

Large, multi-center, prospective registry of Rezūm water vapor therapy for benign prostatic hyperplasia

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Limitations of this report include:

- The study did not include a comparison with other BPH treatments, making it unclear how Rezūm therapy fares against alternative interventions.
- Due to the COVID-19 pandemic, in-person follow-up assessments, such as uroflowmetry and post-void residual volume, were limited, potentially affecting the completeness of data at 12 months.
- Since both patients and physicians knew the treatment, there was no blinding, which could introduce bias in assessing patient-reported outcomes.

Conclusion:

Rezūm therapy is a safe, effective, and minimally invasive treatment for BPH, providing significant symptom relief and functional improvement across a wide range of prostate volumes. Sexual function remains preserved, and the procedure is well-tolerated with minimal complications. The findings are consistent with the Rezūm II Pivotal Trial.

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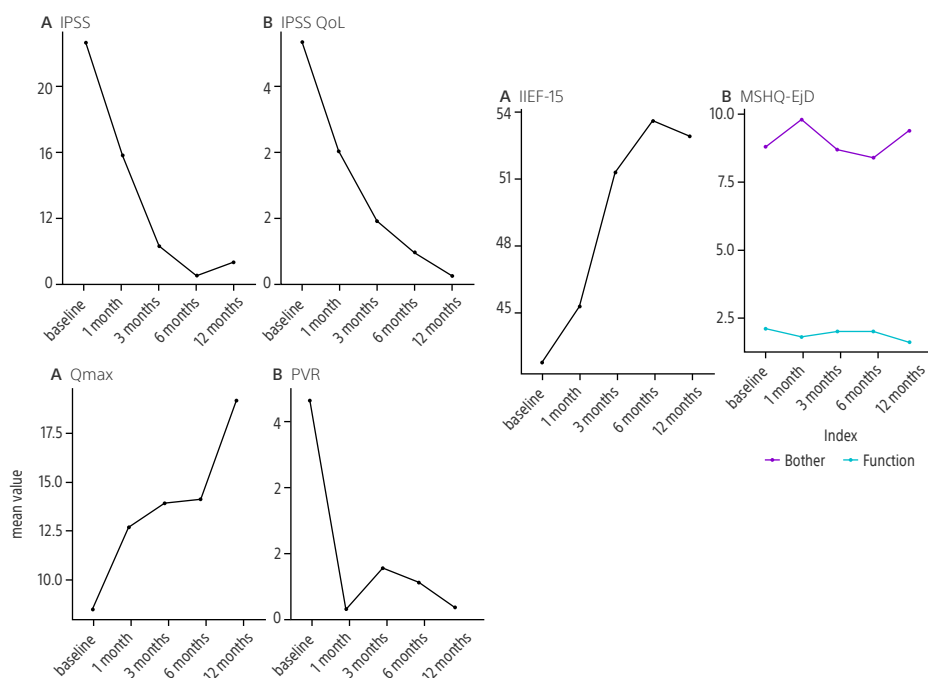
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A prospective registry of 229 BPH patients were treated with Rezūm Therapy at two Canadian centers between April 2019 and December 2020. Data on prostate volume, symptom scores (IPSS), urinary flow, and sexual function were collected at 1, 3, 6, and 12 months to evaluate the efficacy and safety of Rezūm Water Vapor Therapy for treating LUTS secondary to BPH.

- IPSS decreased by 59%, and IPSS-QoL improved by 67% at 12 months.
- Qmax increased by 74% and PVR decreased by 61% at 12 months.
- No significant changes were observed in the IIEF-15 or MSHQ-EjD indicating preservation of sexual function.
- The average post-procedure catheterization lasted 9.8 days.
- Only 2 patients (0.9%) required a second Rezūm procedure, and 5 patients (2.2%) needed endoscopic intervention due to complications.
- In patients with prostate volumes ≥ 80 mL (n=83), improvements were noted in IPSS (59% at 12 months) and Qmax (55% at 3 months).



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