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Surgery in Motion

Waterjet Ablation Therapy for Treating Benign Prostatic Obstruction in Patients with Small- to Medium-size Glands: 12-month Results of the First French Aquablation Clinical Registry

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Abstract

Background: Aquablation has emerged as a novel ablative therapy combining image guidance and robotics for targeted waterjet adenoma resection.
Objective: To describe a standardised technique of aquablation in the treatment of benign prostatic obstruction (BPO), and to report the perioperative and 1-yr functional outcomes obtained by multiple surgeons with no previous experience of the technique.
Design, setting, and participants: Between September 2017 and January 2018, patients referred to three different urological centres for BPO surgical management were prospectively enrolled to undergo an aquablation procedure.
Surgical procedure: Aquablation was performed using the Aquabeam system (Procept BioRobotics, Redwood Shores, CA, USA) that combines transrectal prostatic image guidance and robotics bespoke tissue resection with a high-pressure saline jet. The surgeon defines the area of treatment, and the resection is executed automatically.
Measurements: The primary endpoint was the change in total International Prostate Symptom Score (IPSS) score at 6 and 12 mo. Functional outcomes were assessed at 1, 3, 6, and 12 mo with IPSS, International Index of Erectile Function (IIEF)-15, Sexual Health Inventory for Men, and Male Sexual Health Questionnaire questionnaires and uroflowmetry.
Results and limitations: Thirty patients were enrolled in the study. The median operative time and resection time were 30.5 (24–35) and 4 (3.1–4.9) min, respectively. The median catheterisation time was 43 (23–49) h. The median hospitalisation stay was 2 (2–4) d. The IPSS score improved to 3 (1–6) at the 6 mo, with a mean change of 15.6 points (95% confidence interval 13–18.2). IPSS improvements persisted at month 12. The maximum urinary flow rate improved to 20.4 (17–26) ml/s at 12 mo. The 6-mo rates of Clavien-Dindo grade 2 and 3 events were 13.3%. There were no reports of incontinence or de novo erectile dysfunction. Postoperative de novo ejaculatory dysfunction was observed in 26.7% of patients.
Conclusions: This clinical registry confirmed that aquablation was feasible, safe, and effective, and provided immediate good functional results and similar outcomes to those of prior studies despite the lack of surgeons' previous experience with the technique.
Patient summary: Aquablation is feasible, safe, and reproducible with promising outcomes for treating benign prostatic enlargement.

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1. Introduction

Aquablation is a new ablative surgical approach using water [1]. This technology allows real-time image-guided endourological semiautonomous tissue ablation using a high-velocity waterjet controlled robotically. The aquablation system enables the surgeon to map the transitional zone and target with precision and reproducibility, enables the performance of tissue heat/hand-free resections in a wide range of prostate sizes and anatomies [2,3], and potentially minimises surgeon-to-surgeon variability [4]. First described in 2015, aquablation is certainly not a mature technique, and its level of evidence remains weak. However, a growing number of publications are now supporting the efficacy of aquablation in improving lower urinary tract symptom (LUTS). Short-term outcomes from early aquablation studies [1] were confirmed in a follow-up large international blinded randomised trial showing that aquablation had a similar level of efficacy to that of transurethral resection of the prostate (TURP) and a slight but significant improvement in the preservation of ejaculatory function [5]; similar results were observed in a prospective multicentre trial in patients with larger (80–150 cc) prostates [2]. The aims of the present study were to describe a standardised technique of aquablation, and to report the perioperative and 12-mo functional outcomes of a multicentre prospective registry of patients with small- to medium-sized prostates by three different surgeons without previous experience of the technique.

2. Patients and methods

2.1. Study design

FRANCAIS WATER is a prospective, multicentre, single-arm clinical trial conducted at three centres in France, to assess the safety and effectiveness of aquablation for the surgical treatment of LUTS due to benign prostatic obstruction (BPO) in men with prostate volumes between 30 and 80 cc, as measured by transrectal ultrasound (TRUS). The inclusion criteria were as follows: men aged 45–80 yr complaining of LUTS with evidence of BPO refractory to medications, International Prostate Symptom Score (IPSS) $\geq$12, and a prostate volume of 30–80 cc. Patients were excluded if they had a history of prostate or bladder cancer, neurogenic bladder, bladder stones, urethral stricture, meatal stenosis, bladder neck contracture or external urinary sphincter injury, active infection, prostatitis in the last year, maximum urinary flow rate (Qmax) >15 ml/s or postvoid residual (PVR) >300 ml, history of catheterisation in the last 14 d or the use of intermittent catheterisation, previous prostate or other lower urinary tract surgery, daily use of anticoagulants or aspirin that could not be stopped, use of bladder-acting medications, illicit substance use, or other medical or psychiatric conditions that could prevent study follow-up or potentially confound the results. The study was approved by national French ethics committees prior to the start of the study. All participants signed study-specific consent forms prior to any test that went beyond standard care. At the baseline, the participants completed the IPSS as well as several other validated questionnaires on sexual function (International Index of Erectile Function [IIEF]-15 and Male Sexual Health Questionnaire [MSHQ]), uroflowmetry, and PVR volume measurements; they also underwent standard laboratory blood assessments. The questionnaires, uroflowmetry, PVR, and laboratory tests were repeated at the scheduled postoperative visits. All procedures performed to gather the data presented here were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

2.2. Description of the system

Aquablation was performed using the Aquabeam system (Procept BioRobotics, Redwood Shores, CA, USA) [1]. The device consists of three main components: the conformal planning unit (CPU), the console, and the robotic hand piece (Fig. 1).

2.2.1. The conformal planning unit

Live TRUS videos are imported into and displayed by the CPU, allowing the operator to map the contour of the prostate. The prostatic capsule, verumontanum, and bladder are visualised, allowing the surgeon to identify key anatomical markers to optimise the position of the Aquabeam handpiece and select the target area for treatment. The planned parameters are downloaded to the Aquabeam Console, and aquablation treatment can be initiated. During aquablation treatment, the operating physician utilises the CPU to monitor the progress of the resection.

2.2.2. The console

The Aquabeam console is a reusable component of the Aquabeam system, and it controls the functionality of the high-pressure waterjet delivered by the handpiece. It is connected to the CPU via a USB cable, and connected to the motor pack and foot pedal through custom cables. Prior to the initiation of aquablation treatment, the console is attached to the Aquabeam handpiece, providing the conduit for the saline fluid to be used in treatment. The console generates saline pressure, allowing controlled resection of the prostatic tissue in accordance with the Aquabeam CPU measurements. In addition, the console utilises a peristaltic pump that assists in the evacuation of saline from the bladder.

2.2.3. The robotic handpiece/motor pack

The robotic handpiece is a sterile, single-use component of the Aquabeam system. It obtains its power source and functional commands from the motor pack. The motor pack is a reusable component of the Aquabeam system designed to dock with the disposable handpiece and to move the handpiece probe both rotationally and longitudinally. When “docking” is complete, a light-emitting diode on the console gives a visual indication of successful docking.

2.3. Description of the technique

The patient was placed in a lithotomy position. After induction of general or spinal anaesthesia, a 22F handpiece was inserted under direct vision into the prostatic urethra and secured into place using a bed-mounted rigid arm. The handpiece was advanced through the sheath until the distal end of the device was positioned in the bladder. The articulating arm was locked into place to securely anchor the handpiece within the prostate (Fig. 1). Under real-time TRUS guidance, the surgeon defined the target anatomic resection contour on a computer console (Fig. 2). Although the limits of the resection are automatically suggested by the computer, these finally depend on the surgeon's decision to maintain, extend, or reduce the resection area. Under robotic execution, prostate tissue was resected (“aquablated”) utilising a high-velocity waterjet that can move from a 220° side to another in a controlled manner from the bladder neck to the apical part of the prostate (Fig. 3). The handpiece is placed at the 12 o’clock position of the bladder neck. Thus, the prostate is compressed, allowing the anterior tissue to fall below the range of motion of the waterjet. The contour of tissue to be ablated was drawn to

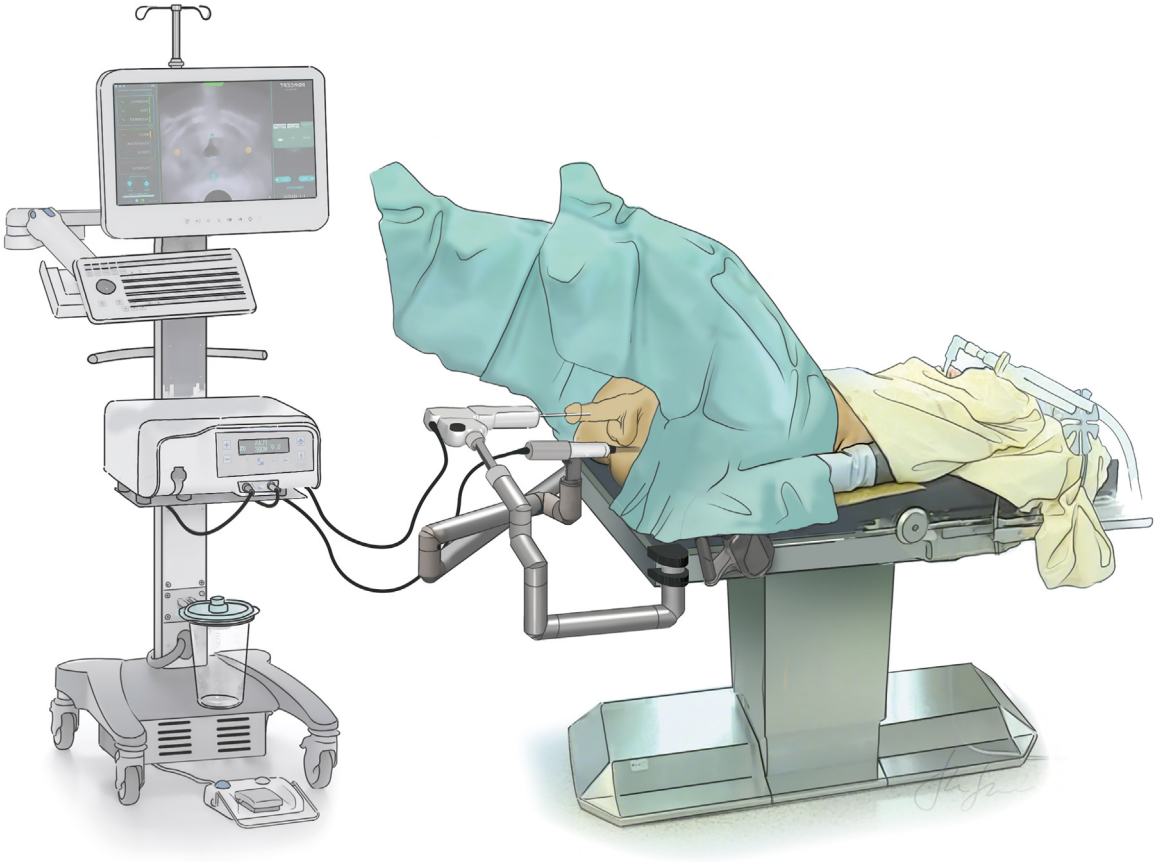

Fig. 1 – The conformal planning unit, the console, and the robotic hand piece.

preserve the anatomy of the bladder neck, verumontanum area, ejaculatory ducts, and external urinary sphincter (Fig. 2). The console generated and adjusted the saline pressure to allow for controlled resection of the prostate tissue. Upon completion of the procedure, the articulating handpiece arm was unlocked, and the coupled robotic handpiece/motor pack was removed from the urethra. Following aquablation, the bladder was thoroughly irrigated to remove the residual floating tissue particles and blood clots that tend to accumulate during resection. Tissue particles can be collected and sent for histological analysis. Haemostasis was achieved using a Foley balloon catheter, which was inflated with 20–80 ml of saline at the bladder neck with adequate traction using TRUS guidance [6]. Constant pressure on the bladder neck was maintained using a catheter tensioning device (Procept BioRobotics), an external catheter accessory mounted at the pubis and secured to the catheter for the following postoperative hours. All patients underwent continuous bladder irrigation postoperatively.

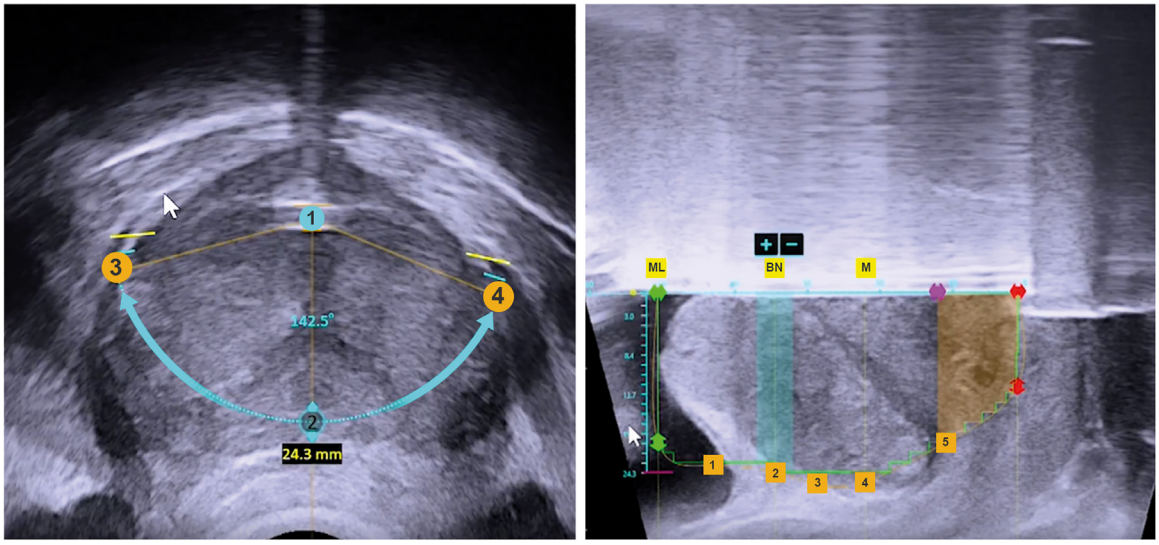

Fig. 2 – The target anatomic resection contour.

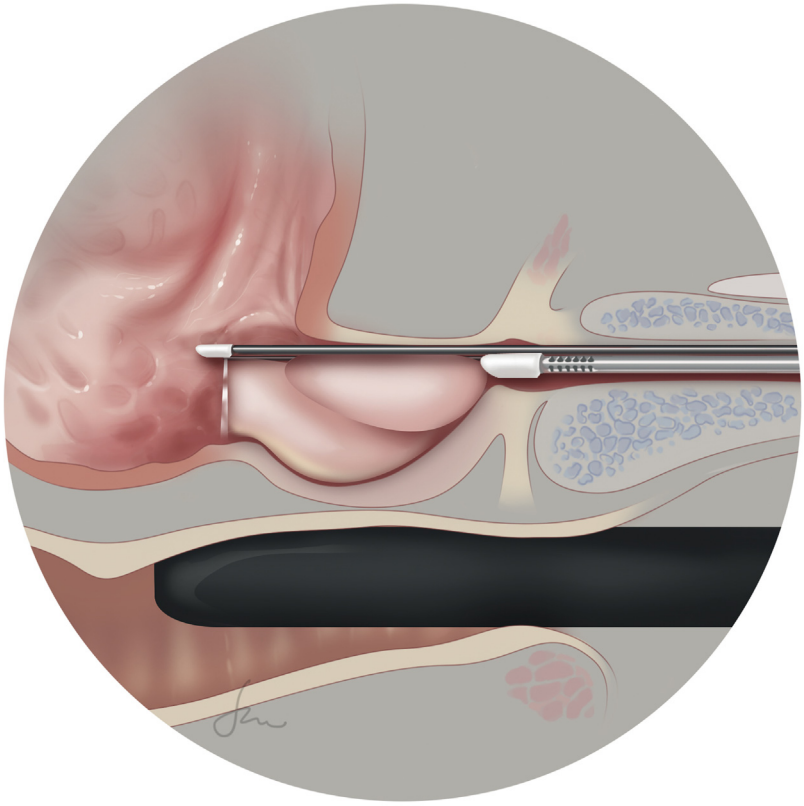

Fig. 3 – Waterjet ablation.

2.4. Previous surgeon's experience

None of the three surgeons involved in this study had previous experience with aquablation but had extensive experience with endoscopic benign prostatic hyperplasia (BPH) surgery. All the surgeons attended two dedicated courses (including videos and lectures) and a cadaver-laboratory teaching session before performing the surgeries. All the surgeons received technical instructions from an expert and were mentored in the theatre during cases. Each consecutive case presented here represents their learning curves.

2.5. Study monitoring

Study data were entered into an electronic data capture system by site coordinators and monitored by a contract monitoring organisation. The trial was sponsored by the device manufacturer.

2.6. Study endpoints and statistical analysis

The study's primary efficacy endpoint was the change in the total IPSS score at 6 and 12 mo. The study was interpreted as a success if the IPSS score change statistically exceeded 10 points, which corresponds to meta-analytic estimates of IPSS score changes after TURP minus six points, a value consistent with the minimum detectable IPSS score change corresponding to a slight improvement in men with severe baseline symptoms [7]. The secondary endpoints included the following: (1) the proportion of individuals with adverse events rated as possibly, probably, or definitely related to the study procedure, which were classified as Clavien-Dindo grade 2 or higher or any grade 1 event, resulting in persistent disability (eg, ejaculatory disorder or erectile dysfunction) evidenced within 3 mo after treatment; (2) a change from the baseline for question 8 on the IPSS; (3) a change in the uroflow parameters (Qmax and PVR); (4) the proportion of sexually active individuals reporting worsening of sexual function on the IIEF-15 or MSHQ questionnaires (ejaculatory function was defined as being sexually active [at baseline and follow-up visits] with a baseline ejaculatory function score of 1 [some ejaculate] or greater based on the patient's response to question 3 on the MSHQ, and zero post-treatment response change [could not ejaculate]); erectile dysfunction was defined as having normal erectile function at the baseline [Sexual Health Inventory for Men {SHIM} score of 22–25] and a post-treatment response of moderate to severe erectile dysfunction [SHIM score of $\leq$11]); and (5) reoperation or reintervention during follow-up. Reoperation was defined as the need to repeat the surgical procedure to diagnose or treat potential problems following aquablation. All adverse events reported by investigators were adjudicated by an independent unblinded clinical events committee (CEC). Assuming an IPSS change score standard deviation of 6 points, a sample size of 30 evaluable individuals provides at least 90% power for the primary efficacy endpoint, provided that the underlying change exceeds 13.7 points, a value lower than those observed in prior aquablation studies. IPSS voiding and storage subscale scores were analysed, but the study was not sufficiently powered to detect particular improvements in subscale scores. A standard statistical approach was used for analysis, with *t* tests used for continuous variables and Fisher's test for ordinal/binary variables. All statistical analyses were performed with R [8].

3. Results

3.1. Patient characteristics

Thirty patients with a median age of 68 (61–72) yr met the eligibility criteria and were treated in three French centres

Table 1 – Patient's baseline characteristics, median (interquartile range)

Characteristic	Statistic
Age (yr)	68 (61–72)
Body mass index	26 (24–28)
Prostate specific antigen (g/dl)	2.5 (1.9–5)
Prostate size (TRUS; cc)	60 (45–69)
Median lobe, *N* (%)	11 (37)
Baseline questionnaires	
IPSS, mean (SD)	18.5 (15–24)
IPSS QOL, mean (SD)	5 (4–6)
Sexually active (MSHQ), *N* (%)	23 (77)
MSHQ[a]	8 (1–12)
MSHQ bother	2 (0–4)
IIEF-15 domains	
Erectile	25 (22–28)
Orgasmic	8 (5–9.5)
Desire	8 (6.5–9)
Intercourse satisfaction	11 (7.5–12)
Overall satisfaction	8 (8–10)

IIEF = International Index of Erectile Function; IPSS = International Prostate Symptom Score; MSHQ = Men's Sexual Health Questionnaire; QOL = quality of life; SD = standard deviation; TRUS = transrectal ultrasound.
[a] *n* = 23 sexually active men.

from September to December 2017. The enrolment numbers by centre were 6 (site 01), 16 (site 02), and 8 (site 03). The patients' characteristics are summarised in Table 1. Four patients (13.3%) reported experiencing urge incontinence, and 23 (76.7%) were sexually active in the month prior to enrolment.

3.2. Perioperative outcomes

Spinal anaesthesia was used in six patients; the remaining 24 underwent general anaesthesia. The median operative time, defined as the interval between handpiece placement and the final urinary catheter placement, was 30.5 (24–35) min (Table 2). The average resection time was 4 (3.1–4.9) min. A mean of 1.3 passes with the aquablation probe was made; the proportions of men requiring a single pass, second pass, and more than two passes were 63%, 27%, and 3.3%, respectively (data missing for two patients). The mean duration of catheterisation was 43 (23–49) h. The median haemoglobin level at discharge was 12.2 (11–13) g/dl. The average length of hospital stay was 2 (2–4) d. None of the patients were discharged with a catheter (Table 2).

No patients were lost to follow-up in the study. Within the 6-mo follow-up period, the median IPSS score improved to 3 (1–6) with a mean change of 15.6 points (95% confidence interval 13–18.2), which exceeded the study's preset primary endpoint threshold ($p < 0.0001$). IPSS improvements were consistent at month 12 (Fig. 4). A significant improvement of 4 (3–5) points was also reported for question 8 on the IPSS; the IPSS voiding subscale changed by 10 (7.2–13) and the IPSS storage subscale changed by 5 (4–8) points. The uroflowmetry measures also improved substantially. Qmax and PVR improved to 20.4 (17–26) ml/s and 54 ± 64 ml at 12 mo, respectively (Fig. 5). Amongst men with an elevated (>100 ml) PVR at the baseline ($n = 11$), PVR improved from 144 (106–245) to 50.5 (19–70) cc, an improvement of 93 cc ($p = 0.0047$). The

Table 2 – Perioperative outcomes

	n = 30	Centre 1 (*n* = 6)	Centre 2 (*n* = 16)	Centre 3 (*n* = 8)
Intraoperative				
TRUS insertion to removal (min)	56 (48–62)			
Handpiece in/out time (min)	21.5 (19–28)			
Aquablation resection time (min)	4 (3.1–4.9)			
Postoperative				
Foley catheter bladder inflation volume (cc)	30 (30–40)			
Catheter placement to end of bladder neck traction (h)	3.8 (2–5.6)			
Catheter placement to removal (h)	43 (23–49)			
Length of stay	2 (2–4)			
Clavien-Dindo complications grade 1				
Bleeding	3.3	1	0	0
Dysuria	10	2	0	1
Pain	3.3	0	1	0
Urinary retention	6.7	1	1	0
Ejaculatory dysfunction	26.7	1	6	1
Clavien-Dindo complications grade 2				
Urinary frequency	3.3	0	0	1
UTI	10	0	1	2
Clavien-Dindo complications grade 3a				
Dysuria	3.3	0	1	0
Meatal stenosis	6.7	1	0	1
Clavien-Dindo complications grade 3b				
Bleeding	3.3	1	0	0

TRUS = transrectal ultrasound; UTI = urinary tract infection.
Procedural variables are reported as medians (interquartile range). Clavien-Dindo events are reported as rates for the full cohort (*n* = 30), and event types are reported as counts by centre. The average duration to the start of event was 6 d postoperatively for CD1 (excluding ejaculatory dysfunction), 9 d postoperatively for CD2, 62 d postoperatively for CD3a, and 0 d postoperatively for CD3b.

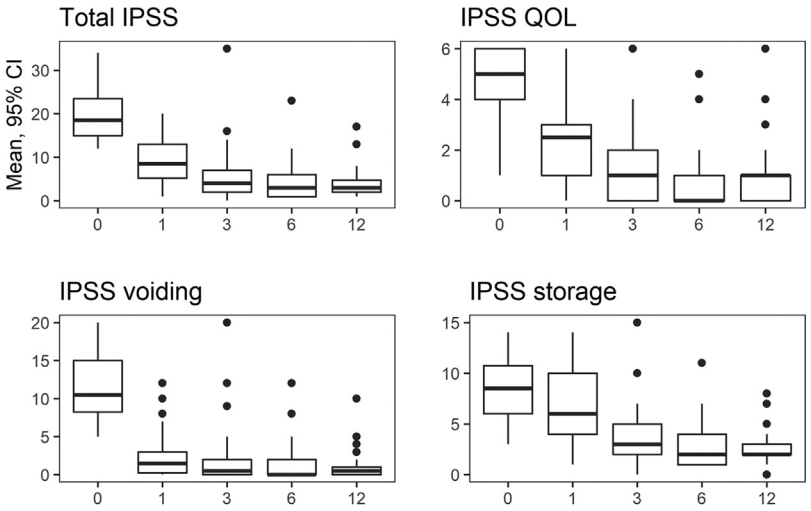

Fig. 4 – Median and interquartile ranges for IPSS, IPSS QOL, and IPSS voiding and storage subscores over time. CI = confidence interval; IPSS = International Prostate Symptom Score; QOL = quality of life.

median prostate-specific antigen level dropped from 2.5 (1.9–5) at the baseline to 1.7 (1.2–3.3) at the 12-mo follow-up ($p = 0.0008$). For the 23 patients who were sexually active at the baseline, the mean baseline MSHQ score was 7.5 ± 4.9. In individuals who were sexually active at the baseline and follow-up visits, both the total MSHQ score and the MSHQ bother domain subscore decreased slightly (transiently for the bother domain subscore), but no change was statistically significant (Fig. 6). The level of erectile function, as measured by the IIEF, decreased slightly or remained stable over time (Fig. 7).

As adjudicated by the CEC, 23 perioperative complications occurred within 210 d (Table 2) in 20 patients. The 6-mo rate of Clavien-Dindo grade 2 events was 13.3% and the

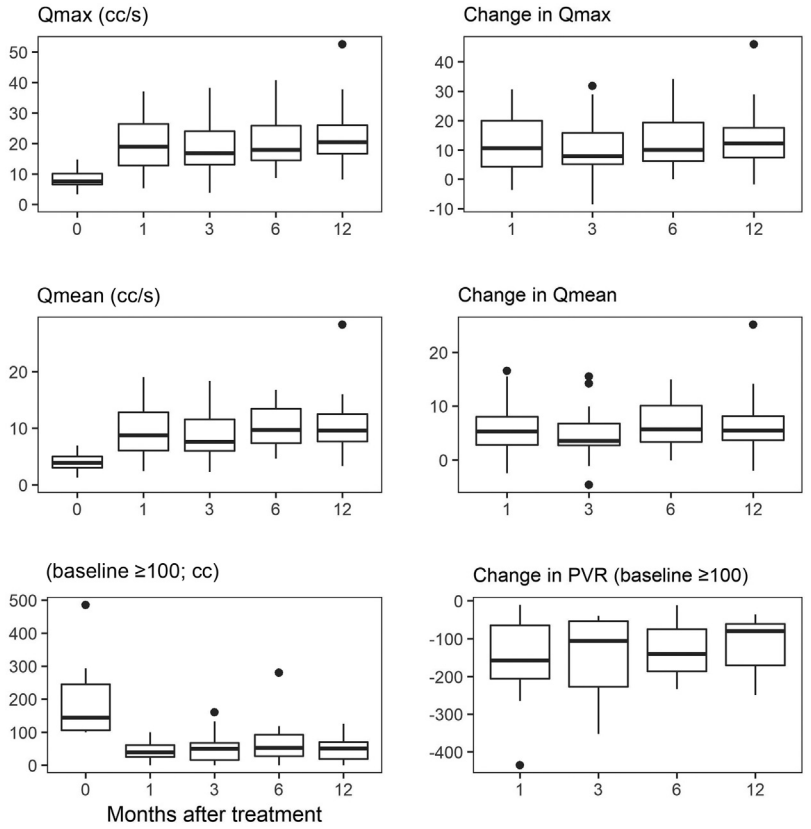

Fig. 5 – Maximum urinary flow (Qmax), mean urinary flow (Qmean), and postvoid residual (PVR). PVR is shown only for patients with an elevated (≥100 cc) PVR at baseline. Graphs on the left show median and interquartile ranges, and those on the right show the changes by median and interquartile ranges.

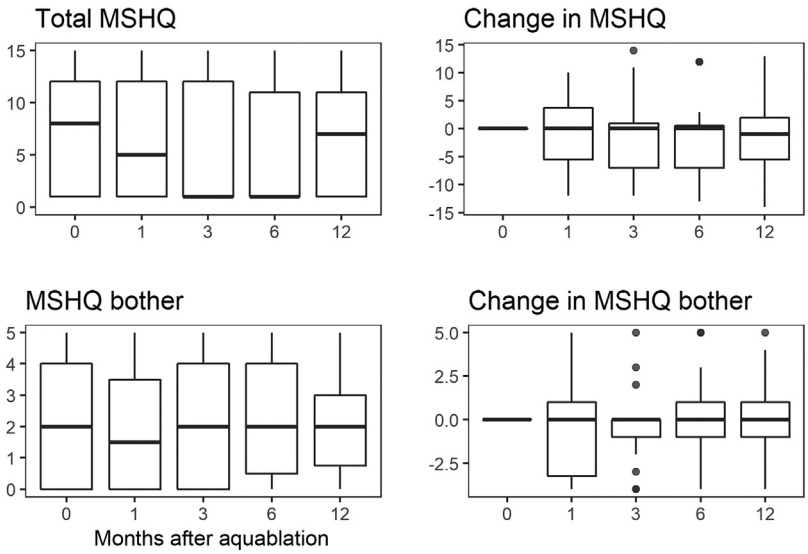

Fig. 6 – MSHQ and MSHQ bother domain scores (median and interquartile ranges at left, and median and interquartile ranges of change scores at right) amongst men who were sexually active at the baseline and at each study visit. MSHQ = Male Sexual Health Questionnaire.

rate of grade 3 event was 13.3%, with one patient having two events (one CD2 and one CD3). Three patients had Clavien-Dindo grade 3a events (one case of dysuria related to a urethral stone treated with urethroscopy and two cases of meatal stenosis treated with dilation), and one patients had a 3b event, namely, bleeding requiring return to the operating room for clot removal, bipolar coagulation, and transfusion on the day of aquablation. Eight (26.7%) patients had ejaculatory dysfunction. There were no reports of incontinence, erectile dysfunction, or retreatment for BPH symptoms within the follow-up of the study.

4. Discussion

The present multicentre prospective registry adds to the growing literature supporting the safety, reliability, and reproducibility of aquablation for the treatment of BPO. Reproducibility in terms of symptom relief efficacy is possible even with a small case load. We observed significant improvements in BPO-related symptoms after aquablation with a concomitant improvement in urinary flow rates and a reduction in the PVR from the baseline to 1-yr follow-up. The observed symptom score changes were identical to those observed in prior studies and met the study's primary endpoint statistical calculation [1,5,9,10].

The results were reproducible in terms of resection time. One of the main advantages attributed to aquablation is the rapid and reliable ablation of the transitional zone, which is mainly attributed to the automated robotic execution of the procedure. Preliminary findings included mean aquablation operative time of 30 min, including resection time of 4 min for prostate volume <80 cc [5]. Our results were consistent with the short resection time reported in previous series, even though the surgeons in this study had no prior experience with the procedure.

The results were reproducible in terms of erectile and ejaculatory function. Sexual function, as measured by the MSHQ and IIEF surveys, appeared to be mostly preserved. Similar to the results reported by Bach et al. [9], we reported antegrade ejaculation preservation in 73.3% of the patients. The rate of ejaculatory dysfunction reported in the literature varies from 10% for prostate volumes ranging from 30 to 80 cc [5] to 6.5% for prostate volumes ranging from 60 to 150 cc [11], and could be influenced by the preoperative prostate size. The smaller the prostate, the more difficult the ultrasound mapping. However, in the subgroup analysis, the rates of ejaculatory dysfunction were found to be similar: 17% in <100 cc patients and 14% in >100 cc patients [5]. Decreases in scores at 1 mo after aquablation may clearly be related to the early postoperative rehabilitation process, and sexual function/activity appeared to recover shortly thereafter. A potential downside of both surveys is that they assume sexual activity and therefore may not be applicable in the perioperative period. Moreover, if a man is not sexually active in the time period prior to the study visit, the scores are not valid.

The results were reproducible in terms of the postoperative haemoglobin drop and Clavien-Dindo adverse events. While the safety profile of aquablation cannot be compared directly with that of TURP in our study, we observed a reasonable rate of serious safety events, with only one case (3.3%) of bleeding requiring surgical reintervention. The 2.9 g/dl haemoglobin drop reported herein was in line with previous publications [5], but did not translate into a high blood transfusion rate. However, the haemostasis strategy might be improved in the future to minimise morbidity because bleeding has been reported as an issue.

Confirming the results of prior trials, the rate of anejaculation after aquablation in our cohort (eight of 30, 27%) appears to be substantially lower than that after TURP or other ablative procedures, probably because targeted resec-

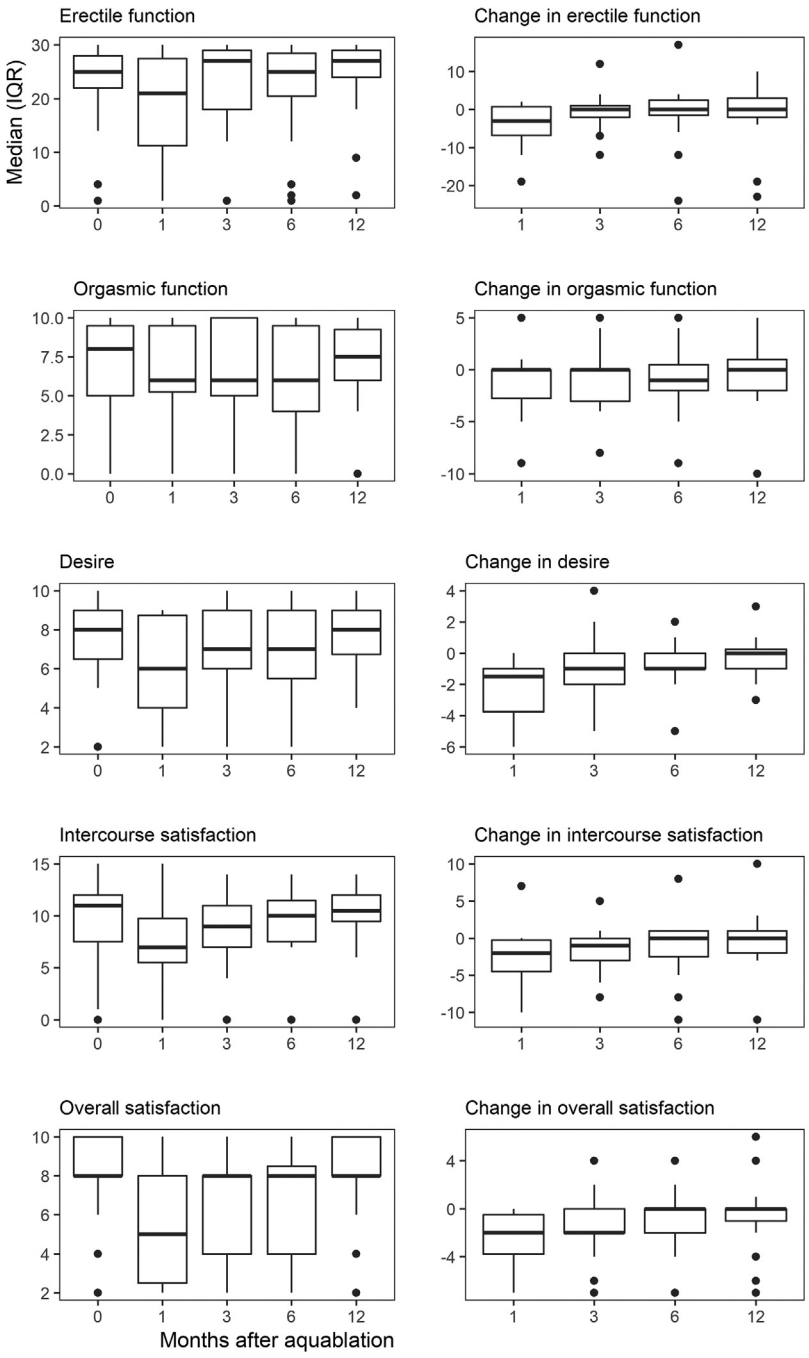

Fig. 7 – Median and interquartile ranges (left) and change scores (right) of IIEF-15 population by domain amongst men who were sexually active at the baseline and at each study visit. IIEF = International Index of Erectile Function; IQR = interquartile range.

tion under conditions of imaging guidance and robotic execution avoids damage to structures critical to sexual function. Surgical treatment options for men with BPH include TURP, transurethral enucleation with lasers, and other treatments. Our preliminary experience suggests that aquablation is equally safe and effective in men with BPH and prostate sizes between 30 and 80 cc. A recently published study [2] suggests that aquablation may be a viable treatment option for men with even larger (80–150 cc) prostates, a prostate size we did not include in the current study.

Although the strengths of our study include its prospective multicentre design, several limitations must be acknowledged. First, there was a lack of a control group and a relatively small sample size. Nonetheless, all functional variables were statistically significant, indicating large effect sizes. Another shortcoming is the absence of homogeneity among patients in the objective of the preservation of ejaculation. In patients specifically requesting ejaculation preservation, adapting the technique by preserving more prostate tissue at the apex might offer better results in sexual

function. The present study included patients regardless of sexual activity. In some cases, ejaculation preservation was not specifically requested by the patient.

5. Conclusions

This report describes in detail the technique of aquablation in a prospective multicentre registry. Despite a limited number of cases performed per surgeon, perioperative and 1-yr functional outcomes appeared to be consistent with those reported in previous series. Our findings suggest that this technique is reproducible by surgeons early in the learning curve. Further data are needed to confirm the findings of the present report.

Author contributions: Vincent Misrai had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Misrai, Barry-Delongchamps, Descazeaud.
Acquisition of data: Misrai, Barry-Delongchamps, Descazeaud.
Analysis and interpretation of data: Misrai, Barry-Delongchamps, Descazeaud.
Drafting of the manuscript: Misrai.
Critical revision of the manuscript for important intellectual content: Barry-Delongchamps, Descazeaud, Rijo, Zorn.
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Supervision: None.
Other: Video: Rijo, Zorn.

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Appendix A. Supplementary data

The Surgery in Motion video accompanying this article can be found in the online version at https://doi.org/10.1016/j.eururo.2019.06.024 and via www.europeanurology.com.

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