INTRODUCTION

Urinary Tract Infection (UTI) is one of the most common bacterial infections both in community and hospital settings, highest incidence is in children especially in girls due to short urethra and close proximity of genitourinary and anal opening. Early treatment is essential because delay in treatment leads to severe morbidity and mortality.1

In symptomatic urinary tract infection, there is a presence of genitourinary symptoms along with bacteriuria while in asymptomatic urinary tract infection; there is a microbiologic diagnosis of urine infection without clinical presentation of urinary tract infection.2 Early detection of urinary tract infection in laboratory by dipstick, microscopy or urine culture is important because failure to diagnose UTI can have serious complications, especially in pregnant women. Clinically the diagnosis of UTI can be difficult as symptoms are non-specific. The only way to reliably exclude a urinary tract infection is by the laboratory examination of a urine specimen.3

Urine samples constitute a major proportion of the samples tested in routine diagnostic laboratories. Many prompt diagnostic methods are available including wet mount microscopy, Gram stain, dipstick and automated assays, but gold standard method for diagnosis of UTI is quantitative urine culture.4 Up to 18 hours are required for bacterial growth on culture media by standard laboratory techniques,5 which means that diagnosis is undecided for the first 24 - 48 hours after presentation, which leads to delay in treatment. Moreover, urine culture is an expensive procedure and needs a well equipped microbiology laboratory with experienced technicians.6 On the other side, reagent strip testing of urine sample is a method designed to allow early detection of infection in the emergency department and an earlier initiation of the treatment.7 Reagent strips have been designed to test markers of infection. Two markers leukocyte esterase and nitrite have been combined on one dipstick to screen urine samples for urinary tract infections.8 Rapid diagnostic tests can rule out urine infection, are inexpensive, less time-consuming and less expensive and are useful in small laboratories having no culture facility. They are also more rapid than culture in

ABSTRACT

Objective: To determine the sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of Urine Nitrite (NIT) and Leukocyte Esterase (LE) test compared with urine culture for diagnosis of UTI.

Study Design: Validation study.

Place and Duration of Study: Department of Microbiology, Army Medical College, Rawalpindi, from January 2013 to December 2013.

Methodology: Three hundred fresh uncentrifuged urine samples with suspicion of UTI, were collected and tested for LE and NIT by using (COMBI-10SL, UK) strip. Nitrite was considered as positive if there was a change in color of dipstick from colorless towards pink within 60 seconds. Leukocyte esterase was considered as positive if there was a change in color from off-white towards purple within 2 minutes. Quantitative urine culture was performed by using the strips calibrated to deliver 0.02 ul of urine on Cystine Lactose Electrolyte Deficient (CLED) medium agar. All plates were incubated at 37°C and read after 24 and 48 hours. Culture was considered as gold standard to evaluate the performance of dipstick test.

Results: Out of 300 samples, 136 were culture positive and 164 were culture negative. Out of 136 positive culture results, 103 were dipstick positive and 33 were negative. Sensitivity, specificity, positive predictive value and negative predictive value of both nitrite and leukocyte esterase were 75.74%, 68.90%, 66.66% and 77.40% respectively considering culture as gold standard.

Conclusion: Dipstick test for the detection of leukocyte esterase and nitrite in urine are sensitive and specific and can be used reliably for the detection of UTI in resource limited setup.

diagnosing complicated and uncomplicated UTI. Sterile urine sample is not required for dipstick test, therefore, it is easy to collect sample especially in children by noninvasive method.\textsuperscript{9} For dip stick method of diagnosing UTI, there is no requirement of trained staff and well equipped laboratory.\textsuperscript{10} Due to clinical significance of early diagnosis, rapid urine tests such as urine dipsticks are used widely, but performance characteristic of dipstick is still questionable.\textsuperscript{11}

The aim of the study was to evaluate the accuracy of dipstick leukocyte esterase and nitrite tests for rapid screening of urine samples, keeping semi quantitative culture as the gold standard for the diagnosis of UTI.

**METHODOLOGY**

It was a validation analytical study, carried out in the Department of Microbiology, Army Medical College, Rawalpindi, National University of Sciences and Technology, Islamabad, affiliated with the Military Hospital, Rawalpindi.

Sample size was calculated from a recent study\textsuperscript{8} using sensitivity and specificity calculator. Three hundred samples were dealt by non-probability, convenience sampling technique. Patients of any gender of suspected UTI were included in this study while duplicate samples from the same course of illness were excluded. Clean catch, Mid-Stream Urine (MSU) samples with suspicion of UTI, were collected in sterile, wide mouthed bottle and tested for LE and NIT by using (COMBI-10SL, UK) strip. Nitrite was considered as positive if there was a change in color of dipstick from colorless towards pink within 60 seconds. Leukocyte esterase was considered as positive if there was a change in color from off-white towards purple within 2 minutes. Urine culture was performed by using the strips calibrated to deliver 0.02 ul of urine on CLED agar.

All plates were incubated at 37°C and read at 24 and 48 hours. Culture was considered as gold standard to assess the performance characteristic of dipstick test. Data was analyzed by using Statistical Package for Social Sciences (SPSS) version 20. Diagnostic measures i.e. sensitivity, specificity, PPV and NPV were calculated by standard formulas using culture as gold standard.

**RESULTS**

Among 300 samples from patients with suspicion of UTI, 136 samples showed > 10\textsuperscript{5} cfu/ml of single type of bacteria and 164 showed no growth on CLED agar. Out of the positive culture results, 103 were dipstick positive and 33 were negative.

Tables I, II and III show the performance characteristics of LE, NIT and combined LE and NIT (either of them positive was considered as positive). Sensitivity, specificity, PPV and NPV of combine LE and NIT is 75.74%, 68.90%, 66.88% and 77.40% respectively considering culture as gold standard.

**DISCUSSION**

In this study, urine culture and dipstick results were compared, urine culture was considered as gold standard,\textsuperscript{12} to reveal the presence or absence of urinary tract infection. Results of this study showed that urine dipstick test may be considered for rapid urinalysis to diagnose UTI. Combined sensitivity of LE and NIT was 75.74% while specificity was 68.90%. In resource limited setup, where the facility of culture is not available, urine dipstick can be used to rule out urinary tract infection in order to avoid unnecessary use of antimicrobials.\textsuperscript{13}

Use of dipstick test decrease patient's time and money, and may also help in earlier initiation of treatment. Although culture is a gold standard for diagnosis of UTI, it has some disadvantages. Urine culture taken at least 48 hours, well equipped laboratory and trained staff give a reliable result. Whereas dipstick tests have the advantage of being rapid and easy to carry out and can be performed in small laboratories by laboratory technicians.

A number of previous studies have shown a correlation between positive LE, NIT and culture results. Laosuangkoon determined the sensitivity and specificity of urine LE test in an outpatient clinic. His study showed sensitivity of combined LE and NIT as 66.7% while that of LE alone was 63.6%. He concluded that dipstick should be added in ER department for quick diagnosis of
UTI especially in children to prevent potential sequel like hypertension and renal scarring. Taneja et al. showed that combined sensitivity and NPV of LE and NIT was 79.6% and 90.9% respectively while sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) of LE were 73.5%, 58.5%, 33.0% and 88.8% respectively and for NIT were 57.1%, 78.7%, 42.7% and 86.8% respectively. He concluded that for faster diagnosis of UTI, dipstick tests for leukocyte esterase and nitrite test should be added in routine laboratory practices.

Another study conducted by Sundvall and Gunnarsson showed that if both NIT and LE were negative, it was less likely that culture results were positive, while Khasriya et al. showed that sensitivity of LE was 56% and NIT was 10%. Results of sensitivity of his study were less than this study while specificities were 66% and 99% respectively. For the specimen of catheterized patient, sensitivity of leukocyte esterase was 59% and nitrite was 20%, while specificities were 84% and 97% respectively.

Jido et al. worked on urinary tract infection in pregnant females. Their study results showed that nitrite was 80.9% sensitive and 57.9% specific while positive predictive value was 41.4%. The respective values of leukocyte esterase were 100% sensitive and 24.6% specific while positive predictive value was 32.8%.

Glissmeyer et al. worked to assess urine dipstick screening test in febrile children of 1 - 90 days and showed that dipstick alone is a screening tool to rule out urinary tract infection in infants and showed higher predictive values for LE and NIT. They concluded that dipstick is a reliable screening tool, and could be used in emergency department for diagnosis of UTI.

CONCLUSION
Although culture is the gold standard test for diagnosis of UTI, dipstick test for the detection of leukocyte esterase and nitrite in urine are sensitive and specific enough and can be used as a diagnostic test for detection of UTI in resource poor setup, where facility of culture is not available. A combination of LE and NIT test appears to be a very functional indicator for the diagnosis of UTI.

REFERENCES