# ACCURACY OF SIMPLE URINE TESTS FOR DIAGNOSIS OF URINARY TRACT INFECTIONS IN LOW-RISK PREGNANT WOMEN[1]

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*Anatomic and physiological alterations during pregnancy predispose pregnant women to urinary tract infections (UTI). This study aimed to identify the accuracy of the simple urine test for UTI diagnosis in low-risk pregnant women. Diagnostic test performance was conducted in Botucatu, SP, involving 230 pregnant women, between 2006 and 2008. Results showed 10% UTI prevalence. Sensitivity, specificity and accuracy of the simple urine test were 95.6%, 63.3% and 66.5%, respectively, in relation to UTI diagnoses. The analysis of positive (PPV) and negative (NPV) predictive values showed that, when a regular simple urine test was performed, the chance of UTI occurrence was small (NPV 99.2%). In view of an altered result for such a test, the possibility of UTI existence was small (PPV 22.4%). It was concluded that the accuracy of the simple urine test as a diagnostic means for UTI was low, and that performing a urine culture is essential for appropriate diagnosis.*

*DESCRIPTORS: urinary tract infections; pregnancy; urine; diagnosis*

## LA EXACTITUD DEL EXAMEN DE ORINA SIMPLE PARA DIAGNOSTICAR INFECCIONES DEL TRACTO URINARIO EN GESTANTES DE BAJO RIESGO

*Las alteraciones anatómicas y fisiológicas de la gravidez predisponen a las gestantes a infecciones del tracto urinario (ITU). El objetivo de este estudio fue identificar la exactitud del examen de orina simple para diagnosticar ITU en gestantes de bajo riesgo. Se hizo uso del estudio de desempeño de prueba de diagnóstico realizado en Botucatu, San Pablo, con 230 gestantes, entre 2006 y 2008. Los resultados muestran que la prevalencia de ITU fue de 10%. La sensibilidad fue 95,6%, la especificidad 63,3% y la exactitud 66,5% del examen de orina simple, en relación al diagnóstico de ITU. El análisis de los valores de predicción positivo y negativo (VPP y VPN) mostró que, en la vigencia de examen de orina simple normal, la probabilidad de haber ITU fue pequeña (VPN 99,2%). Frente al resultado alterado de ese examen, la probabilidad de haber ITU fue baja (VPP 22,4%). Se concluye que la exactitud del examen de orina simple como medio de diagnóstico de ITU fue baja, siendo indispensable la realización de urocultura para el diagnóstico.*

*DESCRIPTORES: infecciones urinarias; embarazo; orina; diagnóstico*

## ACURÁCIA DO EXAME DE URINA SIMPLES PARA DIAGNÓSTICO DE INFECÇÕES DO TRATO URINÁRIO EM GESTANTES DE BAIXO RISCO

*Alterações anatômicas e fisiológicas da gravidez predispõem gestantes a infecções do trato urinário (ITU). O objetivo deste estudo foi identificar a acurácia do exame de urina simples para diagnóstico de ITU em gestantes de baixo risco. Fez-se uso do estudo de desempenho de teste diagnóstico realizado em Botucatu, SP, com 230 gestantes, entre 2006 e 2008. Os resultados mostram que a prevalência de ITU foi de 10%. A sensibilidade foi 95,6%, especificidade 63,3% e acurácia 66,5% do exame de urina simples, em relação ao diagnóstico de ITU. A análise dos valores preditivos positivo e negativo (VPP e VPN) mostrou que, na vigência de exame de urina simples normal, a chance de haver ITU foi pequena (VPN 99,2%). Frente ao resultado alterado desse exame, a probabilidade de haver ITU foi baixa (VPP 22,4%). Conclui-se que a acurácia do exame de urina simples como meio diagnóstico de ITU foi baixa, sendo indispensável a realização de urocultura para o diagnóstico.*

*DESCRITORES: infecções urinárias; gravidez; urina; diagnóstico*

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## INTRODUCTION

Urinary tract infections (UTI) are a very frequent and common pathology that can occur at any age. Considering adulthood, 48% of women present at least one occurrence of UTI. Higher susceptibility is due to shorter urethra, closer proximity of the anus with *vaginal vestibule* and urethra and the beginning of sexual activity[1-2].

During pregnancy, specifically, women go through several alterations, emotional, as well as physical and physiological, which make them more vulnerable to UTIs. Among the physiological changes, there is an observed increase in uterus size, in blood volume due to hemodilution and concentration of circulating hormones, mainly estrogen and progesterone[2-3]. Besides the mentioned alterations, an increase in urine pH, due to the reduction of the kidney's ability to concentrate urine and increases in sodium, glucose and amino acids excretion, increase the susceptibility of a pregnant woman's urinary tract to infections, aiding an appropriate bacterial growing media[1-3].

Recently, studies have indicated that pregnancy, as an isolated event, does not predispose to UTI. However, anatomical and physiological changes imposed by pregnancy on the urinary tract predispose the transformation of women with asymptomatic bacteriuria to pregnant women with symptomatic UTI, leaving the impression that the number of urinary infections is higher in this period of life[4]. In a general way, it can be affirmed that, during pregnancy, mechanical and hormonal factors contribute to cause changes in the maternal urinary tract, making it more susceptible to symptomatic infections[5].

UTI, defined as the adherence of bacteria to the urinary tract walls, affects nearly 10-12% of pregnancies, and is the third highest clinical occurrence during this period[1]. UTIs can occur as asymptomatic bacteriuria, acute cystitis and acute pyelonephritis[6]. The presence of bacteria without clinical symptoms characterizes asymptomatic bacteriuria, which occurs in almost 5% of pregnant women[6]. The importance of asymptomatic bacteriuria is related to the possibility of an evolution to clinical urinary infection in 40-60% of cases, premature labor and hospitalization of pregnant women[1].

Considering the complete absence of symptoms and the possibility of a silent evolution to urinary infections high in the tract, with negative repercussions in perinatal results, active search and treatment of asymptomatic bacteriuria in pregnant women is recommended[5].

Acute cystitis compromises the urethra and, mainly, the bladder. It presents symptoms typical of the lower urinary tract, such as dysuria, pollakiuria, nocturia and suprapubic pain when urinating[5].

*Escherichia coli* is the most common uropathogen of all forms of UTI[1-3,6], and is responsible for 80% of cases[3]. It is notable that, in women, the colonization of the vaginal and periurethral mucous can precede UTI[2], the infection can ascend, causing cystitis and, if not treated, pyelonephritis. Suprapubic vesical puncture permits diagnosis confirmation of urinary tract infection, at any quantity of identified colonies. However, as it is an invasive examination, it is not normally used. Thus, the gold standard urine culture is considered for investigation of UTI[2-3]. However, when only one examination is carried out, false positives can occur in 10-20% of cases and, to avoid false negatives, an examination should be done of the first urine in the morning or with a minimum interval of two hours from the previous urination[2]. Despite this, in some prenatal care services, care protocols for pregnant women do not call for this examination, due to its cost and the delay in obtaining results[3], thus diagnosis is clinically carried out isolated or with the support of the simple urine test only.

In a simple urine test, several urinary properties can be analyzed, among them color, smell, blurriness, specific density, pH and presence of glucose, ketones, blood, protein, bilirubin, urobilinogen, nitrite, leukocyte esterase and urinary sediments. The presence of leukocytes, red blood cells, glucose, crystals, cylinders, bacteria and nitrites is relevant to track UTI. The increase in the number of leukocytes and the presence of nitrites or red blood cells are indicators of a probable infection. It stands out, however, that leukocyturia, proteinuria and cylindruria are only signs of inflammation and do not necessarily mean significant bacteriuria[3]. The presence of bacteriuria always needs to be confirmed by a urine culture[2].

The lack of treatment or improper treatment of UTIs can lead to obstetric and neonatal complications. Among them, the early rupture of membranes, premature delivery and labor, restriction of intrauterine growing, low birth weight, abortion and fetal death are highlighted[1-3,6]. Other complications

have been associated with UTIs: hypertension, pre-eclampsia, anemia, chorioamnionitis, endometritis, septicemias[3,7] and deterioration of kidney function[5]. On the other hand, a recent systematic review concluded that treatment with antibiotics is effective in reducing the risk of pyelonephritis during pregnancy, also suggesting reduction in low birth weight, which is consistent with current theories about the function of infection in adverse results in pregnancy. However, authors show the need to interpret these results with caution, due to the deficient quality of the studies included in the review[7].

Thus, it can be affirmed that the occurrence of urinary infection during pregnancy is related to unfavorable gestational outcomes. Despite that, simple urine frequently remains the only examination available in the prenatal routine for UTI diagnosis. However, studies of prevalence and related to diagnosis tests in these areas are relevant, once scientific evidences should ground clinical practice. Hence, the study aimed to identify the accuracy of the simple urine test to diagnose urinary tract infections in low-risk pregnant women and assess the association between urinary infection and socio-demographic variables and urinary signs and symptoms.

## PATIENTS AND METHODS

### Study design and venue

This analytical cross-sectional study aimed to analyze the performance of a diagnostic test. It was carried out in the city of Botucatu, located in the central region of the state of São Paulo, with an estimated population of 120,800 inhabitants. The public primary care service of Botucatu consists of three polyclinics, three municipal health centers and eight family health units.

### Population and sample

Considering the average prevalence of urinary tract infection as at 10%, with a confidence coefficient of 95%, margin of error of 5%, stratified sampling per health unit considering the coefficient of 0.1371 and the total of 1006 pregnant women receiving care, the minimum sample size calculated was 138 patients. From the pilot study, considering the obtained sensitivity value, the confidence coefficient of 99% and margin of error of 5%, the sample size was calculated to be 140 patients. In the study, 230 pregnant women who received care in all primary care units of the city were included, between October 2006 and March 2008.

### Inclusion and exclusion criteria

Pregnant women at any gestational age, with or without urinary complaint and who handed in urinary samples for simple urine test and urine culture, were included in the study. Pregnant women whose urine culture results indicated contamination of the sample during collection were excluded.

### Data Collection

Data sources were the pregnant women's medical histories with socio-demographic information, personal and obstetric background and data obtained through an instrument.

### Urine collection for diagnosis of urinary tract infections

The midstream clean-catch technique was used to collect urine for a simple urine examination and a urine culture. For the last test, intimate hygiene with water and soup was carried out, according to the routine of the basic health units of the city of Botucatu.

### Diagnosis criteria of urinary tract infections

*Simple urine test:* the following values were considered normal: up to four leukocytes per field; two red blood cells per field; negative nitrites; glucose, proteins, urobilinogen, absence of bilirubin and ketone bodies; absent or moderate epithelial cells.

*Urine culture:* positive if presented bacterial growing, regardless of the number of colonies.

### Studied variables

Socio-demographic variables were: age (years), marital status (married, single, cohabitating and others), educational level (years) and occupation. Among gynecological and obstetric backgrounds: number of partners in the last 6 months, number of pregnancies, parity, number of abortions, numbers of cesarean sections, date of last menstruation (dd/

mm/yy), gestational age (weeks), history of prematurity (yes, no) and newborns (NB) with low weight (yes, no). Background of urinary infection (yes, no), number of occurrences, year of last episode, treatment (yes, no), history during last pregnancy (yes, no) and history of hospitalization for UTI (yes, no) were checked.

The following current signs and symptoms of UTI were verified: burning or pain (yes, no), dark urine (yes, no), strong smell (yes, no) and urination urgency (yes, no). Regarding the results of examinations, for simple urine test it was observed: nitrite (yes, no), protein (yes, no), glucose (yes, no), ketone bodies (yes, no), bilirubin (yes, no), bile pigments (yes, no), blood (yes, no), leukocyte esterase (yes, no), more than four leukocytes per field (yes, no), more than two red blood cells per field (yes, no), abundant epithelial cells (yes, no) and crystals (yes, no); for urine culture (positive, negative)and isolated microorganism.

### Data analysis

A database was developed using Excel to exchange and analyze data from the statistical software EpiInfo. Statistical analysis was carried out using the chi-square test ($\chi^2$), at significance level $\alpha$=0.05, with calculation of the respective odds ratio and confidence interval (CI 95%). Chi-square with Yates' correction was used only for analysis of association between pain or burning when urinating and urinary sediments with urinary infection.

### Ethical procedures

The study was approved by the Research Ethics Committee of the Botucatu Medical School, São Paulo State University, UNESP, (Official Letter 85/2006-CEP) and was carried out in accordance with the ethical principles established by Resolution 196/96 of the National Health Council. Patients who agreed to participate in the study signed a free and informed consent form.

## RESULTS

Of the 230 pregnant women included in the study, most noted having a partner, 40.9% lived with partners and 38.3% were married; nine or more years of education (55.2%); did not have paid activity (54.3%) and 43.5% did not have children.

Of all participants, 19.5% had a background of abortion and 21.8% a previous cesarean section. Premature labor was reported by 11.9%, low weight by 10.4%, dyspareunia by 28.7% and bleeding after sexual relations by 3.9% of women. One of them had had two or more partners in the last six months. Most collections for examinations were carried out up to the 17$^{th}$ week of pregnancy. More than half of pregnant women mentioned having a previous urinary tract infection, of those, 53.1% reported a single episode and 82.8% in the last five years. It is noteworthy that in five cases (3.9%) there was no treatment.

Table 1 presents the relation between urinary infection, socio-demographic variables and history of previous UTI or dyspareunia. There was association only between history of previous UTI and urinary infection among studied pregnant women.

Table 1 - Relation between urinary infection, socio-demographic variables and history of previous UTI or dyspareunia. Botucatu, 2008

| | Urinary infection | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **Yes** | **%** | **No** | **%** | **Total** | **%** | **p value** | **OR (IC 95%)** |
| Age (years) | | | | | | | | |
| >25 | 10 | 43,5 | 97 | 46,9 | 107 | 46,5 | | |
| <25 | 13 | 56,5 | 110 | 53,1 | 123 | 53,5 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,7577 | 0,87 (0,36-2,07) |
| School years | | | | | | | | |
| <8 | 16 | 69,6 | 142 | 68,6 | 158 | 68,7 | | |
| >8 | 7 | 30,4 | 65 | 31,4 | 72 | 31.3 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,9244 | 1,04 (0,41-2,66) |
| Multiparity | | | | | | | | |
| Yes | 13 | 56,5 | 125 | 60,4 | 138 | 60 | | |
| No | 10 | 43,5 | 82 | 39,6 | 92 | 40 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,7196 | 0,85 (0,35-2,03) |
| Previous UTI | | | | | | | | |
| Si | 18 | 78,3 | 110 | 53,1 | 128 | 55,7 | | |
| No | 5 | 21,7 | 97 | 46,9 | 102 | 44,3 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,0214 | 3,17 (1,13-8,87) |
| Dyspareunia | | | | | | | | |
| Yes | 7 | 30,4 | 59 | 28,5 | 66 | 28,7 | | |
| No | 16 | 69,6 | 148 | 71,5 | 164 | 71,3 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,8458 | 1,09 (0,42-2,80) |

Regarding signs and symptoms related to urinary infection, the most frequent complaint presented by pregnant women was dark urine: 42.2%, followed by urination urgency, mentioned by 40.9% of them.

It is observed, in Table 2, that 13% of patients who did not have a urinary infection mentioned pain or burning during urination. There was association only between urinary infection and complaint of dark urine.

Table 2 – Relation between urinary infection and reported urinary signs and symptoms. Botucatu, 2008

| | Urinary infection | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Yes | % | No | % | Total | % | p value* | OR (IC 95%) |
| Pain or burning | | | | | | | | |
| Yes | 2 | 8,7 | 27 | 13 | 29 | 12,6 | | |
| No | 21 | 91,3 | 180 | 87 | 201 | 87,4 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,7384 | 0,60 (0,13-2,72) |
| Dark urine | | | | | | | | |
| Yes | 15 | 65,2 | 82 | 39,6 | 87 | 37,8 | | |
| No | 8 | 34,8 | 125 | 60,4 | 133 | 57,8 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,0315 | 2,54 (1,06-6,07) |
| Urination urgency | | | | | | | | |
| Yes | 13 | 56,5 | 81 | 39,1 | 94 | 40,9 | | |
| No | 10 | 43,5 | 126 | 60,9 | 136 | 50,1 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,1116 | 2,17 (0,92-5,13) |
| Strong smell | | | | | | | | |
| Yes | 9 | 39,1 | 51 | 24,6 | 60 | 26,1 | | |
| No | 14 | 60,9 | 156 | 75,4 | 170 | 73,9 | | |
| Total | 23 | 100 | 207 | 100 | 230 | 100 | 0,2650 | 1,83 (0,75-4,44) |

*chi-square (Yates)

It should be highlighted that 43.5% of pregnant women with a urinary infection did not have any symptomatology. Considering the total number of women, the prevalence of asymptomatic bacteriuria was 4.3%. There was no association between symptoms and urinary infection. The main microorganisms isolated in UTI cases were *Escherichia coli* (47.8%), *Staphylococcus saprophyticus* (8.7%), *Streptococcus agalactiae* (8.7%) and *Klebsiela pneumoniae* (8.7%).

The relation between altered glucose, proteins, urobilinogen, bilirubins, nitrites, ketone bodies, epithelial cells, crystals, leukocytes and red blood cells in simple urine tests and urinary infection showed association only between presence of nitrites and leukocytes (more than four per field) and urinary infection (OR 12.64 [3.35-56.04]).

Simple urine analysis, as a means to diagnose urinary infection, evidenced high sensitivity: 95.6% and negative predictive values: 99.2% (Table 3).

Table 3 – Relation between urinary infection confirmed by urine culture and the result of the simple urine test in pregnant women (n=230). Botucatu, 2008

| | Urinary infection | | |
|---|---|---|---|
| | Yes | No | Total |
| Simple urine test | | | |
| Altered | 22 | 76 | 98 |
| Normal | 1 | 131 | 132 |
| Total | 23 | 207 | 230 |

Sensitivity: 95.6%; specificity: 63.3%; positive predictive value: 22.4%, negative predictive values: 99.2% and accuracy: 66.5%.

## DISCUSSION

The accuracy of the simple urine test to diagnose urinary infection was studied from the representative sample of pregnant women who receive prenatal care in primary care units from Botucatu, responsible for public care to low-risk pregnant women in the city, aiming to contribute to improving the quality of maternal-infant care.

Low socioeconomic level, high parity and advanced age, among others, are factors associated with urinary infection during pregnancy[8]. Investigated pregnant women were young, presenting average and median age of 25 years and 70% were primiparous women or had only one living child, evidencing low parity. Maternal educational level, an indicator frequently associated with a family's socioeconomic level, showed a relatively unfavorable situation, since 44.7% of pregnant women had at most completed their elementary education. Most of them did not perform any paid activity (54.3%). In this study, there was no association between age, educational level and multiparity with UTI. Analysis of the obstetrical background shows that 19.5% of patients had a history of abortion and 21.8% of previous cesarean section, values below the national average, which is around 31% for abortion and 40% for cesarean section[9].

Previous urinary tract infection was reported by 55.7% of women, and in 53.1% of cases it was the first episode. Most women with previous history of UTI were treated (96.1%) and the time passed, since its occurrence, was up to five years (82.8%). It is highlighted that 71.1% of pregnant women reported UTI in previous pregnancy and 7% hospitalization as a consequence of it. Previous urinary infection increases the probability of a new episode in pregnancy, and the risk is between 27 and 47% higher when infection occurred during childhood[10].

Epidemiological study with 6.795 pregnant women, which aimed to identify epidemiological characteristics capable of anticipating symptomatic and asymptomatic urinary infection in early prenatal care, evidenced two strong characteristics: history of urinary infection previous to pregnancy and urinary infection in current pregnancy before the beginning of prenatal care[11]. In this research, the history of UTI was associated with the development of urinary infection during pregnancy. Complaint of dyspareunia, however, was not associated to UTI and, due to the low prevalence, association of UTI with the following variables was not searched: bleeding after sexual relation, number of partners, prematurity and low birth weight.

The most frequent signs and symptoms related to urinary infection, referred to by the pregnant women, was dark urine (42.2%). followed by urination urgency (40.9%). The analysis of the relation between the isolated symptoms, one by one, and urinary infection, evidenced association only in relation to dark urine. However, discussing signs and symptoms of UTI in pregnancy can be paradoxical, as many of them are habitually reported by pregnant women.

On the other hand, the complete absence of symptoms does not necessarily rule out the presence of infection and, consequently, the risk caused by it. Asymptomatic bacteriuria can progress to pyelonephritis in 25 to 40% of the cases, if the patient is not treated[10]. In the present study, the prevalence of asymptomatic bacteriuria was 4.3%, a lower value than found in other studies[1,12].

Currently the epidemiological profile of pregnant women with a greater probability of developing asymptomatic bacteriuria cannot be confirmed, contrary to the situation with symptomatic UTI. In a Brazilian study, its frequency increased with sexual activity, parity, low socioeconomic level and age[5]; in India it was associated to primiparity and adolescence[12] and in Ethiopia, to multiparity[13].

Knowing the increased risk of developing UTI in pregnancy, the possibility of the occurrence of asymptomatic bacteriuria and the possible maternal and perinatal consequences, several researchers state as unquestionable the need to carry out urine cultures routinely at the beginning of pregnancy[3]. However, many questions about urinary infection during pregnancy still require clinical investigation, as they are still controversial.

In the present study, the prevalence of UTI was 10%, in accordance with what was observed in the literature[10]. The most frequent etiological agent was *Escherichia coli (E. coli),* responsible for 47.8% of infections. In the High Risk Pregnancy ward of the *Hospital das Clínicas* in Ribeirão Preto, 75.8% of the pregnant women with a clinical diagnosis of pyelonephritis had *E.coli* as causal agent[3], the same value as in a North American study[14].

There was association only between the presence of nitrites and leukocytes and urinary infection. In a study of the diagnosis of asymptomatic bacteriuria, high specificity (99.2%) and low sensitivity (60%) was observed in nitrite tests. False negatives were attributed to bacteria that do not metabolize nitrates, the insufficient time of urine in the bladder to metabolize nitrates and small amounts of nitrates in subjects' diets[15]. Leukocyte esterase tests have low sensitivity and specificity (25%), besides the possibility of presenting false positives. Hence, neither test should be used in isolation[16].

In this research, the analysis of the simple urine test as a means to diagnose urinary infections, evidenced good sensitivity (90.5%), but low specificity (63.3%). These data indicate that, when simple urine tests are altered, there is not necessarily a urinary infection, and it is necessary to have a complementary examination to have an accurate UTI diagnosis, such as a urine culture. Considering that the positive predictive value indicates the probability of the individual actually having the disease when the test is positive, the low value obtained (22.4%) confirms the statement above. On the other hand, the high negative predictive value found (99.2%) indicates that if the simple urine test is normal, the chance of really not having urinary infection is very high. In synthesizing the results, it can be affirmed that the obtained accuracy of a simple urine test for the diagnosis of UTI (66.5%) was low.

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