CLINICAL SUMMARY

Rezūm™ Water Vapor Therapy

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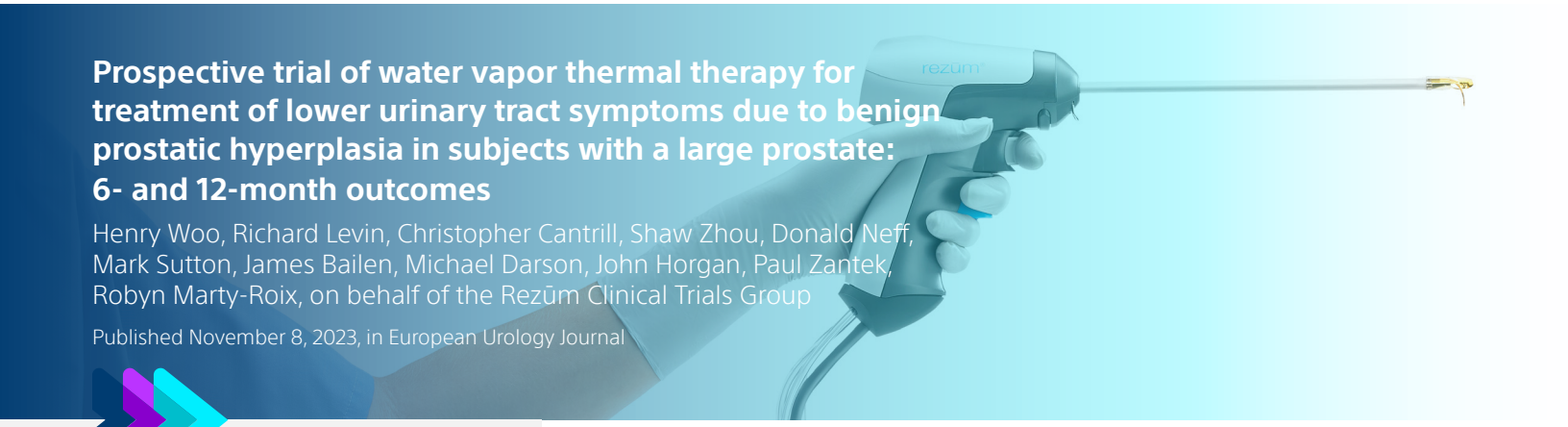

Prospective trial of water vapor thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia in subjects with a large prostate: 6- and 12-month outcomes

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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.

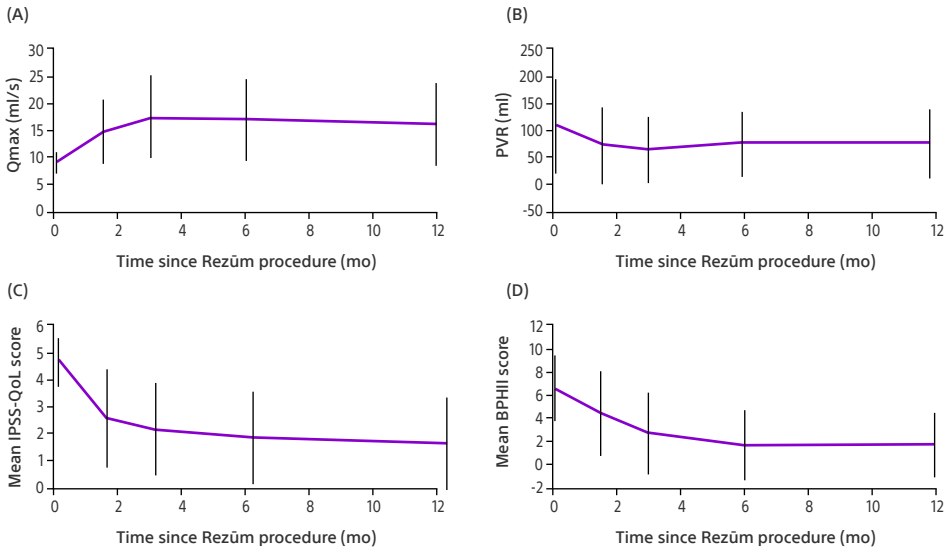
Conclusion:

These results are consistent with previous findings for prostate glands of up to 80 cm,^{3} and indicate the safety and efficacy of Rezūm for BPH in patients with a larger prostate.

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 cm^3 and ≤150 cm^3.

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.



Full Article Reference: 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 – PMC

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