CellDetect Histochemical Stain For The Monitoring Of Urothelial Carcinoma In Clinical Setting

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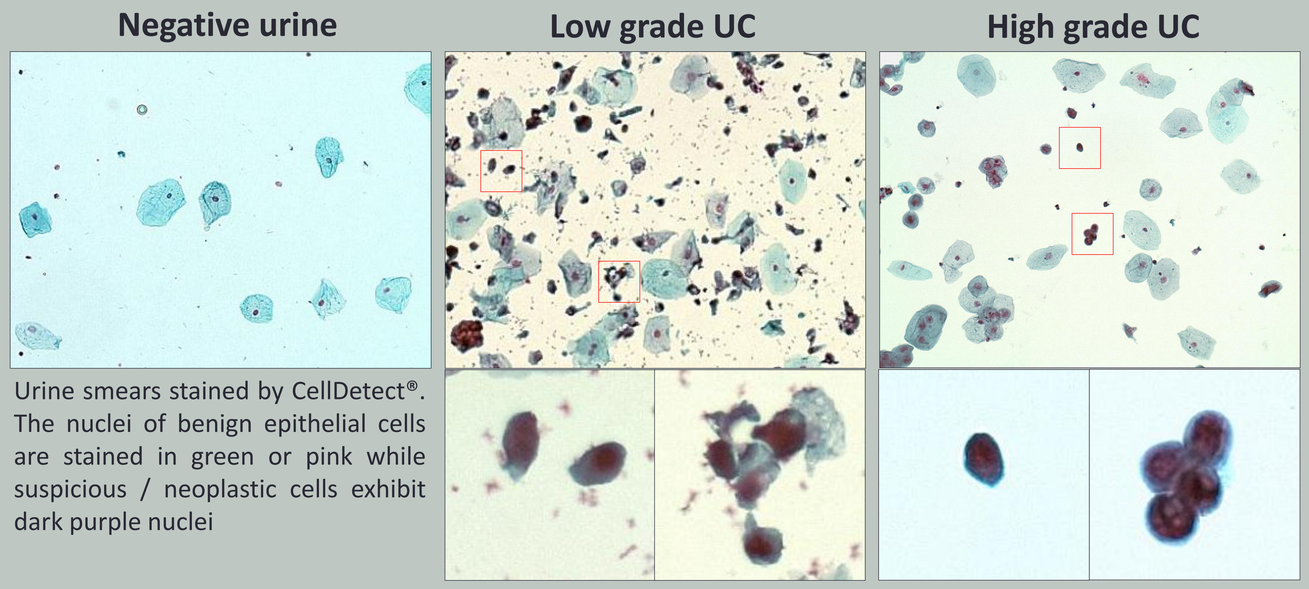
Introduction

Voided urine cytology is a standard test for surveillance of urothelial carcinoma (UC), however of limited validity. Recently introduced histochemical stain, CellDetect®, is based on adding color discrimination to morphological examination of urine specimen. The target of the stain are the nuclei, which are stained green or pink in benign and purple – red or dark red in suspicious / malignant epithelial cells. CellDetect® demonstrated efficacy in multicenter trials. However, there was limited experience on applicability in daily clinical practice. The aim of the present study was to assess the value of CellDetect® in a cohort of patients presenting with suspicion of UC in an academic center.



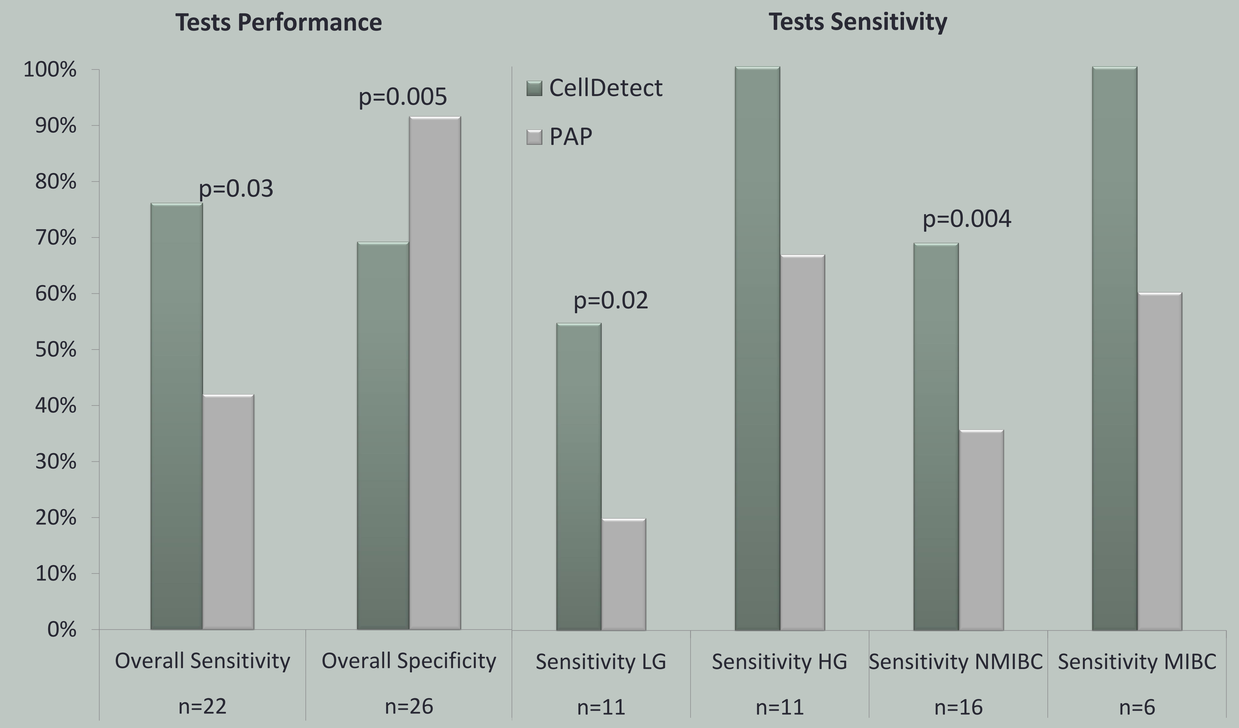
Urine smears stained by CellDetect®. The nuclei of benign epithelial cells are stained in green or pink while suspicious / neoplastic cells exhibit dark purple nuclei

Materials and Methods

Patients under surveillance for UC were enrolled in the prospective study at the University Hospital of Tuebingen. Voided urine samples were collected from patients undergoing routine surveillance or scheduled for TURBT. Samples were divided into two portions of at least 30 ml each and processed by Cytospin. One portion was routinely stained by Papanicolaou (Pap) whereas the other was stained by CellDetect®. For both procedures, a definitive result was given whereby 'suspicious' was determined positive. Cystoscopy and/or histology were used as gold standard.

Results

Forty eight patients (male/female = 34/14, mean age 71) were enrolled in the study, among them 26 were proven negative and 22 positive for UC. Among the positive cases, 11 were low grade (LG) and 11 high grade (HG). The overall sensitivity of CellDetect® was 76% compared to 42% for Pap (p=0.03), specificity of CellDetect® was 69% versus 92% for Pap (p=0.005). Notably, sensitivity for LG/HG was 55%/100% for CellDetect® versus 20%/67% for Pap. When classified according to stages, the UC-positive cases included 11 Ta, one T1, 4 CIS and 6 ≥T2. In non-muscle invasive bladder cancer (NMIBC) sensitivity was 58% for CellDetect® versus 27% for Pap, and in muscle invasive bladder cancer (MIBC) 100% for CellDetect® and 60% for Pap.



Conclusion

The study demonstrates the superiority of CellDetect® upon standard cytology in means of sensitivity and validates its usability in clinical setting. This suggests CellDetect® stain can play a key role as a method in ruling out urothelial carcinoma due to its higher sensitivity and lower specificity compared to the Pap stain. Continued evaluation is warranted to further impact the interpretation recommendations. Moreover, the evaluation of the test in the target population of patients undergoing routine cystoscopic surveillance is necessary to assess applicability.

* Dr. Alexander Shtabsky serves as a consultant to Micromedic Technologies Ltd