

Assessment of rapid dipstick test for diagnosis of urinary tract infection in asymptomatic pregnant female

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ABSTRACT

Background: Bacteriuria during pregnancy has been known to cause many complications like low birth weight and premature delivery.

Objective: This study was done to evaluate the diagnostic accuracy of rapid dipstick test to predict urinary tract infection in pregnancy against the gold standard urine culture.

Material & methods: A total of 200 mid stream urine samples were collected from asymptomatic pregnant females. These specimens were cultured in blood agar and MacConkey's agar by using the standard loop technique and incubated aerobically at 37°C overnight. The criterion for clinically significant bacteriuria was either a pure or predominant culture of $> 10^5$ colony forming units (CFU)/ml. All the specimens were also examined microscopically for pyuria and bacteriuria.

Results: The prevalence of asymptomatic bacteriuria in pregnancy was 15 % in our study. The sensitivity and the specificity for leucocyte esterase were 85.7% and 74.4% and for nitrites, they were 64.2% and 72%.

Conclusion: The study revealed that use of either leukocyte esterase or nitrite for screening of asymptomatic bacteriuria in pregnancy was associated with many false positive and negative results when compared with the gold standard urine culture method. By using their combination maximum negative predictive value of .98 was achieved.

Keywords: Dipstick test, asymptomatic bacteriuria, urinary tract infection, pregnancy, urine

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Introduction

Urinary tract infections (UTI) are a common problem in pregnancy due to the morphological and physiological changes that takes place in the genitourinary tract during pregnancy. It is of two types, symptomatic or asymptomatic. Asymptomatic bacteriuria (ASB) is defined as the "presence of actively multiplying bacteria within the urinary tract excluding the distal urethra", at a time when the patient has no urinary symptoms.^[1] ASB is found in 2 to 10% of pregnant women and they are likely to develop acute pyelonephritis, postpartum UTI, hypertensive disease, anemia, prematurity, low birth weight babies and prenatal death if untreated.^[2] ASB is a microbial diagnosis

based on the isolation of a specified quantitative count of bacteria in a properly collected specimen of urine from pregnant women without signs or symptoms of UTI.^[3] Therefore an easy, fast, non-invasive and cost-effective test that will accurately allow early diagnosis of ASB during prenatal visits is highly desired. Urine culture is the definitive gold standard test for the detection of bacteriuria. However, the full bacteriological analysis is both time-consuming and expensive. Dipstick urine analysis or reagent strip testing is a simple and rapid test that can be done at the bedside of the patients and if it is effective, it can minimize the number of samples which are sent for urine culture and make the patient care better.^[4]

Pregnant women who attended the antenatal clinic at our hospital were screened for asymptomatic bacteriuria with dipstick and compared the results with urine culture. Leukocyte esterase and nitrites have been extensively studied for the screening of urinary infections. We included two infection associated markers which are leukocyte esterase and nitrites, and assessed whether these could improve the diagnostic performance of the reagent strip testing. In India, very few studies have been done on dipstick urine analysis for bacteriuria which prompted us to do this study.

Material and methods

The study was conducted in the Microbiology department of Sri Guru Ram das Institute of Medical Sciences and Research Amritsar; a tertiary care referral centre. Out patients attending the Obstetrics department was recruited for this study. In this prospective double blind study, clean catch midstream urine samples from 200 consecutive pregnant women who attended the routine antenatal check up were collected after taking their informed consent. Certain patients were excluded as per the exclusion criteria described below.

Exclusion Criteria

- History of UTI symptoms (dysuria, frequency and urgency, etc).
- Pregnancy induced Diabetes Mellitus/Hypertension.
- History of antibiotic therapy in the previous two weeks.
- Pyrexia.

Clean voided midstream urine specimen collected after proper verbal instructions and provision of a sterile specimen bottle.

Then each sample was refrigerated in 4°C and transported. All the urine samples were subjected to dipstick analysis and bacteriologic culture. Dipstick urine analysis was done with a Bayer's 10 parameters urine reagent strip which included the infection related markers- leukocyte esterase and nitrites. The specimens were cultured in blood agar and MacConkey's agar by using the standard loop technique. The criterion for clinically significant bacteriuria was a pure or predominant culture of > 10⁵ colony forming units (CFU)/ml, two organisms in similar proportions at > 10⁵ CFU/ml, or 10⁴–10⁵ CFU/ml of a gram negative organism or two organisms where the gram negative organism clearly predominated. All the specimens were also examined microscopically for pyuria and bacteriuria. Microscopy was considered as positive if the results had > 5 pus cells/hpf or >20 bacteria/hpf in the spun samples. Culture was used as a reference method for determining the performance of the urine microscopy and the dipstick data. The sensitivity, specificity, positive predictive value, negative predictive value, was calculated for microscopic urine analysis, leukocyte esterase and nitrites to measure their diagnostic utility in the diagnosis of ASB.

Results

The mean age of the patients who were studied was 26 years (range: 18- 35 years) and the gestational age was between 6 weeks to 32 weeks. The prevalence of ASB in the present study was 15% (30/200) as was determined by the urine culture. The most common organism which was isolated was E.coli, followed by Klebsiella and coagulase negative Staphylococcus. Comparison of

urine reagent strips for leucocyte esterase and nitrites along with microscopic urine analysis are given in Tables 1 and 2. The sensitivity and the specificity for leucocyte esterase were 85.7% and 74.4% and for

nitrites, they were 64.2% and 72%. By using their combination the maximum sensitivity of 93.3% was achieved with maximum negative predictive value of 0.98.

Table 1: Dipstick urine analysis as compared to gold standard urine culture

Marker	Positive	Negative	True Positive	True Negative	False Positive	False Negative
Leucocyte esterase	74	126	24	122	50	04
Nitrite	66	134	18	124	48	10
Leucocyte esterase and Nitrite	54	146	28	144	26	02
Microscopic examination	82	118	16	108	66	10

Table 2: Comparison between nitrite test, leukocyte esterase test, microscopic examination using sensitivity, specificity, positive predictive value and negative predictive value

Marker	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Leucocyte Esterase	85.7%	70.9%	0.32	0.97
Nitrite	64.2%	72%	0.27	0.92
Leucocyte esterase and Nitrite	93.3%	84.7%	0.51	0.98
Microscopic examination	61.5%	62%	0.19	0.91

Discussion

Asymptomatic bacteriuria is common during pregnancy. It gives a clear predisposition to the development of symptomatic UTI, which in turn pose risk to mother and fetus. In our study significant growth was found in 15% cases and 85% samples were sterile. These results were consistent with reports of the recent

studies.^[5,6,7,8] The presence of significant bacteriuria indicates the significance of microbiological culture to clinch the diagnosis of urinary tract infection. The early detection of ASB is essential for an early treatment and for the avoidance of complications. Culture which is needed to confirm urinary infection is time consuming and it requires laboratory facilities and

competent personnel, which may not be available at all levels of healthcare. Bacterial isolates have been changing from time to time from place to place. In our study the most common organisms isolated was *E coli* which correlated with various others studies.^[5,6,7,8] This pattern could be due to the fact that urinary stasis is common in pregnancy and since most *E coli* strains prefer that environment.

In our study the sensitivity and a specificity for leucocyte esterase was 85% and 70.9% and a sensitivity and a specificity for nitrites was 64.2% and 72% and respectively. By using their combination the maximum sensitivity of 93.3% was achieved with maximum negative predictive value of 0.98. High negative predictive value implied that when the test yielded a negative result, it was most likely that it was correct in its assessment. This made reagent strip test a good rule-out test.

Fiona et al in a similar study concluded that in pregnant women a negative test for both leukocyte esterase and nitrites could rule out infection in pregnant women this is parallel to this study as negative predictive value for combined tests was high (0.98).^[9] Our results were comparable to those of Patel et al which also showed 0.96 negative predictive value for leucocyte esterase and nitrite when used in combination.^[10] In another study by Tincello combined LE and nitrite tests showed no added value.^[11]

In a large study applied in USA included 1047 pregnant patients screened for ASB showed that leukocyte esterase test has the highest sensitivity (84%).^[12] This is parallel to the study of Robertson, in which leukocyte esetrase test had high sensitivity (77.4%).^[13]

Leucocyte esterase is an enzyme which is produced by neutrophils and its positivity

suggests pyuria and not necessarily bacteriuria. So its negative results do not exclude infection. The test for nitrites relies on the breakdown of urinary nitrates to nitrites by many gram positive and negative organisms, especially if are found in significant numbers.

Direct examination of urine is rapid and inexpensive and requires little technical expertise; but the sensitivity is low. About 50% of asymptomatic bacteriurics can have <3 leucocytes/hpf in spun urine. Conversely, about one third of pregnant non-bacteriuric women can have 5 or more leucocytes/hpf.^[9]

To conclude, the high prevalence of ASB (15% in our study) and the associated complications warrant the screening of pregnant women for asymptomatic bacteriuria. The strategy of the pre screening of urine samples by using positivity for nitrites and leucocyte esterase, followed by urine culture, ensures a high diagnostic performance and potential cost savings and it reduces the laboratory workload considerably. It's time that we have a look at this strategy for improving the healthcare and for reducing the maternal and foetal morbidity and mortality.

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Cite this article as: Khanna A, Khanna M. Assessment of rapid dipstick test for diagnosis of urinary tract infection in asymptomatic pregnant female. Int J Med and Dent Sci 2016; 5(1):965-969.

**Source of Support: Nil
Conflict of Interest: No**