ARTICLE

Clinical Research

Composite urinary and sexual outcomes after Rezum: an analysis of predictive factors from an Italian multi-centric study

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BACKGROUND: The Rezum system is one of the latest minimally invasive surgical treatments for benign prostatic hyperplasia.
METHODS: We retrospectively reviewed all patients who underwent the Rezum treatment in seven different Italian institutions. A successful urinary outcome was defined as: ≥50% improvement in the IPSS <7, improvement in peak flow ≥50% and/or more than 15 ml/s, ≥1-point improvement in the QoL questionnaire and in the absence of perioperative major complications (AUR, transfusion) or postoperative incontinence. A successful sexual outcome was defined as postoperative (latest follow up consultation) antegrade ejaculation or no variation in ejaculatory function and an increase, or stability or max 1 class reduction, in IIEF-5.
RESULTS: 262 patients were enrolled with a follow-up period of 11 months (IQR 5–15). No early or late serious adverse events (Clavien III–IV) occurred. Early complications occurred in 39.3% of cases, with 4 cases of clot retention and one case of blood transfusion. Urge incontinence was reported by 6 patients (2.2%). A treatment failure requiring re-intervention occurred in 4 cases (1.5%). The preoperative antegrade ejaculation rate was 56.5%, and after the procedure it increased to 78.2%. The increase of ≥1-point in the QoL was achieved in 92.7% of the cases. Optimal urinary and sexual outcomes were achieved in 52.9% and 87.8%, respectively.
CONCLUSIONS: In our series, water vapor intraprostatic injections seem to be an effective and safe procedure.

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INTRODUCTION

The incidence of lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO) increases with age, from 14.8% (40–49 yrs) to 38.4% (above 80 yrs) [1]. Medical therapies are the first line of treatment, with different classes of drugs usually being prescribed (alpha blocker, 5-alpha-reductase inhibitor, phosphodiesterase-5 inhibitors, antimuscarinics/beta3 agonists and phytotherapeutics) either as monotherapy or combination therapy [2]. However, poor medication compliance was demonstrated due to adverse events, especially in terms of erectile dysfunction and retrograde ejaculation [3].

In case of medical failure or discontinuation, surgery represents one of the further therapeutical approaches. Transurethral resection of the prostate (TURP) is still considered the mainstay treatment of LUTS/BPO in case of prostate volume <80cc, together with endoscopic laser (Holmium, Greenlight, Thulium) procedures [2]. Despite overall favorable perioperative outcomes and long-term results, these surgical treatment options carry inherent drawbacks such as postoperative ejaculatory disorders, a need for anesthesia, frequent need for overnight hospital stay, and a risk of high-grade complications (Clavien ≥ III) [2, 4].

Minimally invasive surgical treatments (MISTs) for BPO have been developed to guarantee the same functional results while preserving sexual function and reducing the invasiveness and complication rate. In the last years, various technologies with different mechanisms of action and a safety profile have been introduced: prostatic urethral lift, prostatic arterial embolization, transperineal prostatic laser ablation, temporary implantable nitinol device, and water vapor injections (Rezum system) [5, 6]. These techniques share common features such as the outpatient setting, the possibility to perform them under local anesthesia/mild sedation, and a lack of major procedure-related complications. However, data reporting preservation of sexual function, urinary outcomes and complications are still heterogeneous and sparse [7, 8].

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In this study we aimed to evaluate the functional and sexual outcomes of Rezum in a large multicenter dataset.

MATERIALS AND METHODS

Study design

This is a retrospective review of prospectively collected dataset. All patients with moderate to severe LUTS treated with Rezum (Rezum system, Boston Scientific, Marlborough, MA) for BPO at 7 Italian institutions between June 2019 and April 2021 were included in the analysis. The study was conducted in accordance with good clinical practice guidelines, and informed consent was obtained from patients. According to Italian law (Agenzia Italiana del Farmaco Guidelines for Observational Studies, March 20, 2008), no formal institutional review board or ethics committee approval was required.

Baseline assessment

Examined pre-operative factors included the following: age, body max index (BMI), American Society of Anesthesiology (ASA) score, use of antiplatelet and/or anticoagulant medications, LUTS therapy and history of catheterization or retention. All patients underwent standard pre-operative and follow-up examinations, including digital rectal examination, prostate specific antigen (PSA), transrectal prostate ultrasound, intravesical prostatic protrusion (IPP) measurement, uroflowmetry and post-void residual volume (PVR) measurement. They completed the International Prostate Symptom Score (IPSS) and IPSS quality of life (QoL) subscale, International Consultation on Incontinence Questionnaire-Short Form, the Overactive Bladder Questionnaire-Short Form (OAB-q SF) score, and the International Index of Erectile Function (IIEF-5). The rate of pre- and post-operative antegrade ejaculation, defined as the emission of semen after orgasm, was subjectively recorded at baseline and during the follow-up [9].

A median lobe was defined as a protruding lobe IPP grade 3 (>1 cm) [10].

Exclusion criteria were age <18 years, prior interventions for BPO, mild symptoms at IPSS, peak urinary flow rate (Qmax) >15 mL/s, prostate volume <30 and >120 cc, PVR > 250 ml.

Surgical procedures were performed as previously described [8, 11].

Rezum procedure

The Rezum system generates vapor by application of radiofrequency energy, to create heat via electromagnetic induction in the handle of the delivery device and incorporates a standard endoscopic cystoscopy lens to visualize the positioning of the treatment needle into the obstructing BPH tissue. A needle is rapidly deployed under direct visualization into the obstructive regions of the transition zone and the steam is delivered into the tissue [7]. At the end of the procedure a Foley catheter or a temporary prostatic stent (Exime®, Rocamed), were positioned [12]. The use and type of anesthesia were variable from oral sedation to prostatic block, intravenous sedation, or mild general anesthesia, in accordance with local protocols and patients' preferences. Antibiotics were administered to all patients according to local practice guidelines. Injection density was defined as the ratio between the prostate volume and the number of injections.

Complications were collected as early (within 30 postoperative days) or late (after 90 days) and classified according to the modified Clavien–Dindo classification for transurethral resection of the prostate [13].

Outcomes assessment and analysis

An "optimal urinary" outcome was defined as the achievement of all the following outcomes: reduction ≥50% in IPSS <7, with improvement in peak flow ≥50% and/or more than 15 ml/s, with ≥1-point improvement in the QoL questionnaire and in the absence of the following perioperative complications such as AUR, transfusion, clot retention, Clavien ≥ III and postoperative incontinence [14].

An "optimal sexual" outcome was defined as postoperative (latest follow up consultation) preservation of antegrade ejaculation or no variation in ejaculatory function and increase or stability or ≤1 class reduction in IIEF-5.

Continuous variables were reported as mean and standard deviation (SD) or median and interquartile range (IQR), according to their distribution. Categorical variables were reported as the absolute number and percentage. Differences in the characteristics of patients between groups were tested by means of the Mann–Whitney test and Chi-squared test for continuous and categorical variables, respectively. Associations of patient characteristics with "optimal urinary" or "optimal sexual" outcomes were tested by means of the multivariable logistic regression model. Variables with p value < 0.10 at univariate analysis were included as covariates in the models and results were reported as the odds ratio (OR) and 95% confidence interval (CI). A two-tailed p value < 0.05 was considered significant. Data were analyzed using SAS version 9.4 (SAS Inc, Cary, NC, USA).

RESULTS

Baseline characteristics of the study population

A total of 262 patients were available for the study with a median follow-up period of 11 months (IQR 5–15). The pre- and intra-operative data are reported in Table 1. Patients had a median prostate volume of 59 (IQR 44–77) mL, with a median lobe in 65.6% of cases. An indwelling bladder catheter was present in 14.5% of patients. Intravesical prostatic protrusion (IPP) grade 1, 2, and 3 was present in 36.04%, 45.05% and 18.92%, respectively. 4.6% of the patients had bladder diverticula, the median PVR was 148 mL (IQR 110–177). Antegrade ejaculation was present in 56.5% of patients. A pre-operative QoL ≥ 4 was reported in 77.4% of patients.

Surgical outcomes

The median operative time from instrument transurethral insertion to patient catheterization was 11 (IQR 9–15) minutes. Patients received a median of 7 (IQR 5–9) vapor injections with a median injection density of 9 (IQR 7.5–11.33). Most patients were discharged a few hours after surgery (62.5%), with a bladder

Table 1. Demographic and intraoperative characteristics of the 262 patients treated.

Baseline characteristics	
Age, yrs	65.1 ± 9.2
BMI, Kg/m^2	24.2 ± 2.4
ASA score	1.82 ± 0.67
Pre-operative prostate volume, ml	59 (44–77)
Pre-operative presence of median lobe	143 (65.6%)[a]
Pre-operative indwelling catheter	38 (14.5%)
Previous medical therapy	
None	17 (6.5%)
Alpha-blockers	139 (53.1%)
5-ARI	6 (2.3%)
Combination	81 (30.9%)
Phytotherapy	18 (6.9%)
Antimuscarinics/Beta3 agonists	1 (0.4%)
PDE5i	81 (30.9%)
Antiplatelet/anticoagulant therapy	
None	215 (82%)
Single Antiplatelet	35 (13.3%)
Double Antiplatelet	5 (1.9%)
Anticoagulant	6 (2.3%)
Anticoagulant + Antiplatelet	1 (0.4%)
Surgical outcomes	
Operative time, minutes	11 (9–15)
Number of vapor injections	7 (5–9)
Injection density (injections number/prostate volume), mL	9 (7.5–11.33)
Catheterization time, days	7 (6–10)

Values expressed as median (IQR), mean ± SD, or number (%).
[a](missing = 44).

Table 2. Summary of early and late complications.

Complications	Clavien–Dindo grade	Early (<30 days)	Late (≥30 days)
None	0	159 (60.7)	197 (75.2)
AUR	I	23 (8.8)	15 (5.7)
AUR and dysuria	I	4 (1.6)	4 (1.6)
UTI	II	5 (1.9)	0
UTI + dysuria	II	1 (0.4)	0
Hematuria	I	1 (0.4)	0
Hematuria + Dysuria	I	1 (0.4)	0
Hematuria + Other	I	1 (0.4)	1 (0.4)
Dysuria	I	61 (23.1)	39 (14.8)
Dysuria + Other	I	1 (0.4)	1 (0.4)
Other	I	5 (1.9)	4 (1.6)

Values expressed as *n* (%).

catheter or a temporary prostatic stent placed for a median of 7 (IQR 6–10) days. In 20.1% and 17.3% of cases, one day or greater than one day hospitalization was required (0.58 ± 0.81 days).

Early and late complications are summarized in Table 2. No early or late serious adverse events (Clavien III–IV) occurred. Early complications occurred in 39.3% of cases, including 4 cases of clot retention (1.5%) and one patient requiring blood transfusion (0.39%). The most frequent early and late complication was Clavien I (37.4% and 14%, respectively). Urge incontinence was reported by 6 patients (2.2%), while no cases of stress urinary incontinence occurred. Re-operation was needed in 4 cases due to treatment failure (1.5%).

Urinary and sexual outcomes

After the procedure, all the 38 patients with preoperative indwelling catheter were catheter-free. The increase in ≥1-point in the QoL was achieved in 92.7% of cases. Optimal complete urinary and sexual outcomes were achieved in 52.9% and 87.8% of patients, respectively. When looking at each single urinary outcome, we found a ≥ 50% reduction in IPSS or IPSS < 7 in 70%, a ≥ 50% improvement in peak flow and/or >15 ml/s in 70.2% and a ≥ 1-point(s) improvement in the QoL questionnaire in 92.7% of patients.

After the procedure, the antegrade ejaculation rate was 78.2%, with a 21.7% increase, and 96.6% of patients did not lose ejaculation function. No cases of de novo erectile dysfunction were recorded.

At the latest follow up consultation peak flow, PVR, OAB-q SF, QoL, IPSS and antegrade ejaculation significantly improved. Conversely, IIEF did not change significantly compared to the baseline (Table 3).

At the multivariable logistic regression analysis (Table 4), only the presence of a median lobe (OR 2.08, CI 1.01–4.29, $p = 0.047$) and the injection density (OR 0.87, CI 0.79–0.95, $p = 0.004$) were associated with the achievement of an "optimal urinary" outcome, whereas the ASA score was the only parameter associated to a "optimal sexual" outcome (OR 5.62, CI 1.94–16.32, $p = 0.002$).

Table 3. Postoperative variation of functional parameters.

Variable (median, IQR) or mean ± SD or *n* (%)	Baseline	Latest follow up	*p* value
Peak flow, mL/s	8 (5–10)	14 (11–17)	<0.001
Serum total PSA, ng/mL	2.65 (1.42–3.95)	2.1 (1.18–2.89)	0.554
Post void residual, mL	148 (110–177)	20 (10–70)	<0.001
QoL	4.25 ± 0.96	1.77 ± 1.12	<0.001
QoL			<0.001
1	1 (0.4%)	138 (56.1%)	
2	7 (2.7%)	60 (24.4%)	
3	50 (19.5%)	28 (11.4%)	
4	84 (32.7%)	9 (3.7%)	
5	98 (38.1%)	8 (3.3%)	
6	17 (6.6%)	3 (1.2%)	
IPSS score	21.8 ± 5.7	8.4 ± 5.8	<0.001
IIEF score	17.4 ± 6.5	17.2 ± 7.4	0.964
OAB q SF	39 ± 18	18 ± 8	<0.001
Urinary Incontinence	10 (4.1%)	6 (2.4%)	0.197
Antegrade Ejaculation	148 (56.5%)	205 (78.2%)	<0.001

Values expressed as median (IQR), mean ± SD, or number (%).

DISCUSSION

In this study, we report on one of the largest series regarding Rezum procedures with mid-term follow-up. Notably, we defined an optimal composite outcome for both urinary and sexual functions. This outcome was achieved in 52.9% and 87.8% of the cases, respectively. When considering all parameters individually, we recorded a reduced IPSS, improved peak flow and QoL questionnaire in 70%, 70.2% and 92.7% of cases, respectively. On the other hand, we recorded very low (2.29%) postoperative urge incontinence, and low (17.9%) postoperative complications (AUR, transfusion, clot retention, Clavien ≥ III). These findings mirror those reported in the literature and better define the safety profile of the Rezum procedure.

The 5-year outcomes of the multicenter randomized sham-controlled trial by McVary et al. suggest that treatment of LUTS with Rezum does not translate into a clinically significant decline in erectile or ejaculatory function or urinary results. In fact, they reported a re-treatment rate of 4.4%, 83% of which in the first 2 years of follow-up, when the surgical technique did not always include median lobe treatment and no cases of re-treatment after the 3rd year [7, 15]. These data were confirmed by a recent review, despite the heterogeneity of the data and study design [16]. In the literature, few articles are present with more than 100 treated

Table 4. Multivariable logistic regression analysis of factors predicting "successful" urinary and sexual outcomes.

Variable	OR	95% CI	*p* value
Successful urinary outcome			
Pre-operative peak flow	0.99	0.92–1.08	0.867
Pre-operative IPSS score	1.02	0.96–1.09	0.526
Median Lobe	2.08	1.01–4.29	*0.047*
Injection density	0.87	0.79–0.95	*0.004*
Successful sexual outcome			
Age	1.04	0.97–1.12	0.287
ASA score	5.62	1.94–16.32	*0.002*
Pre-operative peak flow	1.00	0.87–1.15	0.993
Pre-operative PSA	1.14	0.90–1.43	0.290
Pre-operative QoL	1.13	0.64–2.00	0.683
Injection volume	1.01	0.89–1.16	0.855

patients [8, 17–27] and in detail only 7 series, including our first report [8], described both urinary and sexual results [18–20, 22, 23, 25, 27]. Of these, only 4 series reported sexual and ejaculatory dysfunction after the Rezum treatment [19, 20, 25, 27], which ranged between 0% and 10.8% [16].

Johnston et al. [20] reported a mean reduction in IPSS of 78.5% after 12 months (mean 20.4 vs 4.3, $p < 0.001$) and a mean improvement of 97.5% in peak flow rate (mean 9.2 vs 18.2 mL/s, $p < 0.001$) over the same period, with a reduction of QoL questionnaire score of 72%. These data are the highest across all reported studies, however the authors did not define a degree of improvement, and any type of improvement was considered as successful. The complication rate and the re-treatment rate are similar between their study and ours, with 18.5% vs 17.9% Clavien I–IIIb and 0.95% vs 1.5%, respectively. On the contrary, Darson et al. [17] in a post market analysis, and a follow-up period up to 12 months, described an IPSS reduction of 45.2% (mean 19.5 vs 10.1), a peak flow increases of 51.4% (mean 8.6 vs 10 mL/s) and a QoL improvement of 37.8%. Described complications were Clavien ≤ II (14.5%), with a re-treatment rate of 3.05%. However, in this study there was no standardized patient selection, with various prostate volumes (mean 45.1, range 12.9–183 cm^3), and 12% of patients with a previous surgery or MIST procedure for LUTS. The data reported by the randomized controlled trial (RCT) with 97 and 77 patients available for the 4 and 5-year evaluations described an IPSS improvement of 46.7 and 48%, with the maximum flow rate improving by 49.5 and 44%, respectively [7, 19]. These data are lower than Johnston's [20] and our own, but this is explained by the longer follow-up period in the RCT. Nevertheless, the safety profile of the procedure is confirmed also by the 5-year RCT by McVary et al., with 43% of overall complications and only 2 cases of Clavien ≥ III [7].

Most of these studies reported a descriptive analysis of functional results without a cut-off value to define the success of the treatment. Only McVary [7] and Darson [17] define successful treatment as a 30% reduction of IPSS from baseline, achieved in 61% and a ≥ 3-point increase in IPSS relative to baseline in 80% of patients, respectively. These value endpoints are lower than ours, despite not being composite. In our study, in order to stress our model, we considered a composite urinary outcome previously proposed for TURP [14], which means that we asked ourselves: does the Rezum do the same work of a standard procedure? If we consider the single improvement of IPSS and peak flow in our series (70% and 70.2%, respectively), these data are in line with other studies, confirming that the results achievable by Rezum are quite similar (or even better) than a standard TURP.

In our study, we investigated predictors of composite urinary outcomes. At the multivariate analysis neither pre-operative IPSS nor peak flow correlate with the achievement of "optimal urinary" outcome. On the other hand, the presence of a median lobe and the injection density were found to be predictive of an optimal composite urinary outcome. The presence of the median lobe as a predictive factor for an optimal composite urinary outcome is in line with the recent results of Rezum in large prostate and in prostate with median lobe [25, 27]. The correct number of vapor injections is more controversial. In our analysis the injection density correlated with an optimal composite urinary outcome, in contrast with data reported by Aladesuru et al. [28]. In their study, the Authors reported that a single injection per lobe is effective to obtain LUTS improvement in 52 patients with prostate volumes from 30 to 80cc with and without median lobes. Obviously further comparative studies are needed to clarify this issue. Considering the sexual function, after the Rezum procedure we observed an increase in patients with antegrade ejaculation of 21.7% (78.2% vs 56.5%) and a very small rate (3.4%) of de novo retrograde ejaculation. Of course, this could be explained by the drug withdrawal instead of a specific action of the Rezum procedure.

As far as the erectile function is concerned, we reported an increase or stability or max 1 class reduction in IIEF-5 in 91.7% of our patients. These data are in line with the 5-year RCT and the results by Johnston, who reported an improvement of IIEF of 7.6% and 26%, respectively, and no cases of de novo erectile dysfunction [7, 20]. Despite the excellent rate of composite sexual outcomes obtained in our series (87.8%), we found that only the ASA score was a predictive factor for composite sexual outcome after Rezum. From our point of view, the everyday urological clinical practice is changing and we should rely on a systematic and individualized assessment of the patient's needs before any BPO surgery. The choice of an ejaculation preserving technique should be balanced with the patient's and also partner's expectations given that some patients may accept a limited treatment proficiency in terms of urinary symptoms to preserve their ejaculatory function [29].

Some limitations are present in this study. First, it is a retrospective analysis involving different centers and several surgeons. Secondly, due to administrative rules or insurance policies, the hospital stay was longer in some cases without a real clinical necessity. Thirdly, the real impact of the antegrade ejaculation preservation could not be quantified because of concomitant drug withdrawal. Nevertheless, the sample size and the rigorous definition of definite urinary and sexual outcomes are the major strengths of our study.

CONCLUSIONS

In our series, we can confirm that water vapor intraprostatic injection (Rezum) is a safe and well tolerated procedure, with a reduction ≥50% of the IPSS <7 in 70% of patients and improvement in peak flow ≥50% and/or more than 15 ml/s in 70.2%. In 87.8% of the cases, the composite sexual outcome was achieved by showing preserved ejaculatory and erectile functions.

DATA AVAILABILITY

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

DC and GS Conceptualization, Methodology, Writing-Original Draft. PC Methodology, Formal analysis. EC, FF, DM, EM, FV Data Curation. CDN, RA Writing-Review & Editing. BKS and GF Supervision. LC Conceptualization, Methodology, Formal analysis, Writing-Review & Editing.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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