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ARTICLE

Aquablation for LUTS due to BPH in men with localized prostate cancer

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Background: *Benign prostatic hyperplasia (BPH) and prostate cancer (PCa) are common in aging men and are often concomitant. The purpose of the study was to evaluate whether Aquablation in men with BPH and early-stage PCa resulted in improvements in lower urinary tract symptoms (LUTS) and urinary quality of life (QoL) similar to men with only BPH. Furthermore, we explored active surveillance (AS) cancer outcomes in men undergoing Aquablation compared with a control AS population.*

Methods: *Two prospective IRB (institutional review board)-approved databases were used to investigate outcomes in men with GG1 PCa on AS and men with LUTS due to BPH treated with Aquablation. Clinical and demographic data were collected. AS was performed per institutional protocol, and all men undergoing Aquablation did so for relief of symptomatic LUTS/BPH. Between-group comparisons were made using Analysis of variance, with multiple pairwise comparisons or Chi-squared tests were used to compare baseline demographics. Urinary outcomes at baseline, 6 weeks, and 6 months were compared between subgroups using t-tests.*

Results: *1445 men were included in the analysis: 914 on AS, 478 without PCa who underwent Aquablation, and 53 on AS who underwent Aquablation. Aquablation resulted in significant improvement in IPSS, QoL, and Q_{max} in both groups undergoing Aquablation. AS patients who underwent Aquablation had 44% fewer pathologic upgrading events than AS patients who did not undergo Aquablation. This corresponds to a freedom from progression hazard ratio of 0.48 (95%CI [0.24, 0.98], $p = 0.044$).*

Conclusions: *Aquablation is safe and effective for the treatment of LUTS due to BPH in men on AS for early-stage prostate cancer. Additionally, Aquablation in men undergoing AS is associated with a lower risk of pathologic upgrading and favorably alters the oncologic outcomes.*

Key Words: prostate cancer, benign prostatic hyperplasia, active surveillance, prostate-specific antigen, transurethral waterjet therapy

Introduction

Both benign prostatic hyperplasia (BPH) and prostate cancer (PCa) have a high incidence among aging men and are commonly diagnosed in the same patients.[1–3] Historic standard of care surgical treatments escalate in terms of invasiveness with increased prostate volume for BPH, and as the grade/stage worsens for PCa.[4] Historically, men with larger prostates >100 g were often treated with open simple prostatectomies.[5] In addition, men with clinically significant PCa and BPH can be managed with radical surgery, which addresses the cancer and alleviates obstructive lower urinary tract symptoms (LUTS).[6] However, men with NCCN low- and intermediate-risk PCa are increasingly being managed nonoperatively with active surveillance (AS).[7] While AS has the advantage of avoiding side effects such as urinary incontinence

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and erectile dysfunction associated with curative intent treatment, AS does not address LUTS/BPH.[8]

Previous work suggests that cancer management strategies should be independent of a BPH diagnosis and are well defined in the literature and within treatment guidelines.[9–11] Interventions for BPH are not contraindicated among men with PCa. To this end, many studies have explored non-pharmaceutical interventions for bladder outlet obstruction in men with advanced PCa that have provided urinary symptom relief.[12–17] Laser resective procedures such as holmium laser enucleation of the prostate and thulium laser enucleation of the prostate have shown improved urinary outcomes in PCa patients.[18] However, little is reported regarding the treatment of LUTS secondary to BPH among men with early-stage PCa being managed with AS.

For men with symptomatic BPH refractory to medical management, bladder outlet procedures have been shown to result in significant improvement in LUTS and quality of life (QoL). One treatment modality, Aquablation, has been established as an effective endoscopic treatment for BPH through multiple clinical trials, including the WATER and WATER II studies. These studies demonstrated durable efficacy and a favorable morbidity profile compared to traditional transurethral resection of the prostate (TURP).[19,20] Notably, these studies reported no treatment-related erectile dysfunction and negligible incontinence. However, no reports have been published to date on the use of Aquablation in men with LUTS/BPH undergoing AS for PCa. While the randomized WATER IV trial comparing Aquablation and radical prostatectomy for prostate cancer is underway to further study this question, the trial is still recruiting, and results are not yet available.

In this context, we evaluated whether Aquablation in men with LUTS/BPH and early-stage PCa resulted in improvement in LUTS and urinary QoL. Furthermore, for early-stage prostate cancer, we explored AS oncologic outcomes in men undergoing Aquablation compared to similar men in our AS population. Our hypothesis was that Aquablation would safely and effectively treat LUTS in men on AS without increasing upgrading on biopsy or other adverse cancer outcomes. The purpose of the study was to evaluate whether Aquablation in men with BPH and early-stage PCa resulted in improvements in lower urinary tract symptoms (LUTS) and urinary quality of life similar to men with only BPH. Furthermore, we explored active surveillance (AS) cancer outcomes in men undergoing Aquablation compared with men undergoing AS for early-stage PCa.

Methods

Study design

This study utilized two prospective IRB-approved databases at our institution (Institutional Review Board of Endeavor Health, IRB numbers: EH-09-043 and EH-24-123) to investigate outcomes in men with prostate cancer on AS and men with LUTS due to BPH treated with Aquablation. Both databases collected baseline demographic data, including age, prostate volume, serum prostate-specific antigen (PSA) levels, Prostate Health Index (PHI) values, International Prostate Symptom Score (IPSS), and the IPSS QoL scales, as well as uroflow and post-void residual volume (PVR). Baseline demographics are reported as those at the time of PCa diagnosis or, if not diagnosed, the time of Aquablation.

Cohort and therapy

From these two databases, three cohorts were generated:

1. **AS Cohort**: Men diagnosed with grade group (GG)1-3 PCa and managed with AS without receiving Aquablation for LUTS. For the purposes of the present analysis, only men with GG1 cancer were included.
2. **AS + AQUA Cohort**: Men diagnosed with GG1 PCa who were managed with AS and subsequently treated with Aquablation for LUTS due to BPH.
3. **AQUA Cohort**: Men without a diagnosis of PCa who were treated with Aquablation for LUTS secondary to BPH.

AS followed contemporary standards of care and was agnostic to Aquablation treatment. An important constant throughout the study period was the routine use of multiparametric magnetic resonance imaging (MRI) guided biopsy for AS patients. In addition to the overlapping data fields mentioned above, the AS database also tracked outcomes of MRI-guided biopsy findings. For analysis, GG progression was defined as an increase in GG on follow-up biopsy. Kaplan-Meier (KM) survival analysis was performed with the index time being the time of cancer diagnosis. A log-rank test was used to compare two survival curves.

Aquablation was performed according to previously described methodologies.[21] Two passes were routinely performed, and the focal bladder neck cautery technique with a bipolar resectoscope was used to minimize peri- and post-operative bleeding.[21] The Aquablation treatment approach was the same in both the AQUA and AS + AQUA cohorts and was intended as a LUTS due to BPH treatment only. The intention of Aquablation was to alleviate

LUTS/BPH and, as such, no intentional additional waterjet or bipolar loop resection was performed to specifically target cancer in the AS + AQUA cohort. In both groups, Aquablation was intended to be primarily a bilateral transition zone-focused resection. The Aquablation database focused on urinary function changes primarily through IPSS and IPSS QoL measurement. Also, PVR was measured at baseline and during the first follow-up, which was routinely scheduled at 1 month post-Aquablation.

Statistical analysis

One-way analysis of variance with multiple pairwise comparisons or Chi-squared tests was used to compare baseline demographics. Urinary function at baseline, 6 weeks, and 6 months was compared between subgroups using *t*-tests. Statistical analyses were performed using SAS 9.4 (SAS Institute, Cary, NC, USA). *p*-values were considered significant if <0.05 and highly significant if <0.01.

Results

A total of 1445 men were included in the analysis. The AS cohort consisted of 914 men with a mean age of 66.6 ± 7.9 years, all of whom had GG1 prostate cancer at diagnosis, as did the 53 men in the AS + AQUA cohort, whose average age was 70.6 ± 6.8 years. Men undergoing Aquablation (AS + AQUA or AQUA) were older, had larger PVR, and worse LUTS than men on AS alone. Mean time from PCa diagnosis to Aquablation was 2.5 years (range 0–16 years). Demographics are summarized in Table 1.

Table 2 summarizes the changes in IPSS and IPSS QoL in the AS + AQUA and AQUA cohorts. All IPSS improvements compared to baseline were highly significant ($p < 0.001$), and there was no difference in the change in improvement between the cohorts. The IPSS QoL was slightly worse in the AQUA arm vs. AS + AQUA at baseline ($p = 0.029$), but changes from baseline were not statistically different at 6 weeks or at 6 months in the AQUA vs. AS + AQUA cohorts ($p > 0.05$).

PVR volumes in the AS + AQUA cohort decreased from 221 ± 316 cc at baseline to 43 ± 70 cc at first follow-up ($p < 0.001$), representing an 81% decrease. Similarly, the PVR of the AQUA cohort dropped from 211 ± 320 cc to 54 ± 101 cc ($p < 0.001$), a 74% decrease. The improvements in PVR were similar between groups.

Changes in overall IPSS and QoL are shown before and after surgery in Figure 1. The average improvement in overall IPSS was 5.02 (27%) and 7.27 (41%)

TABLE 1. **Patient demographics of the AS cohort (no Aquablation), the AS + AQUA cohort, and the AQUA (no prostate cancer diagnosis) cohorts**

Patient Demographic	Overall (N = 1445)	AS (N = 914)	AS + AQUA (N = 53)	AQUA (N = 478)	*p*-Value[1]	*p*-Value[2]	*p*-Value[3]
Age (years), mean ± SD	66.6 ± 7.9	64.4 ± 7.3	70.6 ± 6.8	69.2 ± 7.8	<0.001	<0.001	0.42
Race, n (%)					0.23	0.002	0.73
Caucasian	1215 (84.1)	770 (84.3)	46 (86.8)	399 (83.5)			
Black	52 (3.6)	45 (4.9)	0 (0.0)	7 (1.5)			
Asian	32 (2.2)	18 (2.0)	0 (0.0)	14 (2.9)			
Other/unknown	146 (10.1)	81 (8.9)	7 (13.2)	58 (12.1)			
PSA (ng/mL), mean ± SD	5.5 ± 4.5	5.5 ± 3.3	8.0 ± 8.1	5.3 ± 5.4	<0.001	0.55	<0.001
Prostate Health Index (PHI), mean ± SD	40.2 ± 20.2	45.0 ± 21.4	46.3 ± 16.0	31.5 ± 15.4	0.89	<0.001	<0.001
Grade group 1, n (%)	967 (66.9)	914 (100)	53 (100)	0 (0)			
Prostate volume (cc), mean ± SD	77.1 ± 54.3	44.2 ± 23.1	102.2 ± 48.9	103.9 ± 58.6	<0.001	<0.001	0.97
IPSS, mean ± SD	14.5 ± 8.9	7.5 ± 6.3	17.8 ± 7.2	18.8 ± 7.6	<0.001	<0.001	0.58
Mild (0–7), n (%)	206 (28.0)	167 (60.7)	4 (7.8)	35 (8.5)			
Moderate (8–19), n (%)	285 (38.7)	88 (32.0)	25 (49.0)	172 (41.9)	<0.001	<0.001	0.62
Several (20–35), n (%)	246 (33.4)	20 (7.3)	22 (43.1)	204 (49.6)			
IPSS QoL, mean ± SD	3.5 ± 1.7	1.6 ± 1.4	3.7 ± 1.1	4.2 ± 1.3	<0.001	<0.001	0.083

Note. [1]*p*-value of AS vs. AS + AQUA, [2]*p*-value of AS vs. AQUA, [3]*p*-value of AS + AQUA vs. AQUA. Abbreviations: SD, standard deviation; AS, active surveillance; AQUA, Aquablation; IPSS, International Prostate Symptom Score.

TABLE 2. **Urinary function at baseline, 6 weeks, and 6 months for the subgroups that underwent Aquablation**

Subgroup	Baseline		First Post-Op Visit		6 Months	
	AS + AQUA	AQUA	AS + AQUA	AQUA	AS + AQUA	AQUA
IPSS	17.8 ± 7.2	18.8 ± 7.6	8.7 ± 5.9**	10.9 ± 7.3**	7.3 ± 6.1**	7.7 ± 5.9*
p-value	0.35		0.057		0.74	
	Change from baseline		−8.8 ± 9.16**	−7.9 ± 8.8**	−9.4 ± 6.4**	−10.7 ± 8.7*
	p-value between groups		0.54		0.49	
IPSS QoL	3.7 ± 1.1	4.2 ± 1.3	1.9 ± 1.4**	2.4 ± 1.8*	1.2 ± 0.9*	2.0 ± 1.6*
p-value	0.029		0.11		0.002	
	Change from baseline		−1.6 ± 2.2**	−1.8 ± 2.1*	−2.3 ± 1.1*	−2.2 ± 1.9*
	p-value between groups		0.69		0.85	

Note. *change from baseline $p < 0.05$; **change from baseline $p < 0.01$. Abbreviations: AS, active surveillance; AQUA, Aquablation; IPSS, International Prostate Symptom Score.

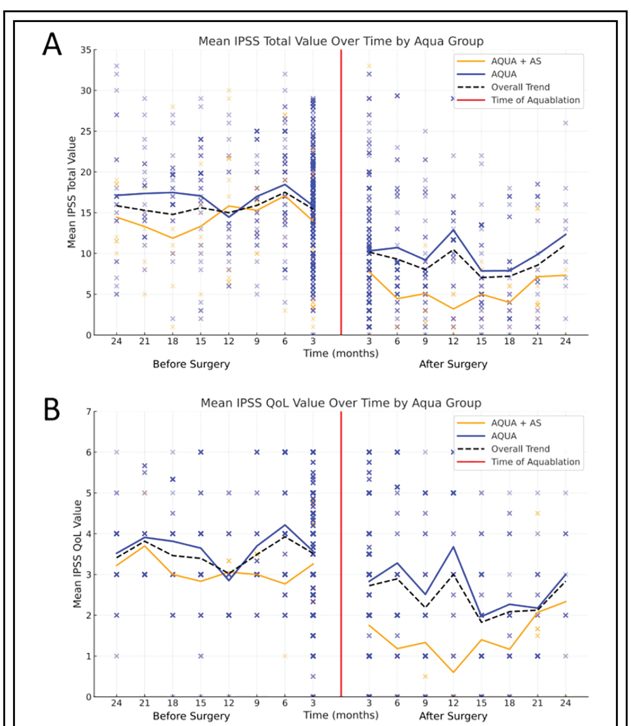

FIGURE 1. International prostate symptom score (IPSS) changes following Aquablation. (**A**) Mean IPSS before and after Aquablation. (**B**) Mean IPSS QoL before and after Aquablation

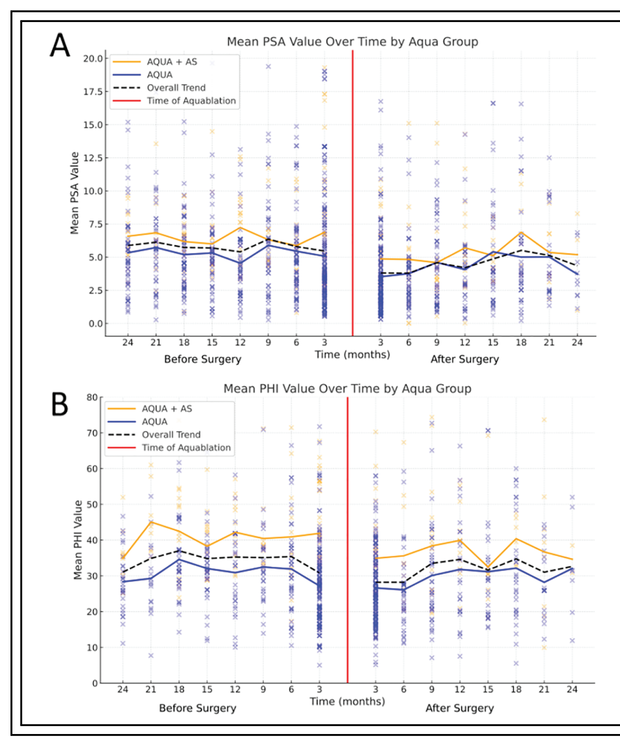

FIGURE 2. Prostate serum biomarker changes after Aquablation. (**A**) Serum prostate-specific antigen (PSA) levels before and after Aquablation. (**B**) Prostate health index (PHI) values before and after Aquablation

in the benign and AS groups, respectively ($p < 0.01$ for all). QoL scores improved by 0.74 (18%) in the benign patients and 1.58 (43%) in the AS patients (all $p < 0.01$).

Changes in serum PSA and Prostate Health Index (PHI) values before and after Aquablation are shown in Figure 2. Following Aquablation, PSA declined

TABLE 3. **Maximum urinary flow rate (Q_{max}, mL/s) before and after Aquablation**

Q_{max}	Overall (N = 531)		AS + AQUA		AQUA		*p*-Value
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	
Pre-op Q_{max}	93	5.1 ± 3.1	7	4.5 ± 2.3	86	5.1 ± 3.2	0.60
Post-op Q_{max}	109	16.9 ± 5.9	11	16.2 ± 4.4	98	17.0 ± 6.0	0.84

Note. Abbreviations: SD, standard deviation; AS, active surveillance; AQUA, Aquablation.

by 1.81 ng/mL (34%) in the benign group and 2.28 ng/mL (29%) in the AS group (both $p < 0.01$). PHI declined by 2.67 (8%) in the benign group and 7.72 (17%) in the AS group (all $p < 0.01$). There were fluctuations in both PSA and PHI values post-Aquablation regardless of PCa status. Interestingly, the median PSA values overlapped at points between those with PCa and those without cancer. However, the median PHI values were always higher among men with PCa.

Table 3 summarizes maximum urinary flow (Q_{max}) before and after Aquablation in the AQUA and AS + AQUA groups. Preoperative mean Q_{max} was 5.1 mL/s and 4.5 mL/s in the AQUA and AS + AQUA groups, respectively (between-group $p = 0.60$). Postoperative mean Q_{max} increased to 16.6 mL/s (226%) and 17.0 mL/s (277%) in the AQUA and AS + AQUA groups, respectively (between-group $p = 0.84$).

We next analyzed cancer-specific outcomes among the AS + AQUA and AS cohorts. Kaplan-Meier analysis of the freedom from GG progression is shown in Figure 3 for the AS + AQUA and AS cohorts. At 5 years, 81% (95% CI[66%, 90%]) of the AS + AQUA were free from GG progression compared to 66% (95% CI [62%, 69%]) of the AS cohort ($p = 0.012$). This corresponds to a 44% reduction in progression events and a freedom from grade progression hazard ratio of 0.48 (95% CI [0.24, 0.98], $p = 0.044$).

The median follow-up of the AS cohort was 6.2 years, and 884 of 914 patients were followed for longer than 6 months. During this time, 91% of subjects underwent at least one follow-up biopsy. The median follow-up of the 53 subjects in the AS + AQUA cohort was 3.0 years. During this time, 37 (70%) had at least one follow-up MRI, and 34 (64%) had at least one surveillance biopsy after Aquablation. Those who did not have a follow-up biopsy tended to be early in their follow-up. Only 9 patients (17%) had neither surveillance biopsy nor MRI following Aquablation.

There were 8 men who upgraded following Aquablation. Of these men, 4 had robotic-assisted laparoscopic prostatectomy (RALP), and 3 had radiation. The remaining patient remained on AS.

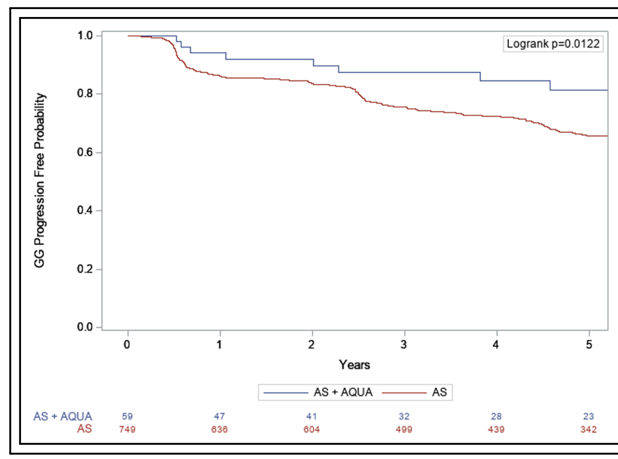

FIGURE 3. Freedom from grade group progression for men on active surveillance without receiving Aquablation (AS) compared to those who were on active surveillance and underwent Aquablation (AS + AQUA)

Treatment decisions were made through shared decision-making, taking into account patient age, co-morbidities, and patient and surgeon preference. There were no Clavien-Dindo 2 or higher complications in the 4 men who underwent RALP after Aquablation, and the procedures were unremarkable in terms of surgical complexity.

Discussion

This study is the first report of both functional and oncologic outcomes of Aquablation as a treatment to manage LUTS secondary to BPH in men with PCa on AS. All PCa patients in this study were being managed with AS per standard of care guidelines, and men were selected for Aquablation based on LUTS and treatment preferences. We found that Aquablation resulted in significant improvement in LUTS and QoL in men on AS, and that improvements in

LUTS and QoL were comparable to men who underwent Aquablation without cancer. We also found that men on AS had significantly lower odds of GG progression if they had undergone Aquablation. Taken together, these findings suggest that Aquablation is an effective and safe treatment for LUTS in men with early-stage prostate cancer on AS. Not only was there no evidence that Aquablation resulted in any oncologic risk there appears to be an efficacy signal for decreased GG progression for those who underwent Aquablation for BPH.

While there were between-group differences in the cohorts, the differences reflect the inherent natures of the individual cohorts. Men undergoing surgery for LUTS would be expected to be older than men not undergoing surgery, given that BPH incidence increases significantly with age.[22] There was no significant age difference between the benign and AS cohorts who underwent Aquablation. Unsurprisingly, men who sought Aquablation for LUTS (the AS + AQUA and AQUA cohorts) had larger prostates, higher baseline IPSS scores, and higher IPSS QoL scores (indicating worse symptoms and QoL). Conversely, PHI was higher for those with a PCa diagnosis. Demographically, the AS + AQUA cohort had a lower proportion of black and Asian subjects and a higher proportion with either other or unknown race.

The 34% 5-year progression rate observed in the AS cohort is not dissimilar to those observed in the current literature. In a 1450-man AS cohort from UCSF, the observed 5-year GG progression rate was 40% and 53% of very low and low-risk disease, respectively.[23] By this time, approximately 25% of the very low-risk and 45% of the low-risk groups had undergone local or systemic treatment. In the Hopkins series of men with predominantly very low-risk disease, the five-year progression rate was lower at 21% however, by this point, 36% had converted to treatment, indicating intervention prior to GG progression.[24] These long-term series contain mostly men diagnosed with systematic biopsy, which is well known to undergrade cancer compared to MRI-guided biopsy. A University College of London series that only included men diagnosed and followed with MRI-guided biopsy observed, at first follow-up biopsy, a 34% upgrade rate for those initially diagnosed with GG1 disease; 45% for those with MRI visible GG1 lesions, and 25% for those whose GG1 disease was not MRI visible.[25]

While there is a theoretical concern that the Aquablation waterjet could liberate tumor cells capable of seeding metastasis, Teoh et al.[26] studied CTC changes following Aquablation in men with prostate cancer and found that the post-Aquablation CTC spike was mild and not present after 2 days. This study also documented that Aquablation could eliminate MRI-visible lesions among men with prostate cancer and LUTS/BPH. This finding suggests, along with our data, that Aquablation could have a role in prostate cancer management as well as BPH/LUTS.

Despite having almost no value in predicting oncologic outcomes, current guidelines recommend following men on AS with regular serum PSA values.[10,11,27] In addition, the ideal way to monitor men on AS after a resective/ablative bladder outlet procedure remains to be defined. Several studies have suggested that biomarkers, including the prostate health index, can predict upgrading among men on AS.[28,29] Our study demonstrates relatively non-overlapping and elevated PHI values among men with AS who underwent Aquablation compared to those without cancer (Figure 2B). These data support that this may be a better biomarker to monitor men with PCa on AS. However, future studies demonstrating differences in PHI values among men who were upgraded after Aquablation should be performed.

There are several reasons that we may have observed lower upgrading rates in the AS patients undergoing Aquablation. In general, they may have had lower PSA density (and thus potentially lower risk) than other AS patients. The large prostates may have led to higher serum PSA levels, resulting in increased diagnosis of truly indolent disease. Alternatively, the Aquablation procedure may have incidentally treated some of the tumors within the prostate or may have resected prostate tissue that was "at risk" of developing cancer over time. This is particularly plausible for transition zone tumors, as Aquablation performed for BPH primarily destroys transition zone tissue. Alternatively, there could be unmeasured selection bias in men who underwent Aquablation after shared decision making with their urologist, potentially leading to differences in baseline disease characteristics that were not captured in our analysis. Reassuringly, there were no findings suggesting Aquablation increases upgrading rates or adverse prostate cancer events.

This study is limited by its retrospective nature and lack of standardized treatment protocols. To minimize bias, we included patients treated consecutively at our center in all 3 cohorts. Furthermore, the data used in this analysis were abstracted from the electronic health record, in which data are recorded contemporaneously with patient care. Thus, the data presented reflect real-world experience.

Conclusions

In conclusion, Aquablation is safe and effective for the treatment of LUTS due to BPH in men on AS for early-stage PCa. Additionally, Aquablation in men undergoing AS is associated with a lower risk of pathologic upgrading. Therefore, a diagnosis of PCa should not be a contraindication for resective bladder outlet surgery in men with significant bothersome LUTS due to BPH. Furthermore, additional study to evaluate the effectiveness of Aquablation as a treatment for early-stage PCa is warranted.

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Author Contributions

The authors confirm contribution to the paper as follows: study conception and design: James T. Kearns, Brian T. Helfand; data collection: James T. Kearns, Christopher Ward, Henry M. Dunnenberger, Kristian Novakovic, Alexander P. Glaser, Brian T. Helfand; analysis and interpretation: James T. Kearns, Cecilia Chang, Chi Wang, Brian T. Helfand; draft manuscript and preparation: James T. Kearns, Brian T. Helfand. All authors reviewed and approved the final version of the manuscript.

Availability of Data and Materials

Data are not available for release, as we do not have IRB approval for the sharing of these data.

Ethics Approval

Institutional Review Board of Endeavor Health approved the two prospective databases used in this study, IRB numbers EH-09-043 and EH-24-123. EH-09-043 requires informed consent from all enrollees, and written informed consent was obtained, while EH-24-123 does not require signed informed consent, as all data were abstracted from clinical care.

Conflicts of Interest

James T. Kearns, Alexander P. Glaser, and Brian T. Helfand are investigators and consultants for Procept Biorobotics.

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