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HIVEC HR: Chemohyperthermia with Mitomycin C vs BCG for High-Risk Non-Muscle Invasive Bladder Cancer. Preliminary Results from a Randomized Controlled Trial

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Introduction & Objectives: The only adjuvant treatment available for high-risk (HR) non-muscle invasive bladder cancer (NMIBC) is bacillus Calmette-Guérin (BCG), no further options remain for patients who cannot tolerate or fail BCG, or in case of another BCG shortage. This study seeks to compare chemohyperthermia (CHT) using mitomycin C (MMC) versus BCG, measuring adverse events, tolerance, progression and recurrence-free survival in patients with HR NMIBC.

Materials & Methods: Between October 2016 and February 2018, Fifty HR NMIBC patients were randomized (1:1) in this controlled, open-label, single center trial.

Inclusion criteria: HR NMIBC.

Exclusion criteria: CIS, unable to receive MMC or BCG, variant histology, upper tract or prostatic urethra invasion, severe urethral stenosis

The protocols used were:

- BCG (TICE strain), a weekly vial for 6 weeks and a monthly vial for 12 months.

- CHT, 40mg of MMC diluted in 40ml of distilled water at 43°C using the COMBAT recirculation system for 60 minutes, one weekly instillation for 6 weeks and one monthly for 6 months.

The follow-up has been done with cystoscopy and urine cytology every 3 months with annual evaluation of the upper urinary tract, according to the EAU guidelines.

(Reg. 2016-001186-85)

Conclusions: Our preliminary results show that CHT with MMC appears to be non-inferior to BCG, with a similar tolerability and safety profile.

Please see overleaf for results



Results: 88% male, with a median age of 73 years. One patient in each group did not received any instillation.

	CHT	BCG
No. patients	n= 24 (%)	n= 24 (%)
Primary tumour	22 (92%)	18 (75%)
Recurrent (<1 year)	2 (8%)	2 (8%)
Recurrent (>1 year)	0 (0%)	4 (16%)
Age >75 years	10 (40%)	9 (37%)
T1	14 (58%)	13 (54%)
HG (G3)	14 (58%)	17 (70%)
Multiple	5 (20%)	7 (29%)
>3cm	8 (33%)	6 (25%)
ReTURBT	6 (25%)	6 (25%)
Post-op MMC	5 (20%)	6 (25%)
Prior BCG	0 (0%)	1 (4%)

Table 1. Patients' Characteristics

	CHT	BCG	
Intention-to-treat analysis	n= 25	n= 24	
Recurrence	1 (4%)	5 (20%)	
Progression	2 (8%)	5 (20%)	
Per-protocol (>6 instillations)	n= 22	n= 22	
Recurrence	0 (0%)	5 (20%)	
Progression	1 (4%)	4 (16%)	
Follow-up since TURBT	12 months	12.5 months	
Patients with at least 12-month follow-up (since TURBT)	14 (56%)	13 (54%)	
Time-to-recurrence (mean)	19.4	21.1	p = 0.091

Table 2. Results. TURBT= transurethral resection of bladder tumour

	CHT	BCG
Incidence of AE	11 (45%)	9 (37%)
Discontinuation due to AE	4 (16%)	4 (16%)
Overall mortality	1 (4%)	4 (16%)
Treatment delayed due to AE	1 patient (3 instillations)	3 (12%)

Table 3. Adverse Events (AE)

Discontinuations in CHT: 1 urinary tract infection (UTI), 3 allergies.

Discontinuations in BCG: 3 UTIs, 1 fever.

Mortality in CHT: myocardial infarction.

Mortality in BCG: pancreatic, lung and colon cancer, severe Guillain-Barré

Conclusions: Our preliminary results show that CHT with MMC appears to be non-inferior to BCG, with a similar tolerability and safety profile.

Please contact us to discuss the clinical evidence or arrange a meeting

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