



CELLDETECT® TESTING FOR THE DIAGNOSIS AND SURVEILLANCE OF BLADDER CANCER IN ROUTINE CLINICAL SETTINGS, HEALTH SERVICE LABORATORIES; THE ROYAL FREE HOSPITAL EXPERIENCE

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INTRODUCTION

Bladder cancer caused 5400 deaths in the UK in 2014. The standard of care for detection is cystoscopy, however this is invasive and relatively expensive. Urine cytology is an alternative non-invasive method of detection, but shows poor sensitivity, particularly in low grade tumours and a relatively high number produce an indeterminate result, such as 'atypia' or 'suspicious'. Therefore, a better test is needed to discriminate between non-neoplastic (reactive) 'atypia' and low-grade urothelial carcinoma. CellDetect® is a novel immunohistochemical stain, which has been shown to discriminate between malignant and benign urothelial cells, with a sensitivity and specificity of 84% (1). In this study, we have investigated the use of the CellDetect® test for this purpose, and compared the performance of the immunohistochemical stain to that of standard urine cytology.

METHOD

Voided urine samples were supplied to the Royal Free Hospital cytology laboratory. Consecutive voided urine samples with sufficient volume were split. Two confidential ThinPrep slides were produced for each sample; a Papanicolou (PAP) stain was automatically applied to one slide, the second was manually stained with CellDetect®. The slides were reviewed by a consultant cytopathologist and the PAP slides were categorized into positive or negative for malignancy, or atypia (i.e. indeterminate). The CellDetect® slides were categorized as positive or negative.

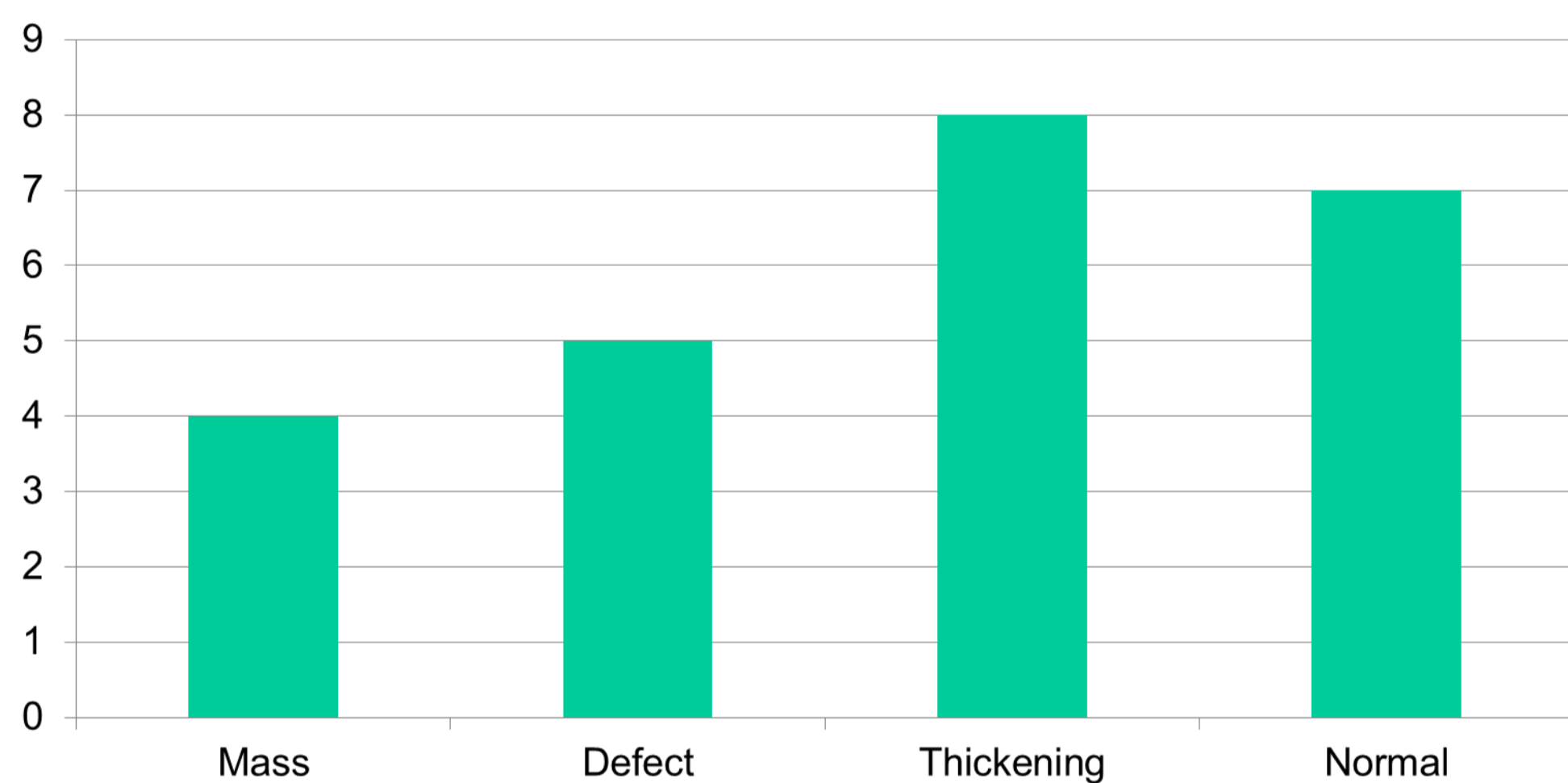


Fig.2. Radiological presentation of samples

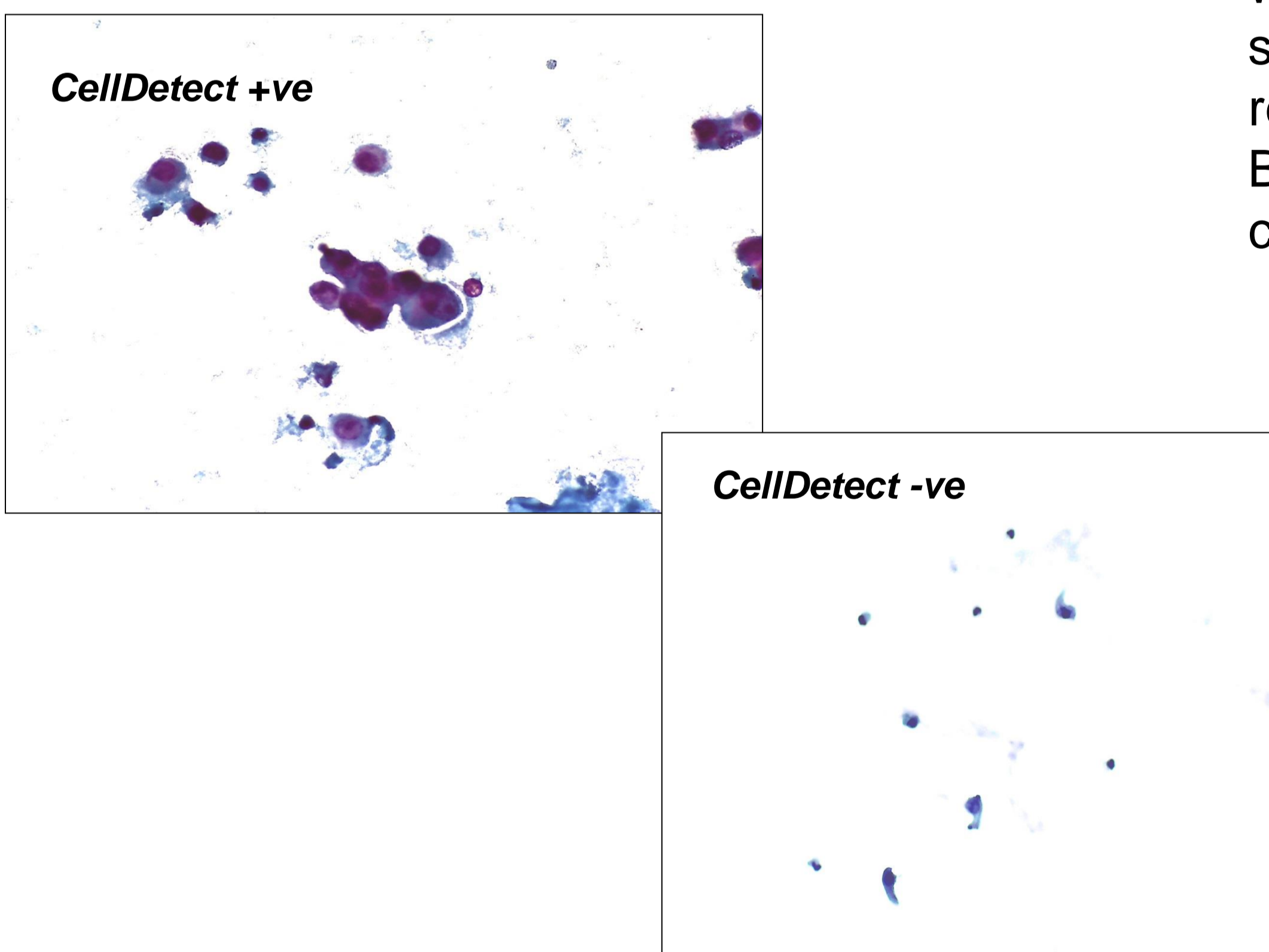


Fig.4. CellDetect® positive and negative staining

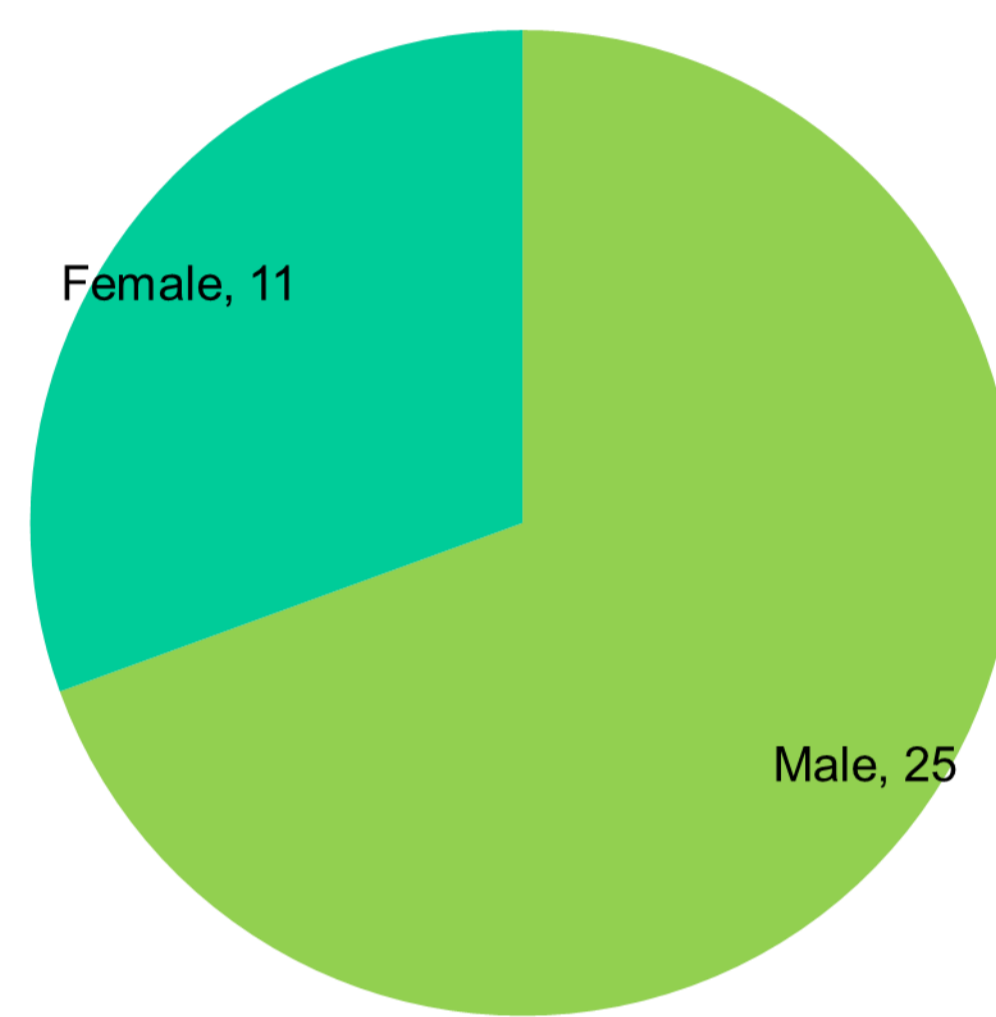


Fig.1 Number of samples by gender

RESULTS

36 cases were included, all of which had CellDetect® and PAP cytological preparations. 25 samples were from male patients and 11 were from female patients (Fig.1). The radiological presentation was available for 24 samples, which was either normal, or showed a mass, a defect or thickening (Fig.2). Of the 36 cases, eight were reported as 'atypical' on cytology. Seven of these cases were CellDetect® positive and one was negative (Fig.3). Two 'atypical' cases had a subsequent biopsy, one showed inflammation with reactive changes, the other showed severe atypia. Both cases showed areas of erythema on cystoscopy.

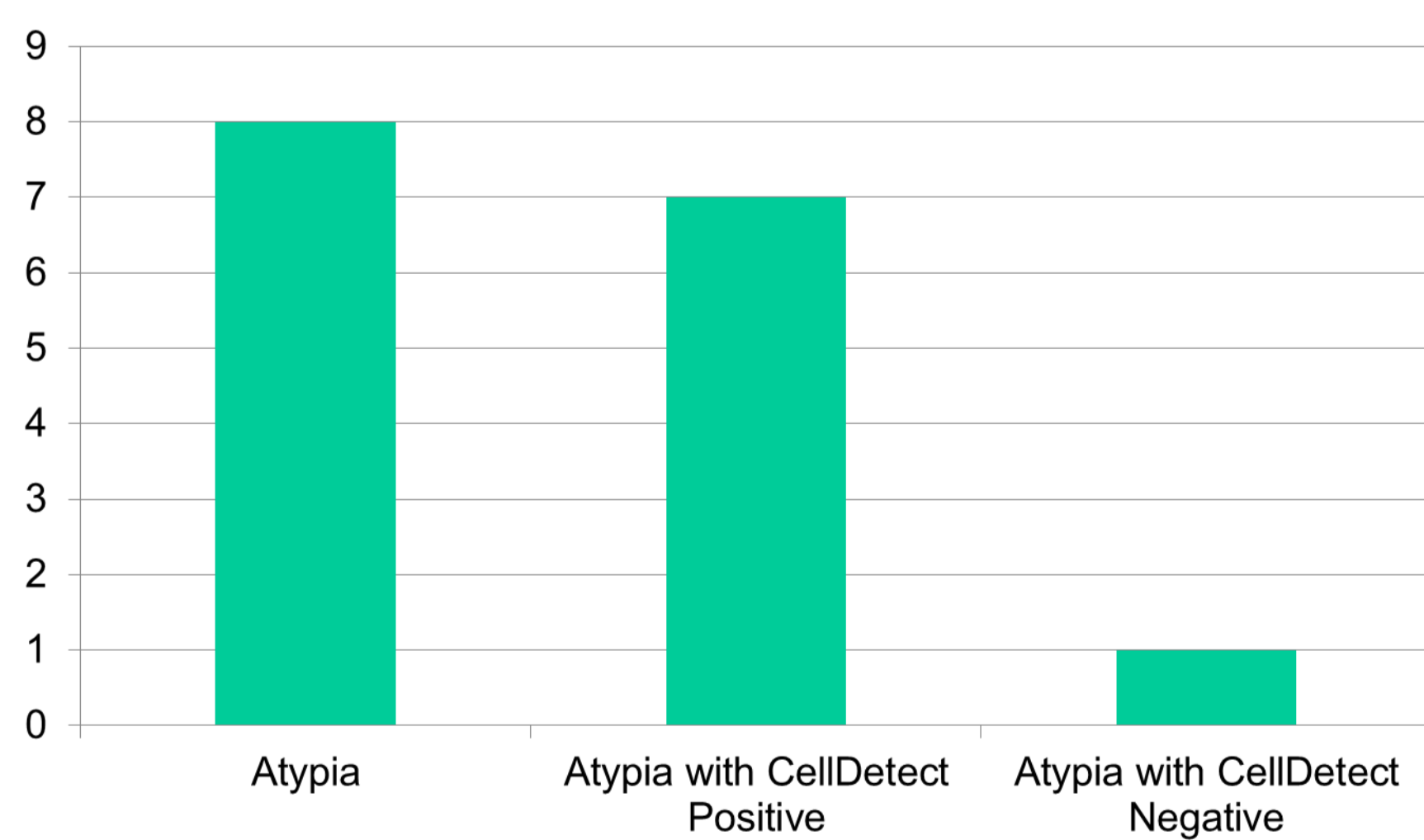


Fig.3. Cytologically 'atypical' cases

CONCLUSION

CellDetect® has been found to be useful as an additional test in cases where urine cytology is atypical or indeterminate. A positive result with CellDetect® supports a diagnosis of malignancy in these cases, whereas a negative result is reassuring, without compromising the sensitivity or the specificity. It would be particularly useful in the adjunctive monitoring of low-risk patients, for whom non-invasive surveillance is not recommended because of the low accuracy of existing markers in the correct diagnosis or recurrent tumours, presumably because of their small size.

References

1. A Novel Urine-Based Assay for Bladder Cancer Diagnosis: Multi-Institutional Validation Study. Eur Urol Focus (2016), <http://dx.doi.org/10/1016/j.euf.2016.10.004>