

Innovative Urinary Marker for Routine Use in the Identification of Bladder Cancer

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Introduction

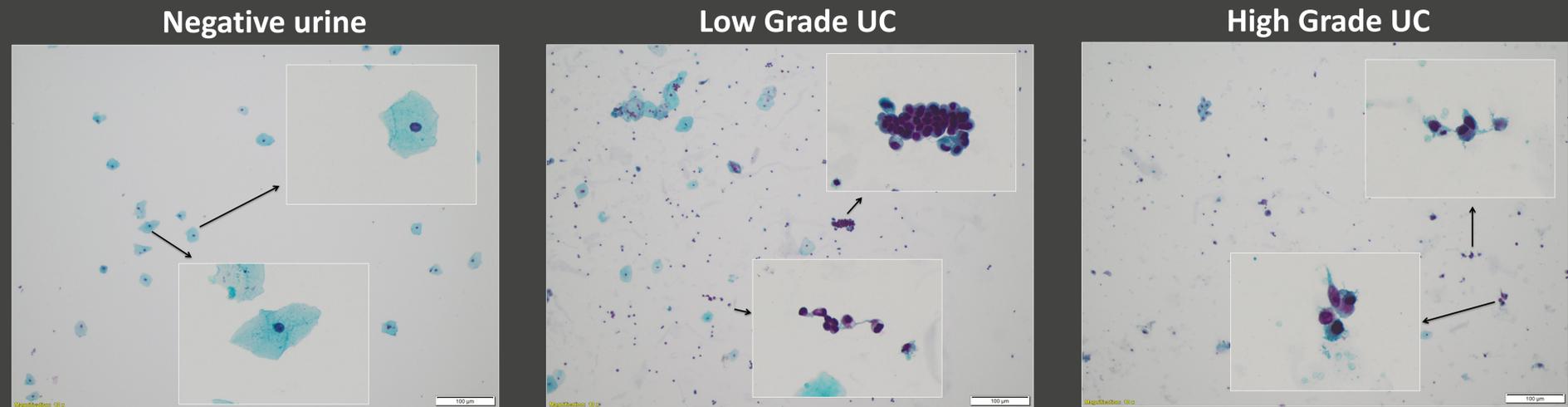
Accurate detection of low-grade (LG) urothelial carcinoma (UC) may be challenging, particularly in cases where cytomorphologic features overlap with those of non-neoplastic changes. CellDetect[®] histochemical stain uses a color feature to highlight neoplastic cells in urine specimens. A blinded study has shown that this color feature significantly improves sensitivity especially for LG tumors, when compared to standard urine cytology (PAP). The objective of the present study was to confirm this finding in routine clinical settings.

Materials and Methods

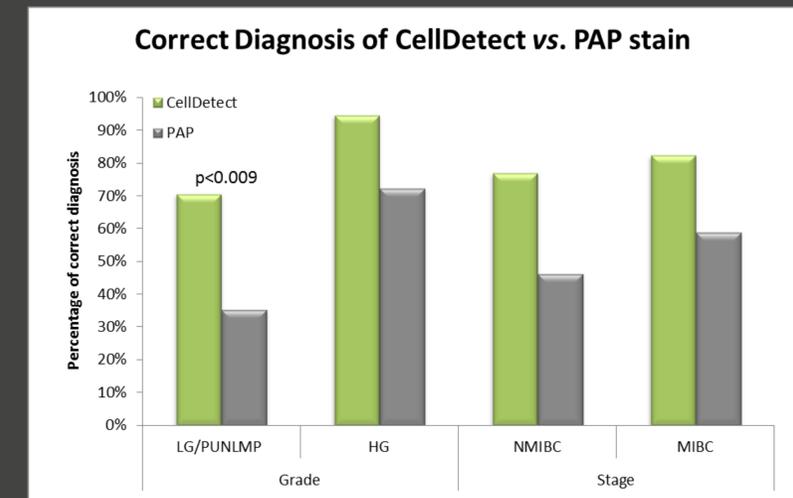
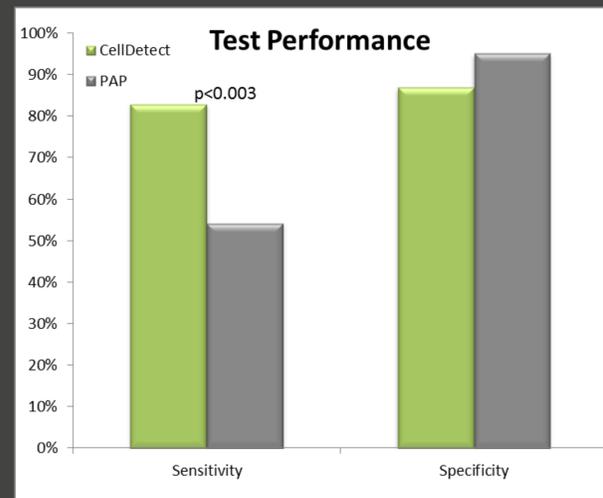
Patients undergoing routine cystoscopic surveillance or TURBT were enrolled. Voided urine samples were preserved and processed into two cyto centrifuge smears. The slides were stained automatically by CellDetect[®] and standard cytology stain. A Cytopathologist, blinded to the final diagnosis, first observed the standard cytology slide and separately the CellDetect[®] slide. The results were then compared to the gold standard (biopsy for positive cases, biopsy or cystoscopy for negative cases).

Results

98 patients were enrolled in this study, 63 UC-negative and 35 UC-positive. The overall sensitivity and specificity of CellDetect[®] were 83% and 87% respectively compared to 54% and 95% for standard staining. The marker was able to detect 71% of the LG/papillary urothelial neoplasm of low malignant potential (PUNLMP) compared to 35% by standard cytology (n=17, p<0.009). In addition, CellDetect[®] correctly diagnosed 94% of 18 high grade tumors compared to 72% by standard staining. Sensitivity of CellDetect[®] was superior compared to standard cytology for both non-muscle invasive bladder cancer (NMIBC, n=26, 77% versus 46%, p<0.008) and muscle invasive bladder cancer (MIBC, n=9, 100% versus 78%). Finally, the biomarker was able to correctly diagnose 77% of cases considered "atypical" by standard cytology.



Urine smears stained by CellDetect[®]. Epithelial cells are stained in green while dysplastic cells exhibit purple nuclei



Conclusions

This study validates the use of CellDetect[®] in routine clinical settings and highlights its strength compare to the standard urine cytology, to identify UC throughout all cancer grades and particularly LG tumors. In addition the study reinforces CellDetect[®] usefulness in reducing the number of undetermined cases. A study comparing CellDetect[®] performance to that of FISH is ongoing.