

Uriscreen, a Rapid Enzymatic Urine Screening Test: Useful Predictor of Significant Bacteriuria in Pregnancy

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Objective: To establish the reliability of a new rapid enzymatic screening test, the Uriscreen, in the detection of significant bacteriuria in pregnancy.

Methods: During a 6-month period, from July 1 to December 30, 1993, 313 consecutive pregnant patients were evaluated. Randomly voided, midstream, clean-catch urine specimens were used. Each sample was tested by routine laboratory culture and four rapid screening tests: the nitrite and leukocyte esterase dipstick, microscopic examination for pyuria, and the Uriscreen test. Results of the four rapid tests were compared with those of the urine culture.

Results: Twenty-four women (7.6%) had urine culture results indicating significant bacteriuria. The sensitivity of the nitrite test, the leukocyte esterase test, and a microscopic examination for pyuria was low (37, 52, and 56%, respectively). The Uriscreen test showed very high sensitivity (100%), lower specificity (81%), a high predictive value of negative results (100%), and a low positive predictive value (30%).

Conclusions: The Uriscreen test is a reliable alternative to culture screening of all pregnant patients. A policy of performing a urine culture during pregnancy only on patients with a positive Uriscreen test will save as much as 80% of unnecessary cultures. (*Obstet Gynecol* 1996;87:410-3)

Asymptomatic bacteriuria occurs in 5-7% of pregnant patients and is associated with a variety of medical conditions and adverse obstetric outcome.¹⁻³ It has been suggested that the major risks of asymptomatic bacteriuria include the development of acute and chronic pyelonephritis, preterm labor, and low birth weight (LBW) infants. Romero et al⁴ demonstrated that infants born to mothers with asymptomatic bacteriuria have one and a half times the risk of LBW and twice the risk of preterm delivery. In some clinical settings where bacteriuria has a high prevalence in the pregnant pop-

ulation, patients are routinely screened by urine culture at their first prenatal visit for bacteriuria.⁵

To avoid screening of all pregnant patients with a time-consuming and expensive urine culture, many rapid screening tests have been developed. Previous studies evaluated dipstick methods, such as the nitrite and the leukocyte esterase test, as well as microscopic urinalysis, with inconsistent results.⁶⁻¹² Most recently, a new rapid enzymatic urine screening test, the Uriscreen (Diatech Diagnostics Ltd, Kiryat Weizmann, Ness Ziona, Israel), was introduced. This test is based on the detection of catalase activity present in most bacterial species commonly causing urinary tract infection and in somatic cells. Thus, the Uriscreen test combines the detection of bacteriuria and the presence of inflammatory cells and kidney epithelial cells.

The purpose of this prospective study was to compare the reliability of four rapid screening tests—the Uriscreen, nitrite, and leukocyte esterase tests, and microscopic urinalysis for pyuria—to that of quantitative culture in the detection of significant bacteriuria in pregnancy.

Materials and Methods

The study took place between July 1 and December 31, 1993, in the Maternal-Fetal Unit of the Department of Obstetrics and Gynecology, Kaplan Hospital, Rehovot, Israel. Clean-catch, randomly voided urine specimens were obtained from 313 consecutive pregnant women who were either symptomatic or asymptomatic, from both inpatient and outpatient clinics. Gestational age at sampling ranged from 16-34 weeks, mean maternal age was 27 ± 5 years, and all patients had unlimited access to medical care. Patients with vaginal bleeding or those on antimicrobial therapy were excluded from the study. After individual instruction by a special nurse (HS) for

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cleaning the vulvar area, urine was collected in sterile containers without preservatives. One aliquot of each sample was processed by routine quantitative culture; a second aliquot was tested using the Uriscreen test. Additional aliquots were tested by other rapid screening methods, which included leukocyte esterase, nitrites, and microscopic examination for the presence of pyuria. All tests were performed in the same order for each specimen. When sample volume was not sufficient to perform all tests, priority was given to the Uriscreen test and culture. The nurse performing the Uriscreen test was blinded to results of the other rapid tests.

Urine specimens for culture were placed in a sterile tube and processed within 2 hours. Urine cultures were carried out on Mackonky agar and blood agar plates, prepared with B.B.K. culture media (Eldantech, Jerusalem, Israel), by using disposable loops (Quadloops, Miniplast-Ein Shemer, Israel). The plates were incubated for 24 hours at 37°C. Enumeration was performed by estimation of colony-forming units/mL on the appropriate plates. Identification of the bacteria colonies was performed by using a Gram-positive or Gram-negative identification of the VITEK system (VITEK System Inc., Hazelwood, MO).

Urine cultures were considered positive if more than 10^5 colonies/mL of a single strain of organism were isolated. Negative cultures had no organisms or fewer than three nonpathogenic organisms of less than 10^5 colonies/mL. In the analysis of the data, contaminated cultures were considered negative if three or more organisms grew in culture, and a repeated culture showed no growth.

The reagent strip test was used to determine the presence of nitrites and leukocyte esterase activity according to the manufacturers' recommendations using the Ames Multistix 10 SG (Bayer Diagnostics UK Ltd, Basingstoke, UK). Pyuria was determined according to the method described by Clarridge et al.¹³ Fresh, uncentrifuged urine was examined in a standard hemacytometer chamber. Pyuria was considered significant at greater than five white blood cells/cm³.

Procedures of the Uriscreen test were performed by a nurse according to the manufacturer's recommendations within 10 minutes of urine collection. A sample of urine (1.5–2 mL) was added to a test tube containing a reagent powder that enables catalase detection. Then, four drops of 10% hydrogen peroxide solution (supplied by manufacturer) were added to the tube. The tube was mixed gently for 10 seconds to avoid production of foam, until the reagent dissolved and the solution turned blue. The tube was observed for up to 2 minutes. A test was interpreted as positive when the formation of foam within 2 minutes was sufficient to form a complete and continuous ring or layer on the

Table 1. Microorganisms Isolated by Quantitative Cultures From 313 Pregnant Patients

Microorganism	No. of cases
<i>Escherichia coli</i>	12
Group B streptococcus	4
<i>Proteus mirabilis</i>	4
<i>Klebsiella</i>	2
<i>Pseudomonas</i>	2

surface of the liquid in the test tube. The resulting foam indicates the presence of catalase originating from bacteria and/or somatic cells in the urine. Lack of foam indicates a negative test result.

The sensitivity, specificity, and predictive values of positive and negative results were calculated for each of the urine screening tests and for combinations of tests. The urine culture was considered in these calculations as the definitive laboratory test for detection of urinary infection.

Results

Three hundred thirteen patients were studied, of whom 24 (7.6%) were identified by culture to have significant bacteriuria. The specific microorganisms which grew in culture are listed in Table 1. Of the 313 specimens sent for culture, all were tested by Uriscreen, 296 and 288 samples were tested by the leukocyte esterase and nitrite test dipsticks, respectively, and 286 samples were examined by microscope for pyuria. In two of the 313 specimens, culture results indicated contamination. Repeated culture revealed negative results in both cases.

Table 2 presents the calculated sensitivity, specificity, and positive and negative predictive values of the four screening urine tests as compared to culture results. The Uriscreen test showed the highest sensitivity (100%) and predictive value for negative results (100%). All other screening tests, pyuria, nitrite, and leukocyte esterase test, showed low sensitivity (56, 37, and 52%, respectively) and high negative predictive values (97, 96, and 97%, respectively). When results of these three tests were combined, the sensitivity was still low (68%). The specificity of the Uriscreen was lower than that of the other tests, 81% compared with 91, 99, and 90% for the pyuria, nitrite, and leukocyte esterase tests, respectively.

Discussion

Untreated bacteriuria during pregnancy may lead to symptomatic disease and to adverse outcome such as preterm labor, LBW infants, and increased perinatal mortality.¹⁻⁴ Therefore, it has become a common prac-

Table 2. Results of Four Rapid Screening Tests Used for the Detection of Significant Bacteriuria, as Compared With Culture Results

Screening test (n)	Sensitivity %	Specificity %	PPV %	NPV %
Uriscreen (313)	100	81 (±4.5)	30 (±10)	100
Pyuria (286)	56 (±24)	91 (±3.3)	27 (±15)	97 (±7)
Nitrite (288)	37 (±22)	99 (±1.1)	75 (±30)	96 (±2)
Leukocyte esterase (296)	52 (±23)	90 (±3.5)	25 (±14)	97 (±2)
Pyuria/nitrite/leukocyte esterase*	68 (±24)	86 (±4.1)	23 (±16)	97 (±2)

PPV = positive predictive value; NPV = negative predictive value. In parentheses next to each value appears the 95% confidence interval.

* Combination of three tests: pyuria, nitrite, leukocyte esterase.

Prediction of positive culture using the rapid screening tests: 1) Uriscreen: true positive = 24, true negative = 233, false positive = 56, false negative = 0. 2) Pyuria: true positive = 9, true negative = 246, false positive = 24, false negative = 7. 3) Leukocyte esterase: true positive = 9, true negative = 252, false positive = 27, false negative = 8. 4) Nitrites: true positive = 6, true negative = 270, false positive = 2, false negative = 10.

tice to perform a routine quantitative urine culture in all pregnant women at the initial antepartum care visit in order to identify patients with significant bacteriuria, and to treat them appropriately. However, because routine quantitative urine culture is both time consuming and expensive, a rapid screening urine test that would be less expensive, easier to perform, and accurate in the detection of bacteriuria was sought. Previous reports have evaluated the efficacy of various urine screening tests.⁷⁻¹² However, to the best of our knowledge, the newly introduced Uriscreen test has not yet been evaluated in an obstetric population.

Because untreated clinically significant bacteriuria in pregnancy may be a serious risk to both mother and fetus, all positive cases must be identified; thus a sensitive test with a high negative predictive value is desirable. In the present prospective study, four rapid screening tests were evaluated. We demonstrated that Uriscreen is the most accurate screening test for the detection of bacteriuria. In fact, the Uriscreen test correctly identified all cases with significant bacteriuria. Furthermore, it had the highest predictive value for negative culture results (100%). Similar results were obtained in nonpregnant population, with a reported sensitivity of 92-95% and specificity of 58-82%.^{14,15} However, it should be stressed that the Uriscreen test specificity and positive predictive value were low (81 and 30%, respectively). In fact, the Uriscreen test was positive in 55 culture-negative patients. Thus, using a positive Uriscreen test as an indication for urine culture, 79 cultures would have identified all 24 positive cultures, which means avoiding the necessity of perform-

ing 80% of cultures. The reason for the high rate of false-positive tests (17.5%) is related to the fact that this test detects catalase activity that is present not only in bacteria but also in somatic cells. In fact, pyuria has been reported to be present in up to 30% of negative cultures and bacteriuria and bacilluria in up to 10% of nonbacteriuric women.¹⁶ In our study, each patient was carefully instructed for sample collection by a single nurse, specially assigned, and in 8% of our patients, pyuria was diagnosed in the absence of bacteriuria. Most importantly, instructing patients to clean the vulvar area, as we did, is necessary in order to avoid a higher rate of false-positive cases caused by contamination.

Lenke and Van Dorsten¹⁶ evaluated the efficiency of the nitrite test and microscopic urinalysis of randomly voided, clean-catch urine specimens in predicting culture results of 16 urine samples of pregnant patients, previously treated for pyelonephritis. They showed that the nitrite test failed to detect 14 of 18 positive cultures, resulting in a low sensitivity of 22%. Czerwinski et al,¹¹ also using randomly voided urine specimens, reported even lower sensitivity for the nitrite test (11%). However, they demonstrated that when the first voided urine specimens are evaluated, the sensitivity is increased to 44%. Using randomly voided urine specimens of 750 consecutive obstetric patients, Robertson and Duff⁸ reported a low sensitivity of 43% for the nitrite test. In our study, the sensitivity of the nitrite test was similarly low (37%). We concluded that although the nitrite test is easy to perform, it is not sensitive enough to detect significant bacteriuria. The possible explanation for this low sensitivity is related to the fact that the nitrite test identifies only nitrate-reducing bacteria. Therefore, microorganisms that normally do not reduce nitrate, such as group B streptococcus, enterococci, and pseudomonas, will not be identified by this test.

In our study, the leukocyte esterase test and microscopic urinalysis for pyuria showed low sensitivity of 52 and 56%, respectively. A previous study by Etherington and James¹⁷ demonstrated a sensitivity of 60% for the leukocyte esterase test, whereas others have shown higher sensitivity (77%).⁸ Our results confirm previous reports that concluded that neither the leukocyte esterase test nor pyuria alone can be used as good predictors of clinically significant bacteriuria.

Two studies demonstrated that the combination of the nitrite and leukocyte esterase tests increase sensitivity to 92⁸ and 69%.¹⁰ In our study, the combination of all three tests, the nitrite test, the leukocyte esterase test, and a microscopic urinalysis for pyuria, increased sensitivity to 68% (Table 2). This value is not acceptable for urine screening tests because 30% of patients with

positive cultures will be missed. However, this combination may be useful in excluding significant bacteriuria (a negative predictive value of 97%).

We conclude that the Uriscreen test is a rapid and accurate alternative to urine culture screening of all pregnant patients. Furthermore, the low cost of the Uriscreen compared with culture screening (\$1.00 versus \$18.00, respectively, technician time included) will save as much as 80% of the cost of urine cultures. Using the costs given above, a savings of \$1,340,000.00 will result for every 100,000 specimens.

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