

## Objective

To prospectively assess the efficacy of hyperthermic intravesical chemotherapy (HIVEC®) with mitomycin-C (MMC) in BCG-unresponsive or BCG-ineligible intermediate and high risk non-muscle invasive bladder cancer (NMIBC) patients.

## Background

Intravesical installations with *bacillus Calmette-Guérin* (BCG) reduce the risk of recurrence in intermediate and high risk NMIBC patients but a significant proportion of patients do not respond to BCG. BCG-unresponsive patients, defined as BCG refractory + relapsing patients <6 months of last BCG exposure are at the highest risk of recurrence. A radical cystectomy is strongly recommended in these patients but this type of surgery has high morbidity rates.

**Therefore, there is a clear clinical need for less invasive treatment options in BCG-unresponsive NMIBC.**

## Materials and Methods

- NMIBC patients who underwent HIVEC® treatment between Jan 2015 and Feb 2017 were assessed.
- HIVEC® consisted of 4 weekly installations + 6 maintenance installations per month.
- Follow-up was by cystoscopy and cytology every 3 months.
- A CT-scan was performed once a year.
- The Common Terminology Criteria for Adverse Events (CTCAE) was used to assess possible side-effects.
- Only patients who had ≥5 HIVEC® installations were included in the data analysis.

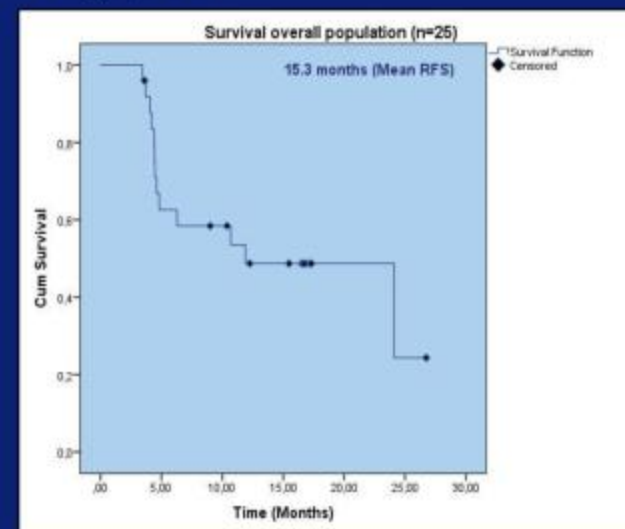
## Results

In total, 25 patients were included and the overall relapse rate was 52% (median follow-up 10.4 months, IQR 4.4-16.7). The mean Recurrence-free survival (RFS) was 15.3 months (SE 2.12) and in BCG-unresponsive patients, the relapse rate was 56% and the RFS was 13.8 months (SE 2.67). No severe side-effects (CTCAE >2) were reported.

**Table 1.** Characteristics of the study population (N = 25)

Gender	22 male	3 female
Age	Mean 71 year	Range 52-86 year
T-stage		
	Ta	N = 8 32%
	T1	N = 3 12%
	T1 + CIS	N = 4 16%
	CIS only	N = 10 40%
Tumor grade		
	G1	N = 3 12%
	G2	N = 4 16%
	G3	N = 18 72%
Risk group		
	Intermediate	N = 7 28%
	High	N = 18 72%
BCG		
	Unresponsive	N = 16 64%
	Unknown number	N = 4 16%
	BCG naive	N = 5 20%

**Figure 1.** Recurrence-free survival (RFS) of the study population



## Conclusion

**In BCG-unresponsive or BCG-ineligible intermediate or high risk NMIBC patients, treatment with HIVEC® resulted in a RFS of >1 year, potentially avoiding or postponing the need for a radical cystectomy.**