Original Article
Özgün Araştırma

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The Rezum procedure in benign prostate hyperplasia: Initial experience at a single center in Turkey

Benign prostat büyümesinde Rezum prosedürü: Türkiye'den tek merkezli ilk deneyimlerimiz

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ÖZET

Amaç: Bu çalışmada üriner ve cinsel sonuçlar dahil olmak üzere Rezum prosedürü ile ilgili ilk deneyimlerimizi sunmayı amaçladık.

Gereç ve Yöntemler: Bu retrospektif çalışmaya Haziran 2021 ile Ağustos 2022 arasında Rezum işlemi uygulanan toplam 24 hasta dahil edildi. Her prosedür için prostatın lateral ve varsa medyan loblarına 2 ila 12 enjeksiyon uygulandı. Başlangıç ve takip verileri analiz edildi. Ayrıca prostat medyan lobu olan ve olmayan hastaların sonuçları da karşılaştırıldı.

Bulgular: Ortalama takip süresi 7,5 aydı. Uluslararası Prostat Semptom Skoru tüm hastalarda ortalama 15 puan azalırken (p<0,001), maksimum idrar akışı benzer değerlere sahip üç hasta dışında tüm hastalarda arttı (ortalama 5 mL/s) (p<0,001). İşeme sonrası rezidüel idrarda azalma ise ortalama 55 mL idi (p<0,001). Medyan lobu olan ve olmayan hastalar arasında hiçbir değişken için anlamlı fark yoktu. Hiçbir hastada herhangi bir cinsel kötüleşme ya da majör bir komplikasyon gözlenmedi. Minör komplikasyon olarak, iki hastada makrohematüri, dördünde non-steroidal antiinflamatuar ilaç tedavisi gerektiren dizüri ve iki hastada idrar retansiyonu nedeniyle tekrar kateterizasyon saptandı.

Sonuç: Rezum işlemi prostat medyan loblu hastalarda dahi cinsel fonksiyonları koruyan etkili ve pratik bir prosedürdür.

Anahtar Kelimeler: alt üriner sistem semptomları, minimal invaziv cerrahi, prostat büyümesi, Rezum

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This study was approved by the Ethics Committee of Koç University (Approval Number: 2022.286.IRB1.117, Date: 2022-09-07). All research was performed in accordance with relevant guidelines/regulations, and informed consent was obtained from all participants.

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ABSTRACT

Objective: In this study, we aimed to present our initial experiences with the Rezum procedure, including voiding and sexual outcomes.

Material and Methods: A total of 24 patients who underwent the Rezum procedure between June 2021 and August 2022 were included in this retrospective study. For each procedure, 2 to 12 injections were applied to the median and lateral prostate lobes. We analyzed the baseline and follow-up data and compared the outcomes of patients with and without the median lobe of the prostate.

Results: The mean follow-up time was 7.5 months. The International Prostate Symptom Score decreased in all patients by 15 points on average ($p<0.001$), while the maximum urinary flow increased by 5 mL/s on average in all patients except three who had similar values ($p<0.001$). The post-void residual decrease was 55 mL ($p<0.001$). In terms of the variables examined, there was no significant difference between patients who had a median lobe and those who had not. Neither any sexual worsening nor any major complications were observed. As for minor complications, two patients had macrohematuria, four had dysuria that required non-steroidal anti-inflammatory drug therapy, and two required re-catheterization due to urinary retention.

Conclusion: The Rezum procedure is an effective and practical method, even in patients who have median lobes of the prostate, and preserves sexual functions.

Keywords: lower urinary tract symptoms, minimally invasive surgery, prostatic hyperplasia, Rezum

INTRODUCTION

Benign prostatic hyperplasia (BPH) is one of the most common diseases in men over the age of 40, with an incidence that increases with age. About 50% of men over the age of 50 and up to 80% of men over the age of 80 encounter lower urinary tract symptoms (LUTS) due to BPH (1, 2). The increase in the incidences of LUTS in the last decade has brought along different treatment modalities. LUTS due to BPH affects the quality of life of patients. While the medical approach is preferred in the first stage in patients who require treatment, surgery is recommended for those who do not want or cannot benefit from medical treatment (3). Among the surgical options, transurethral resection of the prostate (TURP) has been the gold standard for many years (4). In recent years, the armamentarium including minimally invasive approaches (MIA) has been expanding, including options that may differ in terms of invasiveness, effectiveness, side effects, and cost.

Rezum is an ablative MIA procedure, which has been getting popularity since its approval by the FDA in 2015 (4-6). In this method, water vaporization is applied using radiofrequency to create thermal energy (The Rezūm System; Boston Scientific Corp., Marlborough, MA, USA). In the studies conducted so far, advantages such as short procedure time, not affecting sexual functions, and not requiring anesthesia have been reported. In this study, we aimed to share the initial experiences of our center with the Rezum method, which has gained particular popularity in Turkey in the last few years.

MATERIAL AND METHODS

Surgical Procedure

The Rezum method transmits thermal energy to the prostate tissue through the convective water vapor produced by radio frequency, thereby creating the ablation of the prostate tissue. Depending on the prostate anatomy of the patient, thermal energy is transmitted to the lateral and median lobes of the prostate in varying numbers of injections. The technical details of the procedure have previously been described (7, 8).

In the current study, all patients were informed about the Rezum procedure before the operation and were informed that Rezum is less invasive compared to alternative treatment methods, with less possibility of complications such as retrograde ejaculation and erectile dysfunction. The patients were also told that

the possibility of additional treatment methods may be required after the Rezum operation, especially for patients with a prostate size of 80 grams and above.

The operations were performed by three different surgeons. All procedures were performed under general anesthesia. Depending on the prostate characteristics, 2 to 12 injections were applied to the median and lateral lobes of the prostate. The urethral catheters were removed after five to seven days. Alpha-blocker (alfuzosin) was prescribed to the patients for one month after surgery.

After the approval of the ethics committee (2022, 286.IRB1.117), the data of 25 patients who underwent Rezum surgery between June 2021 and August 2022 were analyzed retrospectively.

Data Analysis

Twenty-five patients, who were aged 40-80 and had at least three months of follow-up data, were included in the study. One patient who was lost to the first-month follow-up was excluded from the study; thus, the data of the remaining 24 patients were analyzed. Patient characteristics including prostate-specific antigen (PSA), uroflowmetry, post-void residual (PVR), prostate volume (PV) measurement by urinary ultrasound, International Prostate Symptom Score (IPSS), International Index of Erectile Function (IIEF-5), and ejaculation status were recorded preoperatively. The number of injections applied, the duration of the operation, and the size of the median lobe and bladder neck during the operation were noted. In the postoperative period, the length of hospital stay, the time of removal of the urethral catheter, and the need for re-catheterization were determined. The IPSS and IIEF-5, uroflowmetry, PVR, and ejaculation parameters were reevaluated in the postoperative controls. The data from the final visits (mean: 7.5 months, range: 3 to 12 months) were used in the study.

Statistical Methods

Statistical analyses were performed using IBM SPSS Statistics for Windows v.28.0 (IBM Corp., Armonk, NY, USA). The descriptive statistics were presented using the mean and standard deviation for the normally distributed variables and using the median (minimum-maximum) for the non-normally distributed variables. The evaluation of two independent groups was performed via a non-parametric comparison using the Mann-Whitney U test, while the changes between preop and postop measurements were evaluated using the Wilcoxon signed-rank test.

RESULTS

Patient characteristics are summarized in Table 1. One patient was under active follow-up with the diagnosis of ISUP Grade 1 prostate cancer. The prostate volume of three patients (13%) was over 80 ml. While only one patient had an indwelling Foley catheter, none of the patients had a history of prostate surgery. Six patients (25%) had retrograde ejaculation due to alpha-blockers used preoperatively. Seven patients used alpha-blockers before the operation, however, none of them needed alpha-blockers since they were discontinued at the end of the postoperative first month.

Table 2 shows the comparison between preoperative and postoperative data. The IPSS decreased in all patients by 15 points on average ($p<0.001$), while the maximum urinary flow (Qmax) increased in all patients by 5 mL/s on average except for three who had similar values ($p<0.001$). The average post-void residual decrease was 55 mL ($p<0.001$).

The comparison of the patients who had the median lobe and those who had not is given in Table 3. The mean IPSS, Qmax, PVR, and IIEF changes were similar in both groups (p-value; 0.211, 0.468, 0.309, and 0.522, respectively). Postoperatively, two patients had macrohematuria and four had dysuria requiring NSAIDs after catheter removal. Two patients required re-catheterization due to urinary retention; both patients' symptoms improved following catheter removal after re-catheterization. Urinary tract infection was not observed in any patient. None of the patients had retrograde ejaculation after discontinuation of the alpha-blocker treatment.

Table 1. Patient characteristics and perioperative data.

Variables	
Age, years	63.0±8.7
BMI, kg/m^2	27.8±3.1
PSA, ng/ml	3.1±1.7
Prostate volume, ml	64.2±29.6
Number of patients with a median lobe, n (%)	11 (46)
IPSS	21 (16-29)
Q max, mL/s	8 (3-20)
PVR, ml	88 (20-350)
Number of patients using alpha-blockers, n (%)	7 (29)
IIEF-5	19 (10-25)
Mean duration of operation, minutes	25±5
Mean number of injections	4.1±2.5
Mean length of hospital stay, days	1.4±0.7
Time of urinary catheter removal, days	6.7±1.0
Follow-up time, months	7.5 (3-12)

BMI: *body mass index,* ***IIEF-5:*** *International Index of Erectile Function,* ***IPSS:*** *International Prostate Symptom Score,* ***PSA:*** *prostate-specific antigen,* ***PVR:*** *Post-void residual urine* ***Q max:*** *Maximum flow rate.*
Data are given as mean±SD for the normally distributed data and as median (range) for the non-normally distributed data.

Table 2. Comparison of the baseline and follow-up findings including urinary and sexual functions.

	Preoperative median (range)	Postoperative median (range)	*p**
IPSS	21 (16-29)	6 (2-16)	<0.001
Q max, mL/s	9 (3-20)	14 (6-22)	<0.001
PVR, mL	88 (20-350)	33 (0-170)	<0.001
IIEF-5	19 (10-25)	21 (14-25)	0.014

IIEF-5: *International Index of Erectile Function,* ***IPSS:*** *International Prostate Symptom Score,* ***PVR:*** *Post-void residual urine,* ***Q max:*** *Maximum flow rate, *Wilcoxon Signed Rank test*

Table 3. Comparison of the patients who had a median lobe and those who had not.

	Without median lobe (n=13)			With median lobe (n=11)			*p*
	Preoperative median (range)	Postoperative median (range)	Change	Preoperative median (range)	Postoperative median (range)	Change	
IPSS	19.5 (17-25)	6 (2-16)	13.5	22.5 (16-29)	6.5 (3-8)	16	0.211
Qmax, mL/s	11 (3-17)	15.5 (6-21)	4.5	8 (5-20)	13 (9-22)	5	0.468
PVR, mL	80 (0-300)	35 (0-170)	45	95 (20-350)	33 (0-120)	62	0.309
IIEF-5	19.5 (14-23)	20 (15-25)	0.5	19 (10-25)	21 (14-25)	2	0.522

IIEF-5: *International Index of Erectile Function,* ***IPSS:*** *International Prostate Symptom Score,* ***PVR:*** *Post-void residual urine,* ***Q max:*** *Maximum flow rate*

DISCUSSION

Rezum is one of the minimally invasive methods with increased interest in Turkey as well as in the world in recent years. The procedure has begun to be performed in our center for 1.5 years now. Therefore, in this study, we presented the short-term results of our Rezum experience. Although the number of studies on the Rezum procedure across the world is increasing, the studies have reported follow-up results of five years at the longest so far (9). In our study, we observed significant improvements in the LUTS and micturition findings of the patients. The IPSS decreased in all patients by 67.7% on average, while the Q max increased by 47%. The decrease in PVR was 67%. Only two patients required temporary re-catheterization. Nevertheless, all patients' symptoms improved after a mean follow-up period of 7.5 months. None of our patients needed to continue using alpha-blockers.

The effectiveness of Rezum in voiding functions has been demonstrated by previous studies. Whiting et al. presented the results of 461 patients from two centers. In this study where the mean follow-up period was 16.7 months, the researchers observed a 77% improvement in the IPSS at the third-month follow-up. This improvement was observed to be permanent at the 12th-month follow-up. While the increase in Qmax three months after the intervention was 62%, this rate increased to 85% in the 12th month. On the other hand, PVR decreased by 45% on average in the third postoperative month and was found to be similar in the 12th month (10). In their prospective, randomized controlled trial involving 188 patients with a prostate volume of 30-80 g, McVary et al. shared their outcomes (11). The patients were initially divided according to the severity of the symptoms those who had an IPSS of 13 to 18 (moderate LUTS) and those with an IPSS ≥19 (severe LUTS). Both moderate and severe LUTSs were shown to improve significantly within three months of treatment. While a 50% decrease was observed in the IPSS, patients' Qmax increased by 50%. The authors reported that the improvements in the findings were permanent throughout the four-year follow-up period. In addition, in the study of Bole et al., the effectiveness of Rezum was investigated in patients with a prostate volume below 80 g and above 80 g and the authors noted similar improvement rates in both symptom scores and Qmax and PVR parameters (12). We also observed significant improvement in three of our patients who had a prostate volume greater than 80 ml.

Currently, one of the questions asked regarding the Rezum procedure is the continuity of symptomatic improvement and the need for reoperation. In Whiting et al.'s study, 4.6% of the patients required retreatment (10). The most common causes of reoperation were the presence of the median lobe, bladder neck stenosis, and asymmetric prostate cavity in a few patients. The researchers performed a secondary treatment after a short period of 11 months on average. In the aforementioned McVary et al.'s study, although there was a permanent improvement in the voiding parameters at the end of four years, additional surgical intervention was required for 4.4% of the cohort. Although all of these patients had their median lobe, they were untreated. In our study, the mean follow-up period was 7.5 months, and none of our patients required reoperation during this relatively short period. The presence of the median lobe, which is assumed to be the cause of reoperation, was evaluated in our study. According to our results, there was no significant difference in none of the parameters evaluated among the patients who had a median lobe and those who had not. We believe that the extra injections to the median lobe in addition to the lateral lobe played an important role in this occurrence.

The outcomes regarding sexual functions are one of the most important concerns of patients who undergo prostate surgery. In previous studies, Rezum has been shown to protect sexual functions (13-15). The IIEF-5 in McVary et al.'s randomized controlled trial was preserved after surgery, while improvement was observed in the ejaculation symptoms (9). In our study, among the patients with a normal preoperative ejaculation function, ejaculation was preserved in all patients except one. In patients with ejaculation problems due to alpha-blocker use, the postoperative ejaculation problem was improved by the withdrawal of the alpha-blocker. The high retrograde ejaculation rates of surgical treatments such as holmium laser enucleation of the prostate (HoLEP), laser vaporization methods, and TURP make Rezum stand out in this respect. Surprisingly, in our study, the mean IIEF-5 was preserved, and even slightly increased. In most of

the previous studies, no changes in erectile functions after surgical treatment for BPH were reported, as a matter of fact, erectile functions have improved in some (16).

Although Rezum is a surgical intervention, the absence of prostatic tissue removal on the screen that satisfies the surgeon at the end of the procedure is instinctively a situation that might make surgeons curious and uncomfortable regarding clinical response. Despite the FDA approval for the treatment and the increasing number of reliable publications encouraging us to employ this treatment modality, we prefer to see our results to have absolute confidence in this method and then share them in our publications.

Our study had some limitations. First, the study was conducted retrospectively and the number of patients was small. Second, our cohort lacked a control group. Third, the surgical procedures were performed by three different surgeons. Finally, the follow-up period was short, and the follow-up data belonged to different periods between the third and 12th months postoperatively.

CONCLUSION

As a result, the Rezum procedure is an effective method, even in patients who preserve their median lobes, and can be recommended for select patients by taking their expectations into account. As shown in our study, the Rezum procedure offers acceptable outcomes with its short duration, easy applicability, and ability to preserve sexual functions. However, the outcomes of the procedure still need to be supported with long-term results and further randomized trials.

Informed Consent: The authors declare that informed consent was obtained from all participants in the study.

Conflict of Interest: The authors declare no conflicts of interest.

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Ethical Approval: The study was approved by the Koç University School of Medicine Ethics Committee of Clinical Researches (Approval Number: 2022.286.IRB1.117, Date: 2022-09-07). The study protocol conformed to the ethical guidelines of the Helsinki Declaration.

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