

THE EFFICACY OF TRANSURETHRAL INTERSTITIAL MICROWAVE HYPERTERMIA
IN THE MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA

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Fifteen patients received transurethral interstitial microwave hyperthermia for Benign Prostatic Hyperplasia according to an FDA IDE Study. At thirty and sixty day evaluations, patients reported subjective improvement in voiding pattern, urinary flow rates were increased and residual volume decreased. Thermal mapping indicates adequate heating of the central zone of the prostate. No significant adverse effects related to basic hyperthermia treatments were noted.

We conducted an FDA IDE Study, utilizing transurethral interstitial microwave hyperthermia, incorporating a specially developed urethral catheter, to treat benign prostatic hyperplasia. Currently, some 400,000 men in U.S.A. with this condition, receive transurethral resection of prostate (TURP) as it has the lowest morbidity of surgical alternatives available. However, many men are either poor medical risks for an invasive procedure or refuse the surgery. We therefore conducted a Phase I trial of a nonsurgical, noninvasive alternative to TURP, especially suited for the above mentioned categories of patients for the treatment of Benign Prostatic Hyperplasia.

We used the Prostek 3000 Hyperthermia System manufactured by Clinitherm Corporation, with a new urethral catheter, by TN&A, Inc. Prostek 3000 utilizes a 915 MHZ solid state microwave power generator with four channels, 25 watts each. Interstitial antenna were of Helical microcoaxial heat-to-tip design with 30 mm active length, 1.3 mm in diameter and capable of 15 watts delivery. All temperature readings during the treatments were recorded by Fiber Optic Ga As probes which are non-perturbing to the microwave field and non-perturbed by that field. The new catheter enabled us to pass the three microwave Helical antennae in separate channels to the level of the prostate. Four temperature probes, one in the catheter, two in the prostatic tissue and one in rectum, were used to measure heat distribution.

Treatments were given on an outpatient basis, without sedation or analgesia. Microwave hyperthermia was applied for sixty minutes on four sessions over a two week period. Measured urethral temperatures of 45-47 degrees C

yielded therapeutic heating patterns of approximately 2.1 cm in diameter at the widest point in a tear drop pattern.

Pre and Post treatment evaluation included rectal-digital examination, uroflow, urodynamic testing including CO₂ cystometrogram, residual urine volumes, transrectal ultrasonography, and serum chemistries, i.e., PSA, PAP, hematology. A symptom score analysis based on a questionnaire regarding quality of urinary stream, hesitancy, urgency, nocturia and frequency was utilized. Fifteen patients were enrolled in the trials, and all tolerated the procedure well, with no significant adverse effects noted during the treatments and in follow-up. At thirty and sixty day evaluations, patients reported subjective improvement in voiding pattern with an average 60% improvement in symptom score: urinary flow rates were increased by up to 70%, and residual volume decreased by 65%.

Transurethral Interstitial Microwave Hyperthermia appears to be a safe and efficacious treatment for Benign Prostatic hyperplasia and further expanded trials are needed to confirm our findings.

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