
Aquablation of the prostate: a review and update

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Introduction: Invasive procedures, such as transurethral resection of the prostate (TURP), have long been the gold standard therapy for the treatment of lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia (BPH). In recent years, newer treatment modalities have arisen, such as Aquablation, with similar efficacy and improved adverse event profiles, with particular emphasis on postoperative sexual function.

Materials and methods: Aquablation is a new technology that utilizes machine-controlled water jets to ablate the soft tissue of the prostate as determined by the doctor. In this review, we will discuss the techniques currently being used to complete this procedure, the outcomes and safety, and finally, the long term data as well as the adverse events associated with Aquablation.

Results: Aquablation is rapidly effective in treating patients with LUTS due to BPH. Critically, in head to head comparison with TURP, Aquablation has equivalent objective results with much shorter resections times, and significantly less sexual side effects. Currently, the literature only reports results extending to 12 months post-procedure, and therefore long term durability of results beyond this time point remains unknown.

Conclusions: Aquablation is a safe and effective option for treating LUTS secondary to BPH. Aquablation is a new surgical option that shows very promising short term results, in particular, due to its short resection time regardless of gland size and low rate of sexual side effects. This technology still requires further investigation to confirm durability and efficacy over time.

Key Words: Aquablation, BPH, LUTS

Introduction

Benign prostatic hyperplasia (BPH) is a common condition affecting approximately 25% of men at the age of 50, with almost 80% of men greater than 70 affected.¹ BPH is caused by the unregulated proliferation of the transitional zone of the prostate, which leads to compression of the urethra. Physical

compression of the urethra is what causes an anatomic bladder outlet obstruction (BOO), and leads to the symptoms of BPH, known as lower urinary tract symptoms (LUTS).² The gold standard for endoscopic surgical treatment of this condition has been the transurethral resection of the prostate (TURP), which was first developed during the early 1920s.³ The TURP technique, although effective, has well-established morbidities, such as infection, poor hemostasis, sexual side effects, and others.⁴ This review examines the use of the new robot-assisted waterjet ablation of the prostate for treatment of BPH in a therapy termed Aquablation.

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Newer techniques have been developed with the goal of decreasing surgical morbidity for patients while remaining successful in alleviating BPH symptoms. One of the newest technologies is an ultrasound-guided, robot-assisted waterjet that can precisely ablate prostatic tissue, known as Aquablation. This technique is performed using the Aquabeam system (PROCEPT BioRobotics, Redwood Shores, CA, USA). This surgical intervention was developed with the hope of limiting bleeding, much like laser enucleation or ablation, but requiring significantly less time to complete. Additionally, this technique also shows promise in preserving sexual function, both erectile and ejaculatory, much like the UroLift (Neotract/Teleflex, Pleasanton, CA, USA) and Rezūm (Boston Scientific, Marlborough, MA, USA) procedures.

Technique

The technique for this procedure was first described by Faber et al, in 2015, using the Aquablation system from Aquabeam and has since been updated by multiple others describing their techniques.⁵⁻⁷ In short, the AquaBeam Aquablation system has three main components: the conformal planning unit (CPU); robotic 24F hand-piece; and a console. The procedure can be performed under general anesthesia or spinal anesthesia. From here, the patient is placed in the dorsal lithotomy position, and the bi-planar transrectal ultrasound (TRUS) device is mounted into position. Next, the handpiece is utilized to gain bladder access, and allow visualization using a scope. The handpiece is positioned with the tip just inside the bladder before the scope is retracted to visualize the bladder neck and placed proximal to the external sphincter to protect it. Once proper positioning is confirmed, the handpiece can be stabilized using an articulating attachment mounted to the bed. With the handpiece in the appropriate position, the TRUS probe must be positioned. The TRUS probe is inserted to the center of the prostate. At this point, the surgeon can utilize the TRUS probe to compress the prostate and improve visualization for the Aquabeam handpiece.

Once the proper positioning of both the handpiece and the TRUS probe has been achieved, the software must be adjusted to confirm appropriate planning for the tissue ablation, which is performed using the mapping software. The software allows for changes in depth up to 25 millimeters, and the angle of resection up to 225 degrees. The complete ablation of the transition zone of the prostate is performed by outlining the prostate with the Aquabeam software. The high-velocity

physiological saline is then initiated under the control of a foot pedal. The computer system automatically adjusts the flow rate in each direction to alter the depth of penetration and remove the tissue as outlined in the mapping stage. There are safety mechanisms in place to ensure only the outlined tissue is ablated, and the external sphincter remains protected. Once resection is complete, hemostasis can be completed either through electrocautery or balloon catheter tamponade, though the expert opinion currently favors balloon tamponade.⁸ The balloon remains in place for 2 hours to ensure hemostasis. Post-procedure, a three-way catheter is inserted, and bladder irrigation is commenced. The patient can be discharged the next day following successful voiding after removal of the catheter.

Outcomes and safety of Aquablation

As this is a very new technology, much of the literature is very recent. Some of the earliest outcomes were reported by Gilling et al, who published their findings in a prospective, multicenter trial at three separate Australian centers which included 21 men.⁹ All patients were between the ages 50-80 years and had prostates ranging from 25 mL to 100 mL. The results from this study showed an average procedural duration of 38 minutes and a mean resection time of 5 minutes, with an average hemoglobin drop of 5.7% after the operation. Subjective and objective findings were also reported, with data from 1, 3, 6, and 12 months. Average International Prostate Symptom Scores (IPSS) were significantly decreased down to an average of 6.8 from pre-treatment. Maximum flow rate (Q_{max}) increased to 18.3 mL/s at 12 months follow up. Post-void residual (PVR) volumes decreased down to an average of 31 mL, and the quality of life subjective scores improved significantly as well. The study was able to obtain urodynamic studies after the operation for comparison to baseline and found that detrusor pressure at maximum flow was decreased by 40% on average. Prostate volume reduced by 39% on average. Finally, no adverse events were reported, there was no incontinence seen, and sexual function was preserved in all patients.

Another important study was the WATER trial, which directly compared Aquablation to TURP results across 17 different centers.¹⁰ This double-blind, randomized control trial included 181 patients. There was no significant difference seen in overall mean operative time, but resection time was significantly less with Aquablation. The trial was planned to assess Aquablation and TURP in a non-inferiority trial using composite endpoints for safety and efficacy. The group looked at 3 month postoperative safety data, as well as

6 month postoperative IPSS scores from patients. The primary safety end-point was defined as a persistent Clavien-Dindo grade 1 event, or a Clavien-Dindo grade 2 or higher event. At the 3 month time-point, safety data showed Aquablation to be non-inferior to TURP, with additional analysis showing Aquablation to be superior, with 26% of the Aquablation cohort meeting this safety end-point, while 42% from the TURP group met the criteria. Significantly, all the persistent Clavien-Dindo grade 1 events seen were due to retrograde ejaculation, which was seen in 6.9% of Aquablation patients and 24.6% of TURP patients. To further assess ejaculatory function, MSHQ-EjD self-reported data was collected, showing that 90 days after the procedure, on average the Aquablation patients had a slight improvement overall in ejaculatory scores, while TURP group had a significant decrease in scores, highlighting the superior nature of Aquablation compared to TURP with regard to preservation of ejaculatory dysfunction.

A similar analysis was done to assess incontinence, using the incontinence severity index, which is also self-reported. Result for this showed more significant improvement in the Aquablation group. At 6 months post operation, IPSS scores were compared to baseline scores. The IPSS change over time was utilized to determine the efficacy endpoint. Aquablation had an average IPSS of 6.0 at 6 months, compared to an average of 6.7 for TURP, which satisfied the non-inferior hypothesis. Lastly, Qmax and PVR volumes were assessed at 30-day postoperative intervals up to 180 days. These data show very similar results for

PVR, with slightly improved Qmax at 180 days for the Aquablation compared to TURP. See Table 1 for Aquablation summary.

After the WATER trial, a WATER II trial was completed to assess the safety and feasibility of Aquablation in larger prostates, between 80-150 mL.¹¹ This trial was again prospective, with 16 different centers. In total, 101 men were included in the study. Despite the larger prostate size, average operating time was 37 minutes, with an average resection time of 8 minutes. A total of 66.3% of patients included required additional passes with the machine to complete the resection, but all were completed in a single operation. Again, composite endpoints were used for both safety and efficacy. At 3 months, safety was assessed using the same safety endpoints as described in the WATER trial. For efficacy, the change in IPSS scores at 3 months post operation from baseline was utilized. Both the safety and efficacy endpoints were then compared to an objective performance criterion (OPC) which allowed for assessment of non-inferiority. Intraoperative reports show that 82% of these procedures were done under spinal anesthesia. Safety endpoints at 3 months were met in 45.5% of patients, well below the OPC of 65%. These results were statistically significant and showed the safety endpoint was reached, and the procedure was non-inferior when compared to the OPC. When assessing efficacy, Aquablation greatly exceeded the OPC set for the change in IPSS score, showing the procedure as non-inferior for efficacy as well. Further, prostate volume reduction was measured, showing a 44% reduction in size at

TABLE 1. Aquablation summary

Study	Measure (time point)	Change observed
Aquablation 1 year results	IPSS (1 y)	16.2 points improvement
	Qmax (1 y)	9.7 mL/s increase
	PVR (1y)	89 mL decrease
	Pdet at Qmax (6 mo)	25.1 cm of H ₂ O decrease
	Bladder outlet obstruction index (6 mo)	35.2 points improvement
	Prostate volume (6 mo)	18 mL decrease
	Serum PSA (6 mo)	0.59 ng/mL decrease
WATER trial	IPSS (6 mo)	16.9 points improvement
	IPSS QoL score (6 mo)	3.5 point decrease
	Qmax (6 mo)	10.9 mL/s increase
	PVR (6 mo)	55 mL decrease
	Prostate size reduction (3 mo)	31% average decrease
	Serum PSA (6 mo)	1.2 ng/mL decrease

IPSS = International Prostate Symptom Score; Qmax = maximum flow rate; PVR = post-void residual; Pdet = detrusor pressure; PSA = prostate-specific antigen

3 month post operation. Hemostasis was achieved for most patients using a Foley catheter placed in the bladder under traction overnight using a device from PROCEPT BioRobotics. The other option, utilized in only three patients, was a balloon catheter inflated in the prostatic fossa. The average length of catheter duration was 94 hours, with an average of 18 hours under traction for those utilizing this method of hemostasis management. There was an average hemoglobin drop of 2.9 when comparing baseline to discharge lab values while using this method for hemostasis. Of the 101 patients, there were a total of 10 transfusions required between the completion of the operation and 1 month, with one patient requiring a return to the operating room. No patients needed transfusions beyond 1 month post-treatment.

Durability and adverse events

The same cohort used in the WATER I trial was further studied out to 12 months post-procedure to continue to investigate the safety and efficacy of this procedure when compared to TURP.¹² The notable findings of this study were that TURP and Aquablation operations had similar improvements in Qmax at 1 year, both had a similar decrease in serum PSA measurements at 1 year, and both had low rates of retreatment. The Aquablation group had 2.6% who underwent re-operation within 1 year, compared to 1.5% in TURP, which was not a statistically significant difference. The study also analyzed results in patients who had larger than 50 gram prostates before treatment.¹³ The results in this sub-group heavily favored Aquablation, with both primary safety endpoint and primary efficacy endpoint determining Aquablation was superior to TURP for these patients. This subgroup had no difference in average procedure times, at 33 minutes for Aquablation and 36 minutes for TURP, but did have a significant difference in resection time at 4 minutes compared to 27 minutes for TURP. Additional analysis of this larger prostate size subgroup showed that on average, there was a greater drop in postoperative hemoglobin in the Aquablation than in TURP. When compared, this hemoglobin change postoperatively was significantly greater in the Aquablation group than the TURP group. Aquablation group had one patient requiring a transfusion while none in the TURP group needed it. Overall, this study helps to highlight that Aquablation and TURP have similar outcomes at 1 year, despite the newness and therefore unfamiliarity with the Aquablation procedure.

The same patients that made up the WATER II trial were studied out to 6 months.¹⁴ When analyzing

adverse events at 6 months, 22% of the subjects had experienced a Clavien-Dindo grade II event, 14% a grade III event, and 5% a grade IV event. Looking at efficacy, Qmax increased from 8.7 cc/s at baseline to 18.8 cc/sec at 6 months. PVR volume was lowered from 131 mL to 47 at 6 months. QoL decreased from 4.6 at baseline to 1.4 at 6 months. PSA showed a 44% reduction on average, while TRUS showed a 42% reduction in prostate volume compared to baseline. Looking at the patient's postoperative sexual function, MSHQ-EjD scores at 6 months still showed a slight improvement compared to baseline, though not as much as at 3 months. IIEF-5 scores improved by an average of 0.1 at 3 months, and an average of 0.7 at 6 months. These results depict the best long term data we currently have for Aquablation in patients with larger prostates and portray this procedure as a reasonable alternative.

Conclusions

Aquablation is a novel technique employing robotic and waterjet technology to patients suffering from LUTS associated with BPH. The initial results suggest to be as effective as TURP in treating BPH. This new technique is intriguing due to the extremely short treatment time regardless of gland size, lack of sexual side effects, and possible same day hospital discharge. These factors make this a desirable option for both patients and surgeon. The procedure has had a large randomized clinical trial directly comparing Aquablation to the gold standard of BPH treatment, TURP, and shown superior short term results. While there are many positives of this procedure, it is still very new, and large gaps in the literature remain. Before strong recommendations can be made, long term results from this procedure are required as current data only extends to 12 months after operation for smaller prostates, and 6 months after operation for larger prostates. Further, prostates greater than 150 mL have yet to be reported in the literature, which currently limits Aquablation to below 150 mL. Overall, this is a new surgical option that shows very promising short term results but requires further investigation to confirm durability and efficacy over time.

Disclosures

Dr. Claus Roehrborn is an investigator and consultant for Boston Scientific, NeoTract/Teleflex and PROCEPT BioRobotics.

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