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ORIGINAL ARTICLE

Accuracy of urinalysis in detection of urinary tract infection in a primary care setting

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Abstract

***Aim*:** To determine the accuracy of urinalysis in the detection of urinary tract infection (UTI) in symptomatic patients at primary care level.

***Methods*:** A cross sectional study was undertaken on 100 patients with symptoms of UTI presenting at the Primary Care Clinic of University Malaya Medical Center, Kuala Lumpur, Malaysia during the months of August to November 1999. Their urine samples were tested simultaneously using urine dipstick, urine microscopy and urine culture. Urine culture was used as the gold standard and UTI was diagnosed when the urine culture showed a bacteria count of $\geq 10^5$ organisms per mL. The sensitivity and specificity of each test was calculated.

***Results*:** The prevalence of UTI was 25% in symptomatic patients. The urine dipstick for leukocyte esterase, nitrite and red blood cell had sensitivities of 76, 56 and 76%, respectively. Their specificities were 60, 81 and 61%, respectively. Urine microscopy for leukocytes, red blood cells and bacterial count had sensitivities of 80, 52 and 84%, while their specificities were 76, 80 and 54%, respectively.

***Conclusion*:** The prevalence of UTI in the present study was low despite reported symptoms of UTI. Urinalysis is needed to support the diagnosis of UTI. In the present study, while there is accuracy in the urinalysis (as the sensitivities and specificities of various tests are comparable with other studies); lack of precision in each test because of the wide range of 95% confidence interval make it less reliable. Caution should be made in interpreting each test.

Key words: primary care, urinalysis, urinary tract infection.

Introduction

Urinary tract infections (UTI) are a common condition seen in clinical practice. In a few local studies, UTIs are as frequent as 4% of all consultations.[1–3] Microbiologically, a UTI exists when pathogenic microorganisms are detected in the urine, urethra, bladder, kidney, or prostate. According to standard teaching, growth of more than 10^5 organisms per mL from a properly collected midstream 'clean catch' urine sample indicates infection. In the study by Kass it was found that 95% of women with acute pyelonephritis have a urine culture of $\geq 10^5$ bacteria per mL.[4] He also found that repeated urine cultures in asymptomatic patients with counts $\geq 10^5$ bacteria per mL produced similar counts, whereas with urine counts less than 10^5 bacteria per mL, repeat counts produced different results at different times. On this basis, urine culture of 10^5 per mL or more has been taken as significant bacteriuria.[4]

Urine culture has been the gold standard for diagnosing UTI. However, there are problems with this:

- waiting for laboratory results might delay the diagnosis
- the test is expensive
- not all practicing physicians, especially in small health clinics and general practice clinics are able to use this facility.

For women who have symptoms of UTI and characteristic urine analysis findings it might be more practical and cost effective to manage acute uncomplicated cystitis without an initial urine culture. Carlson and Mulley made a decision analysis model to estimate the

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effects and costs of alternative initial management strategies for women presenting with dysuria and pyuria. It was found that routine pretreatment culture contributed up to 40% in costs while only reducing expected symptoms-days by 10%.[5]

Many studies have been conducted on the reliability of urine dipstick and urine microscopy, but mostly they were carried out under stringent protocols that might not be practical in a busy primary care setting. In primary care clinics, with the pressure of time and many other factors that often compromise the accuracy of the urinalysis, these studies might not have given a true picture of the validity of urinalysis. The present study was undertaken to determine the accuracy of various urinalysis tests in the local primary care setting.

Methods

Sample

All the patients attending the morning clinic in the Primary Care Clinic of the University of Malaya Medical Center during August to November 1999 were screened for their reason(s) for their visit. Those patients with current symptoms of either dysuria, frequency, stranguria or urgency were invited to join the present study. The duration of the symptom was not taken into consideration during screening. The patients were excluded if they had any of the following reasons: less than 12 years old; menstruating women; patients with an indwelling catheter; partially treated UTI or recent ingestion of antibiotic. A total of 100 patients were recruited for the present study. Approval from the hospital ethical committee was obtained before the present study was undertaken. Consent was taken from every patient who agreed to participate.

Study design

All the patients were asked to submit freshly voided urine samples and were given clear instructions on how to collect a midstream urine specimen. The urine sample was collected into a clean urine bottle and a urine culture bottle, respectively.

Urine dipstick

All urine dipstick tests were carried out by one of the researchers. A Boehringer Manheim Combur 10 Test (Mannheim, Germany) urine dipstick was used. The dipstick was dipped into the urine sample collected in the urine bottle and was removed promptly by touching the edge of the bottle to remove excess urine. Readings of the result were made under good lighting after being dipped for 60–120 seconds by means of comparing the color categories on the urine dipstick bottle.[6] Any outcome for leukocyte esterase (LE), nitrates (NIT) or red blood cells (RBC) were documented.

Urine microscopy

The residual urine from the urine container was labeled and sent to the nearby laboratory instantly. A trained laboratory technician who was in charge of urine microscopy for the day would process the microscopy test. A total of 10 mL of the urine sample was placed in a test tube and centrifuged at 1500 rpm for 5 minutes. The supernatant was poured off leaving approximately 1 mL of specimen sediment. A drop of this was placed on a micro chamber and microscopic reading was carried out under 40 high power field.

Appendix 1 shows the reference value for the normal urine microscopy result used in this center.[7]

Urine culture and sensitivity

The urine culture bottle was sent to the microbiology laboratory within 2 hours of urine collection. The urine culture and sensitivity was carried out by means of standard bacteriological methods. Blood agar or MacConkey culture medium was used. If 10^5 per mL of single organism growth was counted it was regarded as significant bacteriuria. Urine samples with two or more types of organism growth were considered as contamination.

Data analysis

Data entry and analysis was carried out using the Statistical Package for Social Sciences (SPSS) 9.05 for windows.

Cross tabulations using 2×2 contingency tables comparing each of the urinalysis markers towards the urine culture. The urine culture was regarded as the gold standard test. The sensitivity and specificity of individual tests were reported as percentages. The (cia.exe) program was used to obtain 95% confidence interval values for each sensitivity and specificity.

Results

A total of 100 patients participated in the present study. The age of patients ranged from 17 to 78 years old (mean age of 39.7 years). The majority of the subjects were women (82%). Fifty-two percent of the subjects were Malays, followed by Indian (23%) and Chinese (20%). Significant bacteriuria was found in 25% of these patients (95% confidence interval (CI), 17–35%).

Symptoms of dysuria and frequency were present in three quarters of the patients, stranguria in 20% and urgency in 34% of the patients. Not many subjects presented with suprapubic pain and loin pain. A similar pattern of symptoms was noted in patients with positive bacteriuria.

The sensitivity and specificity of LE, NIT and RBC tests in urine dipstick is shown in Table 1. The sensitivities of different tests using the urine dipstick varies from 56 to 84%; and the specificity ranges from 60 to 81%. The LE and RBC count had obtained the highest sensitivity test, while NIT had the highest specificity test. The sensitivity of urine dipstick increased to 80% when two positive test results (LE and NIT) were combined and up to 84% by combining three positive test results (LE, NIT and RBC). Combination of these two or three tests gave a negative predictive value of 90%.

As shown in Table 2, using the Meditron (Roche Diagnostics, Germany) machine to read the dipstick will increase the overall sensitivity and specificity of various tests compared to manual reading of the dipstick tests. However, there was a decrease of the sensitivity of the NIT test from 56 to 36%.

The sensitivity and specificity of different tests in urine microscopy is shown in Table 3. The tests in urine microscopy gave sensitivities of 52–84% and specificity of 54–80%. Bacteria detection gave highest sensitivity, while RBC gave the highest reading for specificity. Both tests for leukocytes and bacteria in urine microscopy gave a negative predictive value of 92 and 91%, respectively.

Discussion

A total of 100 patients were included in the present study with 82% of patients being female. Lachs *et al*. in their urinalysis study had a comparable study population.[8] This might be because women are more likely than men to consult a doctor with genitourinary symptoms. However, over half the population sample were also in their reproductive age group which is when UTIs are more common in females.[9,10]

Although all the study patients were symptomatic, only 25% had a significant bacterial urine culture according to the hospital's culture protocol. Although the prevalence of UTI in the present study is considered low for a symptomatic population, it is still higher than the prevalence reported in other studies.

Table 1 The sensitivity and specificity of leukocyte esterase, nitrite and red blood cell tests in urine dipstick (carried out manually)

Urine dipstick	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	+LR	–LR
LE	76 (55,91)	60 (48,71)	39	88	1.9	0.1
NIT	56 (35,76)	81 (71,89)	50	84	3	0.5
RBC	76 (55,91)	61 (49,72)	40	88	1.9	0.4
LE, NIT	80 (59,93)	57 (45,69)	38	90	2	0.4
LE, NIT, RBC	84 (64,95)	46 (35,59)	34	90	1.6	0.4

CI, confidence interval; LE, leukocyte esterase; +LR, positive likelihood ratio; –LR, negative likelihood ratio; NIT, nitrite; NPV, negative predictive value; PPV, positive predictive value; RBC, red blood cells.

Table 2 The sensitivity and specificity of leukocyte esterase, nitrite and red blood cell tests in urine dipstick (carried out by the Meditron machine)

Urine dipstick	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	+LR	–LR
LE	80 (59,93)	67 (55,77)	44	91	2.4	0.3
NIT	36 (18,57)	93 (85,95)	64	81	5.4	0.6
RBC	76 (55,91)	61 (49,72)	40	58	1.9	0.4

CI, confidence interval; LE, leukocyte esterase; +LR, positive likelihood ratio; –LR, negative likelihood ratio; NIT, nitrite; NPV, negative predictive value; PPV, positive predictive value, RBC, red blood cells.

Table 3 The sensitivity and specificity of leukocyte, red blood cell and bacteria presence in urine microscopy

Urine microscopy	Sensitivity (95% CI)	Specificity (95% CI)	PPV	NPV	+LR	– LR
Leukocytes	80 (59,93)	76 (65,85)	53	92	3	0.3
RBC	52 (31,72)	80 (69,88)	46	83	2.5	0.6
Bacteria	84 (64,95)	54 (43,66)	38	91	1.8	0.1

CI, confidence interval; +LR, positive likelihood ratio; –LR, negative likelihood ratio; NPV, negative predictive value; PPV, positive predictive value; RBC, red blood cell.

Semeniuk and Church found in their study that there was an 18.8% positive urine culture, while Lachs *et al*. found a 19.5% positive urine culture.[8,11]

The low yield of significant urine culture in symptomatic patients might be a result of:

1. Other urogenital conditions

Examples are atrophic vaginitis in postmenopausal women and chemical irritation of the urethra (when using strong soap to clean genital area) which can cause dysuria. Kamaroff *et al*. stated in their study that among women who presented with acute dysuria and frequency, significant bacteriuria was only found in 50–60% of them. The majority of those without significant bacteriuria also had urinary tract or urethral symptoms.[12]

Men with benign prostatic hyperplasia who have lower urinary tract symptoms might also present with frequency. Other conditions like urinary incontinence and detrusor muscle instability also have frequency as one of their related symptoms.

All these conditions can mimic symptoms of UTI but will produce a negative urinalysis and urine culture. It is unfortunate that the final diagnosis for patients recruited in the present study was not available. The present study also did not take into account the duration of the symptoms. The diagnosis of UTI is more likely in subjects with acute symptoms.

2. Inadequate urine sample collection

The present study aimed to use an early morning sample of urine. However, as many patients passed urine prior to their clinic visit, the bladder incubation period of many of the urine samples was less than 4 hours. In addition, it could not be guaranteed that the instructions for a midstream urine collection were followed correctly and the sample might have been contaminated as a perineal cleaning set or special sterile container (e.g., kidney dish) were not provided.

3. Problems with the definition of significant bacteriuria

The current practice of using bacterial counts of $\geq 10^5$ per mL of urine as significant bacteriuria could be setting the limit too high; thus causing this criteria to be less sensitive in picking symptomatic patients with true infection.

More significant bacteriuria would be detected if different urine bacterial counts were used for different categories of patients instead of one standard count. Stamm *et al*. has found that at least one third of women with acute coliform infection of the lower urinary tract had $<10^5$ bacteria per mL of midstream urine.[13,14] Another study by Stamm *et al*. has demonstrated that the best diagnostic criterion for significant bacteriuria would be $\geq 10^2$ bacteria per mL (sensitivity of 95% and specificity of 85%) for acute symptomatic women.[15] Lipsky *et al*. found that in men, urine culture of $\geq 10^3$ organisms per mL is the best sign of UTI with sensitivity and specificity of 97%. Conversely, colony counts in excess of 10^5 per mL of midstream urine are occasionally as a result of specimen contamination, especially when multiple species are present.[16,17] In this aspect taking different organism growth counts as significant growth will change the sensitivity and specificity of the urine analysis tests.

Sensitivities and specificities of urine dipstick

A comparison of the urine microscopy test in the present study with other studies is shown in Tables 4 and 5. In the present study both LE test and RBC test have sensitivities of 76% each, whereas the NIT test was only 56%. This finding is comparable with studies done by Seminiuk and Church, Jones *et al*. and Pfaller and Koontz where LE test is more sensitive than NIT test.[11,18,19] Winkens *et al*. however, compared the three tests (LE, NIT and RBC) and found that LE test had the highest sensitivity at 87%; with the sensitivity of NIT and RBC at 66% each.[17] Their finding is slightly differ-

Table 4 The comparison of the sensitivity of urine dipstick in various studies

Sensitivity (%)	Present study	Winkens *et al.*[17]	Semeniuk and Church[11]	Jones *et al.*[18]	Pfaller and Koontz[19]
LE	76	87	84	79.5	68.2
NIT	56	66	44	32.7	44.9
RBC	76	66	Not applicable	Not applicable	Not applicable
LE, NIT	82.3	Not applicable	84	82.3	79.2

LE, leukocyte esterase; NIT, nitrite; RBC, red blood cells.

Table 5 The comparison of the specificity of urine dipstick in various studies

Specificity (%)	Present study	Winkens *et al.*[17]	Semeniuk and Church[11]	Jones *et al.*[18]	Pfaller and Koontz[19]
LE	60	29	59	68.9	82
NIT	81	50	97	98.6	97.2
RBC	61	75	Not applicable	Not applicable	Not applicable
LE, NIT	57	Not applicable	98	67.9	81

LE, leukocyte esterase; NIT, nitrite; RBC, red blood cells.

ent from the present study. This could be explained by the fact that the readings of the urine dipsticks in their study were done by different personnel which might have resulted in individual bias. In the present study, the same person did all the readings.

The NIT test is the most specific in urine dipstick (82%). This finding is also supported by Seminiuk and Church, Jones *et al*. and Pfaller and Koontz who also found NIT test had the highest specificity (97, 98.6, 97.2%, respectively).[11,18,19] Winkens *et al*. also found that NIT test has a higher specificity than LE test. However, when three tests were compared, RBC test had the highest specificity.[17]

Combination of any two or even three positive tests will increase the sensitivity but will decrease the specificity. Most of the studies have similar findings.[18,19] A negative result, when combining two or three tests produces a higher negative predictive value (90% each). This is important as by combining two or three tests that are negative, one can predict that negative results with any of these combination of tests has a 90% chance of containing less than 10^5 bacteria per mL count. Such a combination can be used with confidence by the general practitioner to predict non-infection.

Results of urine dipstick tests read by a Meditron machine showed a similar pattern to manual reading, although some of the sensitivity and specificity of the various tests were increased by up to 15%. The only exception was in the NIT test, where the sensitivity was lower compared to manual reading. Manual reading of urine dipstick can be subject to human bias. This is especially true when the reader wants the tests to be positive or negative, causing the slightest color change to be considered significant when it is actually not. Other problems that might give rise to false reading are when reading is done under poor lighting conditions and/or the person doing the reading is color-blind.

The 95% CI in almost all the tests in the present study are quite wide, thus causing overlapping results in some of the tests. For example, the NIT test was found to have the lowest sensitivity (56%) compared to the LE and RBC tests (76% each). However, the 95% CI level for NIT test could be as low as 35%, while the highest level could be up to 76% which is the same level as the sensitivity levels of both the LE test and the RBC test.

While we could use different tests in urine dipstick to guide us on the diagnosis of UTI, based on the present study, one should be cautious in interpreting each of the levels of sensitivity and specificity as a result of lack of precision in each test. The main reason contributing to the wide range of 95% CI would be because of the small sample size and random error.

The present study has used Boehringer Manheim Combur 10 Test urine dipstick that is well known and perhaps well used by many health practitioners. Despite the claim by the company that this urine dipstick has the least probability of error compared to other urine dipsticks, in any test even a small error will affect the final outcome of the diagnostic test's performance.

Table 6 The comparison of the sensitivity of urine microscopy in various studies

Sensitivity (%)	Present study	Winkens *et al.*[17]	Bailey[20]
Leukocyte >5 high power field	80	91	91
Red blood cell	50	45	Not applicable
Bacteria	84	47	74

Table 7 The comparison of the specificity of urine microscopy in various studies

Specificity (%)	Present study	Winkens *et al.*[17]	Bailey[20]
Leukocyte >5 high power field	76	27	48
Red blood cell	80	65	Not applicable
Bacteria	54	81	80

The sensitivity and specificity of urine microscopy

Both the presence of leukocytes and bacteria give higher sensitivity levels compared to the presence of RBC, while the presence of RBC has the highest specificity and this is comparable to leukocytes. There is a slight difference in the findings of the present study compared to other studies as shown in Tables 6 and 7.

The difference could be explained as follows:

1 The other studies had chosen different criteria for significant bacteria counts and RBC counts compared to the present study. For example Winkens *et al*. have used ≥20 bacteria per visual field and ≥5 RBC per visual field for significant microscopy.[17]
2 In the present study, the sample size was small compared to other studies. While this study had 100 subjects, both Winkens *et al*. and Bailey had more than 1000 subjects.[17,20]
3 The urine microscopy tests were carried out by different technicians which might cause interrater bias in interpretation of the result.

While the positive predictive values in the present study were low (50% and below), the negative predictive values of leukocytes and bacterial count were 92 and 91%, respectively. A patient with negative test results for each one of the variables has approximately 8–9% chance of actually being infected. Similar to urine dipstick tests, the level of 95% CI in various urine microscopy tests are also quite wide. Although different tests of urine microscopy are helpful in reaching the diagnosis of UTI to a certain extent, caution should be made when interpreting the tests.

Summary of implications for general practitioners

In general, urine dipstick is comparable to urine microscopy. Both urinalysis have reasonably high levels of sensitivity and specificity in some of the tests. The more specific tests (such as the NIT test and microscopy RBC test) when positive results are more indicative of UTI. A negative result in sensitive tests (such as LE and RBC in urine dipstick; and leukocyte and bacteria in urine microscopy), are more likely to indicate non-infection.

The result of urinalysis tests in the present study is comparable to other studies, thus indicating that these tests are accurate to a certain extent. However, as a result of a lack of precision in most of the tests, caution should be made in interpreting each and every sensitivity and specificity level.

In primary care clinics where time plays a big role, it is appropriate to use urine dipstick to diagnose simple uncomplicated UTI. It is cheaper, less time consuming and less laborious compared to urine microscopy.

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Appendix 1 Reference value for normal urine microscopy

	Male	**Female**
Red blood cell (per mL)	0–1	0–3
White blood cell (per mL)	0–5	0–10
Bacteria (per mL)	Negative	Negative