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Study Title: ERECTILE AND EJACULATORY FUNCTION PRESERVED WITH CONVECTIVE WATER VAPOR ENERGY TREATMENT OF LOWER URINARY TRACT SYMPTOMS SECONDARY TO BENIGN PROSTATIC HYPERPLASIA: RANDOMIZED CONTROLLED STUDY

Author Block: Kevin T. McVary, MD, Steven N. Gange, MD, Marc C. Gittelman, MD, Kenneth A. Goldberg, MD, Kalpesh Patel, MD, Neal D. Shore, MD, Richard M. Levin, MD, Michael Rousseau, MD, J. Randolph Beahrs, MD, Jed Kaminetsky, MD, Barrett E. Cowan, MD, Christopher H. Cantrill, MD, Lance A. Mynderse, MD, James C. Ulchaker, MD, Thayne R. Larson, MD, Christopher M. Dixon, MD, and Claus G. Roehrborn, MD

Introduction

Most surgical treatments for male lower urinary tract symptoms and benign prostatic hyperplasia affect erectile and ejaculatory functions negatively, leading to patient dissatisfaction.

Aim

To determine whether water vapor thermal therapy, when conducted in a randomized controlled trial, would significantly improve lower urinary tract symptoms (LUTS) secondary to benign prostatic hyperplasia and urinary flow rate while preserving erectile and ejaculatory functions.

Methods

Men at least 50 years old with International Prostate Symptom Scores of at least 13, a peak flow rate of at least 5 to no higher than 15 mL/s, and prostate volume of 30 to 80 cm³ were randomized 2:1 between Rezūm™ System thermal therapy and control. Thermal water vapor (103° C) was injected into lateral and median lobes as required for treatment of benign prostatic hyperplasia. The control procedure entailed rigid cystoscopy with simulated active treatment sounds.

Main Outcome Measures

Blinded group (active= 136, control= 61) comparison occurred at 3 months and the active arm was followed to 12 months for International Prostate Symptom Score, peak flow rate, and sexual function using the International Index of Erectile Function and the Male Sexual Health Questionnaire for Ejaculatory Function. The minimal clinically important difference in erectile function perceived by subjects as beneficial was determined for each erectile function severity category. Subjects not sexually active were censored from sexual function analysis.

Results

No treatment- or device-related de novo erectile dysfunction occurred after thermal therapy. International Index of Erectile Function and Male Sexual Health Questionnaire for Ejaculatory Function scores were not different from the control group at 3 months or from baseline at 1 year. Ejaculatory bother score improved 31% over baseline ($P = .0011$). Also, 32% of subjects achieved minimal clinically important differences in erectile function scores at 3 months, and 27% at 1 year, including those with moderate-to-severe erectile dysfunction. International Prostate Symptom Score and peak flow rate were significantly superior to controls at 3 months and throughout 1 year ($P < .0001$).

Conclusion

Convective water vapor thermal therapy provides sustainable improvements for 12 months to LUTS and urinary flow while preserving erectile and ejaculatory functions.

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

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