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Chemohyperthermia with Mitomycin C (MMC) and COMBAT System in High Risk Non Muscle Invasive Bladder Cancer (HR NMIBC): A New Alternative?

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Introduction and objective: The recommended treatment for high risk non-muscle invasive bladder cancer (HR NMIBC) is maintenance intravesical BCG therapy. However, adverse effects and problems with BCG supply and production has led to significant disruption in the treatment of these patients. We present the results of a multicentre European series of HR patients treated with MMC and chemohyperthermia (CHT) with COMBAT HIVEC™ treatment.

Material and methods: A retrospective analysis of 145 patients with HR papillary only NMIBC, treated by 14 centres across Europe between December 2014 to October 2017 was performed. High risk disease was defined according to EAU risk classification. Following transurethral resection of bladder tumour (TURBT), all patients were treated with adjuvant intravesical instillations of 40mg MMC at 43°C, for 60 minutes using COMBAT HIVEC™ treatment. All patients received CHT treatment because BCG was unavailable, or they could not tolerate BCG due to adverse events. Approval of local ethics committee was obtained. Treatment protocols were decided by individual institutions although majority received 6 weekly instillations of induction with a variable maintenance regime. Performing ReTURBT prior to instillation was at the discretion of the clinician and local institutional recommendation. Patients had check cystoscopy at 3 monthly intervals.

Results: 145 patients were treated with the COMBAT system with a median follow up of 20.8 months. The mean age of patients was 70.6 years. 65% of NMIBC were primary tumours with 65% pTl and 66% G3. 46% of patients had multiple tumours and 36% were >3cm. 116 patients (80%) received a minimum of 6 weekly instillations as part of induction therapy. 79 patients (55%) received some form of maintenance therapy. In the Intention to Treat analysis (145 patients), mean follow up 21 months, recurrence free rate (RFR) was 82% (27 patients) and progression free rate (PFR) to T2 was 98% (3 patients). In the Per Protocol analysis (at least 6 instillations, 116 patients), mean follow up was 22 months, RFR was 83% (20 patients) and PFR to T2 1 was 93% (2 patients). RFR at one year follow up was 87.3%.

Conclusions: CHT with 6 weekly induction 40 mg MMC using the COMBAT system represents an attractive alternative to intravesical BCG therapy. RFR and PRF at 12 months are comparable to EORTC nomograms. Randomised controlled trials are eagerly awaited.