Benign Prostatic Hyperplasia: Surgical Therapy & New Technology I

Moderated Poster 1

Friday, May 3, 2019 7:00 AM-9:00 AM

MP01-01
WATER VS WATER II: AQUABLATION THERAPY FOR BENIGN PROSTATIC HYPERPLASIA

David-Dan Nguyen*, Naem Bhojani, Montreal, Canada

INTRODUCTION AND OBJECTIVES: Surgical options are limited when treating large (~80cc) prostates for lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH); there is a need for novel surgical approaches with shorter learning curves and effective treatment. Aquablation (AquaBeam System, PROCEPT BioRobotics, Inc., USA), an ultrasound-guided, robotically executed waterjet ablative procedure, could be this novel tool. This analysis compares the outcomes of Aquablation in 30cc to 80cc prostates with the outcomes in 80cc to 150cc prostates.

METHODS: WATER (NCT02505919) is a prospective, double-blind, multicenter, international clinical trial comparing the safety and efficacy of Aquablation and transurethral resection of the prostate in the treatment of LUTS/BPH in men 45 to 80 years old with a prostate between 30cc and 80cc. WATER II (NCT03123250) is a prospective, double-blind, multicenter, international clinical trial of Aquablation in men with a prostate between 80cc and 150cc. We herein report baseline parameters and 6-month outcomes in 116 WATER (W-I) and 101 WATER II (W-II) study subjects undergoing Aquablation. Subjects’ t-test or Wilcoxon tests were used for continuous variables and Fisher’s test for binary variables.

RESULTS: Mean operative time was 33±17 minutes in W-I and 37±13 minutes in W-II. The average length of stay post-procedure was 1.4±0.7 days (W-I) vs. 1.6±1.1 days (W-II). Mean changes in International Prostate Symptom Score (IPSS) and IPSS quality of life were substantial, occurring soon after treatment and averaging (at 6 months) 16.9 and 3.5 points, respectively, in W-I and 17.4 and 3.2 points in W-II (p=0.8046 and .2607 respectively). By 3 months Clavien-Dindo grade 2 or higher events occurred in 19.8% of W-I subjects and 34.7% of W-II subjects (p=0.4880). One W-I subject (0.9%) and 6 W-II subjects (5.9%) required postoperative blood transfusion (p=0.0517).

CONCLUSIONS: Aquablation clinically normalizes outcomes between patients with a 30cc to 80cc prostate and patients with an 80cc to 150cc prostate treated for LUTS/BPH with an expected increase in the risk of complication. It is effective in patients with large prostate glands (~80cc) with acceptable complications.

Submitted on behalf of the WATER and WATER II authors.

Table 1. Characteristics and Outcomes of each cohort

<table>
<thead>
<tr>
<th>WATER (n=116)</th>
<th>WATER II (n=101)</th>
<th>P-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years, mean (SD)</td>
<td>65.7±7.3</td>
<td>67.5±6.4</td>
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<tr>
<td>Prostate specific antigen, g/L, mean (SD)</td>
<td>3.7±0.6</td>
<td>7.1±5.9</td>
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<tr>
<td>Prostate size (TRUS), cc, mean (SD)</td>
<td>51.1±16.2</td>
<td>117.4±22.1</td>
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<tr>
<td>Operating time, min, mean (SD)</td>
<td>33±7</td>
<td>37±7</td>
</tr>
<tr>
<td>Resection time, min, mean (SD)</td>
<td>3.9±1.0</td>
<td>8±3</td>
</tr>
<tr>
<td>Length of stay, days, mean (SD)</td>
<td>1.4±0.7</td>
<td>1.6±1.1</td>
</tr>
<tr>
<td>30 Grade 2+ Subjects by 3 months, % (number)</td>
<td>19 (23)</td>
<td>34 (35)</td>
</tr>
<tr>
<td>Maintenance of antegrade ejaculation, % (number)</td>
<td>93.1 (108)</td>
<td>81 (82)</td>
</tr>
</tbody>
</table>

*P<0.05

Source of Funding: PROCEPT BioRobotics

MP01-02
WHAT MINIMAL IMPORTANT DIFFERENCE IN URINARY SYMPTOM RELIEF BENEFITS PATIENT QUALITY OF LIFE? - ASSOCIATED WITH REZUM WATER VAPOR THERMAL THERAPY 4 YEAR OUTCOMES

Kevin McVary*, Maywood, IL; Tyson Rogers, Minneapolis, MN; Christopher Cantrill, San Antonio, TX; Claus Roehrborn, Dallas, TX

INTRODUCTION AND OBJECTIVES: Relief of lower urinary tract symptoms (LUTS), those due to benign prostatic hyperplasia (BPH), is only relevant if commensurate with improving patients’ perception of improved quality of life (QOL). We evaluated 4 year outcome data from the randomized double-blind, controlled trial (RCT) of water vapor thermal therapy for treatment of moderate-to-severe LUTS/BPH, and also determined the minimal important differences (MIDs) in International Prostate Symptom Scores (IPSS) associated with meaningful changes in QOL.

METHODS: Total 188 subjects; 135 men ≥50 years old with IPSS ≥13, maximum flow rate (Qmax) <15 ml/s and prostate volume 30-80 cm³ treated once in the RCT for Rezum® System thermal therapy were followed for 4 years and a subset of 53 men who requalified for cross-over from control (sham rigid cystoscopy) to active treatment were followed for 3 years. IPSS-QOL was used in a method for anchor-based analysis to determine MID in IPSS point changes related to degrees of improved QOL for each severity category of LUTS.

RESULTS: Mean symptom relief was significantly improved within 3 months or less (IPSS 50%, QOL 46%, Qmax 69%, BPH Impact Index 46%) after thermal therapy and remained consistently durable (IPSS 46%, QOL 42%, Qmax 50%, BPH Impact Index 51%) throughout 4 years (p<0.0001); outcomes were similarly sustained in crossover subjects at 3 years. Targeted ablation was to all prostate zones including an obstructing median lobe and/or enlarged central zone. No late adverse events occurred and no de novo erectile dysfunction was reported. IPSS and QOL scores are very strongly correlated (Spearman correlation coefficient = 0.67 - 0.72) after water vapor thermal therapy. The estimated mean change in IPSS score from baseline corresponding to a one point QOL change for each LUTS severity level is approximately -5 points for mild (IPSS 13-19), -8.2 for moderate (IPSS 20-26) and -11.7 for severe LUTS (IPSS 27-35), p<0.0001. The MID was quite consistent across time points over 3 years. In general, men had a mean ~50% improvement in QOL (from “mostly dissatisfied” to “mostly satisfied” with urinary condition; score decrease from 4 to 2).

CONCLUSIONS: The MID offers a threshold above which the outcome is experienced as providing a noticeable improvement in QOL by the patient. Water vapor thermal therapy provided effective symptom relief and improved QOL that remains durable for over 4 years. This minimally invasive therapy is applicable to all prostate zones with procedures performed under local anesthesia in an office setting.

Source of Funding: Boston Scientific

MP01-03
REZUM WATER VAPOUR ABLATION THERAPY FOR BENIGN PROSTATIC HYPERPLASIA: INITIAL RESULTS FROM THE UNITED KINGDOM

Maximilian Johnston*, Basingstoke, United Kingdom; Taimur Shah, London, United Kingdom; Amr Emara, Tina Gehring, Thomas Farmer, Tim Nedas, Raj Kumar, Basingstoke, United Kingdom; Ashley Mcfarlane, Mathias Winkler, Tamer El-Husseiny, Hashim Ahmed, London, United Kingdom; Richard Hindley, Basingstoke, United Kingdom

INTRODUCTION AND OBJECTIVES: The Rezüm System is a minimally invasive thermal therapy for the treatment of symptomatic BPH. It can be safely performed under local anaesthetic and sedation with minimal side effects as a daycare procedure. We evaluated this