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Aquablation: a novel and minimally invasive surgery for benign prostate enlargement

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***Abstract*:** Aquablation is a minimally invasive surgical technology for benign prostate enlargement, which uses high-pressure saline to remove parenchymal tissue through a heat-free mechanism of hydrodissection. Early results show this to be a promising surgical strategy with a strong morbidity profile and reduced resection time. This review serves to provide an overview of the technique and evaluate its safety and efficacy.

Keywords: aquablation, minimally invasive surgery, benign prostatic hyperplasia

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Introduction

Benign prostate hyperplasia (BPH) is a disease of prevalence, present in over 80% of octogenarians.[1] Furthermore, approximately 25% of men over 50 years who develop lower urinary tract symptoms (LUTS) due to this pathology, will require surgical intervention.[2] Not only is it associated with a negative impact on a patient's quality of life, but also the economic burden is substantial. In the USA, the annual expenditure for BPH treatments alone is estimated to exceed US$4 billion.[3]

Where pharmacotherapy has been exhausted, surgery remains the cornerstone of management. In appropriately selected patients, transurethral resection of the prostate (TURP) has represented the gold standard intervention for over 30 years. While its efficacy has remained long established, the morbidity profile offers room for improvement. Rassweiler and colleagues previously summarized the following complications associated with TURP: infection (3.5–21.4%), urethral stricture (2.2–9.8%), bladder neck stenosis (0.3–9.2%), bleeding (1.3–5%) and retrograde ejaculation (53–75%).[4]

Research has continued in order to advance the therapeutic options with a lower morbidity. Along with laser-based procedures such as holmium laser enucleation (HoLEP) and photovaporization, alternative interventions now include the Urolift® system and prostate artery embolization (PAE).[5,6]

More recently, aquablation (AquaBeam®, Procept BioRobotics, Redwood Shores, CA, USA), also termed water-jet ablation, has emerged as the latest surgery of interest in this area.[7] Through a high-pressure saline stream it removes parenchymal tissue through a heat-free mechanism of hydrodissection, which is simultaneously supported by live ultrasound guidance. Aquablation also represents one of the latest applications of robotic technology in urology.[8]

While an increasing number of original studies have been performed on the technique, critical appraisal is under reported. The purpose of this article is to review the world literature in order to evaluate the current status of this minimally invasive technique.

The procedure

The AquaBeam system is made up of three main elements; the conformal planning unit (CPU), robotic hand-piece and a console.[9] With the patient placed in the dorsal lithotomy position and under a general anaesthetic (also possible under spinal anaesthesia), the bi-planar transrectal ultrasound (TRUS) device is mounted into position. The bladder is then accessed using the 24-Fr hand-piece, which accommodates the scope.[10] This can then be stabilized using an articulating arm, which attaches to the bed. Once the optimal position has been confirmed, the system software is activated to adjust the alignment

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Table 1. Inclusion and exclusion criteria for aquablation.

Inclusion criteria	Exclusion criteria
• Moderate to severe lower urinary tract symptoms refractory to pharmacotherapy • Age > 50 years • International Prostate Symptom Score > 12 • Maximal flow rate $Q_{max} \leqslant 12$ ml/s • Prostate size 25–80 ml	• Active infection • Urinary retention • Postvoid residual volume > 400 ml • Abnormal renal function • Raised prostate-specific antigen level • Current/suspected bladder/prostate cancer • Neurogenic bladder/sphincter abnormalities • Previous prostate surgery • High anaesthetic risk

as necessary.[11] Through mapping, the required depth (maximum 25 mm) and angle (maximum 225°) of resection can be formally planned out.[7] The high-velocity physiological saline can then be applied by the console pump under the control of the surgeon's foot pedal. The jet is released at a right angle to the hand-piece. Adjusting the flow rate alters the depth of penetration accordingly.[11] Once resection is complete, haemostasis can be completed through diathermy (loop or roller-ball) as necessary. Postprocedure, 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. Gilling and colleagues now advocate the use of traction with the balloon situated in the prostatic fossa.[7] Maintaining this for a period of up to 2 h can achieve adequate haemostasis and obviate the need for standard cautery for haemostasis.

Patient selection

Careful patient selection is paramount for surgical success. Typical candidates are those with moderate to severe LUTS who have failed to respond to medical therapy for bladder outlet obstruction secondary to BPH. Patients should be formally assessed and counselled in the outpatient setting. This should incorporate use of validated questionnaires such as the International Prostate Symptom Score (IPSS), International Index of Erectile Function and Incontinence Severity Index. To date, and in the trial setting, candidates have been required to also undergo uroflowmetry, TRUS and flexible cystoscopy as part of the selection process. Specific exclusion criteria include active urinary infection, large prostate size (> 100 ml), postvoid residual volume greater than 400 ml and abnormal renal function (Table 1).

Advantages

Aquablation holds a number of advantages (Table 2). Firstly it is associated with a short resection time of less than 10 min. This has been consistently achieved across multiple studies.[11] This high speed is pivotal given the potential dangers associated with prolonged resection. Detailed radiographic mapping and establishment of a precise resection plane allow for key anatomical structures such as the verumontanum and bladder neck to be spared.[9] Moreover, there have been no cases of retrograde ejaculation, erectile dysfunction or incontinence reported in the literature so far. The potential for preservation of sexual function and urinary continence represent key strengths of this novel surgery. However, only long-term results will confirm if this is truly the case. Its heat-free status is considered the fundamental reason for a reduction in irritative urinary symptoms, which can be associated with alternative BPH surgeries. No major complications (> Clavien–Dindo classification III) have been reported in any of the human trials. The implementation of a CPU and integrated software has allowed for the learning curve to be reduced in comparison to counterparts such as HoLEP, which will support its uptake accordingly. Use of ultrasound guidance avoids exposure to ionizing radiation and importantly, specimens can be collected for histological analysis.

Disadvantages

Given the current exclusion criteria such as urinary retention and large prostate volume, a significant proportion of men requiring surgical intervention of some kind may not be suitable for aquablation. Future refinement and experience with the technique will allow its true applicability to be defined. Patients do require general anaesthesia and inpatient admission, as is the case for

Table 2. Advantages and disadvantages of aquablation.

Advantages	Disadvantages
• Reduced resection time • Reduced overall procedure time • Strong safety profile • Preservation of key anatomical structures • Preservation of sexual function • Good learning curve • No ionizing radiation • Avoids thermal damage • Histology specimens available	• Lack of long-term follow up • Lack of Level 1 evidence • Not suitable for large prostates, large median lobes or patients with urinary retention • Experiences from specialist centres only • Requires general anaesthesia and inpatient admission

the majority of alternative surgeries for symptomatic BPH (Table 2). In contrast, PAE and the Urolift system have both been demonstrated to be successful in the day case setting.[12] The biggest weakness is the lack of evidence from randomized trials on this subject, which only time and future research will be able to change. While early findings have been presented from the randomized trial setting, completion and full publication are awaited.

Complications

There have been no reports of a decline in sexual function and there have been no published cases of major (> Clavien–Dindo classification III) adverse events. This includes no cases where blood transfusion has been required or cases which have returned to theatre for bleeding. Grade I complications included dysuria and catheter insertion for urinary retention. Medically treated urinary tract infections have accounted for all the Grade II complications recorded in trials.

Initial outcomes and evidence

Use of high-velocity water-jet technology has been reported previously in other surgical fields including its application for hepatic resection and the treatment of superficial tumours in the gastrointestinal tract.[13] In the urology setting, its applicability has also been investigated for removal of bladder tumours.[14] Only more recently has its potential been explored in the context of BPH surgery. The first study of this kind was performed by Faber and colleagues who reported the feasibility of the technique in canine models in 2014.[10] In 2015, Gilling and colleagues, described their initial human experience with aquablation in 15 patients enrolled in a pilot cohort who had a mean age of 73 years and mean prostate volume of 54 ml.[11] The mean overall procedure time was 48 min with a mean resection time of only 8 min; 14/15 patients were catheter free on day 1 post-surgery. None of the patients experienced serious adverse events, however one patient did require repeat aquablation within 3 months of their initial surgery. The same year Desai and colleagues recorded technical success with the procedure in nine patients.[15] An overall improvement of 90% was recorded for IPSS measurements (22.1–2.3; $p < 0.05$). Anderson and colleagues concluded similar initial results in their Australian phase I trial presented at that time.[16] The following year, Desai and colleagues shared results on a further 20 patients who had undergone this surgery using the second generation AquaBeam system.[17] Cautery was not required in any of these cases and no major complications were reported.

In 2017, results from the first phase II multicentre study were published.[18] Mean prostate volume decreased from 57 ml to 35 ml ($p < 0.0001$), at 12 months the mean IPSS improved from 23 to 6.8 (6.7 at 24 months) ($p < 0.0001$) and maximal flow rate Q_{max} increased from 8.7 ml/s to 18.3 ml/s (14.8 ml/s) ($p < 0.0001$). The 2-year results confirmed that no major complications were recorded between 12 months and 24 months.[19] Roehrborn and Gilling recently presented results from the first randomized controlled trial (WATER STUDY) comparing aquablation with conventional TURP in a total of 184 patients.[20] The mean resection time was significantly lower in the former group (28 min *versus* 4 min; $p < 0.0001$), however there were no statistically significant differences in any of the efficacy measures including IPSS and Q_{max}.

Most recently, in 2018, Desai and colleagues published findings from a single institution

series of 47 patients (mean age 66 years, mean prostate volume 48 ml) undergoing this surgery (AQUABEAM study, ClinicalTrials.gov: Identifier NCT03167294).[21] Follow-up results at 3 months were as follows: Q_{max} improved from 7.1 ml/s to 16.5ml/s ($p < 0.01$), IPSS decreased from 24.4 to 5 ($p < 0.01$), and post-void residual improved from 119 ml to 43 ml ($p < 0.01$). However, six of the sample went into acute urinary retention in the postoperative period and half of these patients eventually needed to undergo TURP.

Cost

To date, cost-effectiveness analyses have not been performed as part of any of the studies. Early expert opinion estimates it to be of a similar cost to current laser-ablation techniques. However, no formal calculations are available at present, largely because the technology is still in evolution.[9,11]

Future research in aquablation

Given how promising early results have been, an increasing amount of research is anticipated on this technology. Indeed, a number of large-scale trials have been registered. These include the OPEN WATER study (ClinicalTrials.gov: Identifier NCT02974751), the first of its kind in the UK. This is an observational study and the primary outcome measure will be total change in IPSS score. This study includes patients with prostate size up to 150 ml. The French aquablation study (ClinicalTrials.gov: Identifier NCT03191734), a single-arm prospective trial, will measure similar outcome measures and is due for completion in early 2019. The WATER (*W*aterjet *A*blation *T*herapy for *E*ndoscopic *R*esection of prostate tissue) II study (ClinicalTrials.gov: Identifier NCT03123250) is a prospective, double-blind randomized trial comparing aquablation with TURP.[22] Patients were aged between 45 years and 80 years with LUTS secondary to benign prostate enlargement. Early follow-up data reveal aquablation to reduce IPSS by a mean of 17 points after 6 months. Flow rates also improved considerably with a mean Q_{max} of 22 ml/s over the same period. Full publications to include formal inclusion/exclusion criteria as well as follow-up results are awaited. As well as providing long-term outcome results, future experience will highlight feasibility and safety in cases of more complex anatomy such as the presence of a significant median lobe.

Further considerations

The results reported so far have all been from highly motivated and experienced investigators in a specialist centre setting. It is worth considering that if and when the technology achieves dissemination and adoption worldwide, the results at least initially may not match the impressive results achieved in the trial setting. It is these results, however, which will truly inform us of the merits of aquablation including time to catheter-free status and re-intervention rates over time, and validate its positive morbidity profile. Future experience as well as development of later generation AquaBeam systems will allow for widening of treatment indications. It will also help determine its feasibility for larger prostates and men with urinary retention.[23] Of note, a newer generation system has already been proven to reduce the mean operative time from 60 min to 45 min and the mean resection time from 8 min to 4 min.[7]

Future research in BPH

As well as an increasing amount of interest in the development of new surgical technologies, research is paramount in understanding BPH pathophysiology. One area of importance related to this is metabolic syndrome. Patients affected by this condition have been found to have a high prevalence of prostatic inflammation, which is considered a possible precipitant for LUTS.[24,25] Of interest, De Nunzio and colleagues found a 50% risk reduction in storage symptoms in patients with metabolic syndrome undergoing TURP. Furthermore, these patients can also have unrecognized erectile dysfunction.[26]

Given therefore, its prevalence and role in determining the future success of intervention, it serves as a reminder for the urologist to implement a detailed medical history and holistic approach in their initial patient evaluation.[27]

Conclusion

Aquablation is a novel and minimally invasive surgical technology, which early studies have shown to yield high clinical efficacy and demonstrate a strong safety profile. Its high-speed resection time and potential for preservation of sexual function are major strengths. Future studies and long-term results from ongoing studies are required to secure its position and acceptance as a true rival to other minimally invasive surgical techniques and conventional TURP.

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Conflict of interest statement

The authors declare no conflicts of interest in preparing this article.

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