
Hyperthermic Intravesical Chemotherapy for BCG-Unresponsive or BCG Ineligible Non-Muscle Invasive Bladder Cancer Patients

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Objective: To assess the efficacy of hyperthermic intravesical chemotherapy (HIVEC™) with mitomycin-C (MMC) in BCG unresponsive or BCG ineligible intermediate and high-risk non-muscle invasive bladder cancer (NMIBC) patients.

Methods: From January 2015 to February 2017 intermediate and high-risk NMIBC patients received HIVEC™ treatment, which consisted of 10 intravesical instillations (4 instillations weekly + 6 monthly). Only patients who had a minimum of 5 HIVEC™ instillations were included in the present analysis and all data were prospectively collected. Patients were followed by cystoscopy and cytology every three months and CT-scan once a year. The primary outcome was the recurrence-free survival (RFS). Questionnaires on micturition were completed before and after treatment. The Common Terminology Criteria for Adverse Events was used for the assessment of side-effects.

Results: A total of 27 NMIBC patients (30% intermediate- and 70% high-risk) were recruited. Twenty-five patients underwent ≥ 5 HIVEC™ treatments and were analyzed for recurrence. Patients were classified as: BCG-unresponsive in 17, 4 patients had received an unknown number of BCG installations, and 6 patients were BCG naïve. The median follow-up was 10.4 months [IQR 4.4-16.7] and the overall relapse rate was 52%. The mean RFS was 15.3 months [SE 2.12]. In BCG-unresponsive patients, the relapse rate was 56% and the RFS was 13.8 months [SE 2.67]. No severe side-effects were reported nor were changes in voiding diary observed. Five out of 14 carcinoma in situ (CIS) positive patients (10 CIS only and 4 concomitant CIS) had a recurrence.

Conclusions: In BCG-unresponsive or BCG ineligible intermediate - or high-risk NMIBC patients, treatment with HIVEC™ resulted in a RFS of >1 year, potentially avoiding or postponing the need for radical surgery.