10/99 An experimental urine test appears to be a promising new way to detect early stages of bladder cancer. It also may apply to techniques in testing for other types of cancers, including colon and prostate.

The test works by detecting a protein that cancer cells shed in high quantities into urine. Researchers at Cambridge University in England say the test could spare patients the need for risky surgical biopsies.

Normally, people don't realize they may have bladder cancer until they consult a doctor about blood in their urine. But physicians only catch about one in 20 cases of bladder cancer, even though the tumors at that point may be large, researchers say.

In the study, researchers studied 36 patients who had blood in their urine. The urine test accurately detected the eight patients whose biopsies later confirmed they had bladder cancer. A ninth patient did show a false-positive, but that patient had an ulcer.

The study appears in the Oct. 30 issue of The Lancet.

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10/99

SIX YEARS LATER:

Urine Test for Bladder Cancer Proves Accurate, 11/05 SOURCE: The National Cancer Institute "Cancer Bulletin"

A new urine test for bladder cancer successfully identifies 90 percent of cases, Italian authors report in a study published in the October 26 Journal of the American Medical Association. The test identifies high levels of the enzyme telomerase, a hallmark of most cancers.

The authors say that the invasiveness and limited sensitivity of current detection techniques, such as cystoscopy, beg the development of a better test. "The test...requires a small amount of urine, is noninvasive, inexpensive, and easy to perform.…

Furthermore, it is objective, reproducible, and specific, and is not reliant on the expertise of the cytopathologist," they write. The test also identifies low-grade tumors generally missed by traditional techniques.

The study evaluated the telomerase assay in 134 men with bladder cancer diagnosed with traditional techniques and in 84 healthy men. The technicians performing the telomerase assay did not know the status of each volunteer.

The researchers included only men because bladder cancer is three times more prevalent in men than in women. A previous pilot study prompted this larger follow-up.

While detecting 90 percent of cases, the test also correctly identified 88 percent of healthy volunteers. The false-positive rate was 12 percent. The test performed slightly better in men younger than 75 years of age than in older men.

While encouraged by their results, the researchers caution that the test should not be used for routine screening. Instead, they advocate testing for people at high risk - namely smokers and those who report blood
in their urine.

January 2006 99% effective urine test for Recurrence

Surveillance for Recurrent Bladder Cancer Using a Point-of-Care Proteomic Assay H. Barton Grossman, MD; Mark Soloway, MD; Edward Messing, MD; Giora Katz, MD; Barry Stein, MD; Vahan Kassabian, MD; Yu Shen, PhD

Context At least 50% of patients with a history of bladder cancer have recurrences, so rigorous surveillance is necessary. Cystoscopy is standard but can fail to detect some bladder cancers, so a urine test is frequently part of the evaluation.

Objective To investigate whether a point-of-care proteomic test that measures the nuclear matrix protein NMP22 in voided urine could improve detection of recurrence during monitoring of patients with a history of bladder cancer.

Design, Setting, and Patients From September 2001 to February 2002, 23 academic, private practice, and hospital facilities in 9 US states prospectively enrolled 668 consecutive patients with a history of bladder cancer in this cross-sectional study. Patients provided a voided urine sample for analysis of NMP22 protein and cytology prior to cystoscopy.

Main Outcome Measures Diagnosis of bladder cancer recurrence, based on cystoscopy with biopsy, was accepted as the reference standard. The performance of the NMP22 test was compared with voided urine cytology as an aid to detection. Testing for the NMP22 tumor marker was conducted in a blinded manner.

Results Bladder cancer was diagnosed in 103 patients.

Cystoscopy alone identified 91.3% of the cancers (94/103; 95% confidence interval [CI], 84.1%-95.9%). The combination of cystoscopy with the NMP22 assay detected 99.0% of the malignancies (102/103; 95% CI, 94.7%-100%; P = .005).

The NMP22 assay detected 8 of 9 cancers that were not visualized during initial cystoscopy, including 7 that were high-grade. The sensitivity and specificity of the NMP22 test alone were 49.5% (51/103; 95% CI, 39.5%-59.5%) and 87.3% (493/565; 95% CI, 84.2%-89.9%), respectively.

Voided cytology detected only 3 of the malignancies missed during initial cystoscopy and did not significantly increase the sensitivity of cystoscopy (94.2%; 95% CI, 87.7%-97.8%; P = .08).

Conclusion The noninvasive point-of-care assay for elevated urinary NMP22 protein can increase the ability to detect recurrent bladder cancer, with test results available during the patient visit.

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