Recirculant Hyperthermic IntraVESical Chemotherapy (HIVEC) in Intermediate – High Risk Non-Muscle Invasive Bladder Cancer

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**Purpose:** To examine the effectiveness of hyperthermic intravesical chemotherapy (HIVEC™) with Mitomycin-C (MMC) for patients with intermediate–high-risk non-muscle invasive bladder cancer.

**Materials and methods:** From November 2010 to April 2015, 40 patients with intermediate–high-risk NMIBC received HIVEC™ treatment with a COMBAT BRS system. Of these patients, 24 received neoadjuvant HIVEC™ treatment (eight weekly instillations) before a transurethral resection of the bladder (TURBT) and 16 received adjuvant HIVEC™ treatment post-TURBT (four instillations weekly + six monthly). The pathological response of each tumour was evaluated after the neoadjuvant treatment. Recurrence rates and adverse effects were evaluated in both groups.

**Results:** A total of 40 patients completed the induction therapy: 24 patients received the Neoadjuvant HIVEC™ treatment. Of these patients, 15 (62.5%) showed a complete response. Eight patients (33.3%) showed a partial response, and one patient (4.1%) showed no response at all. The 4-year cumulative incidence of recurrence was 20.8%. The adjuvant HIVEC™ treatment was given to 16 patients. The 2-year cumulative incidence of recurrence was 12.5% for this group. The incidence and severity of side effects were slightly lower in the adjuvant group than in the neoadjuvant group. However, the difference was not statistically significant (p< 0.3). Most of the side effects were low grade and had virtually no effect on the treatment plan, and 97% of patients completed all of the HIVEC instillations scheduled.

**Conclusions:** The recirculation of hyperthermic MMC using COMBAT’s HIVEC™ treatment is safe and effective and is capable of achieving good success rates in both neoadjuvant and adjuvant settings. This treatment seems to be appropriate for NMIBC intermediate – high-risk patients who cannot tolerate or have contraindications for standard BCG therapy or in cases in which there are supply issues or shortages of BCG.