In urothelial carcinomas, MCM5 is expressed in all layers resulting in full void urine samples were collected from patients presenting with haematuria. 655 patients recruited.

- 78 excluded from analysis
- 31 incomplete CRF/lost to follow up
- 14 other uro-genital cancer diagnosis
- 1 withdrawn consent
- 30 insufficient sample provided (<10ml)
- 2 subsequently diagnosed with prostatitis

Table 1: Clinical characteristics of patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (% or median [IQR])</th>
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</thead>
<tbody>
<tr>
<td>Total Population</td>
<td>577 (100%)</td>
</tr>
<tr>
<td>Bladder cancer Positive</td>
<td>46 (7.96%)</td>
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Introduction

- Urinary biomarkers can act as a non-subjective method of detecting the presence of bladder cancer cells
- MCM5 is a novel biomarker of growth and in normal urothelium expression is restricted to the basal proliferative compartment
- In urothelial carcinomas, MCM5 is expressed in all layers resulting in the exfoliation of MCM5-expressing tumour cells into the urine (Figure 1)

Figure 1: Shows the distribution of MCM5 expressing cells with MCM5 positive cells only being exfoliated in the presence of a malignancy/dysplasia (Figure adapted from Current Opinion in Cell Biology 2007, 19:672–679)

Objective

- To evaluate the performance of a novel MCM5 based ELISA test, (ADXBLADDER), for the primary detection of bladder cancer in patients presenting with haematuria

Materials & Methods

- Performed a multicentre prospective performance evaluation study at 6 UK sites
- Full void urine samples were collected from patients presenting with haematuria
- ADXBLADDER test performed and compared to the diagnosis obtained by cystoscopy, imaging, and resection biopsy of suspect lesions

Results

- 655 patients recruited
- 78 excluded from analysis
- 31 incomplete CRF/lost to follow up
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<tr>
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<th>Age (y)</th>
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<tr>
<td>318 (56%)</td>
<td>248 (44%)</td>
<td>63 (53-72)</td>
</tr>
<tr>
<td>35 (76%)</td>
<td>11 (24%)</td>
<td>71 (63-81)</td>
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Figure 2: Overall sensitivity for ADXBLADDER was 76% (95% CI 61.22% to 87.41%). Specificity is high at 69% (95% CI 65.06% to 73.58%). The overall negative predictive value was 97.1% (95% CI 95.22% to 98.25%).

Conclusion

- ADXBLADDER achieved good overall sensitivity in the detection of bladder cancer in voided urine and high NPV of greater than 97%.
- Sensitivity for the detection of high-risk and muscle invasive disease was 95%, with a 99.7% NPV.
- These results demonstrate that ADXBLADDER can be used to aid in the detection of bladder cancer, and could replace cytology as an adjunctive test in bladder cancer diagnosis.