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LETTER TO EDITOR

Furthering the external validity of Aquablation and implications for real-world patients

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Dear Editor,

Despite international variance, the approval process for novel surgical devices employs various means to evaluate two key aspects of new technology: safety and efficacy. To do so, prior to full clearance, devices are assessed in a controlled experimental setting; ideally, randomized trials would be the default option in this stage [1]. Aquablation, a robotically executed, surgeon-guided, high-pressure water jet technology integrating real-time ultrasonography for the treatment of benign prostatic hyperplasia (BPH), underwent such an evaluation leading to FDA approval in December of 2017 following the WATER clinical trial (NCT02505919) that demonstrated that Aquablation was safe and efficacious in men with prostates between 30 and 80 cc [2].

However, clinical trials are limited by their own design; notably, a well-designed randomized control trial requires stringent inclusion and exclusion criteria limiting its external validity [3]. To palliate to these external validity issues, continued post-market reporting of outcomes and patient data are required. Bach et al. undertook this task in their report of the largest, prospective single-center experience of non-selected patients treated with Aquablation [4]. These prospective outcomes thus provide insight into the first "real-world" experience with Aquablation.

The authors studied 118 *consecutive* patients. *Consecutive* describes the enrollment into a study of all the patients with a particular diagnosis during a defined period of time [5]. This implies that between September 2017 and June 2018, all patients presenting at their institution with BPH, excluding those on anticoagulation therapy other than Aspirin 100 mg, were included and underwent Aquablation [4]. Understanding this strength of the study design is crucial as if done correctly, it theoretically eliminates any form of selection bias and increases external validity [5]. For example, patients with chronic urinary retention were excluded from both WATER studies [2, 6] but can represent up to 40–50% of the patients in certain series [7]. By including these patients, Bach et al. help provide the urological community with clinic-like indications for BPH surgery.

This paper is meaningful insofar that the functional outcomes are in line with that of the WATER clinical trials while surpassing them with much shorter resection time and procedure time as well as fewer blood transfusions and complications [2, 6]. The authors hypothesize that their impressive outcomes might be the result of growing experience and standardization of the postoperative care [4]. Similarly, we agree that high-volume surgeons are the key to better outcomes, regardless of the surgical approach [8]. For example, in this study, the author performed around 11 Aquablation cases *per month*, which is greater than the majority of surgeons from the multicenter WATER trials [2, 6] and of most practicing urologists—it has been reported that the median number of BPH surgeries performed by the average urologist is 12–18 *per year* [9]. This experience directly translates to improved efficacy and safety.

Furthermore, the reported clinical outcomes reported by Bach et al. were comparable to the top standards for BPH management, such as those of Holmium laser enucleation of the prostate (HoLEP). HoLEP has been shown to be equivalent if not superior to transurethral resection of the prostate and photovaporization of the prostate [10–15]. An important strength of HoLEP is volume-independence. Similarly, a published subgroup analysis of trial data demonstrated that Aquablation clinically normalizes the outcomes between patients with lesser than 100 cc and greater than 100 cc prostates—whether this finding translates to clinical routine is still to be determined [16]. Although outside of the scope of the current study, a subgroup analysis of patients with large

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prostates (> 100 cc) in a "real-world" context could have provided additional insight into this comparison between Aquablation and the volume-independent HoLEP.

If longer term follow-up outcomes beyond 1–2 years and additional "real-world" data continue to support Aquablation, one can imagine that this technology will revolutionize and perhaps standardize urologists' surgical management of BPH. Further study addressing its comparison to other enucleation techniques, global reproducibility, optimization of hemostasis to ideally be a same-day surgery, cost and durability are all certainly warranted. The authors should be congratulated on publishing the largest clinical experience to date using Aquablation technology and highlighting its potential as a safe and effective routine surgical option for the management of LUTS due to BPH.

Author contributions DDN: manuscript writing/editing. NB: manuscript writing/editing and review. KCZ: manuscript writing/editing and review.

Compliance with ethical standards

Conflict of interest NB and KCZ participated in WATER II. WATER II study data were entered into an electronic data capture system by site coordinators, were monitored, and source verified by monitors hired by the study sponsor (PROCEPT BioRobotics). No author of this letter has a conflict of interest with PROCEPT BioRobotics.

Research involving human participants and/or animals None for this letter to the editor.

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