
Chemohyperthermia with Mitomycin C and COMBAT System in High Risk Non-Muscle Invasive Bladder Cancer Patients: Initial Experience in a Single Centre

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Introduction and objective: The absence of BCG has led to the treatment of patients with High Risk (HR) Non-Muscle Invasive Bladder Cancer (NMIBC) with instillations different than usual. We present the results of our series in patients treated with Mitomycin C (MMC) and chemohyperthermia with the COMBAT device.

Materials and methods: From November 2014 to May 2017, 74 patients with high-risk NMIBC according to EAU criteria were treated with instillations of 40 mg MMC at 43°C, using the COMBAT recirculation system. The protocol followed uses 6 weekly and 6 monthly maintenance instillations. Patients were selected because of poor tolerance to prior BCG, absence of BCG or participation in clinical trial. Performing ReTURBT prior to instillation was at the discretion of the specialist, depending on the patient's overall condition and tumor size.

Results: With a median follow-up of 14.7 months and a median age of 75 years, 74 patients were analyzed, 57 with primary tumours and 17 have had previous tumours. The TNM was Ta (44 pac); T1 (29 pac); Tis (1 pac). The WHO grade was HG (68 pac), LG (6 pac). Divided by the simplified EAU risk scale, 70 patients and 4 patients were in the high-risk and intermediate-risk groups, respectively. The overall recurrence rate was 24% (16% relapses and 8% progressions). The mean time to relapse was 9.8 months. Of the 6 progressions, 3 were M1 in elderly patients with high surgical risk and with large tumours, suggesting initial underestimation. Stratified by EAU recurrence risk groups, recurrences were 50%, 29% and 17% in the high, intermediate-high and intermediate-low risk groups respectively. Stratified by EAU progression risk groups, progressions were 0%, 10%, 3% and 0% in the high, intermediate high, intermediate-low and low risk groups respectively. Of the total, 46 patients completed treatment, 11 were still on treatment and 17 dropped out (4-5% - due to allergy to mitomycin, 4-5% - due to intolerance, and 9-12% - due to other causes). The median number of instillations until dropout was 5. Of those who completed the treatment, 29% relapsed compared to 28% of those who dropped out.

Conclusions: Chemohyperthermia with MMC and the COMBAT system, used according to the previous protocol, is effective in the treatment of HR-NMIBC. The high rate of progression to M1 in our series corresponds to elderly patients with high surgical risk and probable initial under-staging. Chemohyperthermia is well tolerated, with 10% of withdrawals due to side effects, with no influence on relapse rate.