THE EFFECTIVENESS OF MINIMALLY INVASIVE SURGICAL TREATMENTS WITH REZŪM SYSTEM FOR BENIGN PROSTATIC HYPERPLASIA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

Introduction: *Benign prostatic hyperplasia (BPH) is a common chronic condition frequently associated with the progressive development of voiding and obstructive lower urinary tract symptoms (LUTSs).* ***Objective:*** *This research aims to assess the effectiveness of the Rezūm system for BPH.* ***Material&Methods:*** *A literature search was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Clinical baseline characteristics, international prostate symptom score (IPSS), maximum flow rate (Qmax), postvoid residual (PVR), and quality of life (QoL) were analyzed using Revman 5.3. The risk of bias assessments was conducted by two independent authors and resolved through discussion.* ***Results:*** *A total of 288 studies were retrieved from PubMed, Cochrane, and Google Scholar. Four studies, including 590 patients, were analyzed, witha follow-up period of up to 12 months after treatment using the Rezūm system. The mean (SD) change from baseline to follow-up in IPSS improved from 20.58(5.9) to 9.53(6.7); Qmax increased from 9.2(3.2)to13.48 (6.5); PVR decreased from 128.2 (137.8) to 76.0 (88.8); and QoL improved from 4.6 (1.2) to 2.0(1.4). The greatest improvement was observed in QoL (56.52%) followed by IPSS (55.88%), Qmax (46.74%), and PVR (40.72%).* ***Conclusion:*** *The Rezūm system is an effective therapy for BPH, providing significant relief of LUTSs.*

Keywords: *Benign prostatic hyperplasia, LUTS, Rezūmsystem.*

ABSTRAK

Pendahuluan: *Hiperplasia prostat jinak (BPH) merupakan kondisi kronis yang umum dan dapat menyebabkan gejala saluran kemih bagian bawah (LUTS), terutama gangguan saat berkemih.* ***Tujuan:*** *Penelitian ini bertujuan untuk menilai efektivitas sistem Rezūm untuk BPH.* ***Bahan & Cara:*** *Pencarian literatur dilakukan mengikuti pedoman Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). Karakteristik klinis dasar, International Prostate Symptom Score (IPSS), maximum flow rate (Qmax), postvoid residual (PVR), dan Quality of Life (QoL) dianalisis menggunakan Revman 5.3.* ***Hasil:*** *Sebanyak 288 studi diperoleh dari PubMed, Cochrane, dan Google Scholar. Empat studi yang melibatkan 590 pasien dianalisis, dengan periode follow up hingga 12 bulan setelah pengobatan menggunakan sistem Rezūm. Rata-rata (SD) perubahan dari baseline ke follow up pada IPSS meningkat dari 20,58(5,9) menjadi 9,53(6,7); Qmax meningkat dari 9,2(3,2) menjadi 13,48(6,5); PVR menurun dari 128,2(137,8) menjadi 76,0(88,8);dan QoL membaik dari 4,6(1,2) menjadi 2,0 (1,4). Perbaikan terbesar diamati pada QoL (56.52%), diikuti oleh IPSS (55,88%), Qmax (46.74%), dan PVR (40,72%).* ***Simpulan:*** *Sistem Rezūm merupakan terapi yang efektif untuk BPH, memberikan pengurangan yang signifikan terhadap lower urinary tract symptoms (LUTS).*

Kata kunci: *Benign prostatic hyperplasia, LUTS, Rezūm system.*

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INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common chronic condition frequently associated with the progressive development of voiding and obstructive lower urinary tract symptoms (LUTSs). It ranks as the tenth most prominent and costly disease condition among men over 50 years of age. Minimally invasive surgical treatments (MISTs) offer significant positive outcomes and are a feasible alternative to the gold standard transurethral resection of the prostate (TURP). Additionally,

MISTs help preserve erectile and ejaculatory function, thereby enhancing patients' quality of life (QoL).[1-4]

One type of MIST is transurethral water vapor therapy using the Rezūms ystem, which operates on the principles of convective heat transfer. This innovative technology employs radio frequency currents to generate thermal energy in the form of steam, which is delivered to targeted prostatic tissue. The process destroys cell membranes, triggering cellular necrosis. Subsequently, the body absorbs the necrotic tissue, reducing prostate volume and alleviating LUTSs.[2,3,5,6]

OBJECTIVE

The Rezūm system has gained considerable attention since receiving approval from the United States Food and Drug Administration (US FDA) in 2015. It has been shown to provide rapid, significant, and durable improvements in LUTSs. To validate these effects, we conducted a systematic review and meta-analysis of studies reporting outcomes following the Rezūm system procedure, with a follow-up period of 12 months.

MATERIALAND METHODS

The literature search was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Studies were retrieved from several databases, including PubMed, the Cochrane Central Register of Controlled Trials, and Google Scholar, up to January 2, 2023. The keywords used included "prostatic urethral Rezūm", "Rezūm system", "benignprostatic hyperplasia", "BPH", and "lower urinary tract symptoms" (LUTSs). The search was not restricted by publication date, and only full-text studies were included.

Data were extracted from all eligible studies published in English. The studies included those comparing baseline characteristics with follow-up outcomes at 12 months. Inclusion and exclusion criteria were meticulously reviewed and aligned with the PICO framework (Table 1). The extracted data included clinical baseline characteristics, international prostate symptom score (IPSS), maximum flow rate (Qmax), postvoid residual (PVR), and quality of life (QoL).

Quality assessments and bias evaluations were conducted independently by reviewers (HAM). Bias judgments were categorized as low, high, or unclear. The risk of bias for all included studies was analyzed using Cochrane's Review Manager 5.3.

After identifying studies through the search strategy,they were appraised for inclusion. Data were collected and analyzed using Cochrane's Review Manager 5.3. Dichotomous data were used to calculate mean differences (MDs) with 95% confidence intervals (CIs) under a random-effect model. Heterogeneity between studies was assessed using the I^2 statistic, with values greater than 50% indicating high heterogeneity.

Table1. PICO Design.

Population	Patients underwent transurethral water vapor therapy with Rezūm system for BPH
Intervention	Follow -up 12 months
Comparison	Baseline characteristics
Outcomes	IPSS, Qmax, PVR and QoL

RESULTS

The search yielded 288 studies. After removing duplicates, 179 titles and abstracts were screened. Nineteen studies were assessed for eligibility, and six met the inclusion criteria. Two studies were excluded due to differing follow-up durations. Ultimately, four studies, comprising 590 patients, were included in the quantitative synthesis (meta-analysis) (Figure 1).

The mean age of patients across the included studies was 65.9±7.82 years. The mean prostate-specific antigen (PSA) concentration was 2.9±3.2 ng/mL, and the mean prostate volume was 46.03± 22.9 cc. The mean baseline IPSS was 20.6±5.9, which improved to 9.5±6.7 at the 12-month follow-up. The difference between baseline and follow-up was statistically significant (MD-10.90; 95% CI:-12.50 to -9.30; $p < 0.00001$; $I^2 = 31\%$). A negative value indicates a reduction in IPSS, reflecting an improvement in BPH symptoms. The mean baseline Qmax was 9.2±3.2 mL/s, which increased to 13.5 ± 6.5 mL/s at the 12-month follow-up. The difference was statistically significant (MD 4.92; 95% CI: 3.96 to 5.88; $p < 0.00001$; $I^2 = 0\%$). A positive value indicates an improvement in Qmax, signifying better urinary flow.

The mean baseline PVR was128.2± 137.8 mL, which decreased to 76.0 ± 88.8 mL at the 12-month follow-up. Although PVR showed a

reduction, the difference was not statistically significant (MD-22.07; 95%CI:-49.41 to 5.26; p=0.11;I^2=63%). A negative value indicates a decrease in PVR, suggesting an improvement, but the high heterogeneity may account for the lack of statistical significance.

The mean baseline QoLscore was 4.6 ± 1.2, which improved to 2.0 ± 1.4 at the 12-month follow-up. The difference between baseline and follow-up was statistically significant (MD-2.25; 95% CI:-2.57 to-1.94; p <0.00001; I^2 = 54%). A negative value indicates a reduction in the QoL score, reflecting an improvement in patient satisfaction and relief from BPH symptoms.The greatest percentage improvement was observed in QoL (56.52%), followed by IPSS (55.88%), Qmax (46.74%), and PVR (40.72%).The authors (HAM) independently assessed the risk of bias. Any differences in judgment were resolved through discussion (Figure 2).

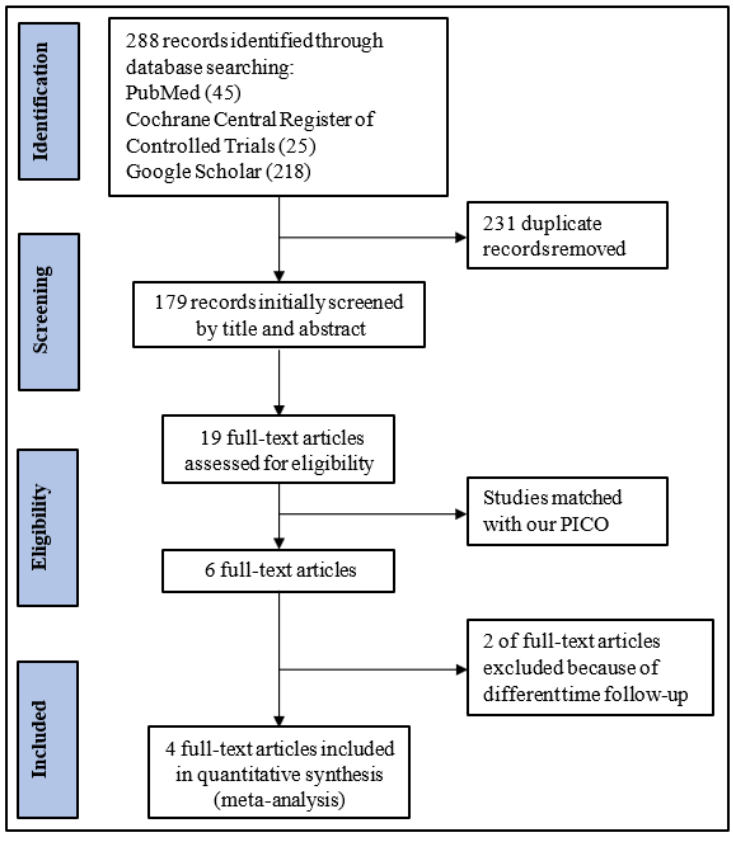

Figure 1. PRISMA searching algorithm.

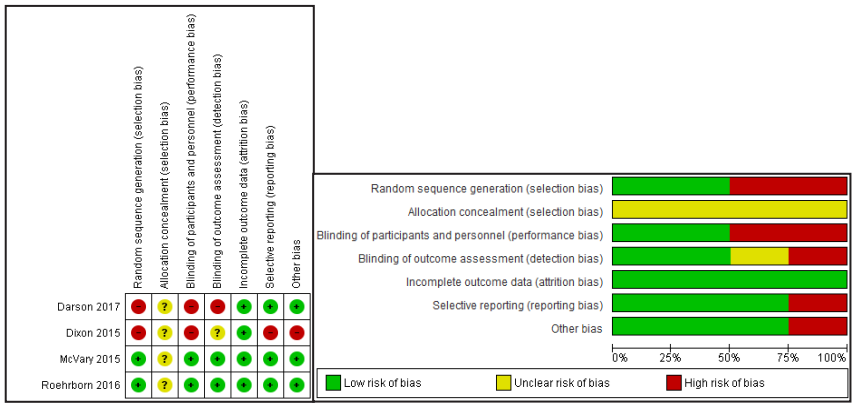

Figure 2. Graph and summary of th erisk of bias assessment.

Table 2. Mean (SD)characteristics details of baseline and follow-up 12 months treatment using Rezūm system among all the studies.

Authors	Sample size	IPSS		Qmax, ml/s		PVR, ml		QoL		Age, years	PSA, ng/ml	Prostate volume, cc
		Baseline	12 months	Baseline	12 months	Baseline	12 months	Baseline	12 months			
McVary 2015[7]	197	21.8 (4.8)	10.2 (6.6)	9.8 (2.2)	14.9 (6.8)	83.2 (51.4)	79.8 (80.3)	4.4 (1.1)	2.1 (1.5)	63.0 (7.05)	2.05 (1.6)	45.2 (13.2)
Dixon 2015[5]	65	21.7 (5.7)	9.2 (6.5)	8.2 (3.3)	12.8 (6.3)	92.0 (79.1)	63.1 (72.2)	4.4 (1.1)	1.7 (1.4)	66.6 (7.7)	3.9 (4.2)	48.8 (20.7)
Roehrborn 2016[9]	197	19.4 (6.6)	8.6 (6.6)	10.3 (3.8)	16.2 (7.9)	101.0 (79.2)	83.8 (80.5)	3.8 (1.3)	1.7 (1.2)	63.2 (7.13)	2.0 (1.5)	45.0 (12.9)
Darson 2017[1]	131	19.4 (6.7)	10.1 (7.2)	8.5 (3.5)	10 (5.0)	236.6 (341.3)	77.3 (122.1)	4.4 (1.3)	2.5 (1.4)	70.9 (9.4)	3.5 (5.6)	45.1 (23.4)
Mean (SD)		20.6 (5.9)	9.5 (6.7)	9.2 (3.2)	13.5 (6.5)	128.2 (137.8)	76.0 (88.8)	4.6 (1.2)	2.0 (1.4)	65.9 (7.82)	2.9 (3.2)	46.0 (22.9)

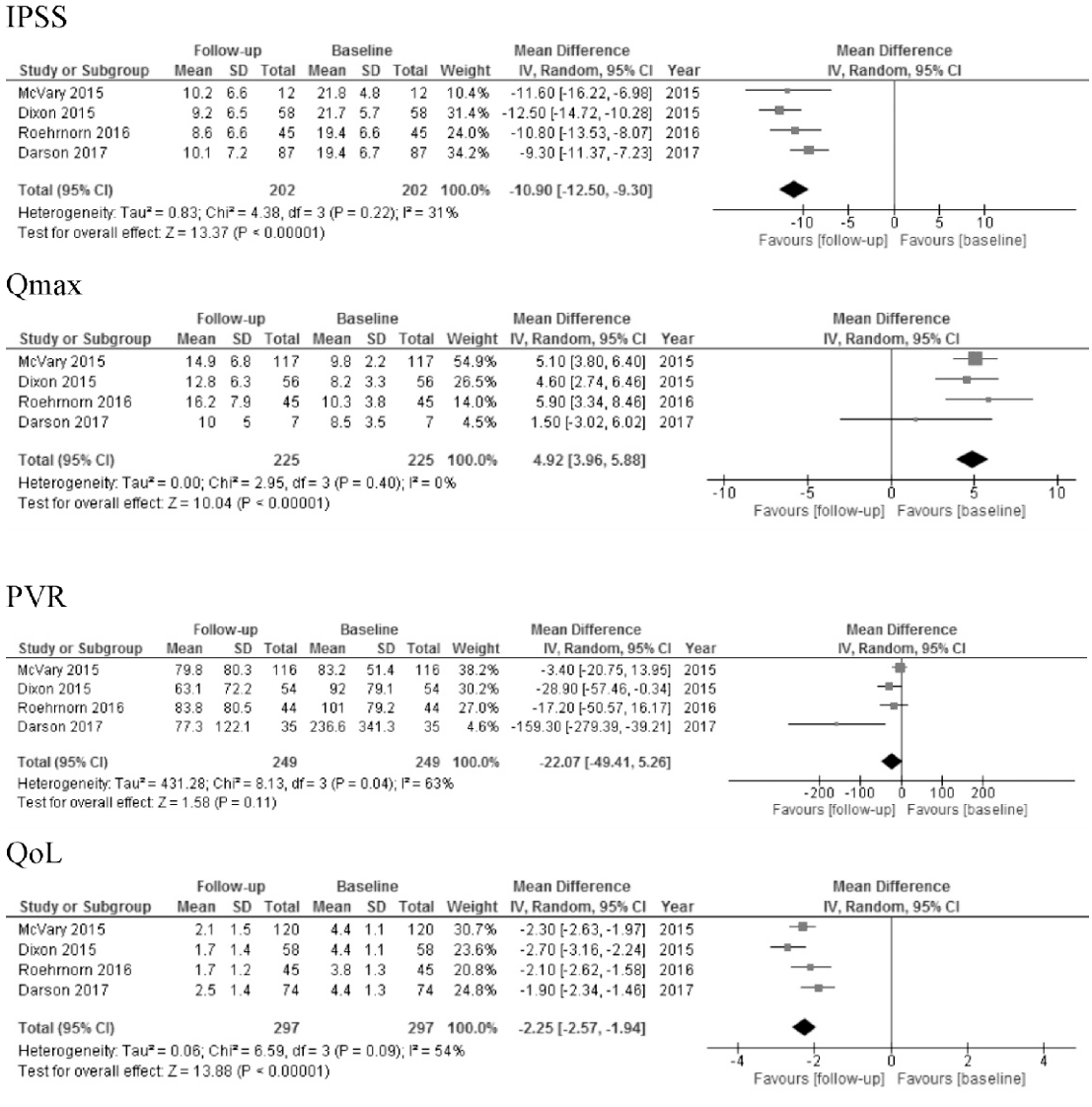

Figure 3. All studies forest plot of IPSS, Qmax, PVR, and QoL.

DISCUSSION

This systematic review and meta-analysis summarize evidence on the clinical outcomes of minimally invasive convective radio frequency thermal therapy using the Rezūm system, with a minimum follow-up period of 12 months. All included studies involved patients with moderate to severe LUTSs.

The thermal energy generated by water vapor is precisely delivered to targeted treatment zones within the prostate.Studies using magnetic resonance imaging (MRI) have confirmed the safety of the Rezūm system, showing that it does not compromise the integrity of peripheral structures such as the bladder, urinary sphincter, or rectum. This safety profile translates to reduced postoperative complication rates and the preservation of sexual functions.[7,10,11]

The Rezūm system has no morphological contraindications and demonstrates flexibility in treating both the transition zone and median lobe of prostate enlargement. These attributes make it a versatile option for various prostate configurations. Additionally, the Rezūm procedure is highly desirable as an outpatient treatment, requiring only local anesthesia, which enhances its appeal for patients and healthcare providers alike.

McVary et al. reported that the adverse events associated with the Rezūm system were transient and ranged from mild to moderate severity. The most common adverse events were dysuria (16.9%), hematuria (11.8%),hematospermia (7.4%), and other irritative symptoms, which typically resolved spontaneously within three weeks.[7] Meanwhile, Roehrbornetal. revealed that serious adverse events were rare, occurring in less than 2% of patients within 3–12 months after the procedure. These events included bladder neck contracture, bladder stone formation, and sepsis, with only one occurrence of each reported.[8]

Prostate volume is an essential parameter in treatment considerations.[2] In this study,the mean prostate volume was 46.03±22.9cc. Darsonetal. included patients with prostate volumes ranging from 13 to 183 cc and demonstrated significant positive improvements in IPSS, quality of life (QoL), and postvoid residual (PVR) volume. However, Westwood et al. suggested that the Rezūm procedure may not be suitable for prostates larger than 120 cc.[11] Dixonetal.assessed the acute ablative effects of transurethral convective water vapor therapy using the Rezūm system in men with BPH through histologic and radiographic studies. They reported a mean lesion volume of 9.6 ± 8.5 cm³, with the largest lesion measuring 35.1 cm³.[7]

Similarly, Mynderse et al. examined 44 patients and reported that convective thermal lesions were confined to the transition zone, corresponding to the targeted treatment areas. At one week post-treatment,the mean lesion volume was 8.2 cm³ (range: 0.5–24.0 cm³). At six months, the mean total prostate volume was reduced by 28.9%, and the transition zone volume decreased by 38.0%, compared with baseline imaging performed one week after treatment. By three and six months post-treatment, lesion volumes had diminished by 91.5% and 95.1%, respectively, with all lesions remaining confined to the targeted treatment zone, preserving the integrity of the bladder, rectum, and urinary sphincter.[10]

Among the analyzed outcomes, QoL demonstrated the greatest percentage improvement from baseline to follow-up (56.52%), followed by IPSS (55.88%), Qmax (46.74%), and PVR (40.72%). These findings align with those reported in other studies. McVary et al. demonstrated sustained improvements in outcomes at three and four years of follow-up, while Roehrbornetal.observed durable improvements lasting up to two years.[8]

The Rezūm system offers a cost-effective treatment option compared to other procedures. Over two years, its costs were significantly lower than those of UroLift ($6,386), Prostiva ($2,855), Greenlight laser therapy ($5,099), and TURP ($5,181).The average cost of the Rezūms ystem was $2,582, encompassing office visits for diagnosis, post-procedure assessments,and follow-ups.[12]

LIMITATIONS

This analysisis limited by the small number of available studies, the relatively short follow-up durations, and the low number of included patients. Additionally, the long-term safety and efficacy of the Rezūm system, as well as its impact on QoL compared with the gold standard TURP, require further investigation to assess deep outcomes and complications.

CONCLUSION

The Rezūm system is an effective therapy for BPH, offering durable and favorable clinical outcomes lasting up to 12 months. However, longer

follow-up and additional randomized studies, particularly in more advanced cases, are necessary to confirm its long-term sustainability and efficacy. These findings will assist in expanding treatment options and helping patients with BPH choose the most suitable procedure for their condition.

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