3-year Treatment Outcomes of Water Vapor Thermal Therapy (Rezūm® System) Compared to Doxazosin, Finasteride and Combination Drug Therapy for Men with Benign Prostatic Hyperplasia: Cohort data from the Medical Therapy of Prostatic Symptoms (MTOPS) trial

Gupta N, Rogers T, Holland B, Helo S, Dynda D, McVary KT

KEY FINDING
A single water vapor thermal therapy procedure (Rezūm) provided effective and durable improvements in symptom scores with lower observed clinical progression rates as compared with daily, long-term use of pharmaceutical agents.

STUDY OBJECTIVE
This evaluation of long-term outcomes of treatment for lower urinary tract symptoms due to benign prostatic hyperplasia compares a one-time water vapor thermal therapy procedure with daily medical therapy in cohorts from the Medical Therapy of Prostatic Symptoms (MTOPS) study.

BACKGROUND
• Pharmaceutical treatment has dominated first-line therapy in the majority of patients for the past two decades.
• Alpha-blockers and 5 ARIs are the two drug classifications to provide LUTS relief.
• Most data from RCTs suggest combination therapy of these two drug classes leads to greater symptom improvement than monotherapy and delays progression of BPH, such as worsening of symptoms, acute urinary retention, incontinence, UTI, bladder stone formation and renal compromise.
• The primary aim of the NIDDK*-sponsored MTOPS trial was to assess the impact of these therapies on BPH progression.
• Lack of compliance with medications is common, as more than 60% of men discontinue BPH medications within the first year.
• Noncompliance is attributed to drug side effects (e.g., dizziness, postural hypotension and sexual dysfunction) and inadequate improvements in symptoms and quality of life that do not meet perceived expectations.
• Daily medication regimes can be costly, particularly for extended periods of time.
• The minimally invasive Rezūm procedure has demonstrated safe, efficacious and durable relief of LUTS while preserving sexual function.
• This is the first evaluation comparing pharmaceutical therapy from the MTOPS study to a minimally invasive procedure.

"In contrast with medical therapy, water vapor thermal therapy is a durable, one-time procedure with transient perioperative side effects, no requirement for general anesthesia, and preserves sexual function.”
– Dr. Kevin McVary, SIU School of Medicine

REFERENCE
STUDY METHODS

• Results compared from the treatment arm of the prospective, randomized Rezūm pivotal trial to MTOPS subjects treated with doxazosin, finasteride or combination therapy.
• MTOPS subject evaluations were restricted to those with a prostate volume 30 to 80cc and an International Prostate Symptom Score (IPSS) of 13 to 30 (1,140 of original 3,047; 37.4%) to include subjects meeting key criteria of both Rezūm pivotal and MTOPS trials.
• The risk of clinical progression of BPH, and objective and subjective outcomes were assessed for a 3-year period after each of the treatments.

STATISTICAL ANALYSIS

• Propensity scores were used to adjust for potential confounders to ensure baseline characteristic was balanced.
• Comparisons of all outcomes used propensity score weighted analyses to provide unbiased estimates to expected differences between therapies.
• Estimates of risk of BPH progression were made using Poisson regression and cumulative incidence.
• P-value of <0.05 was considered statistically significant.

KEY RESULTS

• The rate of BPH clinical progression among subjects treated with doxazosin, finasteride or combination therapy was 1.5 to 1.7 per 100 person-year compared with 0.3 per 100 person-year for Rezūm (Table 1). Three years after treatment, Rezūm patients had five times lower rate of clinical progression than those in the medication therapy groups.
• Rezūm demonstrated greater improvement in IPSS through 3 years as compared to doxazosin and finasteride. Rezūm was better than combination therapy through 12 months (Figure 1).
• Rezūm demonstrated greater improvement in Qmax through 3 years as compared to finasteride. Rezūm was better than doxazosin and combination therapy through 12 months (Figure 1).
• Rezūm demonstrated significant improvement in the BPHII quality of life measure as compared to doxazosin through 36 months, and finasteride over 24 months.

CONCLUSIONS

A single water vapor thermal therapy procedure (Rezūm) provided effective and durable improvements in symptom scores with lower observed clinical progression rates as compared with daily, long-term use of pharmaceutical agents.