

**MULTICENTRIC STUDY
COMPARING INTRAVESICAL
CHEMOTHERAPY
ALONE AND WITH LOCAL
MICROWAVE HYPERTHERMIA
FOR PROPHYLAXIS
OF RECURRENCE OF
SUPERFICIAL TRANSITIONAL
CELL CARCINOMA**

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Purpose: To compare the efficacy and local toxicity of the intravesical instillation of a cytostatic drug versus the same cytostatic agent in combination with local hyperthermia as an adjuvant treatment, after complete transurethral resection (TURB) of superficial transitional cell carcinoma (TCC) of the bladder.

Patients and Methods: The study was designed as a prospective, multicentric, randomized trial. Eighty-three patients suffering from primary or recurrent superficial (Ta-T1) TCC of the bladder, after a complete TURB, were randomly assigned to receive intravesical instillations of mitomycin C (MMC) alone, for 41 patients, and MMC in combination with local microwave-induced hyperthermia, for 42 patients. For the combined approach, a new system, Synergo101-1 (Medical Enterprises, Amsterdam, the Netherlands) was used. The effectiveness evaluation end points of the study were evaluation of recurrence-free side effects and clinical complications. For the efficacy end point, Kaplan-Meier analysis was employed, with the log-rank test for significance. Minimum follow-up time was 24 months.

Results: Of the 83 randomly assigned patients, 75 completed the study according to the protocol and had valid cystoscopy results. Survival analysis of the 75 assessable patients demonstrated a highly significant difference in the survival curves in favor of thermochemotherapy. Subjective intolerance and clinical complications were significantly higher but transient and moderate in the combined treatment group.

Conclusion: In our series, endovesical thermochemotherapy appears to be more effective than standard endovesical chemotherapy as an adjuvant treatment for superficial bladder tumors at 24-month follow-up, despite an increased but acceptable local toxicity.