Point-of-Care Testing For Drugs of Abuse in an Urban Emergency Department

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Abstract. Point-of-care testing (POCT) has been used for illicit substance screening in several settings, primarily in law enforcement and drug treatment centers. In this study, we evaluate the use of this screening approach in the emergency department (ED) of a tertiary-care, urban medical center. Aliquots of urine specimens were tested simultaneously by a POCT device (OnTrak™) and by a laboratory-based screening system (Triage™). The outcomes that were compared included (a) time to completion of test, (b) time until the physician received the results, and (c) concordance of results obtained by the two analytical methods. The study population included pediatric (≤ 21 yr) and adult (> 21 yr) patients; data from 170 subjects were evaluated. We observed significant reductions (p <0.001) in turnaround time (both the time to completion and the time to physician). Concordance between the results obtained by the two analytical methods was excellent (97% agreement for cocaine; 99% agreement for marijuana, opiates, and amphetamines, p <0.001 for all categories). Cost analysis showed at least 37.5% decrease in cost per analyte when urine samples were tested by the POCT device, compared to the laboratory-based screening system. We conclude that POCT for drugs of abuse in the ED was equally effective, less costly, and more rapid than the laboratory-based screening system. (received 29 January 2002; accepted 10 April 2002)

Keywords: Point-of-care testing, clinical decision analysis, drugs of abuse

Introduction

Persons adversely affected by drugs of abuse comprise a substantial proportion of the patients that clinicians examine and treat in hospital emergency departments (ED) [1,2]. The care of acutely intoxicated patients is complex and involves a multidisciplinary approach. While clinical treatment of the intoxicated patient frequently requires rapid action by the ED, laboratory testing for illicit substances is still relatively slow [3].

The time required for turnaround of diagnostic information for a urine drug test is currently at least one hr in most institutions [4]. Recently, point-of-care tests (POCT) have been introduced that may help clinicians acquire the same drug screening information more rapidly at the patient's bedside.

In this study, we evaluated POCT in the ED as a substitute for laboratory-based drug screening of urine specimens. The variables that were compared between the ED and the laboratory were the agreement between the analytical results, the time required for completion of the tests, and the turnaround time for reporting the results to the physician.

Materials and Methods

Study Design. The study protocol was approved by St. Joseph's Institutional Review Board. The study had a prospective, self-controlled, method-comparison design. Included were all patients ≤70
yr old in whom a toxicology screening test was deemed necessary for emergency evaluation. Participants were further subdivided into pediatric (age ≤ 21 yr) and adult (age > 21 yr) groups. Informed consent was obtained from each participant or, in the case of minors, from a parent or legal guardian.

The study was conducted during a 3 mo period. A urine sample was obtained and divided into 2 aliquots. At least 30 ml of urine was subjected to POCT in the ED by an ED technician and the remainder of the specimen was immediately sent to the laboratory for analysis. In both the ED and the laboratory, records were filled out with respect to (a) the drug test result, (b) the time required to complete the drug test, and (c) the time required to notify the physician of the result.

The result of the Triage™ urine drug screening test that was performed in the laboratory was the only result that was used by the physician to make medical decisions. The “result to physician time” for tests done in the laboratory was the time from test completion to the time that the result was printed in the ED and placed in the patient’s chart for physician interpretation. This time included approximately one min needed to verify the result by the laboratory technician. The “result to physician time” for tests done in the ED was the time from test completion to the time when a blank result card reading “ED POCT drug screen complete” was placed in the patient’s chart to mimic a datum for physician interpretation. This blank card was a representation of the ED POCT test and contained no information except the elapsed time to report the test result to the physician.

Setting of study. St. Joseph’s Regional Medical Center (including St. Joseph’s Children’s Hospital) is a large (700 bed), urban, tertiary-care, teaching hospital affiliated with Mt. Sinai School of Medicine. St. Joseph’s ED manages approximately 66,000 visits per year. The ED is a level II trauma center which shuttles specimens to the main laboratory via a pneumatic tube system. Laboratory test results are available in the ED after the test has been completed in the laboratory and reported by the hospital computer system.

Drug Screening Devices. The point-of-care test (POCT) used in the ED was the OnTrak™ (Roche Diagnostic Systems, Somerville, NJ) manual drug screening device [5,6]. The laboratory used the Triage™ (Biosite, San Diego, CA) drug testing device. Both of these devices have the same pre-determined cut-off concentrations for detecting illicit substances in urine (eg, cocaine, 3.0 mg/L; amphetamines, 10 mg/L; THC, 0.5 mg/L; opiates, 3.0 mg/L; PCP, 0.25 mg/L; benzodiazepines, 3.0 mg/L; barbiturates, 3.0 mg/L. Both devices were used in strict accordance with the protocols supplied by the manufacturers in the form of package inserts.

Procedures Eight ED technicians were trained by the study investigators to use the OnTrak™ point-of-care drug screening test, including sample handling, reading of test results, and documentation of test results. Each technician first observed the investigators performing the test and then performed the test under the supervision of the investigators. The ED technicians were blinded and were unaware when the urine drug screening result was completed, verified, and reported to the ED by the laboratory.

Both of the POCT devices that were used in this study have quality control measures incorporated in the POCT test itself. Each product has a zone that indicates whether the POCT test reagents and membrane are present and reactive. As an added quality control measure, whenever a new lot of POCT tests was used in the laboratory or ED, positive and negative controls (Fisher Co., Hanover Park, IL) were performed. During the study, no tests failed either internal or external quality control measures.

Statistics. For all study comparisons, α was set at 0.05 and p < 0.05 was considered statistically significant. Comparison of turnaround time was made by paired-sample t-test. Association between POCT results and laboratory results was analyzed using a binary model (positive/negative) in contingency tables. Significance was assessed by chi-square analysis. Calculations were performed using the “Primer on Biostatistics” program (version 3.02, McGraw-Hill, New York, NY), run on a personal computer [7].
Results

**Turnaround times.** Two aspects of turnaround time were evaluated: the time actually required to complete the test and the time required to provide the ED physician with the results after the test was completed. As shown in Table 1, the times to completion were similar in the overall group and the pediatric sub-group. In regard to both the time to test completion and the reporting time to the physician, the data show that the POCT in the ED was much more rapid than the laboratory-based screening test.

Table 1. Comparison of turnaround times (mean ± SD) for drug screening analyses performed in the emergency department (ED) and the hospital laboratory (Lab).

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Age (mean, yr)</th>
<th>Drug Screen Result Time (min)</th>
<th>Result to Physician Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>ED</td>
<td>Lab</td>
</tr>
<tr>
<td>All Patients</td>
<td>170</td>
<td>33.4</td>
<td>5.6±1.9</td>
<td>12.0±3.6</td>
</tr>
<tr>
<td>Pediatric subgroup</td>
<td>34</td>
<td>16.4</td>
<td>6.3±2.6</td>
<td>12.2±2.7</td>
</tr>
</tbody>
</table>

**Comparison of test results.** Table 2 lists the concordance between the two screening modalities that were evaluated, categorized by drug (A, cocaine; B, marijuana; C, opiates; D, amphetamines). The data show strong association between the modalities (p <0.0001 for all drugs), with 97% agreement of the results for cocaine and 99% agreement for marijuana, opiates, and amphetamines.

Discussion

POCT for the rapid detection of illicit drugs and their metabolites provides quick and essential information to the emergency clinician. In the ED, rapid detection of illicit substances may provide the immediate access to analytical information that is useful in management of critically ill patients [8]. Answers to perplexing symptoms such as syncope, pneumomediastinum, rhabdomyolysis, new-onset seizures, coma, etc., may be achieved faster by use of POCT toxicology screening [4].

In our study, we observed improved turnaround times by using the OnTrak™ test at the bedside. The data showed excellent agreement of test results between POCT and our laboratory drug screening device (Triage™). With the drug screening result available in close to 5 min, instead of over a half-hour, the speed of clinical decision-making may be improved. The OnTrak™ test also had the advantages of being easy to use, needing no reagent preparation or handling, and requiring only minimal sample handling (ie, the testcup was the collection container).

In the pediatric population, rapid detection of illicit drugs may have important social implications for the child and family. Rapid analysis of pediatric urine samples may help clinicians to direct the care
of pediatric patients in a more efficient manner than would otherwise have been possible.

A cost analysis of the products is also of interest. The cost of the laboratory test (Triage™) was $16.80 and assayed 7 drugs of abuse. The cost of the POCT test (OnTrak™) was $6.00 and assayed 4 drugs of abuse. On a per analyte basis, the Triage™ test cost $2.40 per assay and the OnTrak™ test cost $1.50 per assay. Thus, a cost savings of at least $0.90 per analyte (ie, 37.5%) was achieved with the POCT. Although manpower costs are roughly equivalent in respect to performance of the test itself, the laboratory has the additional burden of time associated with specimen acquisition, handling, etc. These probably cause a savings of 50% to be realized. A POCT testing device, similar to the OnTrak™, that will analyze all 7 drugs of abuse, will soon be marketed, but was not available at the time of this study.

We caution against any attempts to infer information regarding outcomes such as sensitivity, specificity, and predictive value. These measures require the application of a confirmatory or “gold-standard” method. For the most part, the decision time needed in the ED is far less than that afforded by such methods. The issue of adulterants, raised in a recent paper [9], is of less importance in the ED setting, as purposeful adulteration of a urine specimen is unexpected and, probably, difficult under emergency conditions. A related issue is false-positivity due to interaction with medications or interfering substances [10]. To address this issue, confirmatory tests would be required and, as noted above, the purpose of this study was not to compare the POCT with a reference method (eg, gas chromatography/mass spectrometry), but rather to compare two methods designed for screening.

The goal of this study was to determine the overall efficacy of POCT for drugs of abuse in a setting which provides the most stringent constraints on the application of POCT (ie, a busy, inner-city ED associated with a large, tertiary-care, teaching institution). Our data indicate that the application of POCT testing for drugs of abuse is an effective step in reducing the time required for the analysis of illicit substances in urine and the cost of such analysis in the ED. In the future, study of additional variables such as length of stay and outcome analysis, as well as a more elaborate cost analysis, may be useful in documenting the clinical usefulness of POCT for drugs of abuse in the ED.

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References