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Aquablation for benign prostatic obstruction: Single center technique evolution and experience

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Purpose: Aquablation is a new technology that relies on real-time ultrasound guidance to ablate prostatic tissues using high velocity pressurized water. We hereby present our data and experience in this technique by exploring the perioperative surgical and functional outcomes.

Materials and Methods: This is a prospectively filled study including consecutive patients who underwent aquablation at our Middle Eastern tertiary care center. Patient demographics, voiding parameters, and prostate disease specific variables were collected. We reported on the surgical and functional outcomes as well as the 3-month adverse events. We also explored the trend in hemoglobin drop and hemostasis method by dividing the consecutive cases into four temporal periods.

Results: Fifty-nine patients underwent aquablation between March 2018 and March 2020. Mean time from transrectal ultrasound to Foley insertion was 48.5±2.5 minutes. Cautery was performed in 35 patients (59.3%) and a catheter-tensioning device was mounted in 50 patients (84.7%). On average, the hemoglobin dropped by -1.7±0.2 ng/dL (p<0.0001). The average length of catheterization and hospital stay were 2.1±0.3 days and 2.2±0.1 days, respectively. Only three patients (5.1%) were re-hospitalized. At three months, the average drop in serum prostate-specific antigen was -36.6±6.0% (p<0.0001) and functional outcomes considerably improved. We also recorded 14 adverse events in 13 patients (overall rate of 22.0%), with grade 1 and grade 2 complications comprising 71.4% of all adverse events.

Conclusions: Our study results confirm the safety and efficacy of the aquablation procedure in the adoption phase.

Keywords: Lower urinary tract symptoms; Prostatic hyperplasia; Robotic surgical procedures; Therapy

INTRODUCTION

Benign prostatic obstruction (BPO) affects a fourth of men in their lifetime and begets a considerable economic burden to the healthcare system [1,2]. If refractory to medical treatment, surgical intervention is offered based on prostate size. Although traditionally performed by transurethral resection of the prostate (TURP) or open adenectomy, these procedures are lengthy and morbid for larger prostates (>80 mL) [3]. Instead, various energy sources are used to endoscopically enucleate medium to large prostatic adenomas [4]. In 2015, aquablation, a semi-autonomous robotic technique, was introduced to the armamentum of BPO surgery. This technology relies on real-time ultrasound feedback to athermally

ablate tissue using high-precision and high-velocity pressurized water [4,5].

Multi-center prospective studies demonstrated the efficacy and safety of this procedure [6,7]. In the Waterjet Ablation Therapy for Endoscopic Resection (WATER I) of prostate tissue trial, the authors showed that aquablation has comparable functional outcomes to TURP, but has a superior ability in preserving ejaculation by sparing the verumontanum [6]. Desai el al.'s [7] WATER II trial also verified the applicability of aquablation to larger prostates (80–150 mL) without extending the procedure time. Since waterjet ablation is heat-free, bleeding is a foreseen adverse event. Hence, hemostasis is achieved using either spot electrocautery at the bladder neck, a catheter-tensioning device (CTD), or by standard tape traction secured to the patient's leg [8]. However, a large study by Elterman el al. [8] showed that robust traction by CTD is associated with elevated transfusion rates. On the other hand, the use of selective cautery mitigated the hemoglobin drop, but did not affect the transfusion rate.

Through our contribution to the first post-marketing multi-center study that validated the results in real-world patients, our institution became a pioneer of aquablation in the Middle East [3]. Thus, our early exposure allows us to share our experience and comment on the evolution of this technique. Therefore, we sought to present our cumulative data in aquablation, explore the perioperative outcomes, and highlight how our progress in the technique impacted the hemoglobin drop in function of the prostate size.

MATERIALS AND METHODS

1. Patient selection

After Institutional Review Board approval, a prospectively filled database was created for consecutive patients who underwent aquablation between March 2018 and March 2020 at our institution, the American University of Beirut Medical Center, Lebanon. The present study protocol was reviewed and approved by Institutional Review Board of American University of Beirut (approval number: SUR. AE03). As per the IRB protocol, oral consent was obtained before including patients' information in the database. A portion of the patients were part of the OPEN WATER study [3]. Three urologists from our institution with no prior experience in aquablation performed the surgeries. Aquablation was offered to patients non-responsive to BPO medical treatment, but denied to patients on anticoagulation (except patients on Aspirin 100 mg which was stopped five days prior to the procedure). Routine patient demograph-

ics as well as prostatic disease relevant variables including prostate-specific antigen (PSA) serum level, prostate volume (mL) procured from either a pelvic ultrasound or a transrectal ultrasound (TRUS) were collected. Then, information was gathered on the types of anesthesia used (general or spinal) and the patients' preoperative hemoglobin and international normalized ratio at presentation.

Then, we reported on the following surgical outcomes: operative time (minutes), hemoglobin drop (g/dL), the length of catheterization (days), the length of hospitalization (days), and the rates of re-catheterization, re-hospitalization, ejaculatory dysfunction, and the 3-month adverse events categorized by the revised Clavien–Dindo classification system [9]. The operative time was defined as the arithmetic difference between TRUS insertion and catheter placement at the end of the surgery; and the hemoglobin difference relied on the first postoperative day hemoglobin level [4]. We also calculated the change between baseline and 3-month functional outcomes including International Prostate Symptom Score (IPSS), single question quality of life (QOL) due to urinary symptoms score, and post-void residue (PVR) as well as the change in prostate size. The PVR and prostate volumes were initially assessed either by TRUS or pelvic ultrasound. The same imaging modality was used to compare the baseline and 3-month PVR and prostate volumes. Ejaculatory function was assessed using the short form of the Male Sexual Health Questionnaire to assess Ejaculatory Dysfunction (MSHQ-EjD) that evaluates frequency, delay, force, and volume of the ejaculate. Baseline and 3-month scores were compared to determine ejaculatory dysfunction [10].

2. Materials

The aquablation was performed using the Aquabeam system (Procept BioRobotics, Redwood Shores, CA, USA). The conformal planning unit (CPU) allows the surgeon to demarcate the area to be resected [4]. Once the resection is complete, the aquablation piece is withdrawn and a 24F resectoscope is inserted to irrigate the remaining prostatic tissue and remove clots (Fig. 1A, B). Then, continuous bladder irrigation is initiated using a 24F 3-way Foley catheter. Hemostasis methods included cauterization at the bladder neck in selected patients and Foley traction (Fig. 1C). Foley traction tamponading the bladder neck was maintained either by CTD, an external device exerting a calibrated force on the Foley, or by tape secured on the patient's leg [8]. Fluoroquinolone (Ciprofloxacin) prophylaxis was given perioperatively for all patients.

Fig. 1. Live transrectal ultrasound image displayed on the conformal planning unit before in sagittal view (A) before and (B) after the resection. (C) Endoscopic view of coagulation post resection.

Table 1. Baseline demographics and perioperative factors for patients undergoing aquablation (n=59)

Baseline demographic	Value
Age (y)	68.3±7.9 (54–86)
Body mass index (kg/m^2)	27.9±3.9 (21–36)
ASA class	
1	13 (22.0)
2	36 (61.0)
3	10 (17.0)
Preoperative prostate biopsies	5 (8.5)
Preoperative PSA (ng/dL)	4.2±3.7 (0.4–18.9)
Prostate volume (cc)	71.4±31.3 (12.7–148.0)
In retention at baseline	14 (23.7)
IPSS	19.9±6.2
Quality of life score	4.1±1.5
Post-void residue (mL)	228±48
Spinal anesthesia	35 (59.3)
Preoperative hemoglobin (g/dL)	14.4±1.4 (10.5–17.0)
Preoperative INR	1.01±0.08 (0.9–1.2)
Hemostasis method	
Cautery use	35 (59.3)
CTD use	50 (84.7)

Values are presented as mean±standard deviation (range) or number (%).

ASA, American Society of Anesthesiology; PSA, prostate-specific antigen; INR, international normalized ratio; CTD, catheter-tensioning device.

3. Statistical analysis

The changes between baseline and 3-month functional outcomes (IPSS and QOL scores), hemoglobin and PSA serum levels, and PVR were compared using Wilcoxon signed rank test. Sub-analysis for procedural outcomes among patients with baseline retention was performed using Mann-U Whitney. To demonstrate the evolution of our technique, the data was divided into four temporal periods. The prostate size, IPSS, QOL, PVR, and hemoglobin drop were compared using Wilcoxon signed-rank test. The analysis was done using the Statistical Package for the Social Sciences IBM SPSS for Windows, version 25 (IBM Corp., Armonk, NY, USA) and p<0.05 was set for significance.

RESULTS

A total of 59 patients underwent aquablation over a span of two years. The average age was 68.3±7.9, 10 patients (17.0%) had an ASA class of 3, and 14 patients (23.7%) were in retention at baseline (Table 1). The average PSA and prostate volume were 4.2±3.7 ng/dL and 71.4±31.3 mL, respectively. The average operative time was 48.5±2.5 minutes with 45 patients (77.6%) receiving two water ablative passes to ensure relief from the obstruction. Baseline voiding parameters of IPSS, QOL, and PVR were 19.9±6.2, 4.1±1.5, and 228±48 mL. Additionally, 35 patients (59.3%) underwent spinal anesthesia. For hemostasis, cautery at the bladder neck was performed in 35 patients (59.3%) and a CTD was mounted in 50 patients (84.7%). The CTD was used in all patients who did not receive cautery. The average time from TRUS to Foley insertion was 48.5±2.5 minutes (Table 2). On the first postoperative day, the hemoglobin dropped by -1.7±0.2 on average (p<0.0001). The average length of catheterization and hospital stay were 2.1±0.3 days and 2.2±0.1 days, respectively. Besides, only three patients were re-hospitalized (5.1%). At three months, the percent drop in serum PSA, change in prostate size, and average drop in IPSS were -36.6±6.0%, -15.6±17.3 grams, and -12.5±1.9, respectively (p<0.0001 for all variables) (Table 2). Similarly, the QOL scores improved by -2.5±0.5 points on average (p=0.001) and the PVR was reduced considerably (p=0.011). Further sub-analysis among patient with retention at baseline revealed similar operative

Table 2. Perioperative surgical and 3-month functional outcomes of patients who underwent aquablation

Surgical outcomes	Value	p-value
Perioperative outcomes		
Operative time (min)	48.5±2.5 (16–103)	-
Hemoglobin drop (g/dL)	-1.7±0.2	<0.0001
Length of catheterization (d)	2.1±0.3 (0–20)	-
Length of hospital stay (d)	2.2±0.1 (1–6)	-
Re-hospitalization	3 (5.1)	-
3-month outcomes		
Percent PSA drop (%)	-36.6±6.0	<0.0001
IPSS score change	-12.5±1.9	<0.0001
QOL score change	-2.5±0.5	0.001
PVR difference (mL)	-186±82	0.011
Change in prostate size (g)	-15.6±17.3	<0.0001
Ejaculatory preservation	24 (82.8)	-
12-month outcomes		
Percent PSA drop (%)	-29.1±31.9	0.004
IPSS score change	-12.4±7.1	<0.0001
QOL score change	-2.7±2.0	0.001
PVR difference (mL)	-58±99	0.263
Ejaculatory preservation	11 (84.6)	-

Values are presented as mean±standard error of the mean (range) or number (%).
PSA, prostate-specific antigen; IPSS, International Prostate Symptom Score; QOL, quality of life; PVR, post-void residue.
Percentage missing for hemoglobin drop (18.6%), PSA drop (55.9%), IPSS (66.1%), QOL (61.0%), PVR (66.1%).

Table 3. Complications by day 90 following aquablation categorized by Clavien–Dindo classification system

| Adverse events (n=14)	n (%)	Management
Clavien–Dindo 1	5 (35.7)	
Acute urinary retention	4 (28.6)	Catheterization
Thrombosed external hemorrhoid	1 (7.1)	Conservative treatment
Clavien–Dindo 2	5 (35.7)	
Urinary tract infection	3 (21.4)	Antibiotics administration
Deep vein thrombosis	1 (7.1)	Anticoagulation
Capsular perforation	1 (7.1)	Prolonged catheterization
Clavien–Dindo 3a	2 (14.3)	
Decreased urinary flow	2 (14.3)	Evaluation by cystoscopy
Clavien–Dindo 3b	1 (7.1)	
Urethral stricture	1 (7.1)	Urethrotomy
Clavien–Dindo 4a	1 (7.1)	
Sepsis	1 (7.1)	Admission to ICU

ICU, intensive care unit.
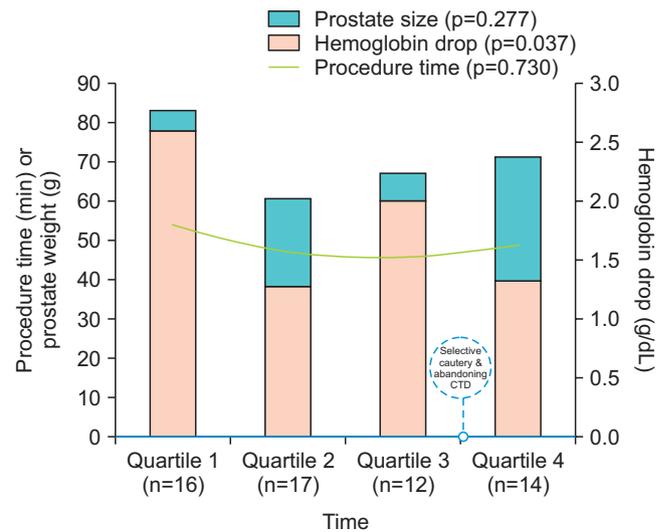
Fig. 2. Trends of prostate size, hemoglobin drop, and aquablation procedure time divided into four periods (March 2018–March 2020). CTD, catheter-tensioning device.

time (p=0.382) length of catheterization (p=0.531), and length of hospital stay (p=0.938). Furthermore, there was no difference in functional outcomes including 3-month changes in prostate size, IPSS, PVR, and QOL (p=0.455, p=0.368, p=0.108, p=0.968, respectively).

At 12-month evaluation, patients' symptoms (IPSS, -12.4±7.1) and QOL (-2.7±2.0) demonstrate sustained relief (p<0.0001 and p=0.001, respectively) (Table 2). Similarly, ejaculation preservation (84.6%) and percent drop in serum PSA (p=0.004) were maintained at 12 months. The change in PVR at 12-months was evaluated only for patients who remained symptomatic (n=8; p=0.263).

We recorded 14 adverse events in 13 (22.0%) of the patients within 90 days of the procedure (Table 3). Five complications were categorized as Clavien–Dindo: grade 1 events, 5 (35.7%); grade 2 events, 5 (35.7%); grade 3a events, 2 (14.3%); and 1 (7.1%) of each grade 3b and grade 4a complications. No grade 4b or grade 5 complications were noted. The only Clavien–Dindo grade 4a complication was attributed to a single case of urosepsis resulting in septic shock and transfer to the intensive care unit. Clavien–Dindo grade 1 and grade 2 constituted 71.4% of all adverse events attributed mostly to acute urinary retention (AUR, 28.6%) and urinary tract infections (21.4%).

Fig. 2 illustrates the prostatic weight in function of the hemoglobin drop and operative time divided into four temporal periods. Bleeding was influenced by the prostate weight and hemostasis method. The group of patients, who all received CTD, had larger prostates (average 83.0±43.8 mL) and a substantial hemoglobin drop (average -2.59±1.79 g/dL). Yet, when cautery and gentle traction by tape was used, aquablation could be performed on medium to larger prostates (71.1 mL in the last group of patients; p=0.277) with limited bleeding (p=0.037). Furthermore, the operative time

was independent of prostate size (p=0.730).

DISCUSSION

We reported on the real-life surgical and functional outcomes of 59 non-selected patients who underwent aquablation at our Middle Eastern tertiary care center during the adoption phase. The results confirmed improved voiding parameters and decreased lower urinary tract symptoms (LUTS) at the 3-month follow-up. A systematic review including seven randomized clinical trials and 5 subgroup analyses reported on the pooled functional outcomes. Effectively, the decrease in IPSS (-16.3±2.32 versus -12.5±1.9 in our study) and QOL scores (-3.48±0.51 versus -2.5±0.5 in our study) are in line with the literature [11]. These numbers are also applicable to larger prostates (>80 mL) [12,13]. The percent PSA drop (-36.6%) also reflects the findings in the WATER (27%) and WATER II (38%) trials [6,7]. However, our study reveals a larger change in post-micturition residue probably because a fourth of the treated patients were in retention at baseline [11]. Furthermore, our results echo the findings of other studies showing that ejaculatory dysfunction can be limited to about 10% (17.2% in our study) thanks to the ability to precisely delineate the area to be resected [11,14]. Nevertheless, ejaculatory dysfunction doubles (19%) when operating on larger prostates and with the use of post-ablation cautery [11,15].

In comparison to aquablation, TURP and open adenectomy are lengthy and morbid procedures especially for larger prostates [3]. When compared to laser enucleation of the prostate (LEP), water ablation has a faster learning curve [7]. Additionally, Gilling et al. [14] compared the 24-month outcomes of aquablation and TURP, a gold standard surgery for BPO, revealing similar IPSS and uroflowmetry parameter scores. Along with significant improvement in LUTS and comparable post-procedural urinary urgency and frequency to TURP, the authors showed stable ejaculatory function in all patients [14]. The anejaculation rates were only 10% in the aquablation group (similar to our findings) and 36% in the TURP group. The main difficulty faced by several series was intraoperative coagulation [8].

Most procedural related adverse events are classified as Clavien–Dindo grade 1 or grade 2. They include LUTS (dysuria, frequency, and urgency), hematuria, and AUR requiring Foley reinsertion and bladder irrigation [5,11]. Based on our experience, AUR could be managed in the emergency department setting after which the patient is discharged. Nevertheless, two patients were re-hospitalized at our institution for AUR because of the significant home to emergency care distance. Besides, only one patient, with a 121 grams prostate size, had a capsular perforation at the level of the bladder neck requiring prolonged catheterization (20 days). This could be encountered if several waterjet passes are done for larger prostates [3]. In this particular case the second treatment pass was performed after significantly deflating the bladder using the suction pedal, this caused a deeper penetration of the waterjet. Furthermore, most re-interventions in the literature are ascribed to bleeding requiring either returning to the operating room or blood transfusion, or due to urethral stricture [11]. In our study, office-based cystoscopy, performed to assess for possible urethral stricture in patients with prolonged postoperative LUTS, comprised most of the grade 3 events.

We found the operative time to be slightly higher (48.5±2.5 minutes) than the pooled estimate of 31.5±15.4 minutes [11]. Although a learning curve of >50 cases was reported for reduction in operative time, several surgeons performed the procedures at our institution [4]. However, the literature revealed comparative outcomes among different institutions despite minimal or no experience among surgeons [7]. Nguyen et al. [16] compared the operative times of different BPO surgeries in function of prostate size and demonstrated that operative time was highest for PVP, intermediate for LEP, and shortest for aquablation [17]. This reinforces our findings that waterjet ablation of tissue is independent of prostatic size (Fig. 1) [16].

In accordance with the published data on aquablation, most of our patients (83.1%) were discharged on the second postoperative day without a catheter after ensuring the clearing of the urine [11]. Patients who needed longer catheterization usually had larger prostates prone to bleeding [8]. Furthermore, Elterman et al. [8] demonstrated that bleeding requiring transfusion was more common among patients receiving robust traction by CTD. Although our transfusion rate was nil, we also experienced a similar trend in hemoglobin drop when the CTD was abandoned; as the latter resulted in pain that induced elevated blood pressure as well as bladder spasms, thereby promoting bleeding and hindering clot formation [8]. Accordingly, postoperative care and pain control is imperative. Despite various opinions in the literature, we endorse selective cautery use at the highly vascular bladder neck to prevent morbidity such as bleeding, extended catheter time, and AUR [4,8]. Effectively, we experienced no grade 1 or grade 2 adverse events in the last group of patients who received selective cautery with standard traction by tape.

CONCLUSIONS

Aquablation is a novel robotic procedure allowing a standardized treatment of BPO with limited adverse events. Our results echo the findings of other studies and confirm the safety and efficacy of the procedure. Evolution of the technique and experience with use of selective cautery at the bladder neck, gentle traction, and appropriate postoperative pain control resulted in less complications.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Albert El-Hajj, Muhammad Bulbul, and Wassim Wazzan. Data acquisition: Albert El-Hajj, Muhammad Bulbul, Wassim Wazzan, Nicolas Abdallah, and Rola Jaafar. Statistical analysis: Muhieddine Labban and Mazen Mansour. Data analysis and interpretation: Muhieddine Labban and Mazen Mansour. Drafting of the manuscript: Muhieddine Labban and Mazen Mansour. Critical revision of the manuscript: Albert El-Hajj, Muhammad Bulbul, Wassim Wazzan, Nicolas Abdallah, Rola Jaafar, Muhieddine Labban, and Mazen Mansour. Obtaining funding: Albert El-Hajj and Muhammad Bulbul. Administrative, technical, or material support: Rola Jaafar. Supervision: Albert El-Hajj, Muhammad Bulbul, and Wassim Wazzan. Approval of the final manuscript: All authors.

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