

Tempro

Bipolar RF Thermotherapy for BPH and Prostatitis Clinical Data and Reports



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A. BPH Clinical Data and Reviews

Efficacy of Bipolar RF Thermotherapy in BPH Treatment

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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)

Q_{max}: 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 Temporo 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 Temporo[®] 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 Temporo 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 Temporo R.F. (n=75)



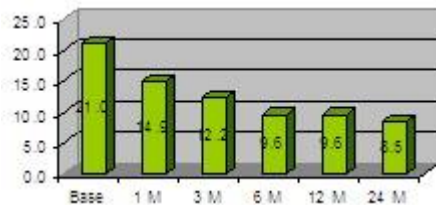
■ Patients with Accute urinary Retention
 ■ Patients with Symptoms BPH

Results

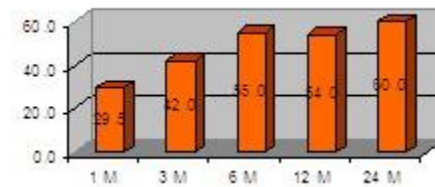
The evaluation of the clinical results included: the-IPSS (International Prostate Symptom Score) and the Maximum Flow (Qmax), tested at 1 month, 3 months, 6 months, 1 year and 2 years follow up.

A) Patients with symptomatic BPH:

ISPP as a Function of Time Post Treatment

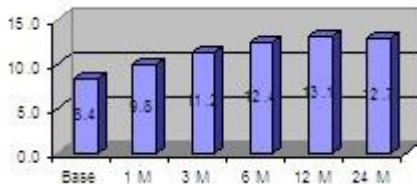


ISPP% Improvement

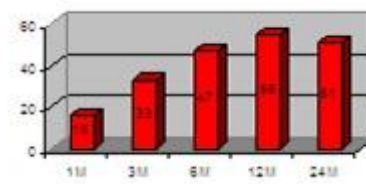


With a follow up range between 1 and 24 months (average of 13 months), we have seen a reduction in IPSS score of 50% and this is maintained during the follow period.

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

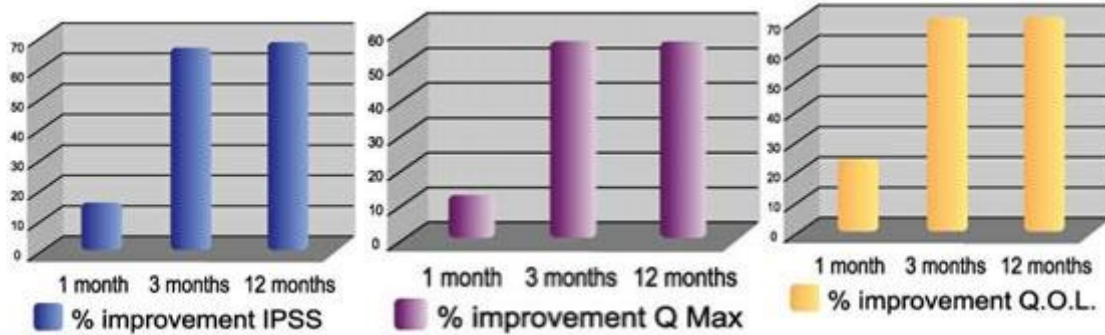
The Tempro uses a special 16 Fr Foley applicator catheter with 6 ring electrodes. The system computer controls the Bipolar RF energy delivery to the prostate using feedback from 3 temperature sensors. Treatment protocols were 55.0 C, 1 hour and recently 60.0 C /15 minutes without cooling. Due to the 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.

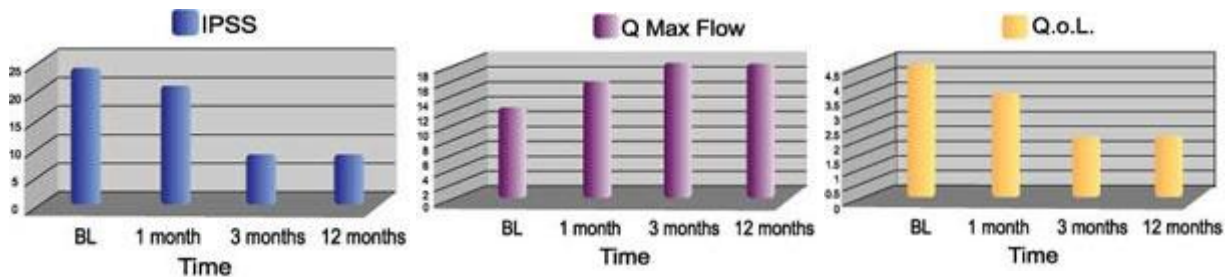
The 3 previous parameters were tested at Baseline (BL), 1 month (1M), 3 months (3M) and 1 year (1YR) or more with the following average and standard deviation results (in brackets).

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

Tempro 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 Tempro 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.

Tempo 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 Tempo 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.

B. Prostatitis Clinical Data and Reviews

Transurethral TEMPRO bipolar radio frequency (RF) for the treatment of chronic abacterial prostatitis/ chronic pelvic pain syndrome (CP/CPPS)

Hong Woo Rhee, MD., Jun Sik Shin, MD., Zai Urology Hospital, Seoul, Korea.

Introduction and Objectives

Chronic abacterial prostatitis/chronic pelvic pain syndrome (NIH category IIIa,b) has been a challenging issue in outpatient urological practice. Although there are several kinds of medical and 2nd line therapies including thermal therapy, patients with CP/CPPS do not satisfy to eradicate or minimize the symptoms, especially pain domain. We evaluate a new bipolar RF thermal therapy to treat CP/CPPS and report our results of 431 patients after at least 3 months follow-up.

Materials and Methods

We used the *Tempo* bipolar RF system with a treatment protocol of 55° C for 50 min. to 71 CP/CPPS patients (high temperature group), and then 360 patients were treated under the condition of 45°C for 60 min. without cooling (low temperature group). All the patients undergoing bipolar RF therapy were initially treated with 1st line classic regimen-ciprofloxacin, alpha blocker, NSAID- for more than 2 weeks and did not respond to improve CPSI score, especially pain domain. We evaluated the symptom improvement according to RF treatment protocol by NIH-CPSI score.

Results

Table 1. Baseline characteristics of CP/CPPS patients

	High temp. group	Low temp. group
No. of pts. (n)	71	360
Age (yrs)	42.5 ± 11.4	39.1 ± 9.6
Prostate vol.(gm)	28.4 ± 8.3.	29.6 ± 7.3
NIH category (n)		
IIIa	41(57.7%)	221(61.4%)
IIIb	30(42.3%)	139(38.6%)

Most bothersome Sx.(n)		
pelvic pain (perineal, testicular, penis tip, pubic or bladder)	49(69.0%)	259(71.9%)
urination assoc. pain	16(22.5%)	78(21.6%)
ejaculation assoc. pain	6(8.5%)	23(6.4%)

Table 2. Side effects of bipolar RF therapy on CP/CPPS according to RF protocol

	High temp. group	Low temp. group	p-value
Urine retention (%)	21 (29.6%)	9 (2.5%)	0.019*
Gross hematuria (%)	16 (22.5%)	31 (8.6%)	0.067
Frequency/Urgency (%)	18 (25.4%)	68 (18.9%)	0.325
UTI/Epididymitis (%)	2 (2.8%)	9 (2.5%)	-

*: significant difference (P<0.05)

Table 3. Results of bipolar RF efficacy on the CPSI score

	Pre-RF CPSI score		Post-RF CPSI score		p-value
	High temp. group	Low temp. group	High temp. group	Low temp. group	
Total CPSI	24.1 ± 7.6	26.4 ± 6.9	16.2 ± 5.1	16.7 ± 4.8	0.074
Pain domain	12.1 ± 4.9	13.2 ± 5.1	6.3 ± 3.2	6.1 ± 4.1	0.041*
Urination domain	5.6 ± 3.2	6.1 ± 3.7	5.2 ± 2.7	5.7 ± 2.6	0.793
QoL domain	6.7 ± 2.3	6.9 ± 2.5	4.5 ± 1.9	4.3 ± 1.8	0.146 -

*: significant difference (P<0.05)

Table 4. Overall Success rate of bipolar RF therapy on CP/CPPS

	High temp. group	Low temp. group	p-value
Total CPSI score	45.1% (32/71)	47.5% (171/360)	0.724
Pain domain score	63.4% (45/71)	66.9% (241/360)	0.575

Overall clinical success: More than 50% reductions in CPSI score at 3 months after *Tempro* bipolar RF therapy.

Conclusion

The *Tempo* bipolar RF therapy to CP/CPSS seems to be simple and effective, especially reduction of CP/CPSS-associated pain. A low temperature protocol of RF is as effective as high temperature RF and has the minimal side effects. Additional long term follow-up and large clinical trials are required to evaluate the therapeutic potential of bipolar RF therapy for CP/CPSS.