

Urine Test Screens for Bladder Cancer in Hematuria

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PARIS — The noninvasive NMP22 BladderChek assay gives general practitioners a way to screen asymptomatic patients with hematuria for bladder cancer during office visits, Dr. H. Barton Grossman said at the annual congress of the European Association of Urology.

"At least in the United States, most of these patients are not being tested at all,

not being referred to urologists, until they have several episodes of significant blood in their urine," said Dr. Grossman, professor and chairman of urology at the M.D. Anderson Cancer Center in Houston.

"I think the best use of this test is actually going to be in the initial diagnosis of people with hematuria in general practice offices," he told European urologists who questioned whether the NMP22 protein assay yields too many false-positive results for urologists to find it clinically useful.

Dr. Grossman presented updated results from a large study that found that the NMP22 protein assay can increase the accuracy of screening when used in combination with cystoscopy (JAMA 2005;293:810-6).

The investigators compared the NMP22 test results with cytology results, with cystoscopy as the reference standard. Patients provided a voided urine sample before undergoing cystoscopy. The urine sample was divided into two

parts: One portion was tested for NMP22 in the office, and the other was sent for routine cytology.

If a tumor was found and removed during cystoscopy, diagnosis was based on pathology of the tumor.

A total of 23 academic, private practice, and veterans' facilities in 10 states recruited high-risk patients from September 2001 to February 2002. Of 1,331 patients enrolled, 79 patients (6%) were found to have bladder cancers.

In the data Dr. Grossman reported at the meeting, the NMP22 test was significantly more sensitive than cytology for detecting every stage of bladder cancer, including low-, mid-, and high-grade tumors. Overall, its sensitivity was 57%, compared with 18% for cytology.

Dr. Grossman said the NMP22 test picked up six bladder cancers that were missed by cystoscopy. Used together, the noninvasive protein assay and the endoscopic procedure detected 94% of cancers (74/79) in the study population. Only 86% (68/79) were found by cystoscopy alone.

Eleven patients had muscle invasive cancers. Dr. Grossman said 10 (91%) were identified by the combination of cystoscopy and NMP22, compared with six (55%) found with cystoscopy alone.

Though less sensitive, cytology was more specific than the NMP22 assay: 99% vs. 86% in patients who did not have cancer.

Taking questions from the audience at the conclusion of his talk, Dr. Grossman debated estimates of the protein test's false-positive rate with European urologists who have argued that it is as high as 80%.

Dr. Grossman rejected the critics' estimates as too high, and said that in any case the test was not considered an alternative to cystoscopy.

"The more tumors you pick up, the fewer tumors you are going to miss, and that results in a greater negative predictive value," he said.

In an interview, he said the NMP22 test is ideal for general practitioners because they can pretty well rule out bladder cancer if it is negative. If it is positive, he said, they should refer the patient to a urologist for further screening.

"It is fast, and it is cheap," he said. "We have a lot of patients we follow with a history of bladder cancer. If you do this test and it is negative ... you can stop right there because it has very good negative prediction. But the positive prediction is not so high, and we would follow that up."

The test uses four drops of urine and gives results in 30 minutes at a cost of \$25-\$50 per patient, according to Dr. Grossman. A positive finding is based on an NMP22 antigen level of 10 U/mL or greater.

Malignant cancer cells have been found with concentrations up to 80 times greater than those found in normal cells, he said.

The assay is approved for use in the United States and Europe. Its manufacturer, Matritech Inc., financed the study. Dr. Grossman said that he has no financial disclosures. ■



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