

Comparison of bipolar radiofrequency thermotherapy and transurethral prostate resection in treatment of benign prostate hyperplasia

Comparación de la termoterapia por radiofrecuencia bipolar y la resección transuretral de próstata en el tratamiento de la hiperplasia prostática benigna

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Abstract

Objectives: Lower urinary tract symptoms due to benign prostatic hyperplasia in men increase with aging. Risks related to anesthesia and surgery have led a search for alternative treatments. Bipolar radiofrequency (RF) thermotherapy is one of the methods adopted in patients with high surgical risks. The aim of this study is to compare the effect of bipolar RF thermotherapy and transurethral resection of the prostate (TURP) methods on voiding symptoms and on post-operative complication rates especially in patients carrying high surgical risks. **Methods:** Pre-operative, post-operative 1st and 6th month International Prostate Symptom Score (IPSS), Qmax, quality of life, prostate volumes, and postoperative complications of the patients underwent TURP and RF for benign prostatic hyperplasia (BPH) were compared. **Results:** In the RF group, the pre-operative median IPSS was 30, prostate volume 41.5 cc, post-void residual (PVR) 80 ml, and Qmax is 5.85 ml/s.; In the TURP group, these were 29, 40 cc, 85 ml, and 5.3 ml/sec, respectively. In the Bipolar RF group, post-operative 1st- and 6th-month median values were IPSS 18, 21; prostate volume 40, 40; PVR 40, 35; Qmax 10.9, 9.15 and in the TURP group IPSS 9, 8; prostate volume 20, 20; PVR 30, 10; Qmax 17.25, 19.1, respectively. **Conclusion:** Bipolar RF thermotherapy is an applicable treatment method for BPH patients with high surgical risks.

Keywords: Prostatic hyperplasia. Radiofrequency. Transurethral resection of prostate. Transurethral Thermotherapy.

Resumen

Objetivos: La termoterapia bipolar por radiofrecuencia es uno de los métodos adoptados en pacientes con alto riesgo quirúrgico. El objetivo de este estudio es comparar el efecto de la termoterapia de radiofrecuencia bipolar y los métodos de RTUP en los síntomas de vaciado y en las tasas de complicaciones posoperatorias, especialmente en pacientes con alto riesgo quirúrgico. **Métodos:** Se compararon el IPSS, el Qmax, la calidad de vida, los volúmenes de próstata y las complicaciones posoperatorias de los pacientes sometidos a RTUP y RF para la HBP preoperatorios, posoperatorios al primer y sexto mes. **Resultados:** En el grupo de RF, la mediana preoperatoria del IPSS fue de 30, el volumen prostático de 41.5 cc, el PVR de 80 ml y el Qmax de 5.85 ml/seg.; En el grupo RTUP estos fueron 29, 40 cc, 85 ml y 5.3 ml/seg, respectivamente. En el grupo de RF bipolar, los valores medianos postoperatorios del primer y sexto mes fueron IPSS 18, 21; volumen de próstata 40, 40; PVR 40, 35; Qmax 10.9, 9.15 y en el grupo TURP IPSS 9, 8; volumen de próstata 20, 20; PVR 30, 10; Qmax 17.25, 19.1, respectivamente. **Conclusión:** La termoterapia de RF bipolar es un método de tratamiento aplicable para pacientes con HPB con alto riesgo quirúrgico.

Palabras clave: Hiperplasia prostática. Radiofrecuencia. Resección transuretral de próstata. Termoterapia transuretral.

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Introduction

Lower urinary tract symptoms (LUTS) in men increase with aging^{1,2}. Although there are many underlying causes to those symptoms, the most common cause is bladder outlet obstruction due to benign prostatic hyperplasia (BPH)³. LUTS decrease the quality of life, falls and bone fractures due to nocturia can be seen, as a result of these, even death may occur⁴.

Depending on the size of the prostate, methods such as open prostatectomy and transurethral resection of the prostate (TURP) are used in the surgical treatment of BPH for decades. In patients with prostates < 80 cc, TURP is the most commonly used and gold standard surgical modality⁵.

Risks related to anesthesia and surgery increase due to chronic diseases, drugs which must be used continuously or discontinuation of these drugs in the pre-operative period⁶. In patients receiving anticoagulant therapy, the need for transfusion, hematuria forming clots in the bladder, and lastly thromboembolic events are observed more frequently⁷. Today, despite the increase to the use of bipolar devices, TURP syndrome is encountered at a rate of 0.8% while the mortality has been observed at a rate of 0.1% after that surgery⁸. Due to these risks, there is an unending search for alternative treatments of TURP. Bipolar radiofrequency (RF) thermotherapy is also one of the methods adopted in patients with high surgical risks⁹. The main aim of this thermal ablation therapy is to destroy an entire tissue using heat to kill the target cells in a minimally invasive modality without damaging adjacent structures¹⁰. In the present study, it was aimed to evaluate the results of RF in comparison TURP to give an insight to that therapy as there is not a comparative study in the literature.

Methods

Approval was obtained from the Local Ethics Committee (Date of the decision: 10.07.2020, Approval Code of the decision: 350). Forty-two patients who underwent bipolar radiofrequency thermotherapy and 45 patients underwent bipolar TURP between June 2018 and January 2020 were included in this retrospective study.

Inclusion criteria of patients were diagnosis of BPH unresponsive to medical therapy, prostatic urethral length in the range of 23-50 mm, prostate volume

between 30 cc and 80 cc, international prostate symptom score (IPSS) > 20, maximum urine flow rate (Qmax) < 14 ml/sec, high surgical risk due to comorbidities (American Society of Anesthesiology [ASA] 3 and above), and between the ages of 50 and 95. Exclusion criteria of patients were the presence of urethral stricture, prostate cancer diagnosis, and the presence of the prostatic median lobe.

Before performing bipolar radiofrequency thermotherapy, the patients were informed about the procedure, and consent form was obtained. Prostatic urethral length was measured with transrectal ultrasound (TRUS). The patient was placed in a supine position and a lubricant gel containing 2% lidocaine was squeezed out of the urethral meatus, the urethra was clamped and waited for 5 min. A 16 F urethral catheter with six heat rings at the tip was inserted transurethrally into the bladder. After the urine output was observed, the balloon of the catheter was inflated with 10 cc saline solution and placed on the bladder neck. The connection cable that provides the transmission of radiofrequency energy is connected to the computer system of RF generator.

The patient's identity information and prostatic urethral length have been entered into the system. The temperature of the electrodes was adjusted to 55°C and the process was started. According to the length of the prostatic urethra and the temperature values coming from the receptors in three different rings, the system activates the electrodes and keeps the temperature constant at 55°C. The process was applied for 1 h.

After the procedure was completed, the RF catheter was removed and a 16F 2-way foley catheter was placed. This catheter was removed after 3 days in all patients. Anti-inflammatory treatment was given for edema that may develop due to the procedure.

Patients who underwent B-TURP were informed before the procedure and consent forms were obtained. Spinal anesthesia was applied to all patients. PlasmaKinetic™ SuperPulse Generator, Gyrus Plasmakinetic Superpulse Pk™. Superloop, Karl-Storz (Germany) 26F Resectoscope Sheath and 30° Karl-Storz Telescope (Solingen, Germany) were used. Patients were placed in the lithotomy position and a lubricant gel containing 2% lidocaine was squeezed out of the urethral meatus before the procedure. The procedure was performed by a single experienced surgeon (more than 100 cases). At the end of the procedure, bleeding was controlled and a 22F 3-way Foley catheter was placed in the bladder. The Foley catheter was removed after 3 days in all patients.

Pre-operative, post-operative 1st- and 6th-month IPSS, Qmax, quality of life, prostate volumes, and post-operative complications of the patients were compared.

Statistical method

The data analyses were performed with PASW 18 (SPSS/IBM, Chicago, IL, USA) software. Kolmogorov–Smirnov and P-P Plot tests were used to verify the normality of the distribution of continuous variables. The results were reported as mean $\pm$ SD, or in situations in which the distributions were skewed, as the median (minimum-maximum). Categorical variables were given as percentages. Mann–Whitney U test was used for the intergroup analysis of continuous variables. Categorical variables were analyzed with Chi-square test. The difference between pre-operative and post-operative values was assessed by Wilcoxon signed rank test, $p < 0.05$ was considered as statistically significant.

Results

The results of 87 patients who underwent Bipolar RF ($n = 42$) and Bipolar TURP ($n = 45$) were evaluated. There were no significant differences in pre-operative descriptive variables of two groups as shown in table 1.

Pre-operative results in the 1st and 6th months in both groups were evaluated. Table 2 shows a summary of the findings at the 1st and 6th month.

The ASA score of 36 (80%) of the patients who underwent TURP was 3, and 9 (20%) patients was 2 while the ASA score of 6 (14.3%) of the patients who underwent RF was 4, and the ASA score of remaining 36 (85.7%) was 3 ($p = 0.001$).

In TURP group, 3 (6.8%) patients had hematuria that did not require transfusion, one patient (2.3%) had indwelling catheterization, and one patient (2.3%) had epididymitis complications postoperatively while no complications were observed in the RF group. In 4 patients (9.5%), treatment was unsuccessful and could not get rid of the indwelling catheter.

Discussion

BPH is a common diagnosis in the aging male population. It can affect the quality of life by causing LUTS. Treatment options for men with BPH exist in a broad spectrum and are determined by the symptoms. TURP has long been considered the gold standard for operative treatment; it is indicated for failure of medical therapy for LUTS, obstructive nephropathy, bladder stone formation, or recurrent episodes of urinary retention⁵.

Table 1. Pre-operative descriptive variables of the patients

Preoperative values	RF ($n = 42$)	TURP ($n = 45$)	p
Age (year)	74.5 $\pm$ 7.29 (60-93)	70.04 $\pm$ 7.34 (51-83)	0.06
Prostate volume (cc)	41.5 $\pm$ 11.4 (30-75)	40.0 $\pm$ 8.74 (30-66)	0.591
IPSS	30.0 $\pm$ 4.7 (18-35)	29.0 $\pm$ 5.68 (20-35)	0.496
Qmax (ml/s)	5.85 $\pm$ 3.23 (1.8-13.1)	5.3 $\pm$ 2.71 (2.1-13.2)	0.165
PVR (ml)	80.0 $\pm$ 69.7 (0-300)	85.0 $\pm$ 64.6 (0-200)	0.523

Values are presented as mean $\pm$ standard deviation (minimum-maximum).

RF: radiofrequency; TURP: transurethral resection of the prostate; IPSS: International Prostate Symptom Score; Qmax: maximum flow rate; PVR: post-void residual.

Numerous innovative treatment options have been developed in recent years, but their both short and long-term effects remain to be determined¹¹⁻¹⁷. One of those innovative and minimally invasive treatment options is prostate thermal therapy. That therapy is often applied using RF currents, microwaves, ultrasound, laser, and thermal conduction sources by transurethral, transrectal, or external applicators. Treatments that procure temperatures lower 44°C are referred to as hyperthermia, those that procure temperatures over 44.5°C as thermotherapy, and those that procure temperatures beyond 65°C as thermoablative¹⁸.

Our study is to compare bipolar RF thermotherapy and bipolar TURP methods in patients carrying high surgical risks. Although there are many studies in the literature regarding these methods, there are very few studies on bipolar radiofrequency thermotherapy. To the best of our knowledge, there is no study comparing bipolar RF and TURP methods in the literature.

The mechanism by which thermal therapy causes a decrease in LUTS is not exactly understood. There are various theories that focus on changes in prostate innervation, or changes in the morphological organization of the prostate. The primary of these ideas appears to be based on the dynamic phenomenon of prostatic obstruction, in which the tone of the prostate's smooth muscle causes obstruction. Thermal damage to adrenergic fibers is thought to primarily cause long-term α -blockade¹⁹. Reduced prostatic urethral sensation may result in decreased input in the urethra-detrusor excitatory reflexes, resulting in an overall improvement in the perception of voiding symptoms.

Another effect of thermal therapy is to induce apoptosis and coagulation necrosis in prostate cells. Temperatures of up to 45°C do not completely impress the

Table 2. 1st- and 6th-month values of IPSS, prostate volume, PVR and Qmax, and QoL in RF and TURP groups

	1 st month			6 th month		
	RF	TURP	p	RF	TURP	p
IPSS	18 (3-30)	9 (2-25)	< 0.001	21 (2-35)	8 (2-16)	< 0.001
Prostate volume (cc)	40 (27-71)	20 (10-28)	< 0.001	40 (25-67)	20 (10-25)	< 0.001
PVR (ml)	40 (0-250)	30 (0-150)	0.428	35 (0-200)	10 (0-120)	0.032
Qmax (ml/s)	10.9 (3.5-19.6)	17.25 (4.5-23.5)	< 0.001	9.15 (3.5-11.3)	19.1 (5.6-23.9)	< 0.001
QoL	2	2	0.015	3	1	< 0.001

Values are presented as the median (minimum-maximum).

RF: radiofrequency; TURP: transurethral resection of the prostate; IPSS: International Prostate Symptom Score; Qmax: maximum flow rate; PVR: post-void residual; QoL: quality of life.

prostate cells. Cell death solely commensates at temperatures over this threshold. The destruction persists even after the procedure is completed, which is known as the delayed effect. Delayed effects include ischemia and reperfusion damage, inflammation-induced cytokine release, and initiation of the immune system's response²⁰. According to our study, a significant reduction in prostate volume was observed ($p < 0.001$). Prostate cells that are developed at 55°C may undergo apoptosis and coagulation necrosis, which would result in a decrease in prostate volume. Benli et al. found a significant increase in Qmax but no significant change in prostate volume²¹. Salar et al. and Engin et al. found improvement in voiding symptoms, but they have not evaluated prostate volume^{22,23}. Based on our study, the transurethral RF method is applied and significant improvement was observed in voiding parameters in the 1st and 6th months ($p < 0.001$). It is obvious that the voiding parameters from the 6th month are superior when the findings of the 1st and 6th months are compared. Although the treatments for both groups were successful, TURP was more effective than bipolar RF thermotherapy ($p = 0.0001$). Clinically, prostate gland size does not always correlate with the severity of obstructive urinary symptoms; a prolonged effect can be obtained due to thermal destruction of alpha adrenergic fibers and probably reduction in prostate volume²⁴.

While Sergey et al. reported acute urinary retention after catheter removal as a complication²⁵, Diri et al. and Salar et al. reported no complication in their groups after RF^{22,26}. In our groups, 3 (6.8%) of the patients who underwent TURP had hematuria that did not require transfusion, 1 (2.3%) had an indwelling catheter, and 1 (2.3%) had epididymitis complications. No complications were observed in the RF group. The treatment was unsuccessful in 4 (9.5%) of the patients and they could

not get rid of the indwelling catheter. When evaluated in terms of complications, there was no statistically significant difference between the groups ($p = 0.204$). Besides RF, there are also different thermal ablative procedures such as laser ablative therapy, microwave ablation, and cold (cryoablation) that provide the heat required to induce coagulation necrosis. RF system uses alternating electric current, vibrating at high frequency between anode and cathode to agitate tissue ions and produce frictional heat¹⁰. In monopolar systems, the applicator probe works as the cathode and uses grounding pad while in bipolar systems, the electric current is limited to the applicator tip, which contains anode and cathode²⁷. Thus, bipolarity eliminates the side effects of monopolar systems such as skin burns in the contact area of grounding pads and on pacemaker implants^{28,29}. The biggest advantages of the procedure are the absence of the need for general anesthesia, the non-discontinuation of drugs used due to comorbidities, and the absence of hospitalization; also no optical system is required²⁶. It may be a viable treatment option in elderly patients due to the absence of side effects or complications.

The limitations of this study were that the data were obtained retrospectively, the number of patients was small, the follow-up period was only 6 months, and patients in the RF group had higher surgical risks. There is a need for expanded and long-term studies to observe the long-term effect of RF thermotherapy in patients with a high ASA score. However, this study was planned because there are only a few studies in the literature and there is no comparison with TURP.

Conclusion

Overall, RF is a relatively effective and safe technique that may be applied in selected patients with

symptomatic BPH. Although RF significantly improves many uroflowmetry parameters and IPSS scores, it cannot achieve as much efficacy and long-term success as TURP. On the other hand, RF appears to be superior to TURP in terms of associated morbidity, anesthetic requirements, length of hospital stay, and cost-effectiveness.

There are insufficient data in the literature regarding the precise mechanism of action of the technique and other factors involved in the success of the treatment. Comparative studies of RF with other minimally invasive treatments, durability with studies out to greater than at least a few years, and the overall cost-effectiveness ratio of the technique would be of critical importance to determine the exact role of RF in the treatment of symptomatic BPH.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained approval from the Ethics Committee for analysis and publication of routinely acquired clinical data and informed consent was not required for this retrospective observational study.

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