Miscellaneous

Radiofrequency-Induced Thermotherapy in Benign Prostatic Hyperplasia

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ABSTRACT

Introduction: We evaluated the efficacy and safety of radiofrequency-induced thermotherapy of the prostate in patients with benign prostatic hyperplasia (BPH).

Materials and Methods: Radiofrequency-induced thermotherapy of the prostate was performed under local anesthesia in 24 patients (median age, 67 years) with BPH. The International Prostate Symptom Score (IPSS), maximum flow rate, postvoid residual urine volume, and prostate volume were measured preoperatively and 4 months postoperatively.

Results: Nine patients (37.5%) had urinary retention preoperatively. One patient (4.2%) required transurethral resection of the prostate due to retention despite improved symptoms, and 2 (8.3%) needed an α-blocker, postoperatively. The success rate was 87.5% after 4 months follow-up. All patients were catheter-free after the procedure. The mean IPSS decreased from 26.08 ± 3.9 to 13.33 ± 4.69 ($P < .001$), and the mean maximum flow rate increased from 4.63 ± 4.4 mL/s to 13.21 ± 4.28 mL/s ($P < .001$). The mean prostate volume and mean residual urine volume were 46.38 ± 16.8 mL and 160 ± 57 mL, which decreased to 39.6 ± 16 mL ($P = .009$) and 61.46 ± 17.45 mL ($P = .003$), respectively. Fever, dysuria, and perineal pain (in 9 patients; 37.5%) were improved with conservative therapy. Retrograde ejaculation, erectile dysfunction, and urinary incontinence were not reported.

Conclusion: Radiofrequency-induced thermotherapy of the prostate is a new, safe, and effective treatment for BPH. This technique is carried out under local anesthesia and mild sedation with little bleeding. It is especially appropriate for patients who present as high risk for general anesthesia.

KEY WORDS: benign prostatic hyperplasia, radiofrequency, thermotherapy

Introduction

Several different medical and surgical treatments exist for benign prostatic hyperplasia (BPH). One of the minimally invasive procedures for the management of BPH is radiofrequency-induced thermotherapy of prostate (RFITT). By increasing temperature, thermotherapy causes necrosis of the prostate tissue and reduces outlet resistance and prostate volume. The aim is to increase prostate tissue temperature to a range between 60°C and 100°C. Transurethral needle ablation (TUNA) of the prostate is also used. In this procedure, radiofrequency energy with low amplitude waves are applied to the prostate tissue by a special needle, causing localized intraprostatic necrotic lesion.[1-4] The advantage

of TUNA is that it yields a controlled necrotic lesion and can be used under local anesthesia.[1-3]

Following the Food and Drug Administration approval and approval for Medicare coverage, TUNA has gained popularity worldwide.[5]

Technology has had a great role in treatment of urinary stones and has influenced the practice of urology worldwide. It is time to search for minimally invasive procedures instead of transurethral resection of prostate (TURP) for the treatment of BPH. Bipolar RFITT of the prostate is a new procedure that is a variation of TUNA. A bipolar needle with 470-kHz waves is used to create an intraprostatic necrotic lesion. New systems with bipolar electrodes minimize injury to contiguous organs, and transrectal ultrasonography is not required to evaluate the location of the needle tip. Also, the needle tip has a thermometer that continuously shows the central temperature of necrotic cavity.

Few studies regarding this new system exist; therefore, we performed the current study to evaluate the efficacy of RFITT in the treatment of BPH.

Materials and Methods

Between July 2003 and October 2003, 24 patients (median age, 67 years; range, 57 to 78 years) with BPH and severe lower urinary tract symptoms who were to undergo RFITT of the prostate were selected to take part in a nonrandomized prospective study at Hasheminejad Hospital. Inclusion criteria were at least a 3-month duration of symptoms and failed medical therapy with α-blocker drugs. Patients with any evidence of prostatic carcinoma, according to the clinical and laboratory findings, were excluded. All patients had concomitant cardiovascular disease (14 had congestive heart failure and poor exercise tolerance, 6 had chronic obstructive pulmonary disease, and 4 were receiving anticoagulant therapy), which put them at high risk (preoperative American Society of Anesthesiologists classes II and III) for general or regional anesthesia. Therefore, they were not candidates for TURP or open prostatectomy. Patients were informed of alternative treatments, and informed consent was obtained.

Nine patients had urinary retention, and a Foley catheter was placed 3 to 24 days before the procedure. Digital rectal examination and transabdominal ultrasonography of the kidneys, bladder, and prostate were performed for all patients before RFITT of the prostate, and serum prostate-specific antigen (PSA), serum creatinine, postvoid residual urine volume, maximum flow rate, and International Prostate Symptom Score (IPSS) score were measured. Serum PSA was determined by enzyme-linked immunosorbent assay method, and ultrasonography was performed by a single experienced radiologist.

In all patients, RFITT was performed under local anesthesia by lidocaine 2% gel. The bipolar RFITT® (Celon AG, Berlin, Germany) was used. Patients received midazolam during the procedure. A 14-F suprapubic catheter was inserted, and the patient was fixed in a lithotomy position. A cystoscope with a 30-degree lens and a 6-F working channel was used. The RFITT electrode was introduced through the working channel of cystoscope until its tip was seen. Irrigation of bladder was accomplished with dextrose 5% or normal saline during the operation. The tip of the cystoscope was moved from the verumontanum toward the bladder neck, and the electrode was inserted into the prostatic tissue at a 45-degree angle. Puncturing was done only at the 2 o'clock to 4 o'clock and the 8 o'clock to 10 o'clock positions of the lateral lobes. The first puncture was made adjacent to the verumontanum, and the needle was inserted at least to the level of black marks (at 21 mm to 26 mm) on the electrode. Then, the system's power was set at 6 W.

The temperature of the tip of the electrode was monitored. The temperature reached 115°C to 120°C, and then it took 1 minute to 3 minutes for the tissue to be coagulated completely. Afterwards, the electrode was withdrawn and moved 1 cm toward the bladder neck to make another puncture for coagulation. For every 5 g of prostate tissue, 1 puncture was required. In the median lobe, the electrode was inserted directly and coagulation was carried out. The lesion size for every puncture was 20 mm × 10 mm.

After the procedure had been carried out, an 18-F 2-way Foley catheter was inserted in all patients, and they were discharged the following day. Oral cephalexin (500 mg) was prescribed every 6 hours for 3 days. The urethral catheter was removed on the seventh postoperative day, and the suprapubic catheter was removed after a voiding trial, 10 to 14 days postoperatively.

At the fourth postoperative month, the IPSS, prostate volume, postvoid residual urine volume, maximum flow rate, serum PSA, and serum

creatinine levels of the patients were measured and compared with those values before the operation.

Continuous variables are shown as means ± standard deviation, and the paired t test was used to compare them before and after RFITT. A value for *P* less than .05 was considered significant.

Results

The mean serum PSA was 3.23 ± 0.96 ng/mL, preoperatively. Two patients had PSA levels greater than 4 ng/mL, and transrectal ultrasonography-guided biopsy of the prostate was carried out, the pathology results of which demonstrated a benign tumor. This also was found in 1 patient with abnormal digital rectal exam results. The mean IPSS, prostate volume, maximum flow rate, and postvoid residual urine volume were 26.08 ± 3.9, 46.38 ± 16.8 mL, 4.63 ± 4.4 mL/s, and 160.60 ± 57 mL, before the procedure.

The mean number of punctures for each patient was 10.5 ± 3.2. The mean operative time was 25 ± 15 minutes, and the mean volume of irrigation fluid used intraoperatively was 5.6 ± 1.6 L.

The measured parameters 4 months after RFITT are shown in Table 1. The IPSS, prostate volume, and postvoid residual urine volume showed a significant decrease compared with these values before treatment ($P < .001$; $P = .009$; $P = .003$). The maximum flow rate increased remarkably ($P < .001$), but no significant changes were seen in serum PSA and creatinine. All patients were catheter-free 4 months after the treatment. Minor complications were fever (3 patients; 12.5%), dysuria (4 patients; 16.6%), and perineal pain (2 patients; 8.3%) all of which subsided with conservative therapy. Retrograde ejaculation, erectile dysfunction, and urinary incontinence were not seen. One patient among those with preoperative retention required TURP despite the improvement of symptoms. Two patients (8.3%) required an α-blocker postoperatively. The success rate was 87.5% at 4 months follow-up. Bleeding was not remarkable, and bladder irrigation was not necessary after the operation.

Discussion

Transurethral resection of prostate remains the gold standard for treatment of BPH; however, it is probably less attractive from the patient's perspective, especially when minimally invasive techniques with a good tolerability are available.[6] Radiofrequency-induced thermotherapy is a cost-effective and quick procedure with a short hospitalization. Radiofrequency ablation has been utilized in several different clinical applications, ranging from cardiac dysrhythmia to primary and metastatic liver lesions, as well as tumors of the nervous system and bone. Urologists have used this technology to treat BPH through a transurethral approach and to treat prostate cancer through a transperineal approach. Thanks to bipolar RFITT technology, the current flow is confined to the treatment area. The use of a return electrode is not required, making the procedure safer compared to monopolar systems (TUNA). The probe carries an alternating current of high-frequency radio waves that causes the local ions to vibrate, and

Table 1. Measured parameters before and 4 months after RFITT in all patients and those with and without preoperative urinary retention

	Before operation	Four months after operation		
	All patients	All patients	Patients with urinary retention	Patients without urinary retention
Number of patients	24	24	9	15
PSA (ng/mL)	3.23 ± 0.96	3.04 ± 0.91	3.78 ± 1.1	2.61 ± 0.67
Maximum flow rate (mL/s)	4.63 ± 4.4	13.21 ± 4.69	11.67 ± 3.43	14.83 ± 4.88
Prostate volume (mL)	46.38 ± 16.8	39.67 ± 16	33.23 ± 16.83	38.89 ± 15.13
IPSS	26.08 ± 3.9	13.33 ± 4.69	14.11 ± 5.1	13.87 ± 4.47
Postvoid residual urine volume (mL)	160.60 ± 57	61.46 ± 17.45	71.11 ± 21.94	55.67 ± 15.63
Creatinine (mg/dL)	1.3 ± 0.8	1.5 ± 0.9	1.5 ± 0.6	1.4 ± 1.0

PSA: prostate-specific antigen, IPSS: International Prostate Symptom Score

the resistance in the tissue creates heat to the point of desiccation (thermal coagulation). Temperature sensor in the tip of the probe controls applicator placement and the procedure. The real time *3-D-impedance feedback* constantly adjusts the power output to the tissue impedance and takes care of automatic termination of the coagulation procedure (automatic power control). This allows optimal energy deposition combined with a minimized procedure time preventing overdosing and carbonization. Microscopic examination immediately after radiofrequency ablation reveals intense stromal and epithelial edema with marked hypereosinophilia and pyknosis. This is replaced in the matter of days to weeks by coagulative necrosis with concentric zones of inflammatory infiltrate, hemorrhage, and fibrosis.[7] The whole procedure can be performed under local anesthesia. Most of our patients are at high risk to undergo anesthesia because of cardiac or other medical problems. Consequently, radiofrequency ablation is a safe technique for high-risk patients.

Minardi and colleague have recently reported the results of a comparison of TURP with minimally invasive treatments of BPH (transurethral electrovaporization, TUNA, interstitial laser coagulation, and water-induced thermotherapy) in 212 patients. In a 24-month follow-up, they showed that TURP achieved the highest decrease in prostate volume (48.8%), the best increase of maximum flow rate (75.3%), and the highest decrease of residual urine volume (89.8%) compared with the other methods. In addition, a marked decrease of IPSS and quality of life (QOL) scores was observed for all the procedures after 6 months, up to 76.7% for TUNA.[6]

Cimentepe and coworkers have shown that the TUNA procedure, compared with TURP, is an effective and safe, minimally invasive treatment for selected patients with symptomatic BPH. In 2003, they carried out a study on 59 patients older than 40 years with BPH (26 treated with TUNA and 33 with TURP). Improvements in maximum flow rate, prostate volume, IPSS, and QOL score were statistically significant for both groups at 3 and 18 months' follow-up. There were no complications associated with the TUNA procedure, while 16 retrograde ejaculation, 4 erectile impairment, 2 urethral stenosis, and 1 urinary incontinence cases were observed after TURP.[3]

In a study on 26 patients with BPH, the IPSS of the patients decreased from 21.2 to 10.5, and the maximum flow rate increased from 10.9 mL/s to 13.7 mL/s after TUNA.[1] In Hill and colleagues' study of a comparison between TUNA and TURP, 121 men were evaluated (56 underwent TURP and 65 were treated with TUNA). For patients treated with TUNA or TURP, significant improvements from baseline were found for IPSS, postvoid residual urine volume, and maximum flow rate; however, the TURP group reported a 41% retrograde ejaculation, while the TUNA group reported none. The incidence of erectile dysfunction, incontinence, and stricture formation was also greater in patients undergoing TURP than in those undergoing TUNA with significantly fewer adverse events for those treating with TUNA than for those receiving TURP.[4]

In our study, similar results were obtained; significant improvement in IPSS, postvoid residual urine volume, and maximum flow rate were seen after RFITT (48%, 61%, and 220%), although these were relatively lower than those in reported TURP cases. However, owing to the general anesthesia risks, our patients could not benefit from TURP. Besides, no major complications occurred in our series, which is in agreement with other studies' outcomes.

Conclusion

Radiofrequency-induced thermotherapy is a fast procedure with low costs and short hospitalization. It is very useful for patients with BPH who have concomitant cardiac diseases, coagulative disorders, or other medical problems which preclude general or regional anesthesia. The therapeutic results are good with few complications. Radiofrequency-induced thermotherapy is a new variation of TUNA, but is easier to perform with fewer complications and better results. Hence, it can be considered as an alternative in patients with BPH.

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