

## **Immunoprophylactic Intravesical Application of Bacillus Calmette-Guerin after Transurethral Resection of Superficial Bladder Cancer**

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**Aim.** To evaluate the effect of intravesical instillation of Bacillus Calmette-Guerin (BCG) in the prevention of recurrence and progression of the superficial bladder cancer.

**Methods.** Between February 1989 and May 1994, 170 patients with histologically proven superficial transitional cell carcinoma of the bladder stage Ta and T1 were assessed as eligible for 6-week + 6-month protocol of intravesical BCG instillation at the Split University Hospital. All patients underwent complete transurethral resection of the tumor, which established tumor size, histology, stage, and absence of muscle invasion. Out of 170 patients offered to receive intravesical BCG instillations, 80 agreed to undergo the treatment (BCG group), and 90 refused it (control group). The median duration of follow-up was 64 months (range, 16-128).

**Results.** The BCG group had lower incidence rates of recurrence (12 vs 26 events per 100 patient-years in controls,  $p < 0.001$ ) and progression (3.0 vs 6.6 events per 100 patient-years in controls,  $p = 0.017$ , large-sample one-sample binomial test in both cases) than the control group, but similar mean intervals to first recurrence or progression. The 5-year recurrence-free rates were 55% in BCG patients and 31% in controls, and in case of progression, 86% and 70%, respectively. Cox regression showed that the independent predictors of recurrence were tumor size ( $p < 0.001$ ), absence of BCG treatment ( $p = 0.002$ ), and patient age ( $p = 0.05$ ). The single independent predictor of tumor progression was absence of BCG treatment, but only in case of tumor grade III (roughly doubling the relative risk of the event).

**Conclusion.** Our data suggest that BCG intravesical instillation, using 6 week + 6 month scheme, prevents against recurrence and progression of superficial bladder tumors. This treatment should be especially advocated in patients with advanced grade tumors, but the scheme remains to be evaluated against other BCG treatment schemes.

**Key words:** bladder; bladder neoplasms; carcinoma in situ; carcinoma, transitional cell; disease progression; Mycobacterium bovis; neoplasm recurrence, local