T03-35 COMPARISON OF 2 NEWLY DEVELOPED BLADDER CANCER TESTS IN THE FOLLOW UP OF PATIENTS WITH NON MUSCLE INVASIVE BLADDER CANCER (NMIBC): PRELIMINARY RESULTS

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INTRODUCTION and OBJECTIVES

Cystoscopy is the most efficient method currently available for the diagnosis of primary or recurrent Bladder cancer (BC), but it is invasive and causes significant discomfort to the patient. Furthermore, flat tumors or carcinoma in situ may be difficult to detect. Urinary cytology is not invasive and very effective in diagnosing high grade lesions but it has a low sensitivity in low grade tumors, which are the most common types of BC.

The limitations of cytology and cystoscopy both for primary diagnosis and monitoring of patients after BC was removed, led to the development of new urine tests for the early detection of BC. The aim of this study was to compare the diagnostic value of 2 newly developed urine tests, the mRNA based Xpert® BC Monitor and the DNA methylation based Bladder Epicheck™ in patients under follow-up after TUR.

PATIENTS AND METHODS

58 patients (mean age 77 yrs, range 51-90) under follow up for NMIBC were studied prospectively. Samples were analyzed with the Bladder Epicheck™ Test, the Xpert® BC Monitor and voided urinary cytology. Subsequently to urine collection, the patient underwent cystoscopy and if cystoscopically positive, a TUR-B.

Cytologies were evaluated according to the Paris System of reporting cytology. For the Bladder Epicheck™ Test a software calculates the EpiScore, a number between 0 and 100 representing the overall methylation level of the sample. If the EpiScore is equal or above 60 it is considered positive. The results of the Xpert® BC Monitor are interpreted by the GeneXpert® Instrument System and given as LDA totals and Analyte Results on the Test Report. A cut-off is set at a LDA of >0.5.

Sensitivity, specificity, PPV and NPV of Bladder Epicheck™ , Xpert® BC Monitor and cytology were calculated using cystoscopy/histology as gold standard.

RESULTS

Of the 58 patients 5 (8.6%) had to be excluded due to insufficient DNA in the Bladder Epicheck Test. 13 out of 53 remaining patients had histologically verified BC of the bladder. 40/53 patients were negative cystoscopically and/or histologically. Of the 13 patients with BC 8 (61.5%) were found positive for Bladder Epicheck™ and Xpert® BC Monitor and 4 (30.7%) for cytology.

The sensitivity of both tests increased from 42.8% for low grade (LG) to 83.3% in high grade (HG) tumours. Specificity was 77.5% (31/40) for Bladder Epicheck™, 65% (26/40) for Xpert® BC Monitor and 97.5% (39/40) for voided urinary cytology.

CONCLUSION

The Bladder Epicheck™ is equal to the Xpert® BC Monitor in sensitivity but superior in specificity. None of the both tests was able to reach the high specificity of cytology.

Xpert® BC Monitor is easy and fast to perform while the Bladder Epicheck™ requires dedicated technicians and is more time consuming. Both tests could be, however, of interest as an additional tool in the follow up of patients with NMIBC, reducing the number of cystoscopies.