Publication Summary

Do Patients Treated with Water Vapor Therapy and Meeting Randomized Clinical Trial Criteria Have Better Urinary and Sexual Outcomes Than an Unselected Cohort?

Cindolo L, Campobasso D, Conti E, Uricchio F, Franzoso F, Maruzzi D, Viola L, Varvello F, Balsamo R, Ferrari G, Morselli S and Siena G. *J. Endourol*. 2021; **37:** 323–9. doi: 10.1089/end.2022.0637.

BACKGROUND

- Rezūm™ therapy has demonstrated significant and durable urinary and sexual function outcomes in a 5-year randomised controlled trial (RCT). This study had strict eligibility criteria; therefore, patients were slightly different from the majority of the real-world population.[1]
- While previous studies have reported results in other subsets of patients, e.g. those with large prostates, indwelling catheters and previous prostate surgery, none of them have directly compared results between these different groups of patients.[2-5]

This study aimed to compare the functional and sexual outcomes as well as the safety profile of the Rezūm procedure between patients who fulfil the eligibility criteria for the 5-year RCT and unselected patients in a large multicentre database.

METHODS

- Retrospective review of all patients with moderate-to-severe lower urinary tract symptoms treated with Rezūm therapy for benign prostatic obstruction (BPO) from September 2019 to February 2022 in eight Italian institutions.
- **426** patients were included and divided into two groups:
  - Group A: those who **fulfilled the criteria for the 5-year RCT** (n=232).
  - Group B: those who had **at least one of the RCT exclusion criteria** (n=194).

Group A

- Male
- ≥50 years of age
- International Prostate Symptom Score (IPSS) ≥13
- Maximum urinary flow (Qmax) ≤15 mL/s
- Postvoid residual (PVR) ≤250 mL
- Prostate volume >30 and ≤80 mL
- **No:** mild or severe comorbidities; antiplatelet or anticoagulant medications; previous prostate surgery; bladder stones or cancer; urethral or bladder neck stenosis; bacterial or nonbacterial prostatitis in the last 1 and 5 years, respectively; and indwelling bladder catheter within 6 months prior to baseline, with the exception of BPO therapies in progress

Group B

All the remaining patients who had at least one of the following RCT exclusion criteria:

- Large prostate
- Presence of indwelling catheter
- Bladder stone or cancer
- Antiplatelet or anticoagulant medications
- Comorbidities

- Pre-, peri- and post-operative data, complications, presence of antegrade ejaculation, and urinary and sexual outcomes were recorded. Patients were followed up in an outpatient clinic after 3, 6 and 12 months, and annually thereafter.
- Median follow-up time was similar for the two groups:
  Group A: 17 months (13–20);
  Group B: 15 months (13–19).

RESULTS

Patient characteristics

	Group A	Group B	p value
Age, years	64 (59–69)	64 (57–71)	0.597
Operative time, minutes	10 (9–14)	13 (10–15)	<0.001
Number of vapor injections	7 (4–8)	9 (6–12)	<0.001
Median lobe injections	1 (0–2)	2 (1–3)	<0.001
Catheterisation time, days	7 (7–7)	7 (7–14)	<0.001
Hospital stay, days	0 (0–1)	1 (0–1)	0.581
Retreatment	6 (2.6)	6 (3.1)	0.808

Values are median (interquartile range [IQR]) or n (%)

Prostate volume

Median prostate volume decreased significantly from preoperative baseline in both groups at the last follow-up:

Group A
55 mL *versus* 34 mL, p<0.001

Group B
80 mL *versus* 38 mL, p<0.001

Urinary outcomes

Postvoid residual volume reduced in both groups

Group A: 75%; Group B: 72%

Maximum urinary flow (Qmax) increased in both groups

Group A: 88%; Group B: 66%

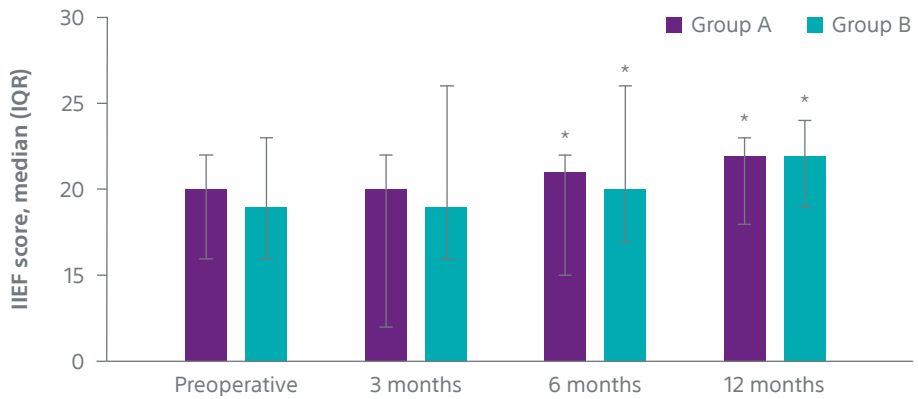
Preoperative baseline *versus* last follow-up

Reintervention

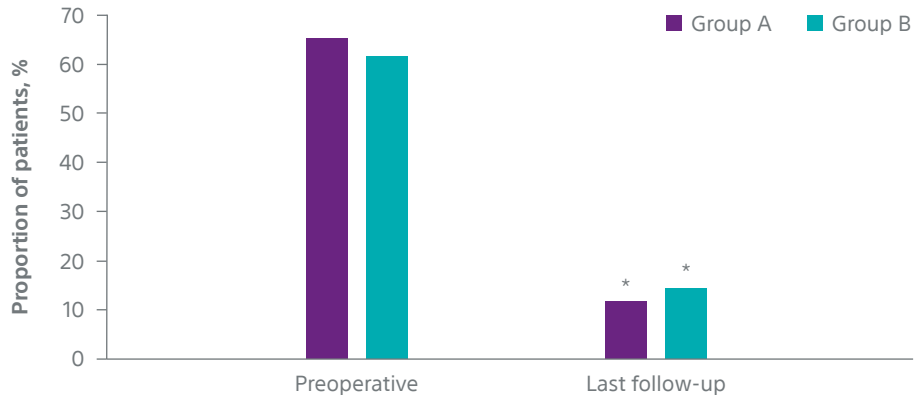
The reintervention rate at the last follow-up was 2.6% for Group A and 3.1% for Group B. Only four patients reported no improvement, with a further eight requiring retreatment after 1 year.

Sexual function outcomes

International Index of Erectile Function (IIEF) score was significantly improved at 6 months in both groups



Retrograde ejaculation was significantly reduced in both groups after the procedure, with no differences between the two groups



*Statistically significant (p<0.05) *versus* preoperative value. IQR, interquartile range

Safety outcomes

- No intraoperative adverse events were reported.
- Complication rates were similar between Group A (31%) and Group B (26%).
  - All reported were Clavien–Dindo Grade I or II, with only one case of blood transfusion (Group B).

CONCLUSION

- Rezūm was confirmed as an effective treatment with a favourable safety profile independent of patients' characteristics.

LIMITATIONS

- This was a retrospective study with a mid-term follow-up.
- Different centres and surgeons were involved and there was no standardised evaluation of ejaculatory function.

REFERENCES

1. McVary KT, Gittelman MC, Goldberg KA *et al*. Final 5-year outcomes of the multicenter randomized sham-controlled trial of a water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. *J Urol*. 2021; **206:** 715–724.
2. Eredics K, Wehrberger C, Henning A *et al*. Rezūm water vapor therapy in multimorbid patients with urinary retention and catheter dependency. *Prostate Cancer Prostatic Dis*. 2022; **25:** 302–5.
3. Gauhar V, Lim EJ, Khan TY *et al*. Rezūm to the rescue: Early outcomes of Rezūm on patients with recurrent lower urinary tract symptoms after surgical interventions for benign prostatic enlargement. *Andrologia*. 2022; **54:** e14450.
4. Elterman D, Bhojani N, Vannabouathong C *et al*. Rezūm therapy for ≥80 ml benign prostatic enlargement: A large, multicentre cohort study. *BJU Int*. 2022; **130:** 522–7.
5. Cindolo L, Campobasso D, Ferrari G *et al*. Expanding indications for Rezūm procedure. *Urol Video J*. 2022; **14:** 100154.

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