

CLINICAL BRIEF

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Rezūm System Water Vapor Treatment for Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia: Validation of Convective Thermal Energy Transfer and Characterization with Magnetic Resonance Imaging and 3-Dimensional Renderings¹

Mynderse LA, Hanson D, Robb RA, Pacik D, Vit V, Varga G, Wagrell L, Tornblom M, Cedano ER, Woodrum D, Dixon CM, Larson TR

KEY FINDING: Convective water vapor energy produces an ablative effect that undergoes near complete resolution by 3 and 6 months, resulting in a concomitant one-third reduction in overall prostate and transition zone volumes.

STUDY OBJECTIVE

Evaluate by MRI the physical effects of convective thermal energy transfer with water vapor as a means of treating lower urinary tract symptoms due to benign prostatic hyperplasia.

STUDY METHODS

- Prospective, single-arm cohort study
- 65 men from 3 sites in Sweden, Czech Republic and Dominican Republic
- 45 of these men consented to undergo a series of MRIs of the prostate after water vapor treatment
- Size and location of lesions, their time course of resolution, and corresponding change in prostate and transition zone tissue volume were monitored at 1 week and 1, 3, and 6 months after treatment

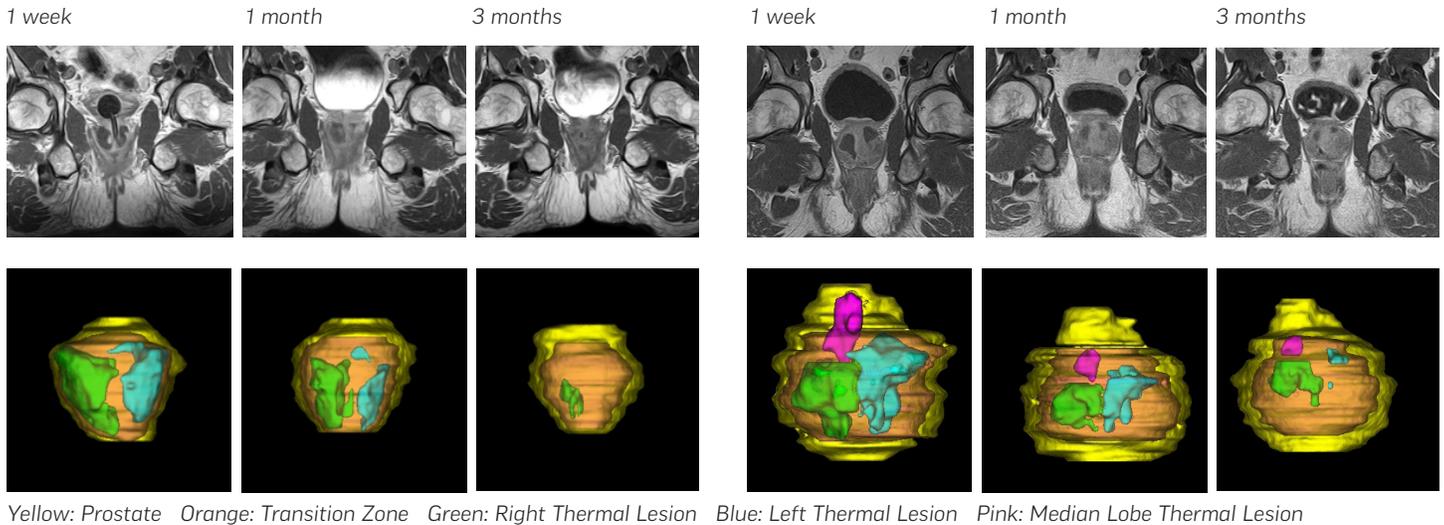
KEY RESULTS

- At 1 week, the mean volume of ablative lesions was 8.2 cm³. At 6 months, whole prostate volume was reduced by a mean of 28.9% and transition zone volume by 38.0% as compared to the baseline 1-week images.

Variable	Time	N	Mean (range) cm ³	Mean (range) Δ cm ³	Mean % Δ
Whole prostate volume (cm ³)	1 week	44	61.2 (20.4-133.2)		
	1 month	42	52.7 (15.4-118.4)	-8.5	-13.9%
	3 months	41	47.0 (15.3-115.4)	-14.2	-23.2%
	6 months	40	43.5 (16.0-116.6)	-17.7	-28.9%
Transition zone volume (cm ³)	1 week	44	36.3 (9.1-87.8)		
	1 month	42	29.8 (8.4-80.3)	-6.5	-17.9%
	3 months	41	25.1 (6.8-79.4)	-11.2	-30.9%
	6 months	40	22.5 (6.6-79.3)	-13.8	-38.0%
Gadolinium defect lesion volume (cm ³)	1 week	44	8.2 (0.5-24.0)		
	1 month	42	3.4 (0.3-11.3)	-4.8	-58.5%
	3 months	41	0.7 (0.0-2.6)	-7.5	-91.5%
	6 months	40	0.4 (0.0-3.7)	-7.8	-95.1%

KEY RESULTS (continued)

- At 3 and 6 months after treatment, the mean lesion volumes had reduced by 91.5% and 95.1%, respectively.
- Lesions remained within the targeted treatment zone of the prostate without compromising the integrity of the bladder, rectum or striated urinary sphincter.



LIMITATIONS

- Although the decrease in prostate and transition zone volumes were significant over 6 months, baseline MRIs were captured at 1 week post-treatment making an absolute amount of volume reduction of the prostate and transition zones difficult to quantify.
- MRI sequences were captured on 3 different 1.5-T MRI scanners, increasing the potential for error.

CONCLUSIONS

Convective water vapor energy produces an ablative effect that undergoes near complete resolution by 3 and 6 months, resulting in a concomitant one-third reduction in overall prostate and transition zone volumes.

REFERENCE

1. Mynderse L, Hanson D, Robb R et al. Rezūm system water vapor treatment for lower urinary tract symptoms/benign prostatic hyperplasia: validation of convective thermal energy transfer and characterization with magnetic resonance imaging and 3-dimensional renderings. *Urology*. 2015;86(1):122-127. doi:10.1016/j.urology.2015.03.021.

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