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## Bipolar prostate thermotherapy for the improvement of chronic prostatitis symptoms and ejaculation problems

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### ABSTRACT

This study aims to evaluate the efficacy of the new bipolar radiofrequency thermotherapy device (TEMPRO) on urinary and sexual functions in patients with chronic prostatitis. Between April 2017 and September 2018, 42 male patients with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) were included. The patients had received at least 6 months of treatment via conventional medical treatments. NIH-Chronic Prostatitis Symptom Index (CPSI), International Index of Erectile Function–Erectile Function part (IIEF-EF), and Premature Ejaculation Profile (PEP). The intravaginal ejaculation latency times (IELT) of the patients were recorded before and 6th months after the procedure. Bipolar radiofrequency thermotherapy was applied with TEMPRO system containing a16Fr applicator. The mean age of the patients was  $42.62 \pm 8.25$  years. All patients were treated with local anesthesia, and three patients were unable to complete the procedure. After 6 months, significant improvements were observed in the NIH-CPSI total ( $20.25$  vs.  $12.18$ ;  $p < .001$ ) and subgroup scores, PEP scores ( $0.98 \pm 1.12$  vs.  $2.06 \pm 1.03$ ;  $p < .001$ ) and IELT ( $68.24 \pm 56.78$  vs.  $103.02 \pm 188.56$ ;  $p < .001$ ). There was no significant difference between IIEF-EF scores. Symptomatic improvement was observed in 78.57% (33/42) of the patients. Bipolar radiofrequency thermotherapy, which is a transurethral method in patients with CP/CPPS, decreases the severity of the disease and improvement of the symptom scores on urinary and sexual function. Additional studies are required to further evaluate treatment effectiveness.

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### Introduction

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS), also known as NIH Category III prostatitis, is a collection of nonspecific symptoms. Despite the absence of uropathogenic bacteria, it is characterized by symptoms such as genitourinary pain, urination and ejaculation and psychosocial disorders [1,2]. It is a prevalent disease that is not well understood. According to the National Institutes of Health (NIH), CP/CPPS is frequently observed among males before fifties [3]. Considering the increasing occurrence percentage, it affects ~50% of men at one point in their lives. Diagnosis of CP/CPPS is made on the basis of persistent pelvic pain for >3 months without any proven infection. In this case, the prostate, perineal, inguinal, scrotal and suprapubic areas may complain of pain and/or discomfort [4].

Despite the increase in the number of affected patients as well as the morbidity, the physiopathology

of CP/CPPS—associated with challenges for several physicians in diagnosis and treatment management—has not yet completely been elucidated [5–8]. Furthermore, there is no standard successful treatment for CP/CPPS. Alternative treatments and multimodal strategies are currently achieving comfortable results for patients [9]. Among these treatments, the heat treatment applied to the prostate gland can support the biological fibrosis process or scar formation in the chronically inflamed area and may shorten the natural course of the inflammation.

The aim of the present study was to assess the effects of bipolar radiofrequency thermotherapy on urinary and sexual functions for patients with CP/CPPS.

### Materials and methods

Male patients aged over 18 years diagnosed with CP between April 2017 and September 2018 were

included in this retrospective study. The patients had received at least 6 months of treatment via conventional medical treatments, such as  $\alpha$ -adrenergic blocker, antibiotics, and/or anti-inflammatory agents, without any symptom improvement.

Institutional ethics committee approval was obtained for the study and written informed consent was obtained from all patients. Following a complete evaluation of medical history, sexual history, and physical examination, the prostate-specific antigen (PSA) level test and digital rectal examination were initially performed to exclude prostate cancer. Two glass test [10] was performed at the beginning and in the 6th month after the procedure. Moreover, the patients were asked to complete the questionnaire forms of NIH-Chronic Prostatitis Symptom Index (CPSI), International Index of Erectile Function–Erectile Function part (IIEF-EF), and Premature Ejaculation Profile (PEP). The intravaginal ejaculation latency times (IELT) of the patients were recorded.

CPSI consists of 13 items categorized as three subgroups—pain (location, frequency, and severity), urinary discharge (irritative and obstructive symptoms), and the quality of life—that are scored with points [11,12]. The clinical importance of NIH-CPSI in the evaluation and monitoring of patients in general urologic applications has been proven. In the evaluation of the treatment results, a 6-point decrease from the total score at the beginning is typically accepted as a “positive treatment response” [13].

The evaluation of erectile function was based on IIEF-EF, a six-question questionnaire [14,15]. The erectile dysfunction-related areas in the scale include the 1st, 2nd, 3rd, 4th, 5th, and 15th questions. These questions classify the level of erectile dysfunction as mild, moderate, or severe.

PEP is a 4-item self-administered questionnaire (with each item assessed on a 5-point response scale) that is designed for evaluating the key elements of premature ejaculation (PE), i.e. control, distress, interpersonal difficulty, and sexual satisfaction [16,17] Tempro Radiofrequency Thermotherapy Procedure An oral NSAID (dexketoprofen 25 mg) was administered to the patients 2 h before the procedure. Tempro was applied using a special 16-Fr Foley applicator catheter, with 6 ring electrodes. The system computer directs the bipolar radiofrequency energy distribution to the prostate via the use of feedback from the three temperature sensors. Local anesthetic gel was intraurethally applied prior to catheter placement. Treatment protocol was performed at 45.0–55.0 °C for 1 h, without any cooling procedures. Due to the use of bipolar

radiofrequency, the heat was concentrated in a small cylinder surrounding the urethra, thus eliminating the need for a rectal probe.

For the localized treatment involving the application of energy to different electrodes of the catheter, the treatment area was selected according to the prostatic urethral length measured using the transabdominal ultrasound. In addition, ultrasonography was used to measure prostate volume of the patients.

The patients were evaluated on the 6th month after the procedure using the NIH-CPSI, IIEF-EF, and PEP questionnaire forms. The observation of >50% decrease in the symptoms was considered as an indication of treatment success.

### Statistical analysis

Statistical analyses were performed using SPSS 21.0 (IBM, Chicago, USA). One sample Kolmogorov–Smirnov test was used to determine the compatibility of the variables with normal distribution. Variables showing normal distribution were shown as mean  $\pm$  standard deviation. Paired-sample *t*-test, Wilcoxon test, independent sample *t*-test, and Mann–Whitney *U* test were used for the statistical analysis. A value of  $p < .05$  was considered statistically significant.

### Results

Overall, 42 patients with CP were included, and the patients were treated in a single session using bipolar radiofrequency thermotherapy performed as an in-office procedure. The procedure was successfully completed in all patients owing to the small diameter of the Foley catheter as well as the smooth and painless nature of the process.

Mean patient age was  $42.62 \pm 8.25$  (range: 35–53), whereas mean PSA value was  $1.12 \pm 0.46$ . Mean prostate volume was  $25.32 \pm 12.34$  ml, and mean prostatic urethral length was  $2.92 \pm 1.25$  cm. The most common complaints reported were urination symptoms and pain (Table 1).

Mean scores decreased in all three subgroups of the NIH-CPSI following the procedure: it decreased from 20.25 to 12.18 for the total score, from 9.18 to 4.03 for the pain subgroup, from 5.34 to 3.03 for urinary symptoms, and from 5.82 to 3.1 for the quality of life (Table 2).

Although there was no significant difference in the IIEF-EF scores of the patients obtained at the 6-month follow-up, significant improvements were observed in the PEP total scores and IELT (Table 3).

**Table 1.** Patient characteristics.

	Mean $\pm$ SD	Range
Age (years)	42.62 $\pm$ 8.25	35–53
PSA (ng/ml)	1.12 $\pm$ 0.46	0.81–3.32
Prostate volume (ml)	25.32 $\pm$ 12.34	18–41
Urethral length (cm)	2.92 $\pm$ 1.25	1.18–3.37

**Table 2.** Comparison of symptom scores of patients.

NIH-CPSI (N = 42)	Preop	Postop	<i>p</i>
Pain	9.18 $\pm$ 2.21	4.03 $\pm$ 1.01	<.001
Urinary	5.34 $\pm$ 0.86	3.03 $\pm$ 0.92	.001
QoL	5.82 $\pm$ 1.23	3.10 $\pm$ 0.75	<.001
Total	20.25 $\pm$ 2.56	12.18 $\pm$ 1.87	<.001

Paired *t*-test was used.

**Table 3.** Erectile and ejaculation changes of patients.

	Preop	Postop	<i>p</i>
IIEF-EF	23.31 $\pm$ 5.11	24.02 $\pm$ 4.86	>.05
PEP-Total	0.98 $\pm$ 1.12	2.06 $\pm$ 1.03	<.001
IELT	68.24 $\pm$ 56.78	103.02 $\pm$ 188.56	<.001

IIEF-EF: International Index of Erectile Function; PEP: Premature Ejaculation Profile; IELT: Intravaginal Ejaculation Latency Time. Paired *t*-test was used.

No side effects were reported throughout the follow-up period. Based on the follow-up examinations, symptomatic improvement was observed in 78.57% (33/42) of the patients.

## Discussion

In the present retrospective study, we determined that bipolar radiofrequency thermotherapy decreased the symptom scores of patients with CP and significant improvements were observed in ejaculation control and IELT despite the absence of any effects on erectile functions. There were no adverse events reported during the procedure and subsequent follow-up period.

Prostatitis is a common urological disease, and urologists in the United States have been reported to have about 5% of patients with prostate inflammatory diseases [18]. The disease is classified according to four categories as acute bacterial prostatitis, chronic bacterial prostatitis, CP/CPPS, and asymptomatic inflammatory prostatitis. The third category of CP/CPPS disease accounts for about 90% of all CP patients. This condition is clinically present with chronic pain in the perineum, rectum, penis, testis, and abdomen [19]. It is typically accompanied by storage or voiding symptoms, such as weak stream and intermittent and frequent urination. The symptoms typically remain stable or slightly decrease over time, but some symptoms may remain persistent for months [20,21].

For patients with CP/CPPS, treatment is initiated with antimicrobial or anti-inflammatory medications.

Moreover, it is observed during follow-up period that the pain persists despite the lack of any proven infection. Urologists have difficulty treating advanced CP/CPPS patients, and options at the start of treatment may not be effective when the condition becomes chronically [22]. In addition, sexual issues, such as erectile dysfunction and PE, can be observed in these patients [23]. The inflammation in the prostate can be responsible for the excessive stimulation of the ejaculation reflex [24].

Among the various strategies suggested for treating CP/CPPS, thermal treatment appears as a promising approach that is reported to clinically decrease pain and symptoms in patients with weak response to standard treatments. In the treatment approaches that have been used to date, overall improvements have been reported using thermal therapy in terms of both objective and subjective evaluations [25]. Thermal therapy can alter afferent nerve fibers which are effective in the transmission of pain caused by inflammation in the prostate gland. Perachino et al. [26] claimed that transurethral thermotherapy induces long-term alpha blockade.

Prostate cells are not completely affected up to temperatures of 45 °C [27]. Therefore, the coagulation necrosis occurring with cell death begins at temperatures >45 °C. Rapid thermoablation occurs when the temperature is increased above 60 °C [28]. The term thermotherapy is used for temperatures >45 °C, whereas the term hyperthermia is used for temperatures below this value [29,30].

There are certain advantages to the Temproware system. The fundamental principle of the system is similar to that of transurethral needle ablation. The objective is prostate tissue ablation and coagulation necrosis via the applicator and specially designed urethral catheter with six heat rings at the end that are both placed in the prostatic urethra. As it does not require anesthesia or a transrectal probe, and as it can be applied as an in-office procedure, it is considered as an appropriate treatment option, particularly for geriatric patients with comorbidities as well as for patients who desire to avoid the possible complications of the standard treatment TUR-P. It differs from the other minimally invasive treatment methods of TUNA and TUMT in terms of the method's application using a simple urinary catheter and easier placement as well as its ability to treat prostates of all sizes using a single catheter independent of the prostate size.

There were some limitations to the present study, the first being the absence of a control group. Measurement of the prostatic urethral length in

patients using a noninvasive method could be considered as another limitation. Finally, the absence of long-term results due to the short follow-up period of 6 months was another limitation.

Bipolar radiofrequency thermotherapy performed for patients with chronic prostatitis is a safe and effective strategy that ensured both an improvement in the symptom scores and increase in the IELT of the patients. The procedure is recommended as one of the treatment options owing to fewer complications observed compared with other surgical treatments, ease of application with local anesthesia, and the fact that it is safe. Additional studies are required to further evaluate the treatment effectiveness.

### Disclosure statement

No potential conflict of interest was reported by the authors.

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