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# AUA VIRTUAL EXPERIENCE

## BCG VS CHEMOHYPERTHERMIA WITH MITOMYCIN C FOR HIGH-RISK NON-MUSCLE INVASIVE BLADDER CARCINOMA: PRELIMINARY RESULTS OF HIVEC-HR RANDOMIZED CLINICAL TRIAL

PD03-01

Abs 1015

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## BACKGROUND

Given the frequent BCG shortages, there is an urgent need for an alternative to BCG in high risk NMIBC

## AIM

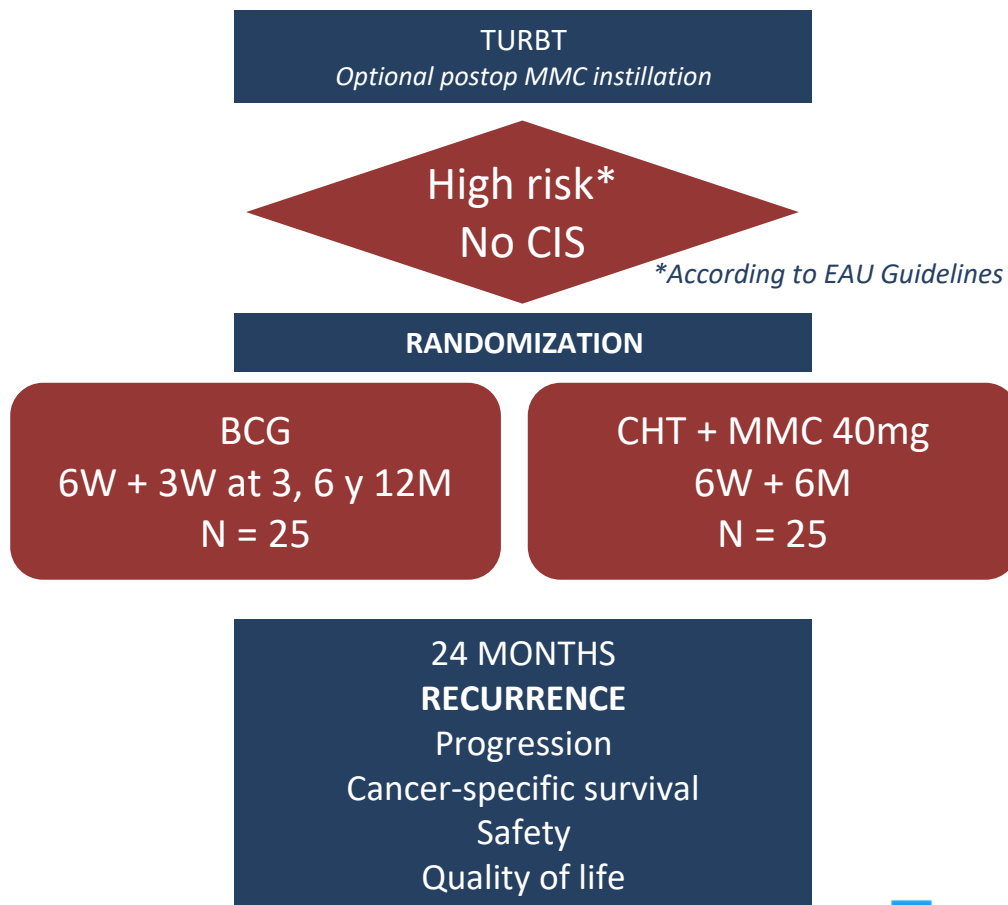
To explore whether recirculant hyperthermic intravesical chemotherapy (HIVEC) with mitomycin C is an alternative to BCG in high risk NMIBC



## MATERIALS & METHODS

- Pilot unicentric study
- Prospective
- Randomized, open label
- N = 50 patients
- Primary objective
  - 24 months RFS
- Secondary objectives
  - Safety
  - Progression
  - Survival
  - Quality of life

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## MATERIALS & METHODS (cont.)

### *INCLUSION CRITERIA*

1. All patients operated of **non muscle invasive** bladder tumor that meet **high risk** criteria
2. Above **18 years** old
3. Accept to participate in the trial and sign the **consent form**

**High-risk patients (excluding CIS)** according to EAU Guidelines (2016 update), such as any of the following:

- **T1**
- **G3 (HG) tumor**
- **Ta, G1G2 AND multiple AND recurrent AND bigger than 3 cm (all the conditions must be met)**

### *EXCLUSION CRITERIA*

1. Patients with **invasive** lesions or **CIS**
2. Hypersensitivity or **allergy** to MMC
3. History of severe **adverse reaction to BCG**
4. Involvement of **prostatic urethra** or **upper urinary tract**
5. Patients with tumors **histologically different** than transitional cell carcinoma
6. Patients that for any reason should receive simultaneous **chemotherapy**
7. Withdrawal of **consent form**
8. **Pregnant** or **lactating** or women at childbearing age who do not want or can not use non-hormonal contraceptives
9. **Urethral stenosis** that contraindicates catheterization for the instillation
10. Treatment with **immunosuppressants** that contraindicates BCG therapy



## RESULTS – baseline &amp; efficacy

	CHT n (%)	BCG n (%)
Randomized	25	25
Analyzed	24	24
Primary tumor	22 (92%)	18 (75%)
Recurrent <1/year	2 (8%)	2 (8%)
Recurrent >1/year	0 (0%)	4 (16%)
>75 years	10 (40%)	9 (37%)
G3	14 (58%)	17 (70%)
T1	10 (40%)	13 (54%)
Multiple	5 (20%)	7 (29%)
>3cm	8 (33%)	6 (25%)
Post-op instillation	5 (20%)	6 (25%)
ReTURBT	6 (25%)	6 (25%)

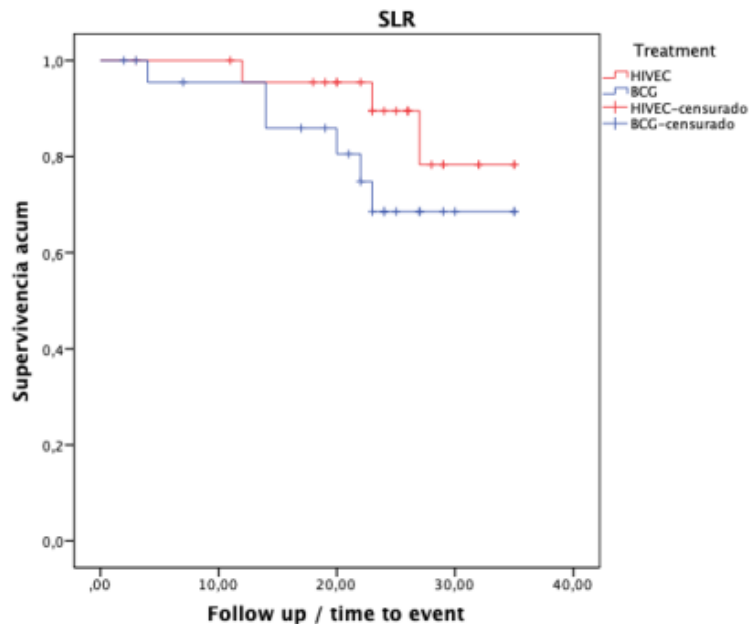
EFFICACY ANALYSIS	HIVEC*	BCG
ITT	24	24
Recurrences	3	6
From which, progression to T2	2	5
PP (at least 6 instillations)	23	22
Recurrences	0	5
From which, progression to T2	0	3
Median follow-up (from TURBT)	22.5 months	24 months
Median time to recurrence	23 months	17 months

\*3 patients from HIVEC group currently have a recurrence diagnosed with cystoscopy, scheduled for TURBT, not performed yet

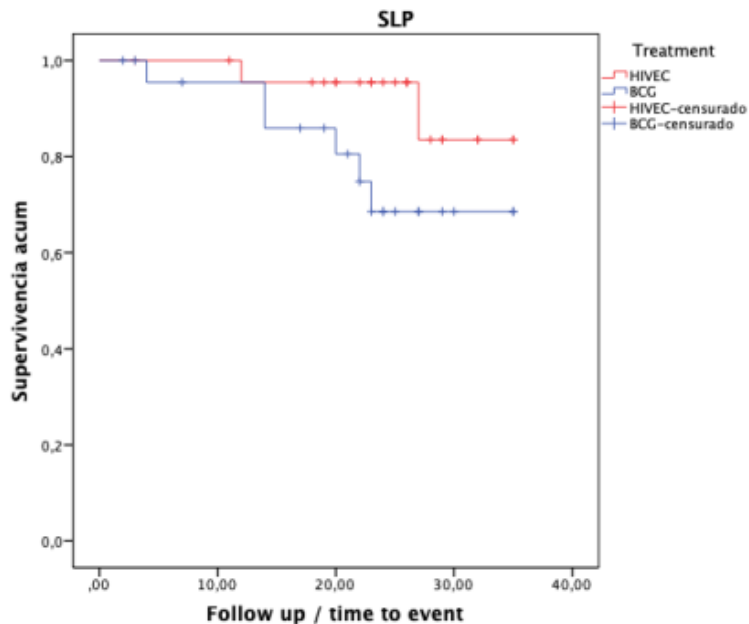


## RESULTS – efficacy

ITT RFS



ITT PFS





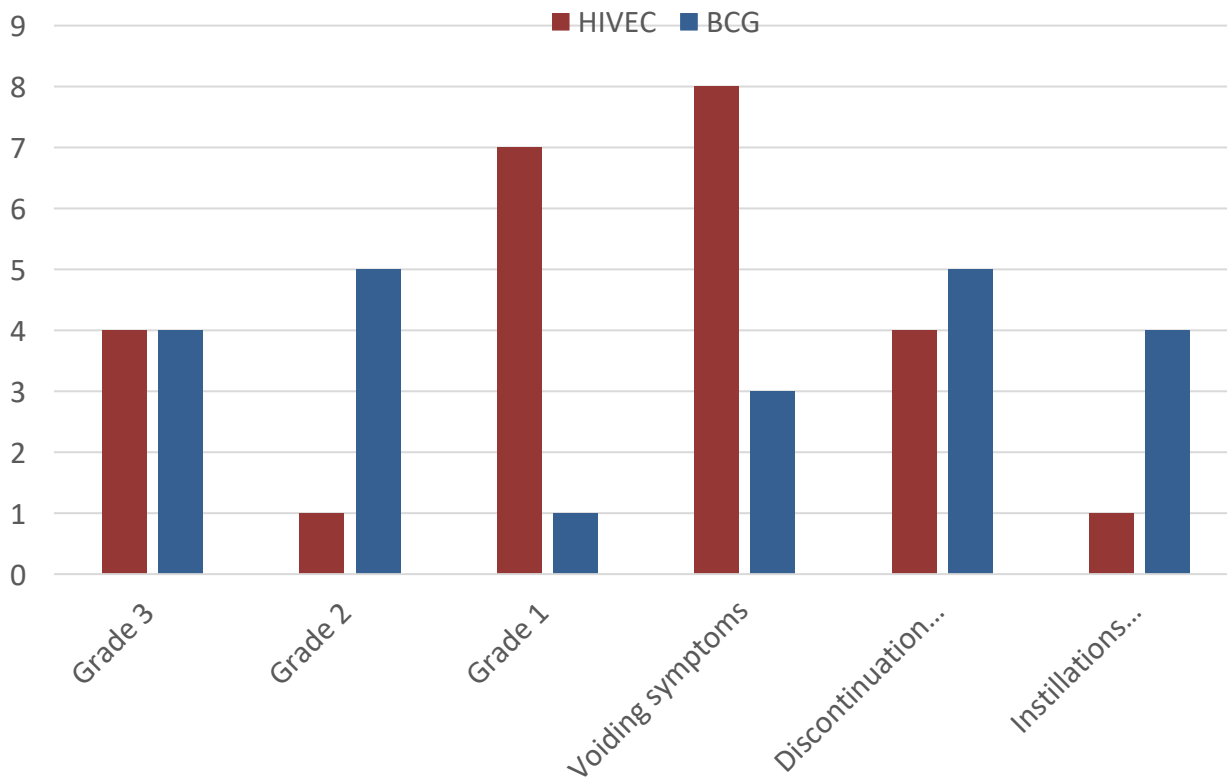
## RESULTS – efficacy

**Is the higher proportion of highly recurrent patients in the BCG group the cause of the “worse” outcomes in this group?**

Baseline characteristics	Rec/Prog HIVEC	Rec/Prog BCG
Primary	22	18
No. Recurrence / Progression	3 Rec / 2 Prog	4 Rec / 4 Prog
Recurrent < 1/year	2	2
No. Recurrence / Progression	No rec / No prog	1 Rec / 0 Prog
Recurrent > 1/year	0	4
No. Recurrence / Progression	No rec / No prog	1 Rec / 1 Prog



## RESULTS – safety







## RESULTS – safety

### MORTALITY

**HIVEC:** 3 deaths (unknown, myocardial infarction, another tumor)

**BCG:** 4 deaths (pancreatic ca, lung ca, bowel-lung ca, Guillain-Barré syndrome)

### NO DISEASE SPECIFIC MORTALITY



## CONCLUSIONS

1. Our preliminary results show that HIVEC with MMC appears to be at least not inferior to BCG in high risk NMIBC patients, in terms of RFS and PFS.
2. Tolerability and safety profile are similar, with milder AEs and more irritative voiding problems associated with HIVEC.
3. These promising outcomes have to be confirmed after complete follow-up and, lately, in larger trials.

**THANKS FOR YOUR ATTENTION**