Clinical Utility Of NMP22 Assay In The Initial Diagnosis Of Patients With Unresolved Hematuria Or Other Risk Factors For Urinary Tract Cancer To Improve The Accuracy Of Voided Cytology: Reduces The Number Of Urological Referral At Primary Care Setting?

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Background and Objective: It is impractical to screen all people at elevated risk for bladder cancer by cystoscopy. Therefore, a cost effective, non-invasive method is necessary. The predicted advantage of indexing atypical cytology with NMP22 test is that, it is equally effective in diagnosing superficial tumors as well as muscle invasive cancers. Evaluating those patients with hematuria utilizing NMP22 and urinary cytology could enhance this paradigm by reducing the number of cystoscopies. NMP-22 Essay is a double monoclonal Ab immunoassay for the quantitative measurement of the nuclear mitotic apparatus protein designated NMP22, performed on a stabilized urine sample.

Experimental design: we retrospectively analyzed, 197 (screening) cases and 71 prevalent (monitoring) cases at risk for bladder cancer (atypical urine cytology). Office cystoscopies were performed on all patients with atypical cytology. All cancers were histologically confirmed. The atypical cytologies were then indexed to NMP22 values in an effort to decrease false-positive results.

Results: In the screening cases, the 126 atypical cytologies detected 17 cancers for a positive predictive value (PPV) of 13% (17/126). When stratified by NMP22, cutoff value of >10U/ML, PPV increased to 71% (15/21). In the monitoring cases, the 71 atypical cytologies detected 43 cancers for a PPV of 61% (43/71). When stratified by NMP22 cutoff >6U/ML, PPV increased to 92% (35/38).

Conclusions: This refinement in the clinical application of atypical cytology indexed with NMP22 can have a significant impact on the early detection of patients with predisposing factors for bladder cancer. When an atypical cytology is indexed to NMP22 the pre-cystoscopy work up alerts the physician to the likelihood of a neoplasm and can therefore enhance the disease detection rate of cystoscopy (92% in the prevalent group; 71% in the incident group).