

# T03-38 XPert® BLADDER CANCER MONITOR IN THE FOLLOW UP OF PATIENTS AFFECTED BY NON MUSCLE INVASIVE BLADDER CANCER (NMIBC): AN UPDATE



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## INTRODUCTION and OBJECTIVES

Bladder cancer (BC) has one of the highest recurrence rates of any other tumour, ranging from 50% to 70% within 5 years of the first treatment, requiring a lifelong follow up with cystoscopy and cytology, limited for its low sensitivity in low grade tumours. The Xpert® Bladder Cancer Monitor kit is a new urinary marker test based on the evaluation of 5 targets mRNAs (ABL1, CRH, IGF2, UPK1B and ANXA10), overexpressed in patient with BC.

The aim of our study was to further evaluate the diagnostic accuracy of the Xpert® BC Monitor test in the follow up of patients with history of NMIBC and to compare it with urinary cytology, cystoscopy and/or histology.

## PATIENTS AND METHODS

290 patients under follow up for NMIBC were included in this prospective study. Samples were analyzed with the Xpert® BC Monitor kit and urinary cytology. Subsequently to urine collection, the patient underwent cystoscopy and if positive a TUR-B.

Cytologies were evaluated according to the Paris System of reporting cytology. For statistical analysis, negative for high grade urothelial cancer and atypical urothelial cells were grouped as negative, suspicious for high grade urothelial cancer, high grade urothelial cancer and low grade urothelial neoplasia as positive. The Xpert® BC Monitor test was reported by the software as negative or positive (cut-off total LDA=0.5).

Sensitivity, specificity, PPV and NPV of Xpert® BC Monitor and cytology were calculated using cystoscopy or histology results, if available, as gold standard

## RESULTS

Median age of the patients was 73.5 years (range 28-95). Patients were followed up for low grade (LG) NMIBC in 188 cases and for high grade (HG) in 102 cases. One patient had to be excluded due to not diagnostic cytology and Xpert BC Monitor. Of the remaining 289 patients, 77 had tumour recurrence (60 LG (77.9%), 17 HG (22.1%)). Overall sensitivity was 19.4 % (15/77) for cytology, 48.05% (37/77) for Xpert® BC Monitor and 51.5% (40/77) for the two tests combined. The sensitivity of cytology increased from 5% (3/60) in low grade (LG) to 70.6% (13/17) in high grade (HG) tumours whereas, for the Xpert® BC Monitor, the sensitivity was 40% (17/60) in LG and 76.5% (13/17) in HG tumours. Combined cytology and Xpert® BC Monitor yielded an overall sensitivity of 41.6% (18/60) for LG and 94.1% (16/17) for HG tumours.

Overall specificity was 99.5% for cytology and 75.5% for Xpert® BC. PPV for cytology was 93.7% and for Xpert® BC Monitor 42% while NPV was similar for the 2 tests: 77.3% for cytology versus 80% for Xpert® BC Monitor.

## CONCLUSION

Our data confirm that the sensitivity of the Xpert® BC Monitor Test is significantly higher than for cytology as previously reported. The test performs very well in terms of specificity but cannot reach the extremely high value of cytology, PPV is significantly lower than for cytology, while NPV performs approximately the same for both tests.