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## One-year Follow - up Results after Sequential Intravesical Bacillus Calmette-Guérin and Device - Assisted Chemo-Hyperthermia (Mitomycin C Delivered by the COMBAT BRS System) for High Risk Non-Muscle Invasive Bladder Cancer Patients... A Bacillus Calmette-Guérin Sparing Strategy

Presentation Authors: TR Leyshon Griffiths\*, William JF Green, Peter T Grice, Jonathan C Goddard, Roger C Kockelbergh, Leicester, United Kingdom  
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**Introduction and objective:** 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 1-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. We reviewed the 1-year follow-up results of 50 HR-NMIBC (high grade [grade 3] and/or carcinoma in situ [CIS]) patients who commenced treatment between October 2014 and September 2015. T1 tumours represented 62% of cases and were routinely re-resected. CIS was detected in 40% of cases. We excluded 11 patients from this series who had concurrent upper urinary tract or prostatic urothelial tumours, previous radiotherapy or BCG or a course of MMC.

**Results:** Of 50 patients, 44 (88%) were disease-free by 1 year; 3 (6%) had refractory HR-NMIBC at 6 months, 2 (4%) progressed to MIBC by 6 months and 1 (2%) presented with metastatic disease at 1 year. All 6 had CIS and/or T1 at diagnosis. Forty-three patients (86%) tolerated COMBAT BRS treatment; 2 reacted with rashes during maintenance and 5 had bladder-related tolerability issues.

**Conclusions:** Our oncological results with sequential BCG/COMBAT BRS at 1 year are at least comparative at this time-point with those expected for HR-NMIBC patients on maintenance BCG. Tolerability and compliance shows great promise.