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: Bladder EpiCheck in high risk population

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5: Urothelial Cancer

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Introduction & Objectives
Bladder carcinoma (BCa) represents the most expensive cancer due to its high rate of recurrence. The main issue of BCa lies in the long follow-up and in the absence of urinary assays currently able to replace and overcome, in terms of diagnostic accuracy, the current gold-standard of follow-up (based on cystoscopy and cytology), in particular in high-risk population. Bladder EpiCheck is a new urinary test that analyzes DNA methylation biomarkers in order to identify high-risk urothelial cancer.

Materials & Methods
A prospective, blinded, single-center, nonrandomized phase-2 study was carried out. Urine for testing was collected before standard-of-care cystoscopy/TURBT. Cytology and Bladder Epicheck analysis were performed by two different blinded experienced urocytopathologist. The inclusion criteria were: patients with high risk BCa (high grade, T1, Carcinoma in situ) in follow-up or as first diagnosis, able to produce 10 ml of urine, and able to consent. We recruited 170 consecutive patients: 133 patients with history of high risk BCa (60 not treated in the last 3 months and 73 recently treated), 10 with a new diagnosis of high risk BCa; the latter were compared to 27 consecutive subjects undergoing endoscopic evaluation for macrohematuria or positive cytology. Sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) of Bladder EpiCheck test were evaluated and compared to cytology and cystoscopy results, taking the confimatory pathology as the reference standard; when absent, the reference standard was considered positive if there was a clinical decision to start oncologic treatment.

Results
In case of first diagnosis, the diagnostic accuracy appeared comparable among the three approaches, with 100% of sensitivity and NPV rates for all of them. In case of previously (>than 3 months) treated patients, overall sensitivity and NPV of Epicheck (90.5% and 91.1%) appeared higher than cytology (82.3% and 46.4%) and cystoscopy (83.3% and 68.1%); the same in case of recent treatment (95.6% and 97.3% for EpiCheck, 82.6% and 88.6% for cytology, 52.6% and 75.0% for cystoscopy, respectively). In patients with CIS, sensitivity and NPV did not differ between Epicheck (88.0% and 87.0%, respectively) and cytology (88.0% and 84.2%, respectively) in previously treated patients, while the differences were higher in case of recent treatment (100% and 100% for Epicheck vs. 81.8% and 86.7% for cytology, respectively).

Conclusions
The Bladder EpiCheck test showed very high diagnostic values, higher than the currently gold standard assessment. The test might clinically improve the BCa management in terms of reduced number of inconclusive/ suspicious reports of cytology and endoscopy, reduced number of further examinations, reduced associated patient and economic burdens. The non-invasive and not expensive Bladder EpiCheck should be incorporated in standard BCa follow-up setting.

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