Maintenance Treatment with Bacillus Calmette-Guérin for Non-Muscle-Invasive Urothelial Carcinoma of Bladder Cancer after Complete TUR-BT

Introduction and Objective: We investigated the effect of maintenance therapy with intravesical instillation of Bacillus Calmette-Guérin (BCG) for high-risk non-muscle invasive bladder cancer (NMIBC) after complete transurethral resection of bladder tumors (TUR-BT).
Materials and Methods: Complete TUR-BT was designed strictly according to our policy. [Cohort 1] 41 patients were diagnosed as having recurrent or multiple NMIBC (stage Ta or T1) without carcinoma *in situ* (CIS) after complete TURBT. The patients were randomized into two treatment groups: a maintenance group (BCG, 81 mg, intravesically instilled once weekly for 8 weeks as induction therapy, followed by three once-weekly instillations at 3, 6, 12 and 18 months after initiation of the induction therapy) and a non-maintenance group (BCG, 81 mg, intravesically instilled once weekly for 8 weeks). The primary endpoint was recurrence-free survival (RFS). [Cohort 2] 47 patients were diagnosed as having with CIS after TURBT. The patients were randomized into two treatment groups: a maintenance group (BCG, 81 mg, intravesically instilled once weekly for 6 weeks as induction therapy, followed by three once-weekly instillations at 3, 6, 12 and 18 months after initiation of the induction therapy) and a non-maintenance group (BCG, 81 mg, intravesically instilled once weekly for 6 weeks). The primary endpoint was RFS.
Results: [Cohort 1] 5-year RFS rates of maintenance group and non-maintenance group were 75.3% and 74.9% respectively. The RFS rates did not show a difference in between the maintenance and non-maintenance groups. [Cohort 2] 5-year RFS rates of maintenance group and non-maintenance group were 84.0% and 84.4% respectively. The RFS rate of the maintenance group was almost similar to the non-maintenance group.
Conclusion: BCG maintenance therapy did not significantly prolong the post-TURBT RFS compared with BCG induction therapy alone after complete TUR-BT.