

Prospective trial of water vapor thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia in subjects with a large prostate: 6- and 12-month outcomes

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Limitations of this report include:

- Non-randomized study design.
- Early study termination was not due to safety or efficacy reasons. However, this did limit sample size and long-term (3-year) follow-up.
- Modest sample size (n=47) may limit generalizability.
- COVID-19 disruptions impacted enrollment and follow-up compliance.
- There was no comparator arm to directly evaluate Rezūm versus alternative therapies.

Conclusion:

These results are consistent with previous findings for prostate glands of up to 80 cm³ and indicate the safety and efficacy of Rezūm for BPH in patients with a larger prostate.

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The culture-proven UTI rate was higher than in the pivotal clinical study. Contributing factors included required urine cultures, longer catheterization, and patient baseline characteristics. The data did not identify any single factor as a clear contributor to UTI risk after a Rezūm procedure. UTIs are 'a typical' known adverse event associated with BPH surgical treatment.

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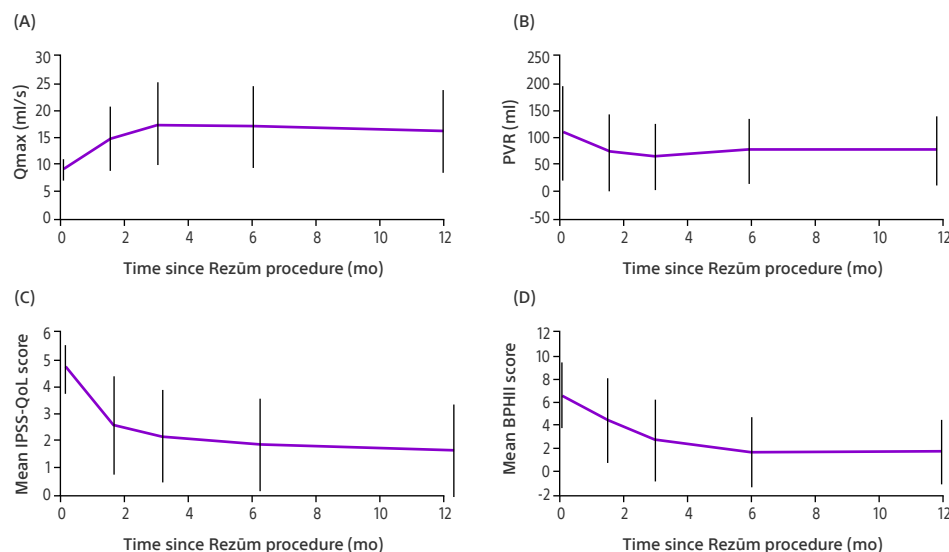
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This prospective, single-arm, multicenter study was conducted in the United States to evaluate the safety and efficacy of Rezūm Water Vapor Therapy in patients with a prostate gland >80 cm³ and ≤150 cm³.

The primary efficacy endpoint was the proportion of men achieving a ≥30% reduction in IPSS from baseline to 6 months. The primary safety endpoint was a composite of serious device-related complications. 47 men were followed at 2 and 6 weeks, and at 3, 6, and 12 months post-procedure, with longitudinal assessment of IPSS, Qmax, PVR, and QoL metrics.

- 83% of patients had ≥30% IPSS improvement at 6 months.
- IPSS improved by a mean of 11.9 ± 7.5 points at 6 months; 69% had ≥8-point improvement at 12 months.
- Qmax increased by a mean of 7.1 ± 7.0 mL/s at 12 months.
- PVR reduced by a mean of 32.1 mL at 12 months.
- No catheters were placed for de novo acute severe urinary retention lasting more than 30 cumulative days after treatment.
- The urinary tract infection (proven by culture) rate was 23.4%.
- No device-related serious adverse events.



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