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The diagnostic accuracy of Bladder EpiCheck in high-risk population

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Introduction & Objectives

Bladder carcinoma (BCa) represents the most expensive cancer. The main issue of BCa lies in the long follow-up and in the absence of urinary assays able to replace, in terms of diagnostic accuracy, the current gold-standard (cystoscopy + cytology), in particular in high-risk BCa. 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, non-randomized phase-2 study was carried out. Urine for testing was collected before standard-of-care cystoscopy/TURBT. Cytology and Epicheck analysis were performed by two different blinded experienced urocytopathologist. The inclusion criteria were: patients with high risk BCa (high grade, T1, CIS), able to produce 10 ml of urine, able to consent. We recruited 167 consecutive patients (151 in follow-up, 16 with a new diagnosis); we performed 321 Epicheck valutations in total (287 in follow-up, 34 in new diagnosis) Patients with a new diagnosis were compared to 41 consecutive healthy subjects undergoing endoscopic evaluation for macrohematuria. Sensitivity, specicity, negative predictive value (NPV) and positive predictive value (PPV) of EpiCheck were compared to cytology and cystoscopy results, taking the conmatory 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 new diagnosis, the diagnostic accuracy appeared comparable among Epicheck, cytology and cystoscopy in terms of sensitivity (82.3%, 79.4% and 79.4%, respectively) and NPV (87.2%, 83.7%, 85.4%, respectively). In case of follow-up, the diagnostic accuracy of Epicheck appeared higher than cytology and cystoscopy in terms of sensitivity (93.5%, 73.9% and 58.1%, respectively) and NPV (96.4%, 87.5%, 79.3%, respectively). In case of follow-up, the higher diagnostic accuracy of Epicheck compared to cytology and cystoscopy was confirmed both in case of papillary (sensitivity: 87.8%, 63.7% and 53.7%, respectively; NPV: 95%, 86.7%, 81,5%, respectively) and in CIS tumors (sensitivity: 97.8%, 88.6% and 60%, respectively; NPV: 98.4%, 92.5%, 76.3%, respectively). Similar results were obtain in case of both recently (<3 months) (sensitivity: 93.8%, 86.4% and 57.1%, respectively; NPV: 96.3%, 92.9% and 79.3%,

respectively) and previously (>3 months) treated patients (sensitivity: 91.4%, 98.6% and 57.1%, respectively; NPV: 95.8%, 87% and 81.5%, respectively).

Conclusions

The EpiCheck test showed very high diagnostic values, higher than the currently gold standard. 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.