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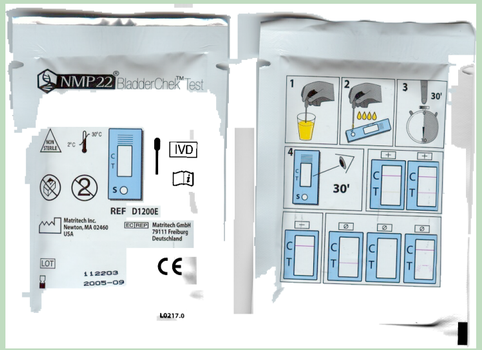
Early detection of bladder cancer in hematuria patients: Vision becomes reality

P. Oehr , University Bonn, Germany.

Objective

The diagnostic power of the new Matritech NMP22-BladderChek® POC assay was investigated.



Material & Methods

This qualitative POC-assay (package + handling shown above) is a 30 min. chromatogrphic analysis of 4 drops fresh voided urine at room temperature including antigen detection by anti-NMP22-(nuclear matrix protein)-antibodies.

Excluding urocystitis, stones, urinary tract infections and incorporated catheters, and prior to endoscopy, 212 hematuria patients in 16 urologic practitioners sites were investigated.

Results

Total patients evaluation achieved 82% sensitivity, 98% specificity, as well as to 82% for the positive- and 98% for the negative predictive value.

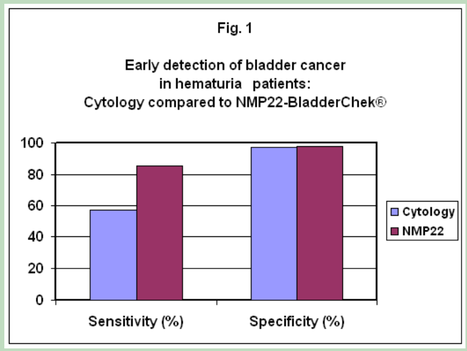
In 113 patients, NMP22-BladderChek® and cytology could be evaluated simultaneously (10 urology sites).

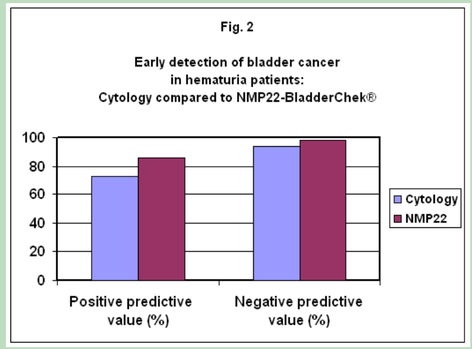
NMP22-BladderChek® had 86% sensitivity and 98% specificity compared to cytology with 57% and 97%, respectively (Figure. 1).

The positive predictive values were 86% and 73%, the negative predictive values were 98% and 94% for BladderChek® and cytology, respectively (Figure 2).

When both tests were positive, every patient turned out to have urinary bladder cancer (8 of 14 cases) (see Table).

Under the condition: "both tests are negative" in the tumor negative group (99 cases), the result was true negative in 94 cases, and false negative in only 2 cases.





Simultaneous determination by cytology und NMP22 BladderChek				
113 patients: 14 patients with urinary bladder cancer, 99 without				
	NMP22 (TP)	NMP22 (TN)	NMP22 (FP)	NMP22 (FN)
Cytology (TP)	8	0	0	0
Cytology (TN)	0	94	2	0
Cytology (FP)	0	3	0	0
Cytology (FN)	4	0	0	2
both tests simultaneously true positive (TP): in 8 of 14 cases (57%)				
both tests simultaneously true negative (TN): in 94 of 99 cases (95%)				
both tests simultaneously false positive (FP): in no case (0%)				
both tests simultaneously false negative (FN): in 2 of 99 cases (2%)				

Conclusions

The superior sensitivity of NMP22-BladderChek® over cytology, at the specificity of 98%, and the negative predictive value of 98%, give reason to call it an easy to handle cancer screening assay.

Combined use with cytology can result in a highly reliable screening: under the condition "both test are positive", no false positive results arose, making this assumption a 100% tumor inclusion criterion in 67% of the patients who had developed a yet undetected urinary bladder cancer.

In addition, a negative predictive value of 98% for NMP22-BladderChek® is an excellent exclusion criterion.

Independently, NMP22-BladderChek® can detect 82% to 86% urinary bladder cancer in supected hematuria with a specificity of 98%.

NMP22- BladderChek® can change the routine patient management of hematuria patients with suspected urinary bladder cancer, and pave the avenue for screening.