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# A0077: Utility of bladder EpiCheck methylation test for the surveillance of bladder cancer patients treated with bacillus Calmette-Guérin

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### **Introduction & Objectives**

To investigate the predictive value of bladder EpiCheck (BE) test after bacillus Calmette-Guérin (BCG) induction treatment in non-muscle-invasive bladder cancer (NMIBC).

#### **Materials & Methods**

BE test was evaluated in voided urine samples obtained from a prospectively collected cohort of 41 subjects with intermediate- (n=16), high- (n=21) and very high-risk (n=4) NMIBC prior and after intravesical BCG induction treatment. This cohort is part of a larger set of patients and include only those patients with a minimum follow-up of one year. BE is a urine assay that uses 15 proprietary DNA methylation markers to assess the presence of bladder cancer using quantitative real time PCR. The ability of the test to predict those patients with higher probability to present tumour recurrence after treatment was tested by Cox regression analysis. Change pattern of BE score was also assessed in relation to recurrence.

#### **Results**

Median follow-up of the cohort was 23 months (range 5-35). During follow-up, 13 (32%) patients had tumour recurrence and 3 (7%) developed tumour progression. Median time to relapse and progression was 7 months (range 2-23) and 19 months (range 7-30), respectively. Overall, 14 of 41 (34%) patients had a positive pre-BCG BE result. Seven of

these 14 patients maintained a positive BE status after BCG induction therapy and four (57%) of them had tumour recurrence. None of the 7 patients whose BE result changed from positive to negative after BCG had tumour recurrence. Overall, 11 of 41 (27%) patients had a positive post-BCG BE result. These patients had a 3.2 times higher risk for tumour recurrence than patients with a negative post-BCG BE status (p=0.04; 95% CI: 1.06–9.48) (Figure 1).

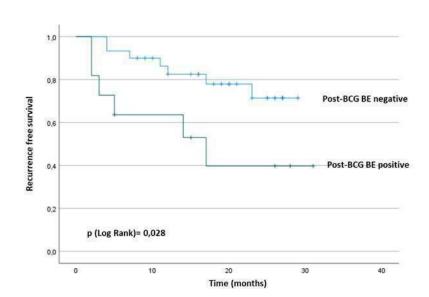


Figure 1. Kaplan-Meier curves comparing recurrence of patients with positive versus negative post-BCG BE results.

#### **Conclusions**

Urinary BE status after BCG induction treatment appears to be a useful tool to predict recurrence after BCG induction treatment. This could be of help for stratifying patients for further therapies and inclusion in clinical trial. Validating these results using larger (currently in progress) and independent series is crucial for assessing its final place in clinical setting.