

Tempro

Bipolar RF Thermotherapy for BPH Clinical Data and Reports



September 2019

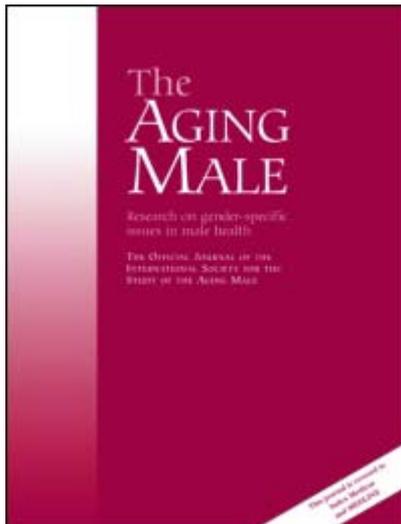
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Table of Contents

Bipolar prostate thermotherapy for the improvement of chronic Prostatitis symptoms and ejaculation problems	3
Mehmet Akif Diri & Murat Gul	
The Aging Male, ISSN: 1368-5538 (Print) 1473-0790 (Online) Journal homepage: https://www.tandfonline.com/loi/itam20	
Efficacy of Bipolar RF Thermotherapy in BPH Treatment	4
Shumoff Sergey, Karapetyan Alexander, Mirkin Yakov	
LUTD congress, Brussels, 2014	
Clinical Experience with Direx Tempro System in the Treatment of the Lower Urinary Tract Symptoms, Following BPH Using Radio Frequency	6
Martín Bazaco, Jesus; Acha Perez, Marks; Padilla Snows, Jesus; Villafruela Mateos, Ainara; Llarena Ibarguren, Robert; Pertusa Rock	
25th World Congress of Endourology, Cancun, 2007	
A New Transurethral Bipolar Radio Frequency Device for BPH Thermal Treatment One Year Follow Up	9
Christian Beck	
28th Societe Internationale D'Urologie Congress, Cape Town, 2006	
Initial Experience with Tempro Treatment for BPH Patients in Italy	9
Maurizio Turriziani, Francesco Esta, A Cupini, A Cefaloni	
24th World Congress of Endourology, Cleveland, Ohio, 2006	
Initial Experience with TEMPRO® - A Novel Bipolar RF Thermal Treatment for BPH	13
C. Beck	
22 nd World Congress on Endourology, Mumbai, 2004	

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

Mehmet Akif Diri & Murat Gul



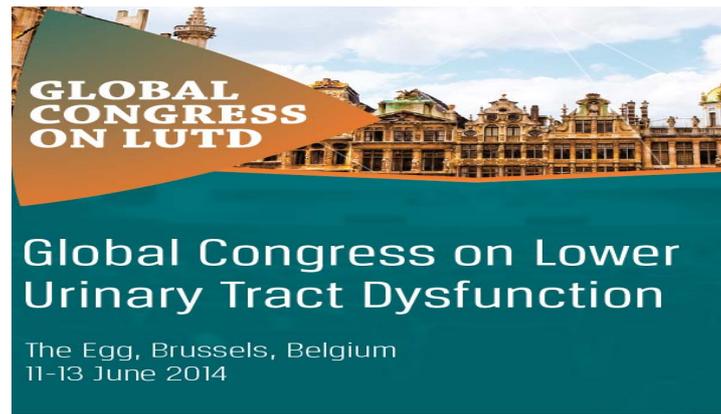
The Aging Male

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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 ± 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 ± 1.12 vs. 2.06 ± 1.03 ; $p < .001$) and IELT (68.24 ± 56.78 vs. 103.02 ± 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.

Efficacy of Bipolar RF Thermotherapy in BPH Treatment

Shumoff Sergey, Karapetyan Alexander, Mirkin Yakov, Urology, URO-PRO Clinics, Krasnodar, Russian Federation



Introduction

Although TURP still remains the "gold standard" in surgical treatment of BPH, urologists and patients are looking for less invasive, outpatient procedures for reducing prostate's size and lower urinary tract symptoms. Such procedures were developed as TUNA, microwave therapy, botulinic toxins or alcohol injections.

In our clinic we've decided to use bipolar-radiofrequency thermotherapy and evaluated the efficacy of this method.

Material & Methods

35 patients were included in this study with ages of 53-76 years.

Average prostate volume was: 52.15 cm³ (33.80-81.40)

Qmax: 9.19 ml/sec (4.40–13.10 ml/s)

PVR: 51.43 ml (0-100 ml)

All patients filled IPSS questionnaire, but we didn't include it in study's protocol, because the IPSS mainly reflects subjective feeling of patients.

Exclusion criteria were: prostate cancer, prostate's volume more than 90 cm³, PVR more than 100 ml.

All patients underwent bipolar-RF thermotherapy with temperature 48-53 C during 1 hour.

Unfortunately, we didn't create a "sham group", because it's difficult to simulate

sensation of thermotherapy.

The follow-up period was 6 months.

Results

Prostate volume (cm³): before- 52.15; 6 months after- 41.53*

Qmax (ml/s): before- 9.19; after- 14.31*

PVR (ml): before- 51.43; after- 20.57*

*p<0.01

The main complication was AUR that indicated permanent catheterization within 24-72 hours.

Conclusions

Certainly, bipolar-RF thermotherapy couldn't compete with TURP, but it could be a solution for patients who have contraindications for surgery or are afraid of it.

Now we are performing a multicenter trial with thermotherapy of BPH and going to present results in 2015.



Clinical Experience with Direx Tempo System in the Treatment of the Lower Urinary Tract Symptoms, Following BPH Using Radio Frequency

Martín Bazaco, Jesus; Acha Perez, Marks; Padilla Snows, Jesus; Villafruela Mateos, Ainara; Llarena Iburguren, Robert; Pertusa Rock, Department of Urology, Carlos Hospital de Cruces, Bilbao, Vizcaya

This paper was presented at the World Congress of Endourology 2007, Cancun, Mexico.

Introduction

Although the TURP is considered the gold standard for surgical treatment of BPH, new minimally invasive therapies alternatives, are being developed to alleviate the BPH symptoms while reducing the risks. The Direx Tempo© provides a thermotherapy treatment, by means of Bipolar Radio Frequency waves of energy, delivering them through a special 16 FR catheter, with electrode rings placed in the prostatic urethra.

Materials and Methods

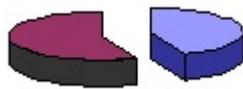
Between May of 2005 and May of 2007, we used the Direx Tempo Radio Frequency system to treat 75 patients, ages ranging between 59 and 93 years, (average 75 years), with significant BPH pathology. The exclusion criteria were patients who presented large Median Lobe and those whose Prostatic urethra length was bigger than 49mm. The treatment consisted of a single session of 60 minutes at a temperature of 55°C. The treatment is ambulatory, requiring only intra-urethral local anesthesia. The volume of the prostates ranges was between 20 and 70cm³ (with an average of 39cm³) and with a Prostatic urethral length ranging between 20mm and 48mm (average was 35mm).

Two group of patients were treated:

A) Patients with symptomatic BPH that are considered moderate to high surgical risk with an average IPSS of 21 and a Qmax Flow average of 8,4 ml/sec.

B) Patients with Acute Urinary Retention in which the Indwelling Catheter can not be avoided.

Total Number of Patients Treated with Tempro R.F. (n=75)



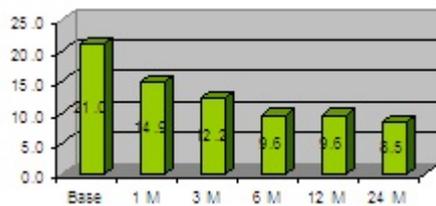
■ Patients with Accute urinary Retention
 ■ Patients with Symptoms BPH

Results

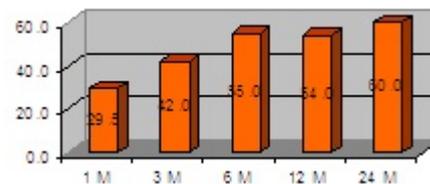
The evaluation of the clinical results included: the-IPSS (International Prostate Symptom Score) and the Maximum Flow (Qmax), tested at 1 month, 3 months, 6 months, 1 year and 2 years follow up.

A) Patients with symptomatic BPH:

ISPP as a Function of Time Post Treatment

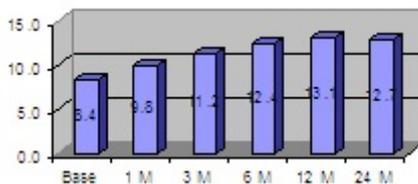


ISPP% Improvement

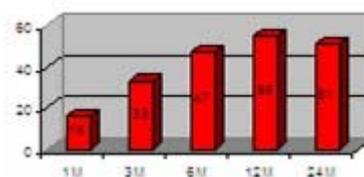


With a follow up range between 1 and 24 months (average of 13 months), we have seen a reduction in IPSS score of 50% and this is maintained during the follow period.

Q Max Post Treatment



Q Max Improvement



Regarding the Maximum Flow, we have seen a continuous increase up to 50%. This improvement was maintained during the whole follow up period.

B) Patients with Acute Urinary Retention:

We obtained a success rate of 72%, eliminating the indwelling catheter and with negative Post- Void Residuals (PVR) with a follow up range of 1 to-24 month an average follow of 13 months.

Complications

The complications were mild: 58% of the patients had temporary urinary irritation, which was perfectly controlled with anti-inflammatory alpha-blockers drugs. Transitory Acute Retention in 9.5% of the cases and initial hematuria in 20% of the patients.

Conclusion

The TEMPRO[®] treatment has been effective in both groups of patients, with a low complication rate and practically with secondary side effects, therefore very advantageous for the treatment of aged patients and patients with serious BPH symptoms. These initial results are very promising. Additional studies are being made to evaluate the long-term effectiveness of this method.



A New Transurethral Bipolar Radio Frequency Device for BPH Thermal Treatment One Year Follow Up

Dr. C. Beck; Institute for Thermotherapy; Dortmund, Germany

This paper was presented at the Societe Internationale D'Urologie Congress, 2006, Cape Town, South Africa.

Introduction

Several minimally invasive systems are being offered to the urologist to treat BPH. They include Thermal therapy using Microwave, Monopolar Radio Frequency (T.U.N.A.) and recently a Bipolar Radio Frequency (T.U.R.F.) system called TEMPRO.

The purpose of the study was to assess the safety and efficacy of the new Tempro device. In the past I presented my initial experience, with a 3 month follow up elsewhere (WCE).

Methods

The Tempro uses a special 16 Fr Foley applicator catheter with 6 ring electrodes. The system computer controls the Bipolar RF energy delivery to the prostate using feedback from 3 temperature sensors. Treatment protocols were 55.0 C, 1 hour and recently 60.0 C /15 minutes without cooling. Due to the use of Bipolar RF, the heat is concentrated in a small cylinder around the urethra, thereby not requiring a rectal probe.

Results

During the last 18 months, a total of 105 patients were treated with this new system. The inclusion criteria were as follows: patients with a high level of BPH symptoms, (IPSS score >20), moderate Qmax flow (range 6 to 14 ml/sec) and bad Quality of life. Out of the 105 patients I am reporting the results of the first 30 patients, which have completed at least one year, follow up.

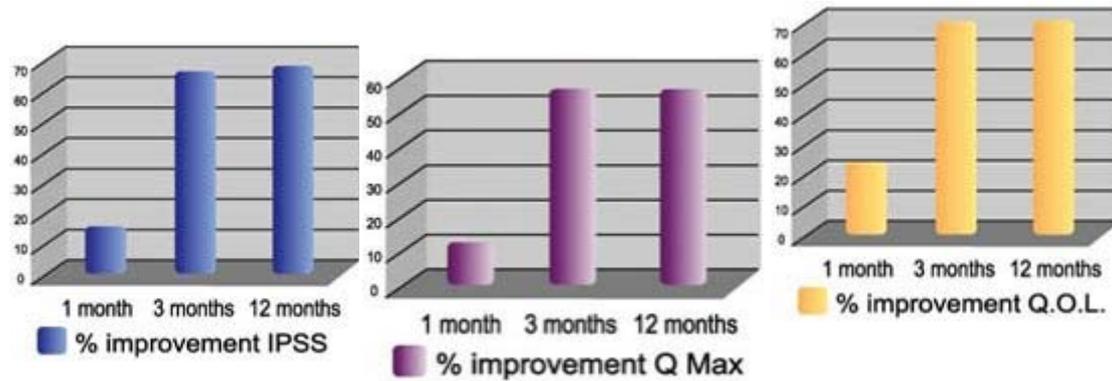
The 3 previous parameters were tested at Baseline (BL), 1 month (1M), 3 months

Bipolar RF Thermotherapy– Clinical Data and reports



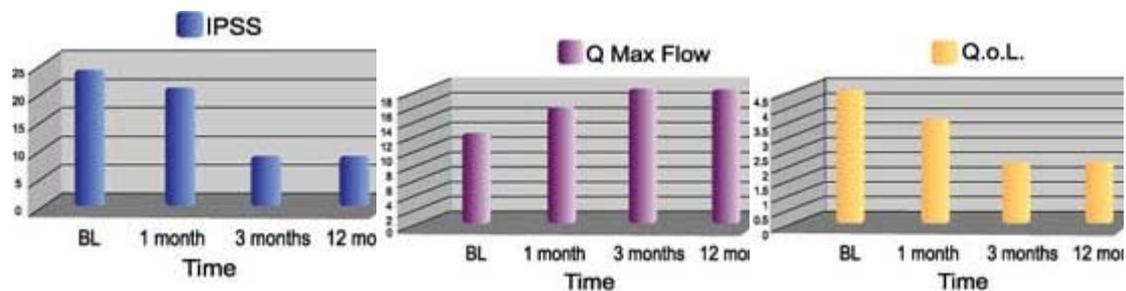
(3M) and 1 year (1YR) or more with the following average and standard deviation results (in brackets).

IPSS	BL=23.2(3.7)	1M=20.2(7.3)	3M=8.5(4.7)	1YR=8.2(3.0)
QMax	BL=11.4(2.8)	1M=12.5(2.6)	3M=17.4(3.3)	1YR=17.5(2.5)
Qol	BL=4.3(0.8)	1M=3.4(1.1)	3M=1.5(0.7)	1YR=1.5(0.5)



The average of absolute % of improvement compared to baseline is as follows:

IPSS	1M=12.9%	3M=63.6%	1YR =64.7%
QMax	1M= 9.5%	3M=53.1%	1YR =53.2%
Qol	1M= 20.9%	3M=66.2%	1YR = 65.3%



The treatment was well tolerated by all patients, and no treatment had to be discontinued due to pain. Analgesia used was a small dose of Tramadol drops. The only side effect was a small percentage of Post Treatment catheterization for 2-4 days.

Conclusion

In my experience the Temprow treatment seems to be safe and effective, and provides an important tool to treat BPH symptomatic patients. Optimal results were reached at 3 months and maintained after one year. These results are encouraging. Additional studies are required to establish the long term effectiveness of this treatment.



Initial Experience with Tempro Treatment for BPH Patients in Italy

Maurizio Turriziani, Francesco Esta, A Cupini, A Cefaloni, "Umberto I" Hospital Frosinone Italy.

This paper was presented at the 24th World Congress of Endourology, August 2006, Cleveland Ohio, U.S.A.

Introduction

Tempo treatment is a new method to treat BPH symptomatic patients. From November 2005, we started to treat 2 types of patients:

- a) High Surgical Risk patients and
- b) Patients with moderate to severe BPH symptoms

Method

The Tempo system uses a special Applicator based on a 16 FR Foley catheter, with ring electrodes which are connected to a Bipolar RF source. We have treated 30 patients with ages 69 to 95 years. Ten patients were High Surgical Risk (ASA IV) with indwelling catheter and 20 patients had moderate to severe BPH symptoms. Ultrasound was used to evaluate the prostatic urethra length, residual volume and also to exclude Median Lobe patients. Uroflow test were performed pre and 2-3 month after treatment. Patients were treated at a target temperature of 55 Degrees C for 1 hour. Twenty eight patients tolerated well the treatment and 2 required pain killers during the treatment.

Results

The patients with indwelling catheters were left with a catheter for 2-3 weeks. After catheter removal, in 6 out of 10 (60%), the treatment was successful (urinating spontaneously). Four patients failed: 2 underwent TURP, and 2 are with indwelling catheter. Regarding the 20 symptomatic patients, 14 (70%) had an average Qmax improvement of 55 % at 2-3 months. Two improved slightly and 4 remained unchanged.

Conclusion

Our initial results show that the Bipolar RF Temprow treatment seems to be a very advantageous treatment for indwelling catheter patients as well as for BPH symptomatic patients.

Initial Experience with TEMPRO® - A Novel Bipolar RF Thermal Treatment for BPH

C. Beck, Dortmund, Germany

This paper was presented at the 22nd World Congress on Endourology, November, 2004, Mumbai, India.

Introduction

A new Radiofrequency Thermotherapy device for BPH treatment has been developed for transurethral bipolar applications. In this abstract I present my initial clinical experience with this device.

Tempro is a RF device consisting of an Applicator and Computer Console. The Bipolar RF energy is applied through the applicator composed of special 16 Fr Foley Catheter with 6 ring electrodes. Energy is delivered to various combinations of ring pairs; allow distributing heat for different prostate sizes and volumes.

Materials and Methods:

30 patients with BPH symptoms were treated for 1 hour with a uniform “Cylindrical” heat pattern. Pre- and post treatment control was performed and filed using IPSS and QoL questionnaires, TRUS and PSA diagnostics.

Results:

The treated group with the Tempro had a urine flow improvement that was superior compared to improvement with a Monopolar device after 3 months.

Average	Pre Treatment	1 month follow up	3 months follow up
<i>Prostate Volume (Average)</i>	40 grs	38 grs	32 grs
<i>Max Flow</i>	11 ml/s	12,5 ml/s	17,7 ml/s
<i>Residual Volume</i>	110 ml	95 ml	50 ml
<i>IPSS</i>	20	17	9
<i>Qol</i>	5	4	2

Complications:

Treatment was well tolerated by 27 out of 30 patients (90%). All patients released after the treatment without indwelling catheter. Afterward 6 out of 30 patients required a catheter for 2-4 days (20%). No Serious complications were recorded.

Conclusions:

The Tempro treatment seems safe and effective. Nocturia and Frequency of urination rates decreased. In addition the possibility of adapting the heating volume for different prostates sizes is very advantageous.

Additional heating patterns will be investigated in future. Further experience and follow up is needed to fully evaluate the potential of this device. The Optimal results and minimum indwelling catheter post treatment are encouraging.