

TRANSPERINEAL MICROWAVE THERMOABLATION IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA: A PHASE I STUDY WITH A NEW MINI-CHOKED MICROWAVE APPLICATOR

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Introduction. The rapidly increasing number of patients affected by lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) and health-related costs containment issues recently led to the development of several minimally invasive and inexpensive therapeutic methods and technologies. The transurethral microwave thermotherapy (TUMT) is nowadays considered to be a valid alternative to the standard surgical treatment (TURP); however, uncontrolled back heating effects exhibited by conventional microwave applicators may result in uncertain and not fully repeatable ablative lesion size and shape. Recently, a new microwave antenna for transperineal thermoablation (TT) has been designed –named AMICA-PROBE–, comprising at once an integrated hydraulic circuit for applicator cooling and a miniaturized device (*mini-choke*) for reflected waves entrapment, in order to attain maximum control over radial and longitudinal coagulative lesion size and to fully overcome back heating effects, while keeping the applicator size at a minimum.

Purpose. We present a phase I study aiming to evaluate the tolerability and safety of the thermoablative treatment of BPH-related LUTS patients with this new mini-choked, internally cooled microwave applicator.

Materials and Methods. All 9 patients (mean age: 72.3) enrolled in our study matched the following inclusion criteria: absence of major diseases, failure of previous LUTS pharmacological treatments, International Prostate Symptom Score (IPSS) greater than 7, maximum urinary flow rate (Q_{max}) of <10 ml/s, PSA less than 4 ng/ml, post void residual urine volume (PVR) greater than 100 ml and prostate volume between 80 and 100 ml. All patients underwent a US-guided TT, upon administering of periprostatic local anaesthesia. Microwave energy was delivered through a coaxial mini-choked antenna with a 15mm long radiating tip, lodged in a 14G introducing needle (operating frequency: 2.45 GHz; power level: 20W; exposure time: 5 minutes per prostatic lobe). Real-time temperature monitoring of periprostatic tissues surrounding the treated region was performed by inserting interstitial thermocouple sensors. Patients were then divided in 3 groups: group 1 (3 patients) underwent transvesical prostatectomy (TP) 7 days after ablative treatment, group 2 (3 patients) after 15 days and group 3 (3 patients) after 30 days. A 18 Ch urethral catheter was placed in each patient before TT and removed upon TP. All surgical samples underwent pathologic analyses in order to evaluate the anathomopathologic characteristics of the lesion. A few days before TT and a few days after TP all patients filled in the validated Italian version of the International Index of Erectile Function (IIEF-5) and SF-36 questionnaires; during TT, the Visual Analogue Scale (VAS) pain score was recorded.

Results. None of the patients reported pain or other symptoms during TT (VAS mean: 1.2) nor exhibited urinary incontinence after TP. Pre-TT and post-TP questionnaires do not show any significant statistical difference (IIEF-5-pre: 18.1, IIEF-5-post: 20.6, SF-36-pre: 85.5, SF-36-post: 90.5; all $p > 0.05$). During all TT treatments, the mean temperature value detected by thermocouple sensors distributed around the lesion (about 3 cm from the antenna tip) was $39 \pm 1^\circ\text{C}$. No complications occurred during TT treatments. The macroscopic inspection of the surgical samples showed very well defined lesion margins and absence of overheating phenomena. The anathomopathologic analyses showed a quasi-spheroidal lesion (longitudinal axis: 16 mm; transversal axis: 18 mm), characterized by a central coagulative necrosis surrounded by an inflammatory infiltrate reaction (thickness: 2.1 mm), beyond which healthy tissue was found. Lesion sizes were approximately equal for all groups of patients, regardless of the amplitude of TT to TP latency, which shows the absence of time-dependant post-treatment effects and thus assures the predictability and reproducibility of TT results.

Conclusions. Our study proves the safety and tolerability of the transperineal thermoablative treatment of patients affected by BPH-related LUTS with the new AMICA-PROBE microwave applicator.