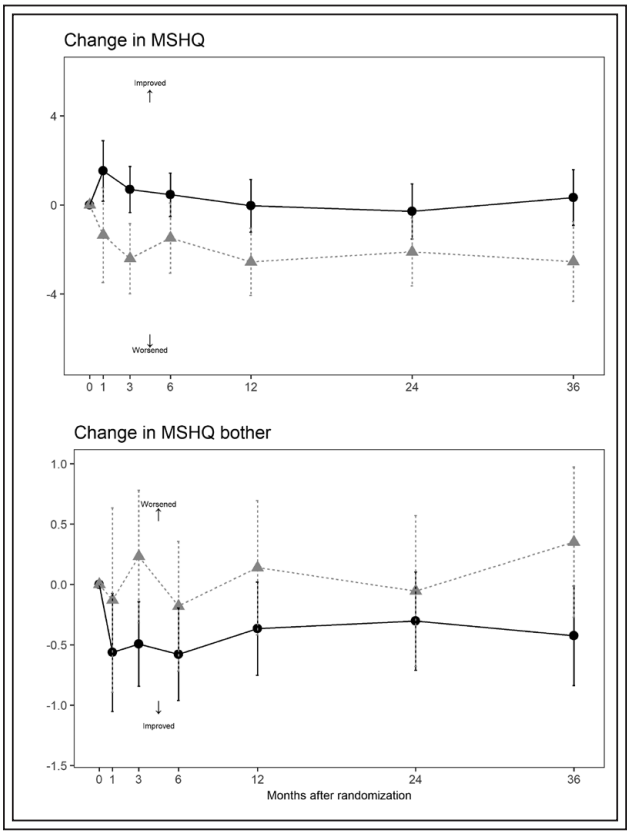


Figure 3. Change in MSHQ-EjD (top) and MSHQ bother scores by time and treatment. Black = Aquablation; gray = TURP.

up. Twenty-four (21%) Aquablation subjects were taking 5-alpha reductase inhibitors preoperatively; of these all but 2 stopped them. Two men assigned to Aquablation started 5-alpha reductase inhibitors anew between surgery and year 3 follow up. Fifteen (23%) TURP subjects were taking 5-alpha reductase inhibitors preoperatively; all of which all where discontinued by year 3. Two men assigned to TURP started 5-alpha reductase inhibitors anew between surgery and year 3 follow up. Medical failure (defined as started on alpha blockers or 5-alpha reductase inhibitors after surgery) at 3 years occurred in 9% of Aquablation and 14% of TURP patients.

Adverse events, evaluated by a clinical events committee to 1 year and reported by investigators thereafter, occurred at similar rates across treatment groups, Table 2, over postoperative, short and long term follow up, with the exception of postoperative anejaculation, which was substantially less frequent in the Aquablation group (11% versus 29%, p = .0039). Between year 2 and 3 there were four serious AEs in the Aquablation group (1 cardiac arrest, two myocardial infarctions and one small bowel obstruction, none of which were related to the Aquablation procedure); there was one serious AE in the TURP group (aspiration pneumonia with respiratory failure, unrelated to TURP, Table 3). One (0.9%) and 4 (6.2%) of Aquablation and TURP subjects had urethral stricture (p = .0567); 3 (2.5%) and 0 (0%) of subjects had meatal or submeatal stenosis

TABLE 2. **Number of subjects with urologic events by event type and days to adverse event**

Time period	Event	Treatment				
		Aquablation		TURP		
		n	Rate*	n	Rate	p value**
0-100 days	Arrhythmia	2	1.7	0	0	0.5371
	Bladder neck contracture	1	0.9	0	0	1.0000
	Bladder pain/spasm	7	6	3	4.6	1.0000
	Bleeding	18	15.5	10	15.4	1.0000
	Decreased libido	0	0	1	1.5	0.3591
	Dysuria	13	11.2	6	9.2	0.8030
	Meatal or submeatal stenosis	2	1.7	0	0	0.5371
	Non-urologic	32	27.6	13	20	0.2865
	Pain	9	7.8	4	6.2	0.7730
	Penile edema	1	0.9	0	0	1.0000
	Penile trauma	1	0.9	0	0	1.0000
	Retrograde ejaculation	9	7.8	15	23.1	0.0055
	Swollen testicles	0	0	1	1.5	0.3591
	Urethral damage	1	0.9	1	1.5	1.0000
	Urethral stricture	1	0.9	2	3.1	0.2932
	Urinary retention	11	9.5	5	7.7	0.7897
	Urinary tract infection	11	9.5	5	7.7	0.7897
	Urinary urgency/frequency/difficulty/leakage	8	6.9	6	9.2	0.5739
3-12 months	Bladder neck contracture	2	1.7	1	1.5	1.0000
	Bleeding	2	1.7	1	1.5	1.0000
	Dysuria	3	2.6	0	0	0.5539
	Erectile dysfunction	0	0	1	1.5	0.3591
	Hydrocele	0	0	1	1.5	0.3591
	Non-urologic	27	23.3	13	20	0.7100
	Pain	2	1.7	0	0	0.5371
	Prostate cancer	0	0	1	1.5	0.3591
	Retrograde ejaculation	1	0.9	3	4.6	0.1328
	Urethral stricture	0	0	1	1.5	0.3591
	Urinary retention	1	0.9	2	3.1	0.2932
	Urinary tract infection	3	2.6	3	4.6	0.6684
	Urinary tract stones	0	0	2	3.1	0.1277
	Urinary urgency/frequency/difficulty/leakage	14	12.1	7	10.8	1.0000
12 months to year 3	Bleeding	2	1.7	4	6.2	0.1898
	Bypassing catheter	0	0	1	1.5	0.3591
	Dysuria	2	1.7	1	1.5	1.0000
	Erectile dysfunction	4	3.4	5	7.7	0.2860
	Kidney	1	0.9	0	0	1.0000
	Meatal or submeatal stenosis	1	0.9	0	0	1.0000
	Non-urologic	46	39.7	19	29.2	0.1969
	Other bleeding	2	1.7	0	0	0.5371
	Other pain	1	0.9	0	0	1.0000
	Pain	0	0	1	1.5	0.3591
	Retrograde ejaculation	3	2.6	1	1.5	1.0000
	Scrotal lump	1	0.9	0	0	1.0000
	Scrotal mass	1	0.9	0	0	1.0000
	Sexual dysfunction	0	0	1	1.5	0.3591
	Urethral stricture	0	0	1	1.5	0.3591
	Urinary retention	2	1.7	2	3.1	0.6191
	Urinary tract infection	6	5.2	3	4.6	1.0000
	Urinary tract stones	2	1.7	0	0	0.5371
	Urinary urgency/frequency/difficulty/leakage	12	10.3	10	15.4	0.3484

*rate per 100 treated men; **Fisher test p value

TABLE 3. **Number of serious adverse events and subjects with event by time frame**

	Aquablation		TURP		
SAE timing (days)	**Events**	**Subjects (%)**	**Events**	**Subjects (%)**	**p value**
0	1	1 (0.9%)	0	0 (%)	1
0-3 months (0-100)	7	7 (6.0%)	5	4 (6.2%)	.7581
3 months-1 year (100-425)	6	5 (4.3%)	5	5 (7.7%)	.4990
1-2 years (425-790)	14	8 (6.9%)	3	2 (3.1%)	.7485
2-3 years (> 790)	4	4 (3.4%)	1	1 (1.5%)	.6557

SAE = serious adverse events

(p = .5539). Overall, 3-year retreatment rates were 5/116 (4.3%) in the Aquablation group and 1/65 (1.5%) in the TURP group (p = .4219). No subjects required surgical retreatment beyond 20 months postoperatively.

Discussion

The evidence base for Aquablation therapy for LUTS due to BPH is increasing. In our prospective blinded randomized controlled trial, improvements at 3 years in symptom scores, quality of life and uroflow parameters were nearly identical after Aquablation therapy compared to TURP, but with a marked reduction in the risk of postoperative anejaculation. Erectile dysfunction related to either procedure was not observed and there were no procedure-related adverse events between years 2 and 3. The risk of retreatment was low (annual rates of approximately 1.4% [Aquablation] and 0.5% [TURP]). Most men were able to stop BPH-related medications (alpha blockers, 5-ARIs); few men started medications anew during follow up. Combined with results of other prospective trials,[14] 3-year results from the current study provide compelling long term evidence for the safety and effectiveness of Aquablation therapy in men with LUTS due to BPH. Improvements in objective parameters (urinary flow rate and post-void residual) were similar to those observed for other resective prostate surgeries, including laser enucleation[15] and laser photovaporisation.[16]

Our long term data speak to the potential advantages of robotic semi-automation in surgery. As others have noted, just as autonomous driving technology may address human weaknesses with respective to driving (not all of us are Formula One champions[17]), Aquablation may offer standardization that improves overall outcomes for all urologists and their patients. Of note, positive outcomes were obtained from surgeon participants who, while experienced with TURP, had, for the most part, no prior experience with Aquablation before starting this study. Addition of image processing incorporating artificial intelligence may enhance further the potential of this procedure to generate positive outcomes. Our study suggests that the learning curve for Aquablation is short and may be shortened in the future with the addition of AI-based features.

The lower rate of postoperative anejaculation after Aquablation therapy comports with the use of image guidance and robotic execution. The procedure's overall approach avoids damage to tissues involved in ejaculation through precise, image-based targeting and robotic execution.

Advantages of our study include its standardized collection of symptom scores and other outcomes in a prospective, multicenter, international and blinded setting.

One limitation to generalizability is the study's maximum prostate size of 80 cc. In another prospective trial of larger prostates (80-150 g, WATER II), high levels of symptom relief with low levels of postoperative anejaculation were observed.[14] Another limitations is whether or not rigorous clinical trial data will translate in a real-world setting. Bach et al reported similar results in their first 118 consecutive patients in Germany.[18] Additionally, a French based study with similar inclusion as the WATER study reported consistent outcomes at 1 year.[19]

Conclusion

The evidence base for Aquablation therapy for LUTS due to BPH is increasing. In summary, our study provides high-quality 3-year evidence of Aquablation therapy for LUTS due to BPH in men with prostate sizes between 30 and 80 cc with clinical efficacy and durability similar to TURP. □

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