EVALUATION OF THE RAPID URINE DIPSTICK TEST AS A POINT OF CARE TEST IN THE DIAGNOSIS OF URINARY TRACT INFECTION IN A TERTIARY CARE HOSPITAL

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ABSTRACT:

Background: Urinary tract infection is the most common bacterial infection, often seen in women, can cause severe morbidity and complications. Urinalysis is the unparalleled way to rule out a urinary tract infection. The gold standard reference method for diagnosis of UTI is the urine culture which can help in diagnosing the pathogen and its antimicrobial susceptibility pattern in 48 hrs. Furthermore, urine culture is a high priced procedure for the patient and needs a well equipped microbiology laboratory with expertise. So there is a need for evaluating the efficacy of rapid dipstick tests which are less time-consuming, less expensive, no required expertise and well equipped laboratory.

Materials and methods: A retrospective study was conducted in the Dept. of Microbiology of our tertiary care centre for urine specimens received between January to June 2018. A total 1204 samples were received in Microbiology laboratory. Two Clean catch, Mid-Stream Urine (MSU) samples with suspicion of UTI, were collected in sterile container and tested for LE and NIT by using Reagent strip (SIEMENS URISTIX). Urine culture was performed by standard loop method on CLED agar.

Results: Diagnostic measures i.e. sensitivity, specificity, PPV and NPV were calculated by standard formulas using culture as gold standard. The diagnostic accuracy of combination tests Leucocyte esterase (LE) and Nitrate reductase (NIT) was more compared to individual tests LE and NIT.

Conclusion: A combination of LE and NIT test appears to be a useful indicator for the diagnosis of UTI.

Keywords: Urine culture, urine dipstick test, urinary tract infection, point of care test

Introduction

Urinary Tract Infection (UTI), one of the most common bacterial infections both in community and hospital settings with more incidence in women. The diagnosis of UTI can be difficult as symptoms are non-specific and quite a good number of patients have a condition called as “asymptomatic bacteruria”. Early treatments of these patients are essential to prevent the severity of the disease.

The urinalysis is the unparalleled way to rule out a urinary tract infection.2 As already known several diagnostic methods like the wet mount microscopy, Gram stain, dipstick and automated assays are available, but gold standard reference method for diagnosis of UTI even till date remains the urine culture which can help in diagnosing the pathogen and its antimicrobial susceptibility pattern in 48 hrs.3 This can lead to delay in treating the patient.4 Furthermore; urine culture is a high priced procedure for the patient and needs a well equipped microbiology laboratory with expertise.5

Reagent strip tests designed to test leucocyte esterase (LE) and nitrates (NIT) as markers of infection of urine sample allow early detection of infection in the emergency department and may
be considered as point of care tests (POCT) and may help in earlier initiation of the treatment.\textsuperscript{6,7} Reagent strips being inexpensive, less time-consuming, less expensive, no required expertise and well equipped laboratory can rule out urine infection.\textsuperscript{9} Sterile urine sample which is a prerequisite for culture, is not required for dipstick test, hence, it is easy to collect sample especially in children by noninvasive method.\textsuperscript{10}

Treatment decision on the basis of a positive urine dipstick is up to the clinician’s discretion. Even though several studies have been done in this area, the performance characteristic of dipstick is still questionable.\textsuperscript{11}

The present study has been done as most of the patient population visiting our hospital is from low socio economic background and urine specimens comprise the considerable sample size in our laboratory. 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.

Materials and methods:

Institutional ethical clearance was obtained to conduct the study. A retrospective study was conducted in the Dept. of Microbiology of our tertiary care centre for urine specimens received between January – June 2018. A total 1204 samples were received in Microbiology laboratory during this period. Patients of any gender and any age of suspected UTI were included in this study while duplicate samples from the same course of illness were excluded. Two Clean catch, Mid-Stream Urine (MSU) samples with suspicion of UTI, were collected in sterile container and tested for LE and NIT by using Reagent strip (SIEMENS URISTIX). 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 standard loop method to deliver 100 µl(0.1 ml) of urine on CLED agar. All plates were incubated at 37°C and read at 24 and 48 hours. A colony count of $>10^5$ CFU/ml was considered as significant growth. Culture was considered as gold standard to assess the performance characteristic of dipstick test.\textsuperscript{12}

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 1204 samples from patients with suspicion of UTI, 524 samples showed $>10^5$ cfu/ml of single type of bacteria and 680 showed no growth on CLED agar. Out of the positive culture results, 432 were dipstick positive (82.4%) and 92 were negative (17.5%).

Table I show the performance characteristics of LE, NIT and combined LE and NIT (either of them positive was considered as positive).

- Sensitivity means the ability of the test to identify the number of true positives i.e.. The percentage of sick people who are correctly identified as having the condition.
- Specificity means the ability of the test to identify the number of true negatives i.e.. The percentage of healthy people who are correctly identified as not having the condition.
- Positive predictive value is the probability that subjects with a positive screening test truly have the disease.
- Negative predictive value is the probability that subjects with a negative screening test truly don't have the disease.

Discussion:

The ideal screening test for significant bacteriuria should be rapid, inexpensive, simple to use and accurate. In the present study Dipstick nitrite and leukocyte esterase were compared with the urine culture results, which were used as a gold standard for detecting UTI.

In our study we found that among the culture positive cases, 82.4% were positive by the dipstick assay. The sensitivity and specificity of
A combination of LE and NIT was more compared to individual tests.

Table 2 shows the Sensitivity, specificity, predictive values positive and negative values for dipstick (both LE and NIT positive) in various studies.

A positive screening test will require culture and sensitivity examination so that the right antibiotic can be prescribed. There will be few cases which could be missed by screening assays. This situation can be tackled by doing a culture in symptomatic cases with a negative screening test. So, a combination of three methods with either of them positive can rule out UTI in nearly 90% of cases.

**Table 1:** show the performance characteristics of LE, NIT and combined LE and NIT (either of them positive was considered as positive).

<table>
<thead>
<tr>
<th></th>
<th>SENSITIVITY</th>
<th>SPECIFICITY</th>
<th>PPV</th>
<th>NPV</th>
<th>Diagnostic accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>LE vs Culture</td>
<td>69.27%</td>
<td>96.47%</td>
<td>93.80%</td>
<td>80.29%</td>
<td>84.63%</td>
</tr>
<tr>
<td>NIT vs Culture</td>
<td>72.71%</td>
<td>96.91%</td>
<td>94.78%</td>
<td>82.17%</td>
<td>86.38%</td>
</tr>
<tr>
<td>LE+NIT vs Culture</td>
<td>79.01%</td>
<td>97.35%</td>
<td>95.83%</td>
<td>85.75%</td>
<td>89.37%</td>
</tr>
</tbody>
</table>

**Table 2:** shows the Sensitivity, specificity, predictive values positive and negative values for dipstick (both LE and NIT positive) in various studies.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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</thead>
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<tr>
<td>Falbo et al (2012)&lt;sup&gt;13&lt;/sup&gt;</td>
<td>98%</td>
<td>59%</td>
<td>34%</td>
<td>99%</td>
</tr>
<tr>
<td>Sara Najeeb(2013)&lt;sup&gt;14&lt;/sup&gt;</td>
<td>75.74%,</td>
<td>68.90%,</td>
<td>66.88%</td>
<td>77.40%</td>
</tr>
<tr>
<td>Cemal polat (2015)&lt;sup&gt;15&lt;/sup&gt;</td>
<td>92%</td>
<td>26%</td>
<td>52%</td>
<td>78%</td>
</tr>
<tr>
<td>Fernandez DJ etal(2018)&lt;sup&gt;16&lt;/sup&gt;</td>
<td>31.58%</td>
<td>96.97%</td>
<td>85.71%</td>
<td>71.11%</td>
</tr>
<tr>
<td>Present study</td>
<td>79.01%</td>
<td>97.35%</td>
<td>95.83%</td>
<td>85.75%</td>
</tr>
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</table>

**Conclusion:**

Dipstick test for the detection of leukocyte esterase and nitrite in urine is sensitive and specific enough as a diagnostic test for detection of UTI in resource poor setup, where facility of culture is not available. For patients who cannot afford the cost of culture and for community based surveillance, urine dipstick can be used as a POCT for rapid screening and identifying the cases.

A combination of LE and NIT test appears to be a useful indicator for the diagnosis of UTI.

**REFERENCES**

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