Aquablation for BPH: United States single-center experience

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Introduction: *To characterize procedure variables and outcome data from men undergoing the Aquablation Therapy of the prostate procedure for lower urinary tract symptoms due to benign prostatic hyperplasia (BPH). We evaluated the safety and efficacy of robotically guided waterjet-based prostate resection in the first study of all-comers in a single-center, commercial setting in the United States.*
Materials and methods: *The analysis was a retrospective review of prospectively collected data.*
Results: *Fifty-five men underwent the Aquablation of the prostate between July 2018 and December 2019. Mean prostate volume was 100 cc, and 85% had a prominent, obstructing middle lobe. Operative time averaged 59 minutes, and the mean hemoglobin drop was 1 g/dL. A substantial improvement of 80% (17 points) was seen in BPH symptoms scores. By uroflowmetry, Qmax improved by 182% (14 mL/sec). Men with prostate volume > 100 cc had similar hospital length of stay, BPH symptom reduction, and Qmax improvement compared to those with volume < 100 cc.*
Conclusion: *In the setting of a community private urology practice, Aquablation Therapy was safe and effective for the treatment of men with BPH regardless of prostate shape or prostate size.*

Key Words: Aquablation, BPH, lower urinary tract symptoms

Introduction

Moderate-to-severe lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) affects 50% of men aged over 50 years[1,2] and as high as 90% by age 85.[3] Men with moderate-to-severe symptoms often fail medical treatment and seek surgical treatments.[4]

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Surgical approaches include tissue resective therapies, such as transurethral resection of the prostate with electrocautery (TURP), photovaporization (PVP), and laser enucleation, and non-tissue resective techniques such as microwave thermotherapy, water vapor thermal therapy, or prostatic urethral lift implants. While TURP remains the reference standard for treatment, it carries risks of bleeding, clot retention, bladder neck contracture or urethral stricture, urinary incontinence, erectile dysfunction and retrograde ejaculation.[5-9] For larger prostates of > 80 mL, many of these options are not recommended per American, Canadian, and European Urological Association guidelines. Open prostatectomy (OP) remains the

global reference standard for the surgical treatment of LUTS due to BPH in large prostates.[10] However, OP requires abdominal-wall access and is associated with longer hospitalization and catheterization times with higher risks of bleeding.

Clinical studies of the robotically guided waterjet for prostate resection (termed Aquablation Therapy) suggest high levels of efficacy with a potentially decreased risk of sexual side effects potentially due to more accurate tissue targeting regardless of prostate size or shape.[11-14] We evaluated the safety and efficacy of robotically guided waterjet-based prostate resection in the first study of all-comers in a single-center, commercial setting in the United States.

Materials and methods

Men with moderate-to-severe lower urinary tract symptoms due to BPH were treated with Aquablation. Patients were excluded if anticoagulants could not be stopped prior to surgery. For example, a patient with a mechanical heart valve was not a candidate. All men were screened and evaluated preoperatively at the author's clinic and treated in the operating room under spinal or general anesthesia. The preoperative evaluation included cystoscopy, volume measurement of the prostate via transrectal ultrasound (TRUS), and urodynamic evaluation of the patients' voiding function and physiology.

Patients were treated between July 2018 and December 2019. Prostate volume was measured with TRUS during the clinic screening visit. Preoperative historical items routinely collected included presence/absence of median lobe as judged on TRUS and cystoscopy, bladder outlet obstruction (BOO) severity, urinary retention, use of a Foley catheter or I & O self cathterization to ensure adequate emptying, and urinary incontinence. As part of routine care, men undergoing surgical treatment for BPH completed International Prostate Symptom Scores (IPSS), Sexual Health Inventory for Men (SHIM) scores, and uroflow (maximum flow rate).

Surgical parameters collected include OR time, hemoglobin preoperatively, postoperatively, and at discharge. After the immediate postoperative period, patients were seen in clinic for follow up at approximately 3 month intervals, where BPH symptom score, measurement of post-void residual urine volume, interval urinary flow rate measurement, and sexual function questionnaires were obtained.

Aquablation was performed as previously described using the AquaBeam Robotic System[15] (PROCEPT BioRobotics, Redwood Shores, CA, USA).

Statistical analysis

Statistical analysis was performed using R. Changes in continuous values were evaluated using two-tailed t-tests. Linear regression was used to evaluate the relationship between symptom and quality of life change scores and maximum urinary flow and prostate volume. P values < .05 were considered statistically significant.

Results

Fifty-five men, nearly half with a history of urinary retention (requiring Foley catheter or management with self I & O catheterization), underwent Aquablation therapy between July 2018 and December 2019. Baseline characteristics are summarized in Table 1. No patient had previous BPH surgery or treatment of urinary stricture or prostate cancer. Mean prostate volume was 100 cc (range 27-252 cc), with 85% having a middle lobe. The mean operative time was 59 minutes. Postoperatively, mean hemoglobin drop was -1.0 g/dL ($p < .0001$). The mean hospital length of stay was 1.8 days. There was no difference in length of stay between patients with prostates < 100 cc versus > 100 cc.

TABLE 1. **Preoperative characteristics**

Characteristic	**Statistic***
Age	67 (8.2), 50-84
Prostate volume	100 (44), 27-223
IPSS	21.6 (6.9), 6-35
IPSS QoL	4.3 (1.1), 2-6
Qmax, cc/sec	7.4 (3.2), 1.9-15
Bladder capacity	237 (131), 30-814
Hemoglobin	14.1 (1.7), 8.6-17
SHIM	10.5 (8.7), 1-25
Erectile dysfunction	44/55 (80%)
BOO severity	
Moderate	4 (7%)
Severe	51 (93%)
Median lobe	47 (85%)
Retention	24 (49%)
Foley catheter use	17 (31%)
Incontinent	2 (4%)

*continuous variables reported as mean (SD), range; proportions reported as n/n (%)
IPSS = International Prostate Symptom Score; QoL = quality of life; SHIM = Sexual Health Inventory for Men; BOO = bladder outlet obstruction

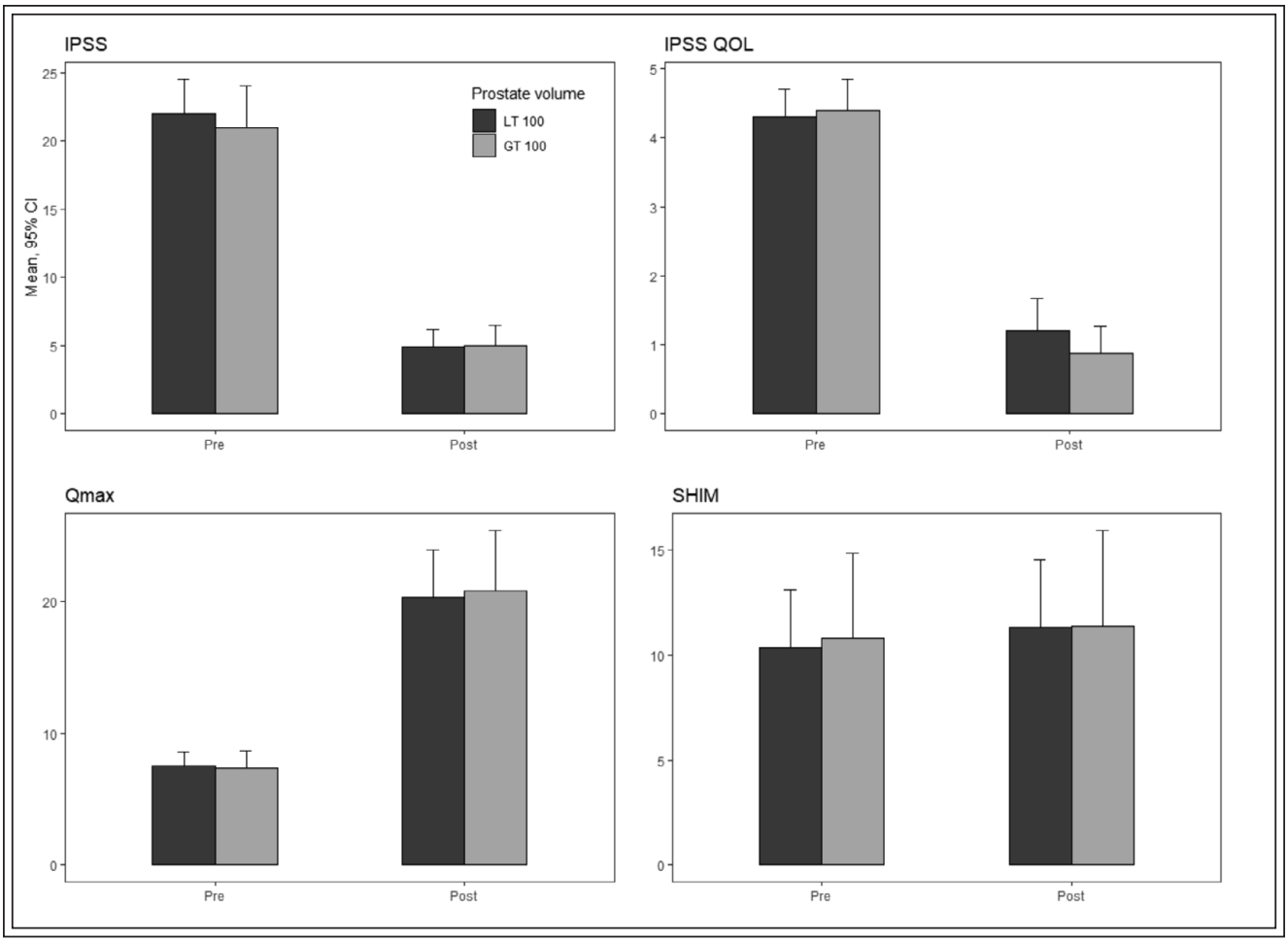

Figure 1. Key urologic parameters at baseline and last follow up. Dark bars = prostate size < 100 cc; light bars = prostate size > 100 cc.

Adverse events occurred in nine men, including hematuria (5, with one requiring a transfusion), bladder spasms (1), dehydration (1), intolerance of Foley catheter (1), and temporarily elevated creatinine (1). One patient with a history of multiple concurrent medical and cardiovascular issues died of cardiovascular causes on postoperative day 1. The Aquablation procedure in this patient was uneventful. Postoperatively, his hemoglobin was stable and his urine remained clear.

At follow up, mean IPSS had improved to 5.0 points, averaging a 17.2-point improvement ($p < .0001$). IPSS QoL improved from 4.3 to 1.1, a 3.3-point improvement ($p < .0001$). The mean Qmax improved from 7.4 cc/sec preoperatively to 20.6 cc/sec postoperatively (a 13.5-cc/sec increase, $p < .0001$). Although the patient population had a high degree of erectile dysfunction at baseline, there was no decline in erectile functionality following the procedure. The improvement in all parameters was independent of prostate size, Figure 1. This was confirmed through regression analysis, which showed that final IPSS, IPSS QoL, change in IPSS and IPSS QoL, final Qmax, and change in Qmax were not related to prostate volume.

Discussion

One of the critical questions in medical device development is how the technology performs in the real world setting outside of rigorously controlled clinical studies. Aquablation is entering that phase in its life cycle development, and this study is the first published experience in the United States.

With the recent addition in guidelines to assess the prostate size, more and more is being learned about the actual distribution of prostate sizes and shapes encountered by surgeons. In our experience, half of our prostates exceeded 100 cc and ranged well over 200 cc.

Not to mention, 85% had a middle lobe adding complexity to the procedure. In the past, men with such prostates would be candidates for open or robotic simple prostatectomies. Aquablation has provided the capability to treat prostates of any size and any shape.

Without the strict inclusion and exclusion of a clinical trial, treating an all-comers population, the reproducibility of outcomes comes into question. Not only do the results in our experience mirror that of the two FDA clinical studies (WATER[11,16] and WATER II[12,17]), but also are consistent with the first commercial experience publication in Germany from Bach et al.[18] The likely credit of the consistent outcomes is due to the ability to plan the tissue resection in real time with live ultrasound and once satisfied, robotic execution of that plan accordingly.

Conclusions

Our single-center experience of 55 patients has been able to replicate the results previously reported in the two FDA clinical studies of Aquablation. Our study confirms Aquablation Therapy to be a safe and effective alternative for the management of BPH in men with prostates of any size and any shape.

Disclosure

PROCEPT BioRobotics provided data analysis support. □

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