**Erectile and Ejaculatory Function Preserved with Convective Water Vapor Energy Treatment of LUTS Secondary to BPH: Randomized Controlled Study**


**KEY FINDINGS:** Convective Water Vapor thermal therapy provides rapid and sustainable improvement in LUTS and urinary flow over a 12-month period while preserving erectile and ejaculatory functions. No de novo ED was reported.

**STUDY ANALYSIS OBJECTIVE**

Determine whether water vapor thermal therapy, when conducted in a randomized controlled trial, had any effect on erectile and ejaculatory function while demonstrating significant improvement in LUTS and urinary flow rates secondary to BPH.

**STUDY METHODS**

- Prospective, randomized, controlled, single-blind study at 15 sites in the United States.
- Men ≥50 years with International Prostate Symptom Scores (IPSS) ≥13; peak flow rate (Qmax) ≥5 to ≤15 mL/s, prostates 30-80 cm³
- 197 men were randomized 2:1 between Rezūm (n=136) and the control (n=61) arm. See Minimally Invasive Prostate Convective Water Vapor Energy Ablation: A Multicenter, Randomized, Controlled Study for the Treatment of Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia for detail on protocol and LUTS specific results.
  - At baseline, 32% of the observed treatment subjects and 33% of the control subjects were not sexually active and were eliminated from the sexual function analysis.
- Radiofrequency thermal water vapor was injected into lateral and median lobes for BPH treatment and simulated the treatment with a rigid cystoscopy and simulated treatment sounds for the control.

**Table 1. Minimal clinically important differences of changes in IIEF-EF score at 3 and 12 months after water vapor thermal therapy**

<table>
<thead>
<tr>
<th>IIEF-EF baseline severity</th>
<th>Month 3 (n = 90 sexually active)</th>
<th>Month 12 (n = 77 sexually active)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>MCID* Increase, mean ± SD Range</td>
<td>MCID* Increase, mean ± SD Range</td>
</tr>
<tr>
<td>Severe (1–10)</td>
<td>12.5 ± 4.9 9–16</td>
<td>11.5 ± 3.5 9–14</td>
</tr>
<tr>
<td>Moderate (11–16)</td>
<td>10.1 ± 4.6 5–17</td>
<td>11.2 ± 4.4 7–18</td>
</tr>
<tr>
<td>Mild (17–&lt;25)</td>
<td>4.0 ± 2.2 2–10</td>
<td>5.3 ± 2.8 2–12</td>
</tr>
<tr>
<td>Improved scores, n (%)</td>
<td>29/90 (32)</td>
<td>21/77 (27)</td>
</tr>
</tbody>
</table>

IIEF-EF = International Index of Erectile Function erectile function domain; MCID = minimal clinically important difference.

*MCID is a minimal IIEF-EF score increase of 2 for men with mild erectile dysfunction, an increase of 5 for moderate erectile dysfunction, and 7 for severe erectile dysfunction.
**KEY RESULTS**

- No de novo ED occurred after thermal therapy.
- 32% of subjects achieved minimal clinically important differences (MCIDs) in EF scores at 3 months, and 27% at 1 year including those with moderate to severe ED (Table 1). The MCID measurement is the first use of this assessment in a nonpharmacological intervention study related to ED.
- Ejaculatory bother score improved 31% over baseline at 1 year (Figure 1).
- IIEF (Figure 2) and MSHQ-EjD Function (Figure 3) scores were not different from control at 3 months or from baseline at 1 year.

**LIMITATIONS**

- Primary endpoint was LUTS, not sexual function; however, well-established patient-reported questionnaires were used. The study was not powered to assess sexual function; however the results of this study would lead to the same conclusions if observed in a study 10x as large.
- Other possible influential conditions that might effect changes in LUTS/BPH treatment and related sexual function were not evaluated (e.g. obesity, smoking, weight loss, etc).

**CONCLUSIONS**

Convective water vapor thermal therapy provides rapid and sustainable improvement of LUTS and urinary flow over a 12-month period without negative effects on erectile and ejaculatory function as measured by validated questionnaires. No de novo ED was reported. These results support the application of WAVE technology as a safe and effective minimally invasive therapeutic alternative for symptomatic BPH without compromising sexual function including treatment of patients with a median lobe.

**REFERENCES**

