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ORIGINAL ARTICLE

A prospective comparison of the NMP22 BladderChek® assay and voided urine cytology in the detection of bladder transitional cell carcinoma: Is it time up for urine cytology?

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KEYWORDS
NMP22 BladderChek®;
Urine cytology;
Bladder carcinoma;
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Summary
Objectives: To prospectively compare the performance of voided urine cytology (VUC) and the Matritech NMP22 BladderChek® assay (NMP22) in their ability to detect urothelial transitional cell carcinoma (TCC).
Methods: Successive patients presenting to our haematuria clinic were enrolled. All patients underwent ultrasound scan (US), intravenous urography (IVU), flexible cystoscopy and VUC. If bladder TCC was detected, urine was tested using the NMP22 BladderChek® assay. The study group (group I) comprised 110 patients diagnosed with bladder tumour on flexible cystoscopy. The control group (group II) included 52 patients with a history of haematuria but no demonstrable bladder tumour. The TCC detecting ability of both the NMP22 BladderChek® assay and VUC were compared.
Results: In group I, the NMP22 result was positive in 62.7% (69/110) patients, while a positive VUC result was noted in 52.0% (52/100) patients. The overall sensitivity, specificity, positive predictive and negative predictive values for NMP22 vs. VUC were 62.7% vs. 52.0%; 86.5% vs. 95.5%; 90.8% vs. 96.3% and 52.3% vs. 48.0% respectively (not significant). The performance of both urine tests improved with increasing tumour grade ($p \leq 0.05$). False positive rate in group II was 13.5% (7/52) for NMP22 and 4.5% (2/42) for VUC.

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Conclusion: The diagnostic accuracy of the NMP22 BladderChek® assay for TCC detection is equivalent to conventional VUC, but the NMP22 BladderChek® has distinct advantages to promote its use over VUC.
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Introduction

Bladder carcinoma is the most common malignancy of the urinary tract in Europe, and though the majority of these are non-muscle invasive transitional cell carcinoma (TCC), tumour recurrence and progression may be noted in up to 70% of patients [1]. Cystoscopy remains the gold standard technique for bladder TCC detection. Repeated flexible cystoscopy procedures are relatively expensive, invasive and uncomfortable and thus a variety of non-invasive urinary markers have been investigated recently, of which two — nuclear matrix protein 22 (NMP22) BladderChek® (Matritech Inc. MA, USA) and UroVysion® (Abbott Molecular, Il, USA) — have received approval from the USA Food and Drug Administration [2].

Voided urine cytology (VUC) has historically been the primary urine based detection method with a high overall specificity. However, drawbacks include a low sensitivity (especially in low grade TCC), often poor cellular yield and inter-observer variability [3]. Many investigators have reported their experience with the qualitative NMP22 BladderChek® point of care assay compared to urine cytology with variable results [4—8]. Our series contains one of the largest numbers of patients with newly diagnosed and histologically confirmed bladder TCC. We present a prospective head-to-head comparison of the performance of the NMP22 BladderChek®NMP22 assay and conventional VUC in bladder tumour detection.

Materials and methods

Approval from the local ethical committee was obtained. Patients ($n = 162$) were prospectively recruited from those attending for a flexible cystoscopy following a recent history of either visible or non-visible haematuria. All flexible cystoscopy examinations were performed by highly experienced urological surgeons. Evaluation of such patients included a thorough physical examination, urine analysis (dipstick, microscopy, culture and cytology), flexible cystoscopy, renal tract ultrasound (US) and intravenous urography (IVU). In addition, a clean, freshly voided urine sample (30 mls) was obtained prior to instrumentation. If a urinary tract TCC was detected, the urine was tested using the NMP22 BladderChek® assay.

Exclusion criteria were based on manufacturer recommendation to eliminate factors potentially interfering with NMP22 or VUC results. Thus patients with the following were excluded — benign inflammatory conditions (e.g. active urinary tract infection); presence or history of foreign body within the urinary tract (e.g. catheter, stent, nephrostomy); renal or bladder calculi; bowel interposition segment (e.g. ileal conduit, continent diversion); irritation of bladder (e.g. due to intravesical BCG or mitomycin); other infiltrating genitourinary malignancies; urinary tract instrumentation within 3 weeks and urine obtained by bladder washout. Those eventually found to have upper tract TCC were excluded in this comparison due to the small numbers ($n = 2$).

The study group (group I) comprised 110 consecutive patients diagnosed with a bladder tumour on flexible cystoscopy. These patients underwent subsequent transurethral resection (TUR) of bladder tumour and the tumour tissue was graded using the 1973 WHO grading classification [9]. The control group (group II) included 52 patients with a history of haematuria but no demonstrable bladder tumour on cystoscopy. All patients in group II underwent NMP22 and VUC urine testing.

Urine tests

The NMP22 BladderChek® is an immunochromatographic assay which requires placement of four drops of fresh urine into the sample well. The monoclonal capture and reporter antibodies will detect the presence of NMP22 if present in a urinary concentration of >10 U/ml. A visible positive reading, akin to a pregnancy test kit, is seen within 30 min. All patients had NMP22 data available for analysis.

Voided urine cytological analysis (Papanicolaou-stained sample) was performed by a cytopathologist blinded to the outcome of the NMP22 test. VUC demonstrating frankly malignant or suspicious cells

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