

Publication Summary



Preservation of sexual function five years after water vapour thermal therapy for benign prostatic hyperplasia

McVary KT *et al.* *Sex Med.* 2021, Oct 30; doi: 10.1016/j.esxm.2021.100454

BACKGROUND



- Worsening of sexual function is a common occurrence in men with lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH)^{1,2}
- Erectile and ejaculatory dysfunction (ED and EjD) are known outcomes of traditional surgery and some pharmacotherapies for the treatment of LUTS/BPH^{3,4}
- Water vapour thermal therapy (Rezūm™) is available to treat LUTS/BPH and there are no reports of device- or procedure-related *de novo* cases of erectile dysfunction^{5,6}

The basis of the present *post hoc* analysis of the Rezūm II study was to evaluate the long-term impact of a single water vapour thermal therapy procedure on erectile and ejaculatory function.

METHODS



197 patients with LUTS/BPH (136 treated, 61 control) enrolled the study. Unblinded at the 3-month follow-up

53 control patients crossed over to treatment

125 patients **sexually active** from the treatment and crossover groups were included in the *post hoc* analysis

67 remained at the 5-year follow-up



- ✓ Age ≥50 years
- ✓ International Prostate Symptom Score (IPSS) ≥13
- ✓ Maximum flow rate (Q_{max}) ≤15 mL/s
- ✓ Prostate volume 30–80 cm³ (no restrictions on presence of a middle lobe)
- ✓ No prior prostate intervention or surgery
- ✓ Includes patients with medical history of ED and/or EjD and those with normal function



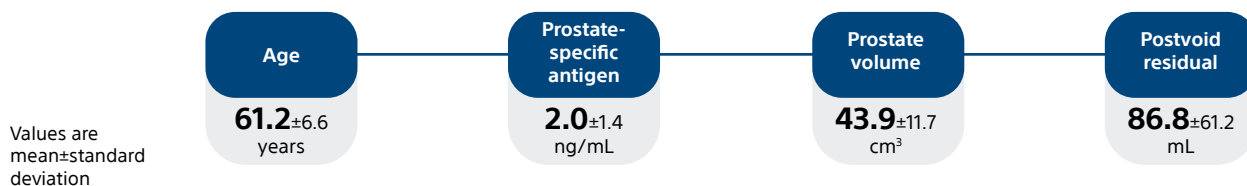
5-year follow-up (followed at 3, 6, 12 months and 2, 3, 4 and 5 years)

Evaluation of outcomes

LUTS	IPSS and IPSS-Quality of life Benign Prostatic Hyperplasia Impact Index (BPHII) Q_{max}
Sexual function	International Index of Erectile Dysfunction (IIEF-EF)* Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD): Function and bother domains

RESULTS

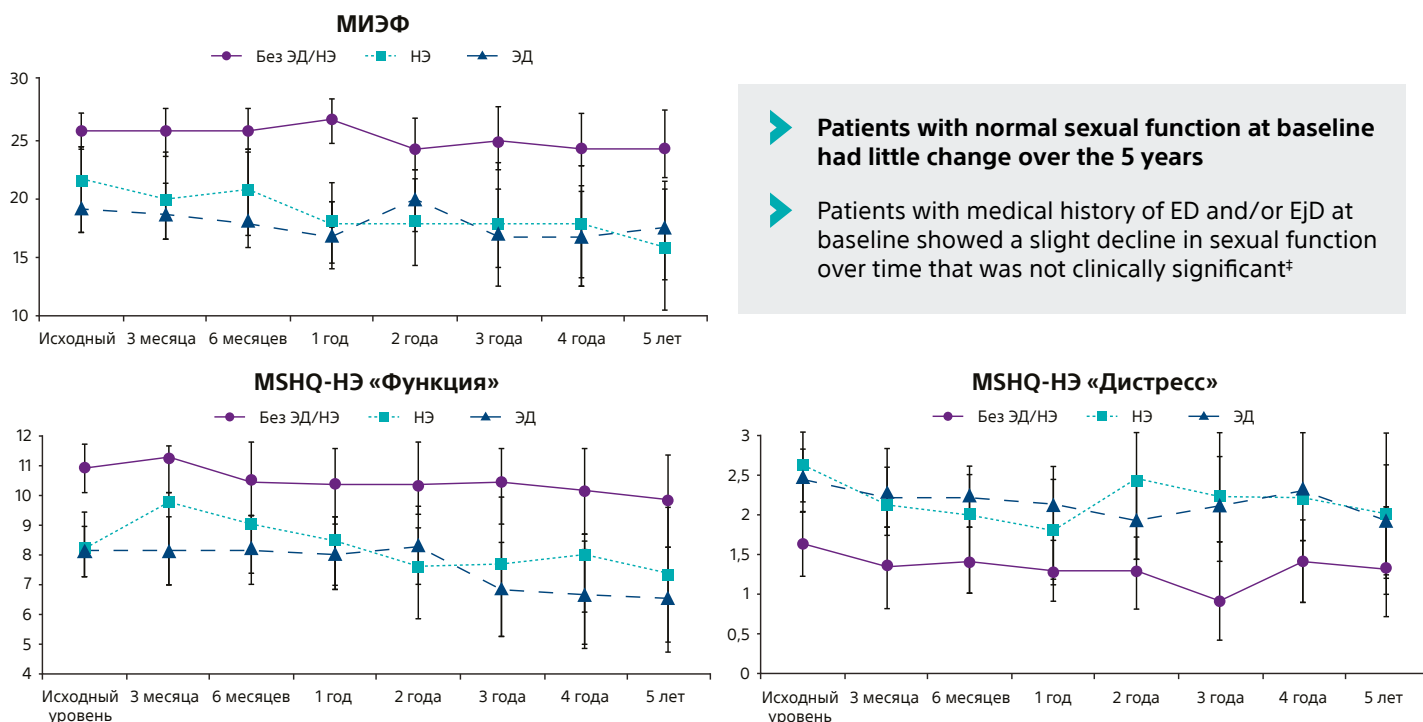
Baseline characteristics (n=125)[†]



The results of this analysis provide long-term evidence of durable outcomes after treatment with Rezūm™:

- Water vapour thermal therapy had a **significant and durable improvement in IPSS, IPSS-QoL, Q_{max} and BPHII through the 5-year period** (p<0.0001)
- All subgroups (No ED or EjD/ ED/ EjD) experienced a significant improvement in IPSS at the 3-month follow-up and through the 5-year period, **regardless of the ED/EjD status at baseline** (p<0.0001)
- Erectile function (IIEF-EF) scores trended toward a gradual decline throughout the study period starting 1 year after treatment; **none of the patients changed their category of sexual function** (no dysfunction, mild, moderate or severe)

Change in sexual function scores by baseline medical history



Error bars represent 95% confidence intervals

Graphical representation redrawn by Boston Scientific, adapted from Figure 1 in McVary KT et al. *Sex Med*, October 2021

CONCLUSION

Water vapour thermal therapy provides sustained improvement in LUTS/BPH symptoms for 5 years **with no clinically relevant impact on sexual function.**

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Note: Rezūm II (NCT01912339) is a prospective, multicentre, randomised, single-blinded control study.

*The IIEF-EF is the gold standard measure of male sexual function; this study focused on erectile function.

[†]Patients had no other BPH intervention during the study and underwent washout period for antihistamines, α-blockers, anticholinergics, daily dose phosphodiesterase-5 inhibitors, 5-α reductase inhibitors, oestrogen, androgen suppressing drugs and anabolic steroids.

[‡]No clinically significant[†] defined as no change in sexual function category.

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