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# Meta-analysis with individual data of functional outcomes following Aquablation for lower urinary tract symptoms due to BPH in various prostate anatomies

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## ABSTRACT

**Objectives** To evaluate functional outcomes following Aquablation in various prostate volume and anatomical subgroups.

**Design** A meta-analysis with individual patient data undergoing Aquablation therapy from four prospective, global, clinical studies that have been conducted with Aquablation; WATER, WATER II, FRANCAIS WATER and OPEN WATER.

**Setting** Australia, Canada, Lebanon, Germany, New Zealand, UK and the USA.

**Participants** 425 men with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) with 1-year follow-up.

**Interventions** Aquablation therapy is an ultrasound guided, robotically executed waterjet ablative procedure for the prostate.

**Main outcome measures** The analyses focus International Prostate Symptom Score (IPSS), uroflowmetry, postoperative Incontinence Severity Index (ISI) and surgical retreatment.

**Results** 425 men with prostates ranging in size from 20 to 150 mL underwent Aquablation therapy. The outcomes from the seven questions in the IPSS questionnaire were grouped by the following; prostates <100 mL, prostates ≥100 mL, prostate anatomy with an obstructive median lobe identifed by imaging, and prostate anatomy without an obstructive median lobe. Regardless of subgroup, all outcomes are consistent and demonstrate a significant improvement from baseline. Specifically, improvements in frequency, urgency and nocturia demonstrated bladder function improvement. Patients entering treatment with severe incontinence, ISI score >4, and regardless of prostate size, showed a reduction in incontinence during patient follow-up. Surgical retreatment due to BPH symptoms occurred in 0.7% (95% CI 0.1%–2.0%).

**Conclusions** Across a variety of prostate anatomies, Aquablation therapy showed remarkable functional improvements following the index procedure. Additionally, men with moderate to severe LUTS/BPH and overactive bladder resulting in urge incontinence showed a reduction in incontinence symptoms postprocedure.

## Key messages

### What is already known about this subject?

- Various interventions are offered to men suffering from lower urinary tract symptoms due to benign prostatic hyperplasia based on size, surgeon skill and technology limitations. All of these options present a trade-off to the patient to choose to maximise efficacy or minimise irreversible complications (erectile dysfunction, ejaculatory dysfunction and incontinence).

### What are the new findings?

- This meta-analysis has shown that regardless of prostate size or anatomical shape, Aquablation therapy by using real-time imaging and robotic execution can maximise efficacy and minimise irreversible complications.

### How might these results affect future research or surgical practice?

- This may consolidate the treatment options physicans offer to patients. This may also push the upper boundary of 80 ml prostates as the typical limit in clinical research to a larger number.

## INTRODUCTION

Multiple treatment modalities for benign prostatic hyperplasia (BPH) are available, including watchful waiting, medications, transurethral surgical procedures where adenoma is not removed at the time of procedure, and several techniques for transurethral surgical prostate resection where adenoma is removed. It is generally accepted that resective techniques are most efficacious at symptom relief but carry the highest perioperative risk. Recent data have suggested that an obstructive median lobe may play a critical role in response to resective prostate treatments for BPH.[1 2] The median lobe is variably enlarged, with 10%–42% of men having

a severe intravesical prostatic protrusion (IPP).[3] In the presence of IPP, medical therapy is less effective at reducing International Prostate Symptom Score (IPSS) and improving Qmax.[1] Median lobe-only transurethral resection of the prostate (TURP) has been reported to be safe and effective, with improved postoperative symptoms and uroflow while simultaneously preserving ejaculatory function.[2] One of the explanations is preservation of the para-collicular tissue where the ejaculatory ducts emerge at the verumontanum. Other resective procedures focused on anatomy preservation may also prevent postoperative anejaculation commonly seen after a typical TURP.[4] Non-resective procedures for BPH, such as convective water vapour ablation of the prostate, can also address men with enlarged median lobes. The American Urology Aassociation does not recommend other minimally invasive procedures (eg, prostatic urethral lift) for men with BPH and enlarged median lobes, despite some recent evidence of effectiveness.[5]

Treatment options (eg, photoselective vaporisation of the prostate (PVP), holmium laser enucleation of the prostate (HoLEP), thulium laser enucleation of the prostate (ThuLEP)) for men with large prostates, exceeding 80–100 mL, is a rapidly growing area. However, procedure times are long and in many cases, a simple prostatectomy may be required. Aquablation is a relatively new technique that resects the prostate using image guidance and robotic execution under surgeon control. A blinded randomised trial showed superior efficacy in prostates>50 mL and prostates with median lobes versus TURP[6] and a lower rate of postoperative anejaculation.[7] To date, four prospective international studies of Aquablation have been performed showing consistent results in symptom reduction and low rates of irreversible complications in prostate sizes up to 150 mL.[8–11] Herein, we report a combined individual-patient meta-analysis undergoing the Aquablation procedure; combining data enabled more detailed analysis (subgroup analysis) of men with larger prostate size (>100 mL) and presence of an obstructive median lobe. While most guidelines reference 80 mL as the prostate size cut-off to consider alternative surgical options, common practice may push this up to 100 mL. By defining large prostates as over 100 mL, there should not be a debate as to whether this is a true large prostate population. Our analysis focuses on both storage and voiding symptom improvement, uroflowmetry, and impact on incontinence, a common finding in men with moderate-to-severe lower urinary tract symptoms (LUTS) due to BPH.

## METHODS

The analysis methodology undertaken is categorised as a type III meta-analysis defined as a reanalysis of individual data based on primary clinical studies as described by Blettner *et al*.[12] This type of analysis may also be referred to as a pooled analysis.

### Data sources

The goal of this study was to combine data from prospective, multicentre studies of the Aquablation procedure using the contemporary version of the AquaBeam Robotic System (PROCEPT BioRobotics, Redwood City, California, USA), which was first used in 2014, with scheduled follow-up to at least 1 year sufficient to support detailed subgroup analyses on an individual patient level. Retrospective studies or studies without scheduled follow-up or using a prior version of the robot were excluded. A PubMed search conducted 26 January 2021 using the term 'Aquablation' identified 99 published articles to date; of these, only four clinical trials met the above criteria and described in table 1. The notable data sets excluded due to lack of 1-year follow-up and multicentre format were Desai *et al*[13] 47 patients from India, Bach *et al*[14] 118 patients from Germany and Kasraeian *et al*[15] 55 patients from the USA. The device manufacturer confirmed no other ongoing studies were being conducted or could contribute study data.

**Table 1** Summary table of prospective, multicentre clinical trials that have at least 1 year following Aquablation treatment

| | Population | Study type | Dates | Country | Aquablation procedures | % 1 year visit completed |
|---|---|---|---|---|---|---|
| WATER (Gilling *et al*, 2019)[16] | Moderate to severe LUTS due to BPH, 30–80 mL prostate size | Randomised, controlled trial | 2015–17 | Australia, New Zealand, UK, USA | 116 | 99.1% |
| WATER II (Bhojani *et al*, 2019)[17] | Moderate to severe LUTS due to BPH, 80–150 mL prostate size | Single-arm with objective performance criteria, controlled trial | 2016–17 | Canada, USA | 101 | 95.0% |
| FRANCAIS WATER (Misrai *et al*, 2019)[11] | Moderate to severe LUTS due to BPH, 30–80 mL prostate size | Single-arm with objective performance criteria, controlled trial | 2017–18 | France | 30 | 100% |
| OPEN WATER (Bach *et al*, 2020)[10] | Moderate to severe LUTS due to BPH, 20–150 mL prostate size | Observational study | 2017–19 | Australia, Germany, Lebanon, New Zealand, UK | 178 | 80.9% |

BPH, benign prostatic hyperplasia; LUTS, lower urinary tract symptoms.

We pooled individual patient data from four trials of men with moderate-to-severe LUTS due to BPH who had not undergong prior prostate surgery. Data extraction was not required as individual patient data were available for all studies and provided by the manufacturer/study sponsor. WATER (NCT02505919)[16] was a prospective multicenter international double-blinded randomised controlled trial of Aquablation treatment versus TURP in men with moderate-to-severe LUTS/BPH and prostate sizes from 30 to 80 mL. Seventeen centres participated, and 116 subjects were randomised and treated with Aquablation. WATER II (NCT03123250)[17] was a prospective multicentre international single-arm clinical trial of men with prostate sizes from 80 to 150 mL. Sixteen centres in Canada and the USA participated, and 101 subjects were treated with Aquablation. FRANCAIS WATER (NCT03191734)[11] was a prospective multicenter single-arm clinical trial of initial commercial experience with Aquablation in France. Three centres participated, and 30 subjects with moderate-to-severe BPH and prostate sizes from 30 to 80 mL were treated with Aquablation. OPEN WATER (NCT02974751)[10] was a prospective multicentre international single-arm clinical trial of initial commercial experience with Aquablation. Five centres in Australia, Germany, Lebanon and New Zealand participated, and 178 subjects with prostate size 20–150 mL were treated with Aquablation.

In each study, participants were evaluated preoperatively using transrectal ultrasound (TRUS), serum prostate specific antigen (PSA) and uroflow measures. Subjects also completed several questionnaires on symptoms related to BPH, including IPSS[18] and Incontinence Severity Index (ISI). The ISI consists of two questions on the frequency and amount of urinary leakage and has been used in epidemiological surveys and clinical trials of LUTS treatment. An incontinence threshold of ISI>4 corresponds to the threshold for severe incontinence in the three-level index.[19] ISI score is the product of self-reported frequency and severity of incontinence, each category rated on an ordinal scale. For men not reporting incontinence, a score of 0 was assumed. Ejaculatory dysfunction was defined as subjects with a baseline ejaculatory function score of 1 (some ejaculate) or greater based on his response to male sexual health questionnaire for ejaculatory dysfunction short form (MSHQ-EjD-SF) question 3 and the post-treatment response change to zero (could not ejaculate). Erectile dysfunction (ED) was defined as subjects who had normal erectile function at baseline (sexual health inventory for men (SHIM) score of 22–25) and a post-treatment response of moderate-to-severe ED (SHIM score of 11 or less). After baseline evaluation and surgery, subjects returned to the clinic for research-related follow-up visits that included responses to the same questionnaire set.

Other than differences in prostate size requirements and study setting (premarket vs postmarket), studies were similar with very comparable eligibility criteria, table 2. All investigators were trained by the manufacturer and used robotic devices that were functionally identical. All questionnaire administration was similar across studies. All studies were sponsored by the device manufacturer (PROCEPT BioRobotics, Redwood City, California, USA), and data were collected on the same electronic platform. All data underwent independent monitoring. For these reasons, data were considered poolable across studies.

## Statistical analysis

Individual patient-level data were combined across studies. Because of the similarity in study design across studies, most key data elements were evaluable for the vast majority of enrolled patients. The focus of our analysis was change in key outcome parameters (symptom scores, components of IPSS, uroflow and incontinence) as a function of the following subgroups: prostate size ≥100 mL vs <100 mL and presence/absence of obstructive median lobe on preoperative imaging (cystoscopy or TRUS). Given the large sample size resulting from combining four studies, we also studied responses to each of the seven IPSS questions. Statistical techniques used included tabular and graphic analysis, multivariate linear regression and repeated measures analysis of variance. Analyses were performed in R[20] on the RStudio platform.[21]

**Table 2** Summary table of key inclusion/exclusion criteria across clinical trials

| | WATER | WATER II | FRANCAIS WATER | OPEN WATER |
|---|---|---|---|---|
| **Inclusion criteria** | | | | |
| Prostate size | 30–80 mL | 80–150 mL | 30–80 mL | 20–150 mL |
| IPSS | ≥12 | ≥12 | ≥12 | Diagnosed with LUTS/BPH |
| Qmax | <15 mL/s | <15 mL/s | <15 mL/s | Diagnosed with LUTS/BPH |
| **Exclusion criteria** | | | | |
| PVR | >300 mL | None | >300 mL | None |
| History of urinary retention | Yes | Only if catheter use exceeded 90 days | Yes | None |
| Previous prostate surgery | Yes | None | Yes | None |
| ASA Classification | III or higher | None | None | None |

ASA, American Society of Anesthesiologists; BPH, benign prostatic hyperplasia; IPSS, International Prostate Symptom Score; LUTS, lower urinary tract symptoms; PVR, postvoid residual urine.

Table 3 Baseline characteristics of Aquablation subjects by prostate volume and presence/absence of median lobe reported as mean (SD)

| | Prostate volume | | | Median lobe | | |
|---|---|---|---|---|---|---|
| | <100 mL n=350 | ≥100 mL n=75 | P value | Absent n=144 | Present n=264 | P value |
| Age, years | 66.9 (8.0) | 67.6 (6.0) | 0.3965 | 68.1 (8.1) | 66.5 (7.3) | 0.0401 |
| BMI | 27.8 (4.0) | 29.1 (4.4) | 0.0403 | 28.4 (4.6) | 25.0 (3.0) | 0.5132 |
| Prostate volume, mL | 57.7 (20.2) | 126.7 (26.4) | <0.0001 | 58.5 (26.7) | 77.5 (35.6) | <0.0001 |
| IPSS | 22.1 (6.5) | 23.3 (6.6) | 0.1811 | 21.8 (6.5) | 22.4 (6.5) | 0.3919 |
| IPSS QOL | 4.7 (1.1) | 4.6 (1.1) | 0.3432 | 4.6 (1.3) | 4.7 (1.0) | 0.4177 |
| Qmax, mL/s | 9.6 (4.1) | 8.2 (4.0) | 0.0117 | 9.3 (3.4) | 9.2 (4.3) | 0.9138 |
| PVR, mL | 101.3 (98.2) | 150.1 (132.8) | 0.0052 | 87.4 (87.5) | 122.9 (113.5) | 0.0008 |
| ISI | 2.4 (2.8) | 2.3 (2.7) | 0.7003 | 2.4 (2.8) | 2.2 (2.7) | 0.5076 |

BMI, body mass index; IPSS, International Prostate Symptom Score; ISI, Incontinence Severity Index; QOL, quality of life.

## RESULTS

A total of 425 men underwent Aquablation in the four studies where 91% completed the 1-year visit. Baseline characteristics by study are shown in table 3. There was no relationship between prostate volume (categorised as ≥or <100 mL or as a continuous variable) or presence/absence of an obstructive median lobe and baseline IPSS or IPSS quality of life (QOL) score. Seventy per cent of the median lobes had an intravesical component. The average procedure time, defined as TRUS insertion to urinary catheter placement, was 40 min (median 38, range 8–111 min).

The mean baseline IPSS was approximately 23 points (median 24, range 12–35); baseline score was slightly lower in FRANCAIS WATER (p=0.0467). IPSS scores improved significantly in all studies; at 1 year, the mean improvement from baseline was 16 points with no variation across studies. One year IPSS scores were independent of baseline IPSS score, providing strong evidence for near-maximal improvement (ie, a ceiling effect). The IPSS data were assessed by region (North America, Europe and Australia/New Zealand) and showed no effect on IPSS changes scores. Additionally, 16% of procedures used cautery for haemostasis following Aquablation and observed no systematic effect on change in IPSS. Similarly, mean IPSS QOL improved from 4.7 at baseline to 1.4 at 1 year. There was no variation in baseline IPSS QOL or 1-year change score across studies. Similar to IPSS, IPSS QOL scores were only slightly related to baseline IPSS QOL, indicating near-maximal improvements (ceiling effect).

Baseline Qmax averaged 9.4 mL/s (median 9 mL/s, range 2–36). Statistically significant variation in baseline Qmax was observed across studies, but the differences were modest (at most 1.3 mL/s). The 1-year change in Qmax was independent of studies. The average Qmax at 1 year was 20.5 mL/s, an improvement of 9.4 mL/. Mean baseline PVR was 109.8 mL (median 80.5 mL, range 0–762) with larger values in WATER II, consistent with men having larger prostates by design in this study. One year improvement in PVR averaged 62 mL (median 41 mL) with larger improvements in WATER II compared with other studies. The improvement in PVR was strongly dependent on baseline PVR and was largest in WATER II. In men with elevated (>50 mL) baseline PVR, PVR at follow-up improved. For example, in men with PVR of 51–100 mL, the mean 1-year improvement was 31 mL (42%); for men with PVR of 101–200, mean improvement was 97 mL (66%); for men with PVR >200 mL, mean improvement was 204 mL (68%).

Improvements in these four key parameters (IPSS, IPSS QOL, Qmax and PVR) were independent of both prostate size and presence/absence of median lobe (figure 1). Not surprisingly, baseline PVR was higher in patients with large prostates and those with median lobes; similarly, baseline Qmax was lowest in men with large prostates. However, improvements in both Qmax and PVR were large and clinically important across all subgroups. Improvements in PVR depended strongly on baseline PVR (higher baseline PVR led to a larger decrease in PVR); in multivariate regression models controlling for prostate size and baseline PVR, improvements were slightly smaller (by 17 mL, p=0.0161) in men with middle lobe versus without.

Analysis of individual components of IPSS showed statistically significant improvement in each component over time (figure 2); improvements were independent of prostate size and presence/absence of median lobe. The IPSS-Voiding subdomain is the sum of the answers to question 1 (incomplete emptying), question 3 (intermittency), question 5 (weak stream) and question 6 (straining to void). By contrast, the IPSS-Storage subdomain is the sum of the answers to question 2 (frequency), question 4 (urgency) and question 7 (nocturia). Significant and sustained improvements were observed in both subdomains. This indicates Aquablation's removing tissue to a significant degree so as to see not just obstructive voiding symptoms improve but also bladder voiding function as well. The clinically significant improvement in symptom reduction translated into a low surgical retreatment in 0.7% (95% CI 0.1%–2.0%) patients while preserving erectile and ejaculatory function. Across the 425 men, there were no reports of postoperative de novo ED, whereas postoperative de novo ejaculatory dysfunction, defined as losing the ability to emit seminal fluid, was observed in 10.8% of men. Clavien-Dindo II-IV adverse

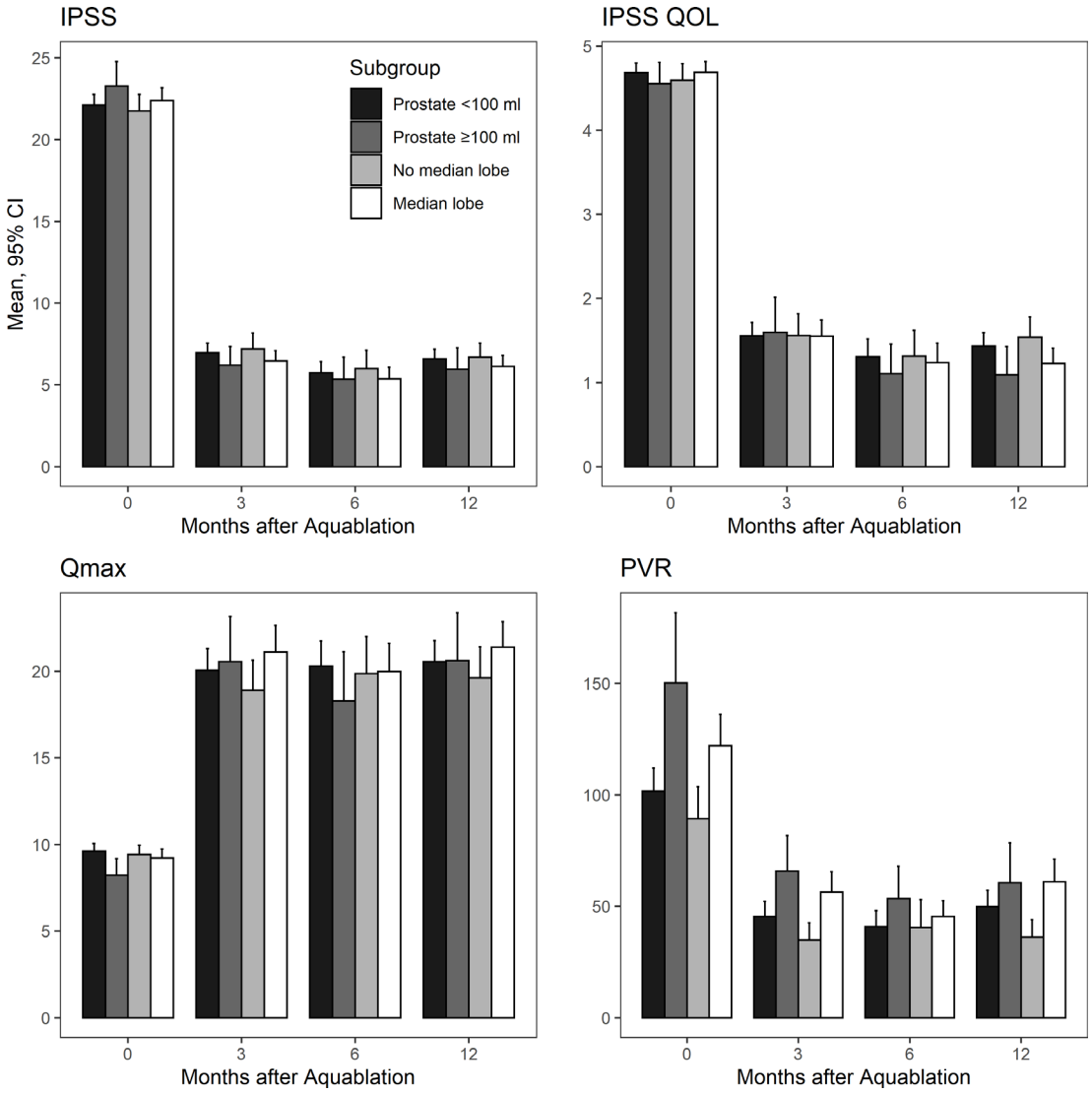


**Figure 1** Mean values (95% CI shown as error bars) in IPSS, IPSS QOL, Qmax and PVR by prostate size and presence/absence of obstructive median lobe. Each patient will be represented in one category of size and one category of median lobe. IPSS, International Prostate Symptom Score; QOL, quality of life.

events were similar across studies. In the only randomised study, the Clavien-Dindo II-IV adverse events were similar between Aquablation and TURP.

Many men with BPH also experience urge incontinence, mostly due to bladder overactivity (detrusor instability). Subjects with low baseline ISI scores (4 or less) had modest perioperative rises in ISI score, but values reduced back to baseline in subjects with all prostate volumes (figure 3). In patients with clinically significant incontinence (baseline score>4), ISI scores improved in men with both small and large prostates.

## DISCUSSION

The individual patient data meta-anlaysis performed from four studies of Aquablation resulted in 425 patients, the largest dataset to date, which enabled more detailed analyses of response to treatment compared with those restricted to single smaller studies.

First, the late (6 month and 1 year) IPSS scores were nearly independent of the baseline score. That is, no matter what initial degree of symptoms was present (baseline score), final scores were low (5–8 points, ie, near normal, reflected by a near flat linear fit in figure 1). This phenomenon, which was observed for both IPSS and IPSS QOL scores, indicates a ceiling effect, namely that robotically executed, waterjet-based prostate resection and relief of bladder outlet obstruction likely restore bladder function maximally. This finding may explain why long-term (3 years) results to date indicate sustained improvement.[8] With high rates of follow-up indicating a complete data set and little loss to attrition, Aquablation was able to achieve exceptionally low rates of retreatment, 0.7%, across prostate sizes up to 150 mL. Hwang *et al* published a Cochrane Review paper assessing the WATER study.[22] The authors assigned the WATER 1-year retreatment rate as low-certainty evidence. Their conclusions were likely due to a low sample size from a single study. The

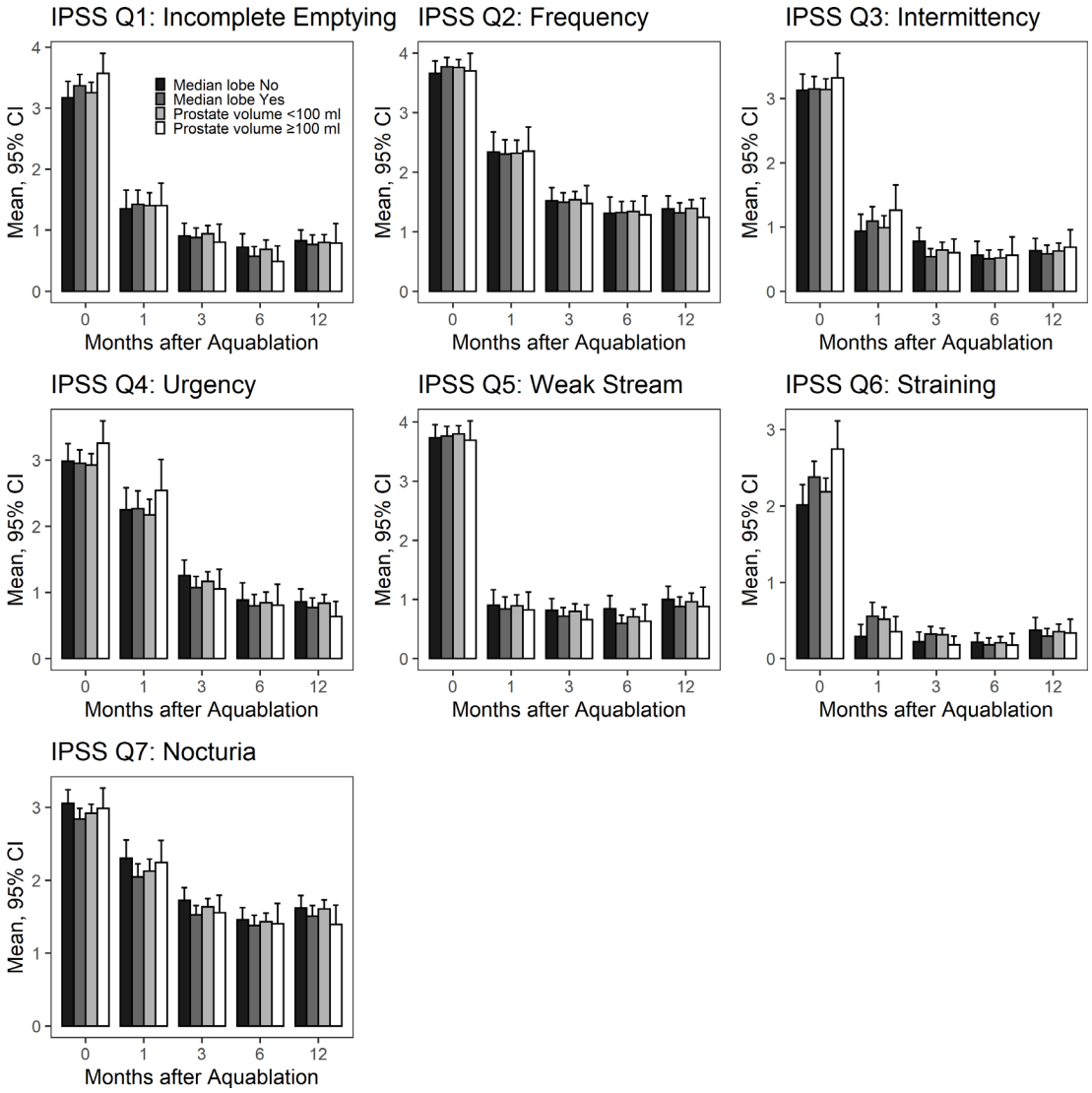


**Figure 2** Change in individual components of IPSS by prostate volume <100 mL vs ≥100 mL and presence/absence of obstructive median lobe. IPSS, International Prostate Symptom Score.

data presented in this manuscript are more than 3.5 times as large and demonstrates a remarkably low retreatment rate. Newer BPH technologies, which have reported data only in prostate sizes <80 mL with less pronounced efficacy as compared with tissue-resective procedures, include Rezum with a surgical retreatment rate of 4.4%[23] at 5 years and UroLift (study excluded obstructive median lobe anatomy) with a surgical retreatment rate of 13.6%[24] at 5 years. More applicable are the tissue-resective procedures where Gilfrich *et al* reported on 43 041 men undergoing TURP, PVP, enucleation or open simple prostatectomy with an approximated 3-year freedom from surgical retreatment of 93%, 89%, 94% and 96%, respectively.[25]

Second, there were statistically significant and clinically important improvements in all key parameters (IPSS, IPSS QOL, Qmax and PVR) across subgroups of prostate size (<100 vs ≥100 and obstructive median lobe present or absent). These findings suggest that more complex anatomy (larger prostates with median lobes) can be more than adequately treated with Aquablation. For other technologies, these prostate subgroups are challenging, such as prostatic urethral lift and convective water vapour ablation, which are contraindicated in prostates over 100 mL and 80 mL, respectively. TURP and PVP are typically performed in prostates less than 80 mL due to the amount of time needed to properly address the amount of tissue.[26] Enucleation and simple prostatectomy are applicable for large prostates but have their limitations. In further analysis, improvements in these parameters were similar among men with both large prostate volume (≥100 mL) and a median lobe.

There were statistically significant and clinically important improvement across all IPSS individual questions and in men with both simple and complex prostate anatomy. Several studies have shown improvements in storage symptoms after transurethral surgery for bladder outlet obstruction.[27–30] As was seen in the current study, storage symptoms often take slightly longer to improve compared with voiding symptoms, likely as a result of neuromuscular changes that must take place in the detrusor muscle once the obstruction is removed.

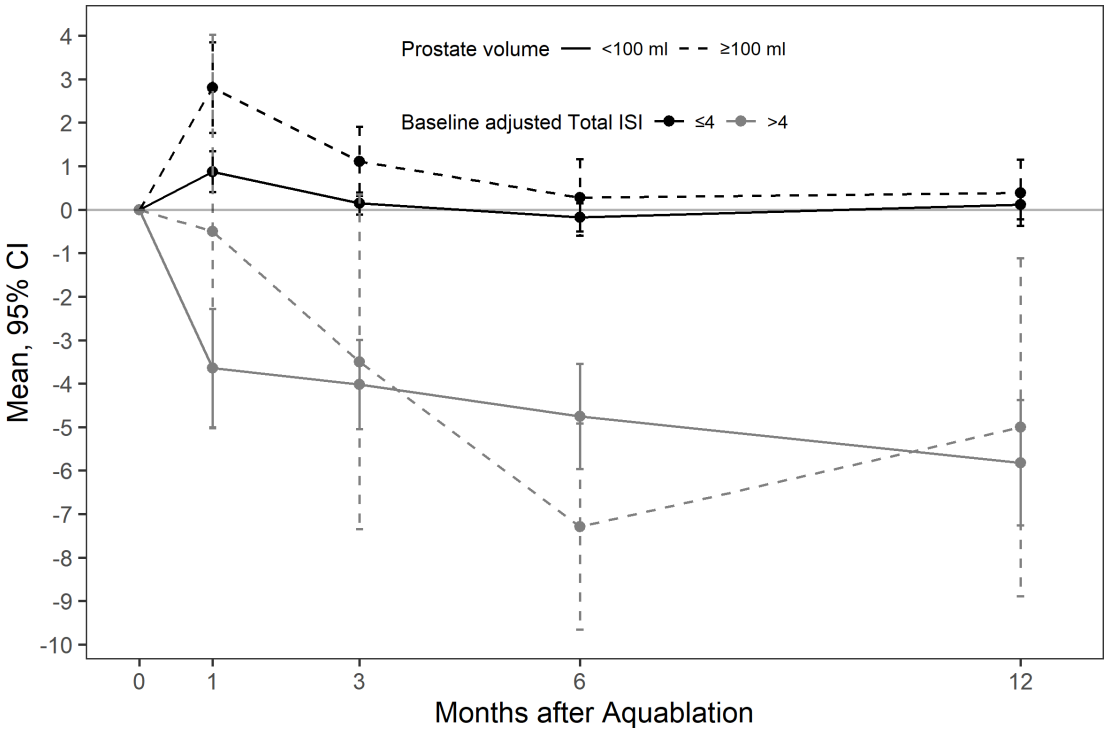


**Figure 3** Change in ISI, Incontinence Severity Index by time, prostate volume category, and presence/absence of an obstructive median lobe. ISI, Incontinence Severity Index.

Finally, urgency incontinence is a common symptom in men with LUTS/BPH. Incontinence is likely due to overactive bladder, which develops as a direct result of chronic bladder outlet obstruction through the increased sensitivity of cholinergic receptors and structural changes due to ischaemia of the detrusor muscle.[31] For men with incontinence at baseline, relief of bladder outlet obstruction through waterjet-based prostate resection resulted in improved frequency and severity of incontinence. For men with low baseline incontinence scores (indicating no or only minor problems with incontinence), late scores returned to preoperative values after a brief perioperative rise.

The advantages of our study include (1) sufficient sample size as a result of combining multiple studies from a diverse set of surgeons with a high follow-up rate, (2) availability of individual patient data from monitored clinical trials, (3) structured follow-up at similar time points and (4) a uniform set of symptom questionnaires and uroflowmetry analyses. All of these enabled us to perform detailed subgroup analyses, including multivariate analyses. All studies were prospective, multicentre trials, and all were conducted with similar eligibility criteria, treatments, and assessment tools. The trial data were sufficiently homogeneous to allow pooling across trials.

The disadvantages to the analysis include: Data after 1 year were not available in all studies, limiting the potential to examine longer-term outcomes. However, 3-year outcomes after Aquablation appear to be sustained from the published WATER trial data.[8] The enrolled patient populations and settings were slightly different: WATER (international) and FRANCAIS (France only) enrolled men with smaller prostates (30–80 mL); WATER II (North America) enrolled men with larger prostates only (80–150 mL); WATER and WATER II were conducted in a pre-market setting whereas FRANCAIS and OPEN WATER were conducted in the post-market setting. The technique using the loop for haemostasis following Aquablation has evolved since the conduct of these trials. Although a thorough review and process was completed to conduct this systematic review, the research was not governed by a registered protocol.

## CONCLUSION

Aquablation improves symptoms and uroflowmetry measures in men with both small and large prostates as well as those with an obstructive median lobe. All functional symptom components of storage and voiding were improved. Incontinence severity improved in men with severe baseline incontinence.

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