CIRUGÍA GUIADA POR LA IMAGEN Y OTROS AVANCES EN LA AYUDA AL DIAGNÓSTICO Y TRATAMIENTO QUIRÚRGICO UROLÓGICO

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PROSTATIC HYDROABLATION (AQUABLATION): A NEW EFFECTIVE ULTRASOUND GUIDED ROBOTIC WATERJET ABLATIVE SURGERY FOR TREATMENT OF BENIGN PROSTATIC HYPERPLASIA

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Summary.- *INTRODUCTION: Bothersome lower urinary tract symptoms secondary to benign prostatic hyperplasia (BPH) are increasingly common amongst ageing men leading to poor quality of life. Surgical treatment options targeted at the obstructing prostate are often required to relief the bladder outlet obstruction, following failure or discontinuation of medical therapies. Transurethral resection of the prostate (TURP) has been the mainstay and gold standard for benign prostate surgery for last few decades. Currently with technological advancements, numerous minimally invasive surgical therapies have been employed to provide effective symptom relief while minimalizing morbidities and preserving sexual function. Prostatic hydroablation (Aquablation) is a new technique which involves high velocity water jets used in non-thermal ablation of the obstructing prostatic tissue robotically delivered by a transurethral cystoscopic handpiece and guided by real time transrectal ultrasound imaging. Recent trials have shown that aquablation is safe and effective in the treatment of symptomatic BPH while maintaining sexual preservation.*

METHOD: Aquablation using the Aquabeam system (PROCEPT BioRobotics, Redwood Shores, CA, USA) combines the precision of autonomous robotic execution in delivering high velocity waterjets via a cystoscopic handpiece with accurate anatomical prostatic mapping using real time transrectal ultrasound imaging. The initial part of the surgery involves careful treatment planning tailored to the prostatic anatomy with preservation of important landmarks nearby, then, high velocity waterjet streams are delivered to ablate the obstructing prostatic tissue without use of any heat. Following the ablation and removal of handpiece, a routine cystoscopic bladder washout is performed and haemostasis achieved with balloon tamponade from a 3 way catheter placed under tension empolying a custom designed catheter tensioning device.

RESULTS: Initial studies involving a few case series and a phase II trial demonstrated the safety and effectiveness of aquablation in treatment of symptomatic BPH. Subsequently, a large multicentre international prospective randomised blinded clinical trial (WATER) was conducted to assess the efficacy of aquablation versus TURP. Results from this pivotal trial showed non-inferior symptom relief compared to transurethral prostate resection but with a lower risk of sexual dysfunction. WATER II study was then conducted to assess the safety and feasibility from a multicentre prospective study of aquablation in the treatment of symptomatic large-volume BPH. The results from this study showed that aquablation is feasible and safe in treating men with men with large prostates (80-150 mL).

CONCLUSION: The current landscape of BPH surgical treatment should be individualized with a shared decision-making process based on prostatic anatomy and clinical parameters combined with patient's preferences to select the ideal treatment option for each patient. Aquablation is one such option that involves a robotically delivered hydroablation technique based on individ-

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ualised real time ultrasonic prostatic mapping that can offer safe and effective treatment for symptomatic BPH while minimising sexual dysfunction. Larger trials with longer follow up data will be required to further validate the long term effectiveness of aquablation.

Keywords: *Aquablation. Waterjet ablation. Image guided prostate surgery. Benign prostatic hyperplasia. Lower urinary tract symptoms.*

Resumen.- *INTRODUCCIÓN: Los molestos síntomas del tracto urinario inferior secundarios a hiperplasia benigna de próstata son cada vez más frecuentes entre los varones, con el envejecimiento, y conllevan una pobre calidad de vida. Con frecuencia, son necesarias diferentes opciones de tratamiento quirúrgico dirigidas a la próstata obstructiva para mejorar la obstrucción del vaciado vesical. La resección transuretral de próstata ha sido el pilar y patrón de referencia de la cirugía de la próstata benigna durante las últimas décadas. Actualmente, con los avances tecnológicos, se han utilizado numerosos tratamientos quirúrgicos mínimamente invasivos para obtener un alivio sintomático y a la vez minimizar la morbilidad y conservar la función sexual. La hidroablación prostática (Aquablation) es una técnica nueva que implica utilizar chorros de agua de alta velocidad para la ablación no térmica del tejido prostático obstructivo administrados robóticamente mediante un cistoscopio y guiados por ecografía transrectal en tiempo real. Los ensayos clínicos recientes han mostrado que aquablation es seguro y efectivo en el tratameinto de la HBP sintomática, a la vez que mantiene la conservación de la potencia sexual.*

MÉTODOS: Aquablation utiliza el sistema Aquabeam (PROCEPT BioRobotics, Redwood Shores, CA, USA) y combina la precisión de la ejecución robotizada autónoma para aplicar chorros de agua de alta velocidad mediante un cistoscopio con el mapeo anatómico prostático preciso utilizando ecografía transrectal en tiempo real. La parte inicial de la cirugía implica una planificación cuidadosa ajustada a la anatomía prostática con conservación de las referencias anatómicas cercanas, y después, se aplican chorros de agua de alta velocidad para la ablación del tejido prostático obstructivo sin utilizar nada de calor. Después de la ablación y extracción de la vaina del cistoscopio se procede a un lavado vesical mediante cistoscopia de rutina y la hemostasia se consigue con taponamiento mediante balón utilizando una sonda de 3 vías colocado mediante tracción utilizando un aparato de tracción de diseñado a medida.

RESULTADOS: Los estudios iniciales incluyendo unas pocas series y un ensayo clínico fase II demostraron la seguridad y efectividad de aquablation en el tratamiento de la HBP sintomática. Posteriormente, se llevó a cabo un estudio prospectivo, aleatorizado ciego, multicéntrico e internacional (WATER) para evaluar la eficacia de aquablation frente a RTUP. Los resultados de este ensayo clínico primordial mostraban una mejoría de los síntomas no inferior en comparación con la resección transuretral, pero con un riesgo de disfunción sexual menor. Después, se hizo el estudio WATER II para evaluar seguridad y factibilidad, en un ensayo prospectivo, multicéntrico de aquablation en el tratamiento de HBP sintomática con próstatas grandes. Los resultados de este estudio mostraron que aquablation es factible y seguro en el tratamiento de varones con próstatas grandes (80-150 mL).

CONCLUSION: El panorama actual del tratamiento quirúrgico de la HBP debe ser individualizado, con un proceso de toma de decisiones compartido basado en la anatomía prostática y parámetros clínicos combinados con las preferencias del paciente para seleccionar el tratamiento ideal para cada paciente. Aquablation es una de las opciones que consiste en una técnica de hidroablación aplicada mediante robot, basándose en un mapeo prostático ecográfico en tiempo real, que puede ofrecer un tratamiento efectivo y seguro de la HBP sintomática minimizando la disfunción sexual. Serán necesarios ensayos clínicos más grandes, con seguimientos más largos, para validar aún más la efectividad de aquablation a largo plazo.

Palabras clave: *Aquablation. Ablación por chorro de agua. Cirugía prostática guiada por la imagen. Hiperplasia benigna de próstata. Síntomas de tracto urinario inferior.*

INTRODUCTION

Lower urinary tract symptoms (LUTS) is a common complaint, affecting many men, especially elderly men. The prevalence of LUTS increases with age, with 20% of men aged fifty affected and this figure increasing to 40% of men in their seventies (1). LUTS in men is largely due to benign prostatic enlargement and its complex interaction with bladder function, leading to both storage and voiding symptoms. Bladder outlet obstruction as a result of benign prostatic enlargement is often caused by the histological entity of benign prostatic hyperplasia (BPH). Autopsy histological results have shown that prevalence of BPH increases with age; with 8%, 50%, and 80% in the 4th, 6th, and 9th decades of life, respectively(2). With improving life expectancies, more elderly men will seek medical attention for their LUTS secondary to BPH, leading to an increased burden to healthcare systems all over the world.

The majority of men with clinical diagnosis of symptomatic BPH will be managed either with watchful waiting if symptoms are not bothersome, medical treatment or surgery. There have been numerous surgical options targeted at the prostate to relieve the bladder outlet obstruction employed over the years. Transurethral resection of the prostate (TURP) introduced in 1920s was the first transurethral approach using a resectoscope with an electrical loop. In fact, TURP is still the gold standard for surgical treatment of BPH due to the robust effectiveness in symptom relief and improvements in both subjective and objective urinary flow parameters. However, there are significant post operative complications which include bleeding, erectile dysfunction, retrograde ejaculation, urinary incontinence, urinary retention, infection and dilutional hyponatraemia. Therefore over the last few decades, numerous strategies involving various methods of prostatic surgeries have been trialled and performed, with the hope of providing similar efficacy while minimising the morbidities of TURP.

As a result, many centres around the world often offer different prostate surgeries including TURP to their patients. These options include laser prostate surgery (greenlight laser photovapourisation, Holmium laser enucleation, thulium, diode), water vapour steam ablation (Rezum), implants (Urolift), prostatic stents (Memokath, iTIND) and aquablation (Aquabeam system, PROCEPT). Despite all these effective surgical options, there are numerous trials involving other minimally invasive surgical options for treatment of BPH being conducted. Therefore, bearing in mind the subtle but real differences between these may options, the choice of surgical treatment should be individualised and tailored to the patients' preferences and expectations based on their prostate anatomy and clinical parameters following discussion of the available options with the treating doctor.

Aquablation uses the Aquabeam system (PROCEPT BioRobotics, Redwood Shores, CA, USA) where high velocity water jets are used to precisely ablate the obstructing prostatic tissue robotically delivered by a transurethral handpiece and guided by real time transrectal ultrasound imaging. Recent trials have shown that aquablation achieved similar effective improvement in urinary flow results with better preservation of sexual function. In 2017, U.S. Food and Drug Administration (FDA) has approved AQUABEAM® System for the resection and removal of prostate tissue for the treatment of lower urinary tract symptoms (LUTS) as a result of BPH. While in the United Kingdom recently, Aquablation has received the Interventional Procedure Guidance (IPG) recommendation from National Institute for Health and Clinical Excellence (NICE), approving the use of Aquablation therapy as an alternative to other surgical techniques for the treatment of BPH.

MATERIAL AND TECHNIQUE

Aquabeam therapy combines real time intraoperative ultrasound with cystoscopic view which provides the surgeon with enhanced multi-dimensional images to allow for precise individualised treatment

Figure 1. Aquabeam robotic system.

Figure 2. Real time planning and treatment images on Aquabeam monitor.

Figure 3. Catheter tensioning device.

planning. Once treatment planning is done, the autonomous robotic execution of heat-free high velocity waterjet is delivered to the earlier identified prostatic tissue to be resected.

The Aquabeam system is comprised of 3 components: the conformal planning unit (CPU), the cystoscopic handpiece attached to robotic arm and a console (Figure 1). Real time ultrasound images obtained from a transrectal biplanar ultrasound probe (BK Medical, Peabody, MA, USA) is displayed onto the conformal planning unit.

Following spinal or general anaesthesia, the patient is placed in a dorsal lithotomy position and the transrectal ultrasound (TRUS) probe is inserted into the rectum and secured in place on a stand-mounted stepper. The live TRUS images are then displayed onto the CPU (Figure 2). Next, the Aquabeam robotic handpiece is inserted under direct cystocopic vision and secured into place to allow the waterjet delivery nozzle within the prostate. Treatment planning then starts utilising the live ultrasound images where the surgeon can adjust the length, depth and angle of resection to precisely map the resection contour to allow accurate prostatic tissue resection while preserving important landmarks like verumontamum, sphincter and bladder neck.

Resection then starts when the surgeon presses on the foot pedal which pumps the high velocity heat free saline waterjet into the prostatic tissue according to the earlier planned treatment contour. Continuous fluid is aspirated from the bladder and the waterjet treatment can be stopped or repeated as a second pass through the prostatic tissue under the control of the surgeon. Mean resection time is about 4 to 5 minutes. Following resection, resected prostatic tissue together with any blood clots are removed with a regular cystoscopic washout and haemostasis achieved using the balloon tamponade of 3 way catheter under traction. Proper placement of the balloon within the bladder neck is guided by the TRUS. The traction on the 3 way catheter is maintained using a catheter tensioning device (CTD) as shown in Figure 3 to ensure tamponade for better haemostasis and bladder irrigation.

DISCUSSION

Early studies

An initial preclinical non-human study utilising the Aquabeam system was in 8 beagles, where it was shown that aquablation was effective in ablating the adenomatous elements of BPH (3). The first human study published by Gilling et al. (4), involving 15 patients, showed a significant improvement in mean reduction in International Prostate Symptom Score (IPSS) and improvement in urinary Qmax, with a mean resection time of 8 minutes. Aquablation was shown to be safe, technically feasible, delivering a conformal, quantifiable, and standardised heat-free ablation of the prostate with benefits of reduction in resection time and potential to preserve sexual function. Two other early human trials also reported effective and safe treatment with aquablation. Desai et al. and Anderson et al. reported patient series of 20 and 9 patients with shorter mean resection times of 4 and 5minutes, IPSS improvement of 19.5 and 18.1 and Qmax improvement of 8.3 and 9.6 mls/sec respectively (5, 6). Gilling et al. then published their phase II one year results of 21 patients who underwent Aquablation for symptomatic BPH in 3 centres (7). Their results showed mean IPSS score improved from 23.0 at baseline to 6.8 at 12 months ($p<0.0001$) and maximum urinary flow increased from 8.7 to 18.3 ml per second ($p<0.0001$). There were no important perioperative adverse events, no incontinence and sexual function was preserved postoperatively.

Larger studies

Following these early promising results, studies involving larger cohorts of men with larger prostate volumes were being conducted. Desai et al. (8) demonstrated the efficacy and safety profile of aquablation in their 47 consecutive patients treated in a single centre, with marked improvement in IPSS, quality of life scores, peak urinary flow rates and low levels of Clavien-Dindo graded >1 complications in only 8 patients. Another single centre experience with a larger cohort of 118 consecutive men treated with aquablation also showed similar results. Bach et al. (9) reported mean operation time of 20 minutes, a decrease in TRUS prostate of 65%, with 73% of the patients retaining antegrade ejaculation and only 13 adverse events (>Clavien-Dindo I) occurred in 10 patients. All these clinical outcomes from human trials are summarised below in Table I. However, much of the momentum and excitement surrounding aquablation as a safe, effective therapeutic option for symptomatic BPH with good preservation of sexual function arose from 2 pivotal trials: WATER and WATER II trials.

WATER (NCT02505919) trial is a double-blind, multicenter, prospective, randomized, controlled trial of 181 patients with moderate to severe LUTS related to BPH who underwent TURP or Aquablation. The primary endpoint was reduction in IPSS at 6 months and primary safety endpoint was development of Clavien-Dindo (grade 1 or 2 or higher) complications. The authors reported lower resection times for aquablation than in TURP, both arms produced large and similar IPSS improvements, leading to the satisfaction of noninferiority hypothesis for aquablation. The anejaculation rate was significantly lower in aquablation cohort when compared to TURP (10% vs 36%, p=0.0003) and primary safety endpoint was lower in aquablation than in TURP (26% vs 42%) (10).

In fact a subgroup analysis from the WATER study noted that in larger BPH glands (50-80g) or with large median lobes, aquablation was associated with both superior symptom score improvements and a superior safety profile, with a significantly lower rate of postoperative anejaculation (11). In this subgroup analysis, mean IPSS reduction was four points greater after aquablation than after TURP (p=0.001), a larger difference than the overall result (1.8 points; p=0.135), primary safety endpoint difference (20% vs 46% [26% difference]; P=0.008) was greater for men with large prostate compared with the overall result (26% vs 42% [16% difference]; P=0.015) and postoperative anejaculation was also less common after aquablation compared with TURP in sexually active men with large prostates (2% vs 41%; p<0.001) vs the overall results (10% vs 36%; p<0.001). This result has suggested that with precise planning and standardised robotically executed aquablation approach, larger or more complex BPH glands can be treated more effectively and safely and may overcome variable clinical outcomes obtained from TURP in such complex cases.

The one year outcomes from the WATER study has also been recently published (12). The symptom score improvements were similar for both arms with a reduction of 15.1 points with no significant difference in rates of retreatment in both cohorts. There was no difference between the mean improvements of maximum urinary flow rates between the two groups and rates of complications were low with no procedure related adverse events after 6 months. Follow up data from this WATER study patients are still ongoing and we await the results which will determine the mid-term efficacy of aquablation compared to TURP.

Table I. Summary of aquablation clinical trials.

Study	**Patients (n)**	**Mean resection time (min)**	**IPSS reduction**	**Increase Qmax (mls/sec)**	**Sexual function Erectile dysfunction (ED) Retrograde ejaculation (RE)**	**Complications Clavien Dindo (CD) Adverse event (AE)**
Gilling et al. (4)	15	8	14.5	10	No ED	No serious 30 AE
Desai et al. (5)	20	4	19.5	8.3	NA	AE mild transient
Anderson et al. (6)	9	5	18.1	9.6	NA	NA
Gilling et al. (7)	21	5	16	9.6	No new ED or RE	6 mild AE
Desai et al. (8)	47	4	19.4	9.4	NA	8 (5 CD I/II, 5 CD III)
Bach et al. (9)	118	3.2	13.8	10.8	73% antegrade ejaculation	10 (13 CD>1)
WATER (10)	114	4	17	10.9	10% anejaculation (36% TURP)	26% primary safety endpoint (42% TURP)
WATER II (13)	101	8	16.5	10.3	NA	29.7% CD ≥2 (1 month)

WATER II trial (NCT03123250) was conducted to assess the safety and feasibility of aquablation in treatment of men with large volume BPH (80-150mls) in a multicentre prospective study in 13 USA and 3 Canadian sites (13). Here 101 men with mean prostate volume of 107mls were treated with mean operating time of 37 (15-97) minutes and aquablation resection time of 8 (3-15) minutes. Adequate adenoma resection was achieved with a single pass in 34 patients and with additional passes in 67 patients (mean 1.8 treatment passes), all in a single operating session. Haemostasis was achieved with balloon catheter placed on traction, with no patient requiring electrocautery for haemostasis. Mean length of hospital stay was 1.6 days with Clavien-Dindo grade ≥2 event rate of 29.7% (at 1 month). Bleeding complications were recorded in 10 patients (9.9%) during the index procedure hospitalization prior to discharge, and included six (5.9%) peri-operative transfusions.

A subgroup analysis of WATER II study revealed that similar safe and effective outcomes can be achieved between patients with <100cc or >100cc BPH glands. In this subgroup analysis, Bhojani et al. showed that mean operative time was 31.2 ± 8 min in the <100 cc subgroup and 41.7 ± 14.9 min in the >100 cc subgroup. The average length of stay following the procedure for the <100 cc subgroup was 1.5 ± 0.7 days versus 1.7 ± 1.1 days for the >100 cc subgroup. Mean changes in IPSS and quality of life were substantial, occurring soon after treatment and averaging (at 3 months) 16.5 and 2.8 respectively.

In fact the pooled aquablation results of 107 American men from both the WATER and WATER II study (14) revealed mean prostate volume of 99.4 ± 24.1 cc with an average procedure time of less than 36 min. Patients were discharged on average 1.6 ± 1 days and the IPSS decreased by 16.7 ± 8.1 points (3 months) and Qmax increased by 11.2 ± 12.4 ml/s. The Clavien-Dindo (CD) grade 2 or higher event rate at 3 months was 29%.

Following the encouraging results from WATER and WATER II studies, a global post-market registry using waterjet ablation therapy for endoscopic resection of prostate tissue (OPEN WATER) study has completed recruitment, enrolling 178 patients from 4 international centres with primary outcome measure of IPSS change for a total duration of 12 months follow up.

This body of increasingly high quality clinical data into aquablation confirm that it is a safe and effective BPH treatment for at least the short term period. There are many advantages of aquablation compared to TURP which is still the reference standard measure for BPH treatment. Aqublation has been shown to be safe, with a much shorter resection and overall operating time and low morbidity rates. The efficacy is non-inferior to TURP as shown in the WATER study, with similar clinical improvements at one year follow up. Due to its precise treatment planning with real time ultrasound and robotic execution of high velocity waterjet delivery without any form of heat, hydroablative resection can be tailored accurately to remove the obstructing tissue while preserving crucial anatomical landmarks like verumontanum, sphincters and bladder neck. The non-thermal nature of waterjet ablation combined with preservation of important landmarks have led to increased sexual preservation with no deterioration of erectile dysfunction and much lower rates of anejaculation compared to other forms of prostate surgeries involving heat energy. The incidence of scarring leading to bladder neck contractures or urethral strictures will be less common due to the non-heat nature of aquablation technique compared to other heat based surgeries. In addition, the learning curve required for aquablation is less compared to other surgical techniques as the Aquabeam machine is adaptive and user friendly.

In addition, results from WATER II study have shown that larger prostate glands together with enlarged median lobes are effectively and safely treated with aquablation with no significant increase in operation time, length of hospital stay or perioperative bleeding issues. This is reassuring as often many other surgical options for large prostate glands will have variable outcomes with increased morbidity rates. Mean length of hospital stay following WATER and WATER II studies were 1.4 and 1.6 days respectively. This short hospital stay will help reduce the hospital workload and overall cost involved with the procedure.

In our experience being involved in WATER and OPEN WATER clinical trials, adequate attention to post ablation haemostasis is required. In our centre, we have refined our aquablation technique to incorporate three critical steps to ensure good haemostasis which will enhance recovery and reduce time of catheterisation. One is the administration of intravenous tranexamic acid at induction followed by 3 more doses of post operative tranexamic acid. This will prevent any fibrin degradation and reduce haematuria. Secondly, adequate cystoscopic bladder washout to remove post ablative tissue and/or blood clots is required immediately following the removal of the handpiece and thirdly, proper application of the catheter tensioning device to ensure that the balloon tamponade is snuggly placed at bladder neck. The attention to these details have resulted in decreased post operative bleeding, lesser bladder irrigation, quicker removal of catheter and discharge usually on post op day one.

In the majority of cases, the cystoscopic bladder washout following the aquablation process will ensure that post ablation prostatic tissue can be sent away for histological diagnosis, which is also an advantage compared to other ablative prostatic surgery where no tissue can be obtained. Recovery time following the aquablation surgery has not been well described in the previous studies. Nonetheless, in the authors' opinion, generally patients will describe a return to normality with good urinary flows by the third week post procedure.

Despite all the efficacy and advantages of aquablation in the treatment of BPH described so far, one main disadvantage is that there is unfortunately no mid to long term clinical outcomes yet. Certainly long term data will be required from clinical trials to assess failure or retreatment rates in patients who had aquablation. Another disadvantage of aquablation is that it has to be done under spinal or general anaesthesia with requirement of inpatient stay. Therefore, some patients will prefer other minimally aggressive prostate surgery like urolift, Rezum or ITIND where they can be performed on a day surgery basis with local anaesthesia or minimal sedation. Nonetheless, patient preference and selection based on their prostatic and clinical parameters will dictate whether these other forms of minimally aggressive surgery can be available.

In a similar note, another small disadvantage of aquablation will be the rate of anejaculation at 10% compared to a minimally aggressive surgery like urolift which can ensure complete sexual preservation with zero rates of retrograde ejaculation and erectile dysfunction post procedure. Nonetheless, a recent systematic review by Lebdai et al. (15) showed that the ejaculation preservation rate of either urolift or aquablation compared to regular TURP was 100% and 90% versus 34%, respectively. Currently, aquabation is only being offered in specialised urological centres and therefore not freely available to most patients. However, we believe that this scenario will improve as aquablation gains further reputation and interest. There is also no cost effectiveness analysis yet on the total cost of aquablation procedure compared to the standard TURP.

Therefore, the promising results so far have shown that aquablation is an effective and safe surgical treatment for symptomatic BPH with good effect on sexual preservation. Results from ongoing studies and further larger studies with longer follow up data involving aquablation will definitely be eagerly awaited. The landscape for BPH treatment is exciting with many novel minimally invasive therapies being developed to provide effective clinical outcomes while maintaining sexual preservation with emphasis on day surgery performed with minimal sedation or local anaesthetic and emphasis on quicker return to normality and work.

Therefore currently with all the available armamentarium of prostatic surgical techniques, patients with symptomatic BPH should have a shared decision making process with the surgeon, to choose which surgical technique is best tailored for his needs/preferences based on his prostatic anatomy and clinical parameters.

CONCLUSION

Aquablation using Aquabeam has the advantage of combining real time transrectal ultrasound image with cystoscopic views coupled with precise treatment planning and autonomous robotic delivery of non-thermal high velocity saline for aquablation allowing accurate individualised resection of the obstructing prostate, while preserving important structures nearby. Aquablation treatment for symptomatic BPH is a safe, effective therapy in providing improved urinary symptoms and flow rates while maintaining better sexual preservation outcomes.

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