

Initial Clinical experience using Direx Tempro Bipolar Radiofrequency Thermotherapy system to treat L.U.T.S in BPH patients

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Introduction and Objectives

Minimally Invasive devices for BPH treatments are being offered nowadays. The Direx Tempro is a new Thermotherapy device using a small 16 FR catheter to deliver Bipolar Radiofrequency to the Prostate. The objective of the study was to evaluate the safety and efficacy in 2 types of patients:

- A) Patients with moderate BPH LUTS.
- B) Surgical Risk patients with Indwelling Catheter.

During the last 20 months (February 2005 to October 2006), we have treated 44 patients with the Direx Tempro system. Patients belonged to one the a/m categories with ages ranging from 61 to 88 years (average 74 years).

We excluded patients with Median Lobe and/or Prostatic Urethra length above 49 mm.

The treatment was performed in a 1-hour session at a temperature of 55° C. They were done ambulatory and there was no need for anesthesia, except for local transurethral Lidocaine gel.

- A) Patients in this category had the following baseline average values: IPSS: 24, Qmax Flow: 8.8 ml/sec., and Quality of Life: 4.5.
- B) 16 Patients with indwelling catheter were treated

Results

Category A

The average results and improvements at one-year follow-up are present in the table:

	Pre-treatment	1 year follow-up	The average of absolute % improvement
Max Flow rate (Qmax)	8.8 ml/s	11.2 ml/sec	27 %
IPSS score	24	12.3	49 %
QOL (quality of life)	4.5	1.71	62 %

Side effects were the following: indwelling catheter-13.6%, mild hematuria – 20% and mild temporary irritative symptoms – 58%.

Category B

16 patients with the indwelling catheters presented this group. More than 2/3 of patients (68.75%) are catheter free with minimal residual volume for an average of 9.8 months.

Conclusions

The Tempro treatment seems to be very effective for both categories of patients, with minimal side effects and no serious complications.

The initial results of the study are very encouraging. Additional studies have to be performed to evaluate the long-term effectiveness of this promissory treatment