Short-term Outcomes of Water Vapor Therapy (Rezūm) for BPH/LUTS in the First Czech Cohort

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Purpose: To evaluate the short-term results of water vapor therapy (Rezūm) for BPH/LUTS in the first cohort of Czech patients.

Materials and methods: Patients with BPH and moderate to severe LUTS (N = 76) who underwent Rezūm treatment from December 2019 to July 2020 were included in the prospective study. Prior to the procedure, they completed the IPSS and OABv8 questionnaires and underwent uroflowmetry, transrectal ultrasound of the prostate, and PSA sampling. The parameters before and 3 months after the procedure were compared and statistically evaluated.

Results: The study protocol was completed by 92% of patients (N = 70). We observed a significant increase in Qmax (median 17.7 vs. 8.8 mL/s, $P < .001$), Qave (9 vs. 4.5 mL/s, $P = .001$) and voided volume (241 vs. 171 mL, $P < .001$) and a significant reduction in post-void residual (average 17.5 vs. 67.7 mL), prostate volume (39.3 vs. 62.3 mL) and total PSA (median 1.9 vs. 2.5 ng/mL, resp. P values < .001). There was also a significant decrease in OABv8 score (average 7.6 vs. 16.6, $P < .001$) and IPSS QoL (1.6 vs. 4.0, $P = .037$). The improvement in the IPSS score was apparent, yet statistically insignificant (6.8 vs. 16, $P = .079$).

Conclusion: Water vapor therapy is an effective and safe method of BPH/LUTS treatment in the short-term.

Keywords: benign prostatic hyperplasia; lower urinary tract symptoms; minimally invasive treatment; vapor; water

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a common cause of lower urinary tract symptoms (LUTS) in an aging population. After failure of pharmacotherapy or in case of other BPH-related complications, surgical treatment is indicated. Standard methods include transurethral resection of the prostate (TURP), open adenomectomy or laser enucleation of the prostate[1]. One of the new minimally invasive methods of treatment is Rezūm, a method that uses a radiofrequency generator to convert water into water vapor, which causes coagulation necrosis of prostate cells by convective conduction of heat in prostate tissue[2]. Data regarding the efficacy and safety of Rezūm are primarily based on one large randomized controlled study, further supported by a few retrospective, prospective or crossover studies[3]. The effectiveness of this method is most often evaluated by uroflowmetry (Qmax – maximum flow rate, PVR – postvoid residual) and IPSS (International Prostate Symptom Score) questionnaire including QoL (quality of life) assessment.

In the randomized, sham-controlled study, the most significant improvement in Qmax (maximum urinary flow) and IPSS scores was achieved after 3 months, however, durable symptom relief and flow rate improvement were observed even 5 years after the procedure[4]. Usually, prostates 30-80 g are indicated for the procedure. A study evaluating the effect of the Rezūm method even for larger prostates 80-150 g is already underway[5]. Compared to standard surgical methods, no effect on sexual function or erection has been reported. McVary did not describe any de novo erectile dysfunction after the procedure and during one year there was no deterioration of sexual function compared to the initial values according to the IIEF-EF and MSQH-EjD questionnaires[6]. The incidence of complications is reported to be low, usually mild and resolving in the order of days to weeks, 75% occurring within 1 month of the procedure[7]. The need for surgical re-treatment is 4.4%, which is significantly lower compared to other minimally invasive methods such as transurethral needle ablation (TUNA), transurethral microwave therapy (TUMT) or prostatic urethral lift (PUL)[4]. In the long term, late complications such as urethral stricture or bladder neck sclerosis, known after standard surgical techniques, have not been reported[4,7]. The aim of this prospective study was to evaluate the short-term results of the minimally invasive treatment with the Rezūm method in the first cohort of patients treated at a center in the Czech Republic, one of three centers in the world where a pilot study with this method took place[2].

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Table 1. Characteristics of the study group.

	N (%)
Number of Patients	76 (100 %)
Age	
Average (SD)	65.3 (7.1)
Median	66
Min-max	49-81
Type of Anesthesia	
Analgosedation	70 (92.1)
General	1 (1.3)
Local	5 (6.6)
Length of Hospital Stay (Days)	
Average (SD)	0.2 (0.7)
Median	0
Min-max	0-5
Prostate Volume (mL)	
Average (SD)	61.8 (29.2)
Median	52
Min-max	20-149
PSA (ng/mL)	
Average (SD)	3.5 (2.8)
Median 2.5	
Min-max	0.2-13.9
IPSS Score	
Average (SD)	19.1 (6.3)
Median	20
Min-max	6-30
IPSS QoL	
Average (SD)	4.0 (1.1)
Median	4
Min-max	1-6
OABv8 Score	
Average (SD)	16.5 (7.6)
Median	16
Min-max	3-40

Abbreviations: IPSS, International Prostate Symptom Score; OABv8, Overactive Bladder-validated 8-item Screener; PSA, prostatic specific antigen; QoL, Quality of Life; SD, standard deviation.

MATERIALS ANS METHODS

Study population

The prospective study included patients with BPH and moderate to severe LUTS (N = 76) who underwent surgical treatment with the minimally invasive Rezūm method (Rezūm system, Boston Scientific, Marlborough, MA) between December 2019 and July 2020.

Inclusion and exclusion criteria

Patients with IPSS score ≥ 8 (moderate and severe LUTS) and prostate size ≤ 150 mL, in whom surgical treatment was indicated due to the unsatisfactory effect of pharmacotherapy, were included. Permanent catheter after the trial without the catheter in patients with urinary retention was allowed. Patients with prostates > 150 mL, suspicious digital rectal examination (DRE) or untreated urinary tract infection were excluded.

Evaluations

All patients underwent standard pre-follow-up examinations, including DRE, prostate specific antigen (PSA), transrectal prostate ultrasound (TRUS), uroflowmetry (UFM), postvoid residual (PVR) and completed the International Prostate Symptom Score (IPSS) and OABv8 (Overactive Bladder- validated 8-question Screeener).

The same examinations were performed

3 months after the procedure. All patients signed an informed consent for the procedure and the study was approved by the local ethics committee (approval No. 101119 / EK).

Procedure

The operation was performed by one surgeon at the Department of Urology, University Hospital Brno. The number of injections depended on the size of the prostate with the interval of 1 cm in the caudal direction, starting from distal to the bladder neck. Two to three injections were applied to one lobe (in one case only, four injections were needed for a large prostate), in the case of the expressed middle lobe another 1-2 injections were added. The procedure was performed in 92% in analgosedation. The vast majority of patients went home on the day of surgery; only one patient was hospitalized at his own request until the catheter extraction. The catheter was normally extracted on days 5 to 7 after the procedure.

Statistical Analysis

Preoperative and postoperative values of the monitored parameters were compared and statistically evaluated at the 5% level of significance. Data normality was tested using the Shapiro-Wilk test. Paired t-test was used for normally distributed data, and Wilcoxon paired test was used for the others. The results were evaluated using IBM® SPSS® Statistics Version 27.

RESULTS

Input characteristics of patients and values of monitored parameters are presented in Table 1. Eleven patients (14.5%) had urinary retention before treatment, of which six patients had a catheter inserted at the time of surgery.

Ninety-six percent of patients underwent follow-up examinations three months after surgery (N = 73). In the six patients who had a permanent urinary catheter inserted before surgery, it was not possible to compare some parameters before and after surgery, so these patients were not included in the evaluation of these parameters. Two patients did not return for the check-up due to the COVID epidemic; the third was outside of the Czech Republic long-term due to personal reasons. The first monitored group of parameters were the findings at UFM (**Table 2**). Three months after surgery, there was a significant increase in Qmax, Qave and voided volume and a decrease in postvoid residual ($P < .001$). The reduction in urination time was not statistically significant ($P = .089$). Comparing the scores from the IPSS and OABv8 questionnaires (Table 2) showed a significant improvement in the QoL domain of the IPSS questionnaire (question 8, $P = .037$) and in the overall OABv8 score (median after and before surgery 6 and 16, respectively, $P < .001$). The median IPSS score after and before surgery was 6 and 20, respectively. Despite the distinct decrease, it closely did not reach the statistical significance ($P = .079$). After the procedure, there was a significant reduction in PSA levels and prostate volume according to TRUS measurements (respective P-value < .001). Of the complications that persisted for more than one week, haematuria occurred in 15% (N = 11), urinary tract infection in 12% (N = 9), urinary retention in 7% (N = 5), urgency in 5% (N = 4), clot retention in 4% (N = 3) and erectile dysfunction in 1% (N = 1). Although a validated satisfaction questionnaire was not used, up to 96% of patients expressed satisfaction with the condition after surgery and would recommend the procedure to others, two patients were only partially satisfied and one patient was indicated for TURP due to persistent urinary retention.

Table 2. Comparison of uroflowmetry parameters, scores from questionnaires, prostate volume by transrectal ultrasound and total PSA values.

	Preoperatively	3 Months After Surgery	*P*-value
Qmax (mL/s)	N = 68	N = 68	
Average ± SD (range)	8.8 ± 3.7 (1.0-18.6)	16.9 ± 5.7 (2.0-33.0)	< .001
Median	8.8	17.7	
Qave (ml/s)	N = 67	N = 67	
Average ± SD (range)	4.8 ± 2.0 (1.0-12.6)	9.0 ± 3.4 (1.0-19.0)	.001
Median	4.5	9	
V (mL)	N = 68	N = 68	
Average ± SD (range)	196.8 ± 109.1 (3-497)	260.7 ± 126.2 (45-606)	< .001
Median	177	241	
PVR (mL)	N = 67	N = 67	
Average ± SD (range)	67.7 ± 98.1 (0-760)	17.5 ± 47.6 (0-373)	< .001
Median	50	0	
t (s)	N = 66	N = 66	
Average ± SD (range)	45.0 ± 21.7 (7-125)	30.7 ± 15.0 (10-84)	.089
Median	42	27	
IPSS Score	N = 72	N = 72	
Average ± SD (range)	19.0 ± 6.4 (6-30)	6.8 ± 4.3 (0-21)	.079
Median	20	6	
IPSS QoL	N = 72	N = 72	
Average ± SD (range)	4.0 ± 1.1 (1-6)	1.6 ± 0.9 (0-4)	.037
Median	4	2	
OABv8	N = 72	N = 72	
Average ± SD (range)	16.6 ± 7.5 (5-40)	7.6 ± 4.8 (1-23)	< .001
Median	16	6	
Prostate Volume (mL)	N = 73	N = 73	
Average ± SD (range)	62.3 ± 29.7 (20-149)	39.3 ± 18.8 (16-92)	< .001
Median	52	34	
tPSA (ng/mL)	N = 70	N = 70	
Average ± SD (range)	3.4 ± 2.8 (0.2-13.9)	2.3 ± 1.8 (0.2-9.2)	< .001
Median	2.5	1.9	

Abbreviations: IPSS, International Prostate Symptom Score; OABv8, Overactive Bladder-validated 8-item Screener; PVR, post-void residual; Qave, average flow; Qmax, maximum flow; QoL, Quality of Life; SD, standard deviation; t, voiding time; tPSA, total prostatic specific antigen; V, voided volume.

DISCUSSION

Minimally invasive methods of BPH treatment are methods that burden the patient as little as possible, are sufficiently effective and safe, and have a minimal incidence of serious complications. These include methods such as HIFU (high-intensity focused ultrasound), TUMT, TUNA, selective prostate embolization, intraprostatic ethanol application or prostate stent implantation. Newer methods include PUL and Rezūm[8]. Both of these methods are entering common clinical practice[9]. The Rezūm method is often compared to the PUL for similar indications and results. While the principle of PUL is, in addition to the mechanical opening effect of the device, tissue ischemia with subsequent atrophy and resorption of prostate tissue[10], in Rezūm the result of water vapor is coagulative necrosis, which in several weeks leads to resorption of necrotic tissue and reduction of prostate volume. Our center was a part of a multicenter pilot study, in which 18 patients were treated with the Rezum system in 2014-2015. Based on this study, the FDA then enabled a larger clinical study to be conducted in the United States[7]. The method was introduced into clinical practice in the Czech Republic at the end of 2019, which enabled the procedure to be performed on a larger number of patients. The presented cohort of patients is the first group evaluated in this way not only within the Czech Republic, but also the Central European region. Short-term treatment results were published in a pilot prospective study by Dixon et al.[11] and the work of McVary[12]. In the available studies with 1-2 years of follow-up, the mean changes in IPSS score, QoL, Qmax and PVR reach 45-60%, 38-59%, 44-72% and 11-35%, respectively. Clavien I-II short-term complications include urinary retention, dysuria, urgency, urinary tract infection and, gross hematuria whereas few III-IV complications such as sepsis or clot retention have been reported[4]. Our results correspond with these results. We observed an overall lower incidence of adverse events compared to the Dixon study. Haematuria was more common in our cohort (15% vs. 13%); on the contrary, the incidence of urinary retention was lower (7% vs. 33%). Other complications are not comparable due to the low number of patients. The initial results of a similar short-term multicenter Italian study in 135 patients[13] showed a significant reduction in IPSS score after 3 months (4.2 vs. 21, P < .0001). There was also an apparent decrease in the IPSS score in our cohort (6.8 vs. 16), but it did not reach statistical significance by a small margin (*P* = .079). We recorded a lower incidence of acute urinary retention (7% vs. 11.8%) and, conversely, a higher incidence of urinary tract infection (12% vs. 6%). The limitation of our study is the short follow-up time and the smaller number of patients, which is due to the short time that the device has been available on the market. However, published work demonstrates a long-lasting effect of treatment even after 5 years of follow-up, concerning the reduction of IPSS by 48% and improvement of Qmax and quality of life by 44% and 45%, respectively [4]. The strength of the study is its prospective nature, as well as the fact that all procedures were performed by only one surgeon with experience from the pilot study. From the point of view of the benefit for the patient, we consider an independent assessment of QoL according to IPSS to be important, which in the short-term follow-up showed a significant improvement. Longer term

follow-up and more patients are needed to confirm our results. Studies in larger prostates and in patients with preoperative urinary retention are also needed in the future. In this regard, published data on 37 patients have so far demonstrated spontaneous micturition after surgery in 70% of patients who had a preoperative urinary catheter[14]. We did not assess the impact on erectile or ejaculatory function. According to available studies, the impact of Rezūm is minimal. Anejaculation within the first 3 months occurs in less than 3% and only one retrospective study reported de novo erectile dysfunction in 3% of patients[15]. An important limitation concerning more frequent implementation of the procedure in the Czech Republic is the lack of reimbursement from public health insurance, so the procedure is covered by the patient.

CONCLUSIONS

Water vapor therapy using the Rezūm system leads to a significant increase in Qmax, Qave, voided volume and a significant decrease in post-void residual, OABv8 score, prostate size and total PSA during short-term follow-up. The quality of life of patients after the operation is significantly higher compared to the condition before the operation. Confirmation of these promising results in a larger group of patients and with a longer follow-up period is a prerequisite for the extension of this new minimally invasive treatment to routine clinical practice.

CONFLICT OF INTEREST

There is no potential conflict of interest to declare.

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