
Two-Year Follow-Up Results After Sequential Intravesical Bacillus Calmette-Guérin (BCG) and Device-Assisted Chemo-Hyperthermia (Combat BRS) for High-Risk (HR) Non-Muscle Invasive Bladder Cancer (NMIBC) Patients... a BCG-Sparing Strategy

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Introduction & Objectives: Until October 2014, our standard bladder sparing treatment for HR-NMIBC was a full-dose intravesical BCG 6-week induction course and maintenance BCG for 1-3 years. In response to the BCG shortage, we modified our regimen to sequential full-dose BCG and device-assisted chemo-hyperthermia (Mitomycin C [MMC] delivered by the Combat BRS system). Here we present our 2-year results after start of treatment.

Material & Methods: The 6-week induction regimen became BCG (weeks 1,2), Combat BRS (weeks 3,4,5) and BCG (week 6). Nine further Combat BRS maintenance treatments were given by 1 year comprising 3 sets of weekly instillations for 3 weeks. Sixty-one patients commenced treatment for HR-NMIBC (high grade [grade 3] and/or carcinoma in situ [CIS]) between October 2014 and September 2015. T1 tumours were routinely re-resected. We excluded 11 patients because of concurrent upper urinary tract or prostatic urothelial tumours, previous radiotherapy or BCG or a course of MMC. During this time-period, only 5 patients with HR-NMIBC underwent primary cystectomy.

Results: We report on 50 patients with HR-NMIBC (CIS detected in 40% and T1 in 62%) who now have 2-year follow-up. Of these, 47 (94%) are progression-free, 46 (92%) are cystectomy-free, 38 (76%) are disease free. In the 4 patients with refractory HG-NMIBC who underwent cystectomy, we report no pathological upstaging to MIBC. Forty-seven patients are alive (2 deaths due to metastatic BC and 1 non BC-related death). Forty-two patients (84%) tolerated Combat BRS treatment; 3 stopped because of rashes during maintenance and 5 discontinued following bladder-related tolerability issues.

Conclusions: In an era of BCG shortage, we are pleased with the 2-year follow-up results of this regimen where 12 of 15 instillations utilized heated MMC using the Combat BRS device. In this non-selected HR NMIBC series, the low progression rates and good tolerability are reassuring.