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BENIGN PROSTATIC HYPERPLASIA (K MCVARY, SECTION EDITOR)

# The Role of Aquablation for the Surgical Treatment of LUTS/BPH

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## Abstract

**Purpose of Review** To explore the potential applicability of a novel, heat-free, and robotically controlled ablative therapy for surgical management of benign prostatic enlargement.

**Recent Findings** With the emergence of new technology to provide personalized care and overcome the complications associated with options such as TURP, holmium laser enucleation of the prostate, GreenLight laser, or simple prostatectomy, Aquablation has been studied across a variety of prostate volumes.

**Summary** The functional outcome of Aquablation seems to be uncompromised by prostate volume. The sexual profile seems superior to TURP and the risk of retrograde ejaculation is lower. The robotic system provides a reproducible ablation, independent of prostate volume, without requiring extensive training for performing the procedure. The mean ablation time in the prostate as large as 150 ml does not exceed 9.1 min, and the blood transfusion rates do not seem to be higher than open prostatectomy.

**Keywords** LUTS · BPH · Aquablation · Outcomes

## Introduction

Benign prostatic enlargement (BPE) is common among men, affecting about 50% of those in their 50s and more than 70% of those in their 70s with an annual incidence of 34.4 per 1000 people [1, 2]. The conventional approach for the management of lower urinary tract symptoms (LUTS) arising from benign prostatic hyperplasia (BPH) has been to start with oral pharmacological options; however, due to the limited efficacy and significant side effects of these medications, many patients proceed to surgical options.

TURP is still suggested as the gold-standard surgery for prostates smaller than 80 ml [3]; however, the risks including ejaculatory and erectile dysfunction following a TURP, even in small prostates, are a major deterrent. Several non-ablative procedures such as prostatic urethral lift (UroLift), temporary implantable nitinol device (iTIND), or water vapor thermal therapy (Rezum) have shown acceptable safety profile [4–6], allowing them to be used as a bridge between pills and TURP or even as an upfront option before taking oral medications. Having said that, the utility of these options is also restricted by the prostate volume (PV).

When it comes to surgical management of prostates larger than 100 ml, obtaining a good functional outcome can be challenging with TURP and would entail a long learning curve and extensive experience. Furthermore, the associated risks such as transurethral (TUR) syndrome (in case using monopolar systems) and bleeding are much higher for TURP in large prostates. The decision for introducing a gold-standard option for large prostates is hindered by the significant complications associated with simple prostatectomy and the long learning curve of endourological procedures such as holmium laser enucleation of the prostate (HoLEP) [3, 7, 8].

Aquablation, using the AquaBeam system, uses a novel approach utilizing a heat-free, robotically controlled waterjet to ablate the prostate. It features a short ablation time independent of prostate volume, with good functional urinary and sexual outcomes. The AquaBeam system consists of a console, a transrectal ultrasound (TRUS) probe for surgical mapping, and the ablative hand-piece which is passed through a rigid cystoscope [9]. Tissue ablation is achieved using high-

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velocity saline jet under robotic control, guided by real-time TRUS mapping, which is performed by the surgeon. This can be achieved under spinal or general anesthesia [9, 10•].

Following the initial report on the feasibility and safety of Aquablation in humans [9], more data has become available addressing the long-term clinical outcomes and also the applicability of this novel technology in patients with large prostate volumes. Here, we review the evolution of this system and its safety and functional outcomes.

## Methods

A PubMed search using the term "Aquablation" was conducted. After removing the duplicates, the non-English articles, review articles, and abstract-only publications, the remaining results were reviewed for population included or excluded, intervention, comparator, and outcomes.

## Publication Timeline and Evolution of the Device

The reviewed clinical trials using Aquablation are listed in Table 1. The first clinical trial enrolled men with moderate-severe LUTS and prostate volume (PV) of 25–80 ml. The authors reported their initial experience in 2016. The first seven patients were treated with the first generation AquaBeam system, which used a 3–5 W coagulating laser during the ablative procedure. This laser was eliminated from the system as it was not deemed to add any advantage, and therefore, the next eight procedures were performed with generation 1.6 which also had an integrated TRUS and an integrated suction pump. Hemostasis was achieved with roller-ball or loop cautery; however, this is not a common practice in the more recent trials. These changes resulted in less ablation time, operation time, hospital stay, and catheter requirement [9] (Table 1).

Following this successful experiment, a single-arm phase 2 prospective clinical trial was conducted by Gilling et al. (2017), using the same inclusion criteria [11]. The primary performance end-point, which was the completion of the target procedure, was met in all the 21 patients. Further details on procedural outcomes are summarized in Table 1. One-year functional results of this study are published and are discussed in the next section.

Technical feasibility of Aquablation was compared with TURP in a double-blinded, prospective randomized controlled trial (WATER study) [10•]. As with the previous study, this trial also defined the maximum PV of 80 ml as the inclusion criteria. Aquablation was the treatment method in 116 and TURP was done for 65 patients. Mean resection time and intraoperative fluid use were significantly less for Aquablation as opposed to TURP (4 versus 27 min). Aquablation was performed under general anesthesia in 94% and spinal anesthesia in 6%. The hemostasis method has been electrocautery or a Foley catheter balloon in the prostatic fossa.

In February 2018, Desai et al. reported using a more advanced generation of AquaBeam system in a prospective clinical trial [12]. Larger prostates were enrolled in this study (20–120 ml) as this model of AquaBeam had an increased resection length and resection depth (reaching 70 mm and 25 mm, respectively, while they were only 30 mm and 15 mm in the previous model). Forty-seven patients with PV ranging from 20 to 118 ml underwent Aquablation and electrocautery was used in 20 patients (43%) to obtain hemostasis. Mean prostate ablation time was 4 min in this report.

The usage of the AquaBeam system was taken to the next step by targeting larger prostates in the WATER II study [14••], which is a prospective study in 13 US and 3 Canadian centers. This was the first study to include large glands only; ranging in prostate volume between 80 and 150 ml. The mean PV in this cohort of 101 patients reached 107.4 ml (± 22.1). Unlike prior studies, most patients in this trial received spinal anesthesia (82%). Hemostasis was achieved with Foley traction using the "catheter tensioning device" (CTD) in 98 patients (97.0%) while 3 patients were managed with a prostatic balloon creating a tamponade. The authors indicate that spinal anesthesia had made the Foley traction more tolerable. Mean prostate ablation time in this cohort of large prostates increased only to 7.8 min. Subgroup analysis in those with PV between 100 and 150 (mean 120 ml) showed an ablation time of only 9.1 min [15••].

Mean total procedure time for the abovementioned studies ranged between 20 and 38 min. The procedural time in the WATER II study has been defined as "hand-piece placement until the final urinary catheter placement" [14••] while others have used pre-ablation cystoscopy/visualization [10•, 11, 12] as the start point. Unfortunately, the time for primary setup and TRUS mapping has not been provided in these studies.

TRUS probe insertion has been considered the start point for an operative time in a large cohort of 118 patients who underwent Aquablation procedure in Germany. No specific inclusion criteria were set and subjects were excluded only if they were anticoagulated (except for ASA 100 mg). Patients were given tranexamic acid 30 min prior to the procedure, unless contraindicated. Hemostasis was obtained only with the Foley catheter traction in 96% of the cases. A catheter-tensioning device, CTD, (PRO- CEPT BioRobotics, Redwood Shores, CA, USA) was utilized in this study. The mean operative time was 20 ± 7.91 min and ranged from 9 to 53 min [13].

## Functional Urinary and Sexual Outcomes

Apart from the functional outcome of the previously mentioned clinical trials, several post hoc/subgroup analyses of

**Table 1** Timeline of major publications reviewed

| Author and year* | Description |
|---|---|
| Gilling et al. 2016[9] | • The first study of using AquaBeam system on human subjects; a non-randomized trial<br>• Inclusion: IPSS of > 12, Qmax ≤ 12 ml/s, Schaffer scale of ≥ 2, prostate size of 25–80 ml<br>• 15 patients with PV of 27–85 ml, six of which had a median lobe: mean PV = 57 (27–85) ml<br>• Aquablation was successful in all 15 patients without procedure or device-related AEs<br>• Mean hospital stay, 1.3 days with Generation 1.6 (with Generation 1.0 = 2.3 days)<br>• Mean duration of catheter, 1 day with Generation 1.6 (with Generation 1.0 = 1.8) |
| Gilling et al. 2017[11] | • Phase II clinical trial: 1 year data available<br>• 21 patients with inclusion criteria that were similar to previous study<br>• Mean PV was 57.2 ml with median lobe in 12 patients<br>• Post-Aquablation cautery: mean cautery time was 7.5 min with monopolar loops in 12 cases and with a roller-ball in 9<br>• Mean hospital stay, 1 day for 19/21 patients<br>• Mean duration of catheter, 1 day in 20/21 patients |
| Gilling et al. Jan 2018 (WATER) [10•] | • Aquablation: 116 patients and TURP, 65 patients; 1 year data available<br>• Inclusion criteria, PV = 30–80; IPSS, 12 or greater and Qmax < 15 ml/s<br>• Mean PV = 54.1 (± 16.2) vs 51.8 (± 13.8); median lobe present in 66/116 and 34/65<br>• Intraoperative fluid use, 5.2 vs 13.2 l ($p < 0.0001$)<br>• Mean hospital stay, 1.4 days<br>• Mean duration of having a catheter, 1 day |
| Desai et al. Feb 2018 (AquaBeam India) [12] | • Prospective trial using a second generation of AquaBeam in 47 patients: duration of follow-up, 3 months<br>• Inclusion criteria: men aged 50–80 years, IPSS > 12, PV = 20–120 ml, Qmax ≤15 ml/s and a history of inadequate response, contraindication to or refusal of medical therapy<br>• Mean PV = 48 ml; 53% had a median lobe<br>• Mean hospital stay, not provided<br>• Mean duration of having a catheter1.9 (1–11) days. The patient who has needed 11 days of catheterization had a prior history of prolonged catheter dependency |
| Bach et al. Oct 2018[13] | • A non-selected cohort study; duration of follow-up, 3 months<br>• 118 patients with mean PV = 64.3 ± 32 ml (range 20–154 ml)<br>• Mean hospital stay, not provided<br>• Mean duration of having a catheter, 2.2 ± 0.46 (range 2–4) days. Six patients discharged with catheter |
| Desai et al. June 2018 (WATER II) [14••] | • First study not allowing prostates smaller than 80 ml; 6 months results available<br>• Inclusion criteria, PV = 80–150 ml, IPSS ≥ 12, Qmax < 15 ml/s, serum creatinine < 2 mg/dl, a history of inadequate or failed response to medical therapy<br>• 101 patients with mean PV = 107 (± 20) ml; medial lobe present in 83%<br>• Mean hospital stay, 1.6 days (0 to 6 days)<br>• Mean duration of having a catheter, 3.9 days |

these studies have been published. These include the US cohort of WATER and WATER II studies [16, 17], and also the subgroup comparison of patients in the WATER II by dividing them into those with prostates larger or smaller than 100 ml [15••]. The improvements observed after treatment are illustrated in Figs. 1 and 2.

The 1-year follow-up results of the phase II clinical trial showed significant improvement of urinary functional outcomes (IPSS, IPSS-QoL, and Qmax; $p < 0.01$). The mean post-void residual volume also improved significantly by 89 ml. Regarding ejaculatory and orgasmic changes after Aquablation, no deterioration in the IIEF-15 scores was noted, and on the contrary, the scores trended toward a non-significant improvement. The intercourse satisfaction assessed by IIEF-15 questions 6 to 8 improved significantly ($p < 0.01$) [11].

The water study compared the AquaBeam system with TURP and the results from both US cohort and the whole cohort indicate significantly shorter ablation time with AquaBeam compared with TURP (4 versus 27 min in WATER and 3.9 versus 29.8 min in its US cohort). The procedure time in the US cohort was reported to be significantly lower with AquaBeam (27.6 min and 37.4 min, respectively, $p = 0.0037$) while this significance was not observed in the whole WATER project cohort (33 and 36 min, $p = 0.27$). Once again, it should be mentioned that this time has been calculated from the pretreatment cystoscopy to indwelling catheter insertion. The urinary functional outcomes (IPSS, IPSS-QoL, Qmax, and PVR) improved significantly by both treatment modalities and these improvements were not statistically different between the TURP and AquaBeam systems (Figs. 2 and 3) [17, 18]. The rate of retrograde ejaculation was significantly lower in the Aquablation group (9% versus 45%, $p = 0.0006$) [17].

Although the 12-month results of the WATER study showed no significant difference between Aquablation and

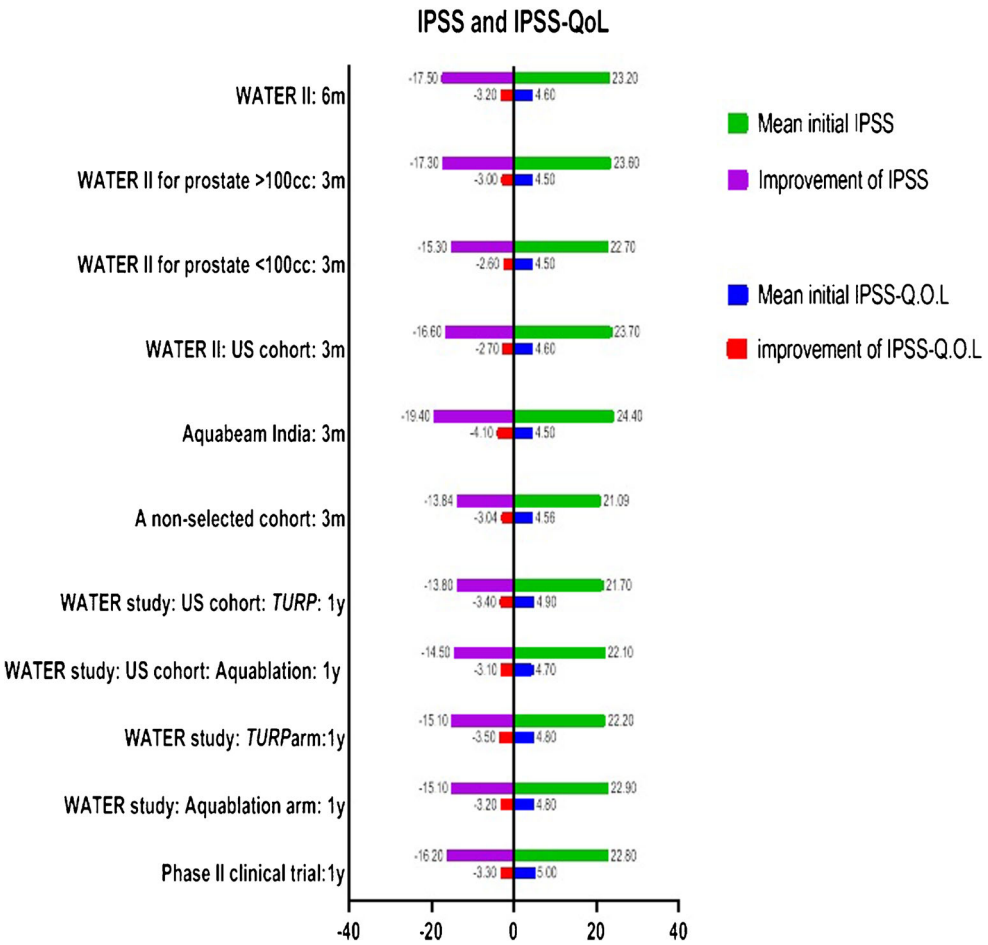


**Fig. 1** IPSS and IPSS-QoL in different trials

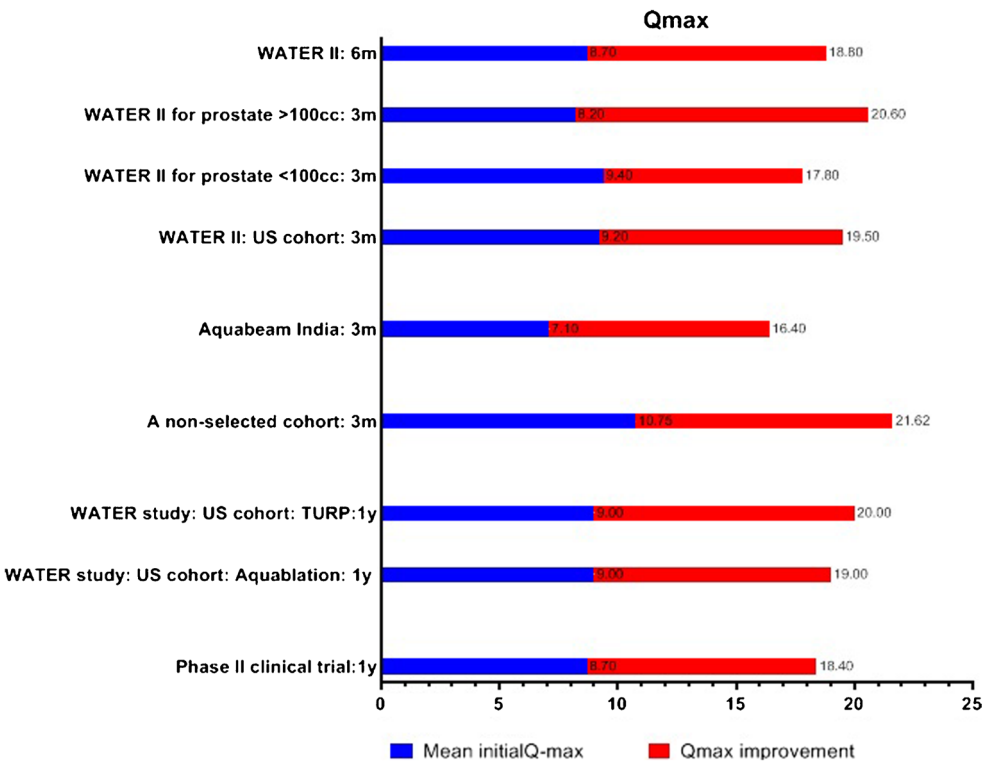


**Fig. 2** Qmax and its improvement in different trials

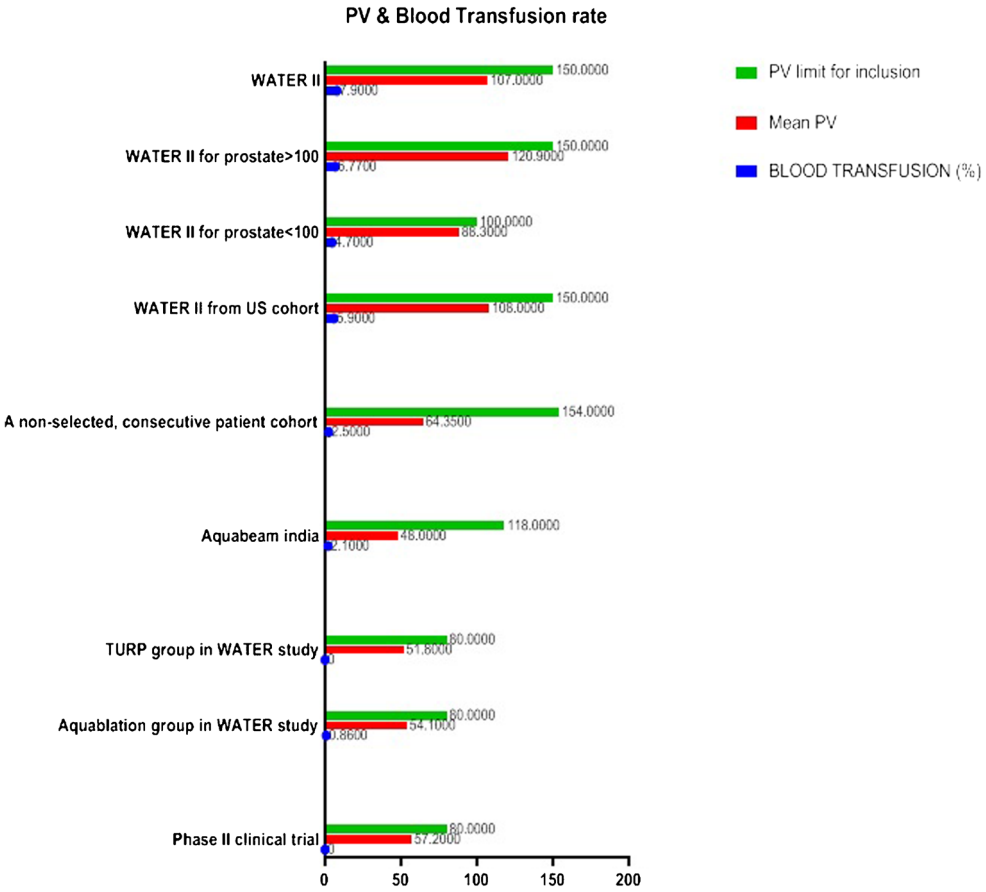


**Fig. 3** Post ablation blood transfusion rates in different studies

TURP in improving IPSS, IPSS-QoL, and Qmax, an exploratory subgroup analysis showed that men with prostates larger than 50 ml experienced significantly greater IPSS improvement [19]. This hypothesis that Aquablation can be a superior treatment modality for larger prostates was tested in the WATER II project. With a mean PV of 107 ml in WATER II and 108 ml in its US subgroup, the IPSS improvement peaked to 17.5 and 16.6-point change, respectively. The subgroup of WATER II with the mean PV of 121 ml had an IPSS improvement of 17.3. These should be opposed to the prior studies with a maximum PV of 80 ml or the max mean PV of only 64.35 ml, which had lower IPSS improvement (Fig. 2) [7, 11, 15••, 17, 20]. Improvement of IPSS-QoL was similar between the WATER and WATER II studies. Patients with PV > 100 ml showed an improvement of 3 points in IPSS-QoL, while this was 2.6 for PV between 80 and 100 (this difference was not statistically significant). [7, 15••] Same is true for Qmax (improvement of 12.4 ml/s vs 8.4 ml/s in PV > 100 ml and PV < 100 ml, respectively). These differences were also not statistically significant.

The mean MSHQ and IIEF-15 score did not change significantly in either the US cohort or the 100 ml subgroup analysis of the WATER II study. The rate of ejaculatory dysfunction was 19% in the WATER II trial with no significant difference between those with PV larger or smaller than 100 ml. [7, 15••] Ejaculatory dysfunction was reported in 11% of the US part of the WATER II [20].

The urinary functional improvements observed in AquaBeam India and the previously mentioned non-selected were also statistically significant. There were no cases of erectile or ejaculatory dysfunction in AquaBeam India; however, a 27% ejaculatory dysfunction has been reported by Bach et al. [12, 13]

## Hemoglobin Drop, Blood Transfusion Rate, and Adverse Events

The blood transfusion rates and its relation to both mean PV and range of PV are depicted in Fig. 3. This figure shows that when the range of PV was wide, and hence, the distance between the mean PV and the upper limit of PV was wide, the blood transfusion rate mostly correlated with the PV range than with the PV mean. This becomes more apparent when looking at AquaBeam India and the non-selected cohort studies which have a mean PV close to that of WATER study but have a higher transfusion rate, due to having a wide range of PV.

Studies with inclusion criteria of PV < 80 (phase II clinical trial, WATER study and its US cohort) reported the mean post Aquablation hemoglobin (HGB) decrease to range from 0.8 to

2 g/dl; with only one blood transfusion reported which was in the Aquablation group of the WATER trial (1/116 patients). On the other hand, AquaBeam India and the non-selected cohort studies which allowed PV to reach 118 and 154 reported a mean HGB decrease of 1.4 g/dl and 1.78 g/dl, respectively. The transfusion rates were 2.1% and 2.5% [12, 13].

When the prostates between 80 and 100 ml were allowed in the study, the HGB drop was 2.5 g/dl and the blood transfusion rates went up to 4.76% (2/42 patients in the subgroup of WATER II with PV < 100 ml, mean PV = 88 ml) [15••]. The mean hospital stay was 1.5 days.

Limiting the PV between 100 and 150 ml in the second subgroup of WATER II, caused the transfusion rates to go higher and reach 6.7% (4/59 patients) [15••]. This group had a mean hospital stay of 1.7 days. The 6 months results of WATER II indicate that apart from the 8 patients who required blood transfusion or any intervention for their bleeding, 6 patient also required blood transfusion/intervention after discharge.

Interestingly, the adverse events, which have been assessed by the Clavien-Dindo (CD) classification, seem to correlate with mean PV. The rate of CD grade 2 and higher adverse events in the WATER study and studies with broader inclusion criteria for PV but still with a mean PV reaching only to 64.35 [12, 13]did not pass 14% [12, 13, 17]. Furthermore the WATER study showed that grade 1 or 2 or higher grades of adverse events were only 26% in the Aquablation arm while the figures for the TURP group were significantly higher at 42%. The mean duration of hospital stay when PV was limited to 80 ml was 1–1.4 days [10•, 11, 17].

The rate of CD grade 2 and higher adverse events in the WATER II study were 22%, 14%, and 5% for CD grade 2, 3, and 4, respectively) [7]. Five cases of urinary incontinence (mixed and urge types) were reported in WATER II at 6 months. No erectile dysfunction has been observed in this study and the rate of ejaculatory dysfunction among sexually active men has only been 19% [7]. The Canadian subgroup WATER II trial, which was performed by novice users of the system, has reported a CD grade 2 or higher adverse event rate of only 31.6% at 3 months [21].

## Discussion

Due to limited efficacy, technical challenges, or perioperative morbidities of many options such as transurethral incision of prostate (TUIP), transurethral microwave therapy (TUMT), or transurethral needle ablation of the prostate (TUNA), TURP is still considered the gold-standard surgical option for prostates smaller than 80–100 ml [3, 8]. This is despite all the potential complications associated with TURP. When it comes to endosurgical options to address larger prostates, the high complication rate of TURP and the long learning curve required for establishing a good outcome with modalities such as GreenLight (GL) and HOLEP push the decision toward a simple prostatectomy, with an even higher risk for complications [22].

The fact that functional outcomes of Aquablation were not impacted by larger sizes of the prostate is of great importance. Although the improvements observed with TURP and Aquablation were similar in the WATER study, the applicability of TURP stops at PV of 100 ml, while Aquablation continues to provide at least similar improvements even in prostates as large as 150 ml (Figs. 2 and 3). This importance can be further highlighted when it comes to the learning curve required for HoLEP and GL for large prostates as opposed to the ease of operation with the AquaBeam system. With the AquaBeam system, the ablation part of the procedure is done robotically and the surgeons' role is mostly to map the ablation field with a TRUS. Since most urologists are familiar with TRUS, the procedure can be adopted and replicated far more easily compared with the skills required to master performing a HoLEP or an effective GL in a large prostate [23]. Bach et al. reported the mean OR time for Aquablation in their first 50 cases to have been 24.2 min while the next 68 cases were done during a period of 17 min [13]. To our knowledge, the majority of centers in the WATER and WATER II studies were novice to the technique and had no prior experience with AquaBeam system, and despite this, the mean ablation time in the largest cohorts of 100 to 150 g prostates was only 9.1 min.

In light of the learning difficulties with GL and HoLEP, and the complications expected with simple prostatectomy, Aquablation has the potential of becoming the standard of care for prostates larger than 100 ml. The blood transfusion rates following open prostatectomy are reported to be between 7 and 14% [3, 7]. Urinary incontinence rates can reach 10% after simple prostatectomy while this was less than 5% with Aquablation. Although HoLEP has lower blood transfusion risk, the risk of retrograde ejaculation is above 50% [24]. Randomized controlled trials to compare Aquablation with simple prostatectomy, HoLEP, and GL, addressing long-term functional outcomes and complications, are required to reach a good level of evidence and proper recommendations.

Regarding smaller prostates, although the short-term urinary functional results of Aquablation seem to be similar to TURP, the long-term outcomes might be better with Aquablation due to good ablative potentials. Furthermore, the sexual profile of AquaBeam system seems superior to that of TURP. Having said that, the lower risks associated with novel technologies, such as UroLift and Rezum which have provided promising long-term outcomes, have made the decision making in small prostates more interesting and interactive [4, 6].

## Conclusion

Aquablation seems to be a promising option for the management of LUTS resulting from BPE with varying degree of prostate volumes. The safety profile, including the preservation of ejaculatory function, seems to surpass the other available options for patients with larger prostate volumes. The robotic system provides a reproducible ablation, independent of prostate volume, without requiring extensive training for performing the procedure.

### Compliance with Ethical Standards

**Conflict of Interest** The authors declare that they have no conflicts of interest.

**Human and Animal Rights and Informed Consent** This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance


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