

**LONG-TERM OUTCOMES OF A
RANDOMIZED CONTROLLED
TRIAL COMPARING THERMO-
CHEMOTHERAPY TO MITOMYCIN
ALONE AS
AN ADJUVANT TREATMENT OF
NON-MUSCLE-INVASIVE
BLADDER CANCER.**

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OBJECTIVES. This study presents long-term efficacy of intravesical chemochemotherapy versus chemotherapy alone with Mitomycin C randomly administered to patients with non-muscle-invasive bladder cancer as an adjuvant treatment after complete transurethral resection.

SUBJECTS AND METHODS. Eighty-three patients with intermediate/high-risk non-muscle invasive urothelial cell carcinoma of the bladder, following complete trans-urethral resection, were randomly assigned to receive either intravesical thermochemotherapy (by means of Synergo®) or intravesical chemotherapy alone, for prophylaxis of tumor recurrence. Mitomycin C (namely, two doses of 20 mg dissolved in 50 ml distilled water administered throughout two consecutive sessions) was used as the chemotherapeutic agent in both arms. Seventy-five patients completed the original study (35 of 42 in the treatment arm, 40 of 41 in the control arm), whose results at minimum 2-year follow-up have already been published. Recently, the files of these patients have been updated for long-term outcome definition. Data regarding general health, follow-up exams, tumor relapse or progression, and cause of death were collected and analyzed.

RESULTS. Updated complete data collection was available for 65/75 (87%) of the original patients. Median follow-up for tumor-free patients was 91 months. The 10-year disease-free survival rate for thermo-chemotherapy and chemotherapy alone were 53% and 15%, respectively ($P < 0.0001$). An "intent to treat" analysis performed to overcome the potential bias introduced by the asymmetrical drop rate, still showed a significant advantage of the active treatment over the control treatment. Bladder preservation rates for thermo-chemotherapy and chemotherapy alone were 86% and 79%, respectively.

CONCLUSIONS. This is the first analysis of long-term follow-up of patients treated with intravesical thermo-chemotherapy. The high rate (53%) of patients documented to be tumor-free 10 years after treatment completion as well as the high rate (86%) of bladder preservation, confirms the efficacy of this adjuvant approach for non-muscle invasive bladder cancer also at long term follow-up, even in patients with multiple tumors.