

# Initial Experience with Tempro Treatment for BPH Patients in Italy

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"Umberto I" Hospital Frosinone, Italy, the study was presented on the 24th World Congress of Endourology

## Introduction

Minimally Invasive procedures are continuously developed to treat BPH. We are reporting here our Initial experience with the Tempro, a new Thermal Treatment device using heat to coagulate selectively a volume of tissue surrounding the Prostatic Urethra. Some devices using Microwave energy as a source of heat (T.U.M.T.) are available in the market for several years. The Tempro uses a unique technology of Bipolar Radio Frequency energy (T.U.R.F.) with some specific advantages. The purpose of the study was to assess the safety and efficacy of the Tempro treatment for 2 types of patients:

- A) High Surgical Risk patients
- B) Patients with moderate to severe BPH symptoms

## Material and Methods

The Tempro system uses a unique Applicator based on a 16 FR Foley catheter, with 6 ring electrodes which are connected to a Bipolar RF source. The Bipolar source can be connected by the Controlling computer to different rings, so as to adapt the heating volume to the Prostatic Urethra Length, previously measured by TRUS. Between November 2005 and March 2006 we have treated 30 patients, with average age of 72 years (range 69 to 95) the 2 categories mentioned. Transrectal Ultrasound was used to evaluate the Prostatic Urethra Length, residual volume and also to exclude Median Lobe patients. Uroflow tests were performed, pre and 2-3 month post treatment, for the patients with moderate to severe patients' BPH symptoms. The treatment procedure is easily performed and consists of inserting the Applicator - similar to the insertion of a simple Foley Catheter. Due to the use of Radio Frequency, there is no need for a Rectal Probe. All patients were treated at a target temperature of 55 Degrees C for 1 hour.



## Results

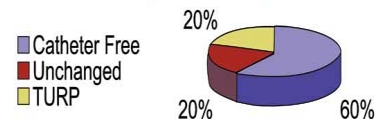
The results in different groups were as follows:

1) Efficacy-Category A - High Surgical Risk Patients

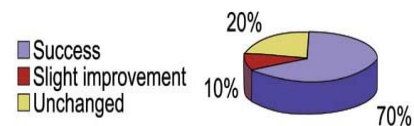
Ten patients with indwelling catheter, who were High Surgical Risk as defined by the American Society of Anesthesiology (ASA) category IV were treated. The patients were left with a catheter for 2 to 3 weeks. After catheter removal, in 6 out of 10 (60%), the treatment was successful with patients urinating spontaneously. In 4 patients the treatment did not succeed:

- A) Two patients underwent TURP
- B) Two patients were again with the indwelling catheter

### Tempro Treatment Indwelling catheter patients



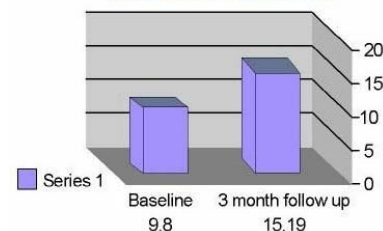
### Q Max Flow Improvement



2) Category B-Patients with moderate to severe BPH symptoms

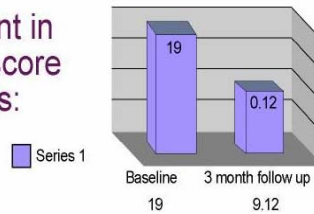
We treated 20 patients in this category. Efficacy was measured by success of improvement in IPSS symptom Score, Qmax Flow and Quality of life. Regarding the improvement in Qmax flow, 70% of patients were responders with an average improvement of 55% in Q Max. as follows:

### Q Max ml/sec



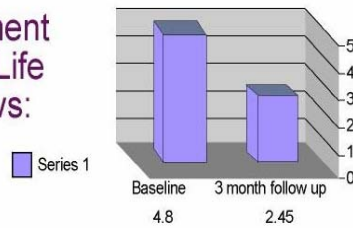
## IPSS

The improvement in IPSS symptom score was as follows:



## Quality of Life

The improvement on Quality of Life was as follows:



## Safety/Complications

The treatment was well tolerated by 28 patients, and only 2 patients required pain-killers during treatment. From category B patients, 2 (10%) required an indwelling catheter for 3-4 days. No serious complications were reported

## Conclusions

Although ours is a small series, these initial results are very encouraging. The Tempro treatment being a Minimally Invasive procedure seems to be a very advantageous treatment for indwelling catheter patients as well as for BPH symptomatic patients. Further studies are required to assess this new technology more in depth.