Accuracy and speed of urine pregnancy tests done in the emergency department: a prospective study

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Abstract

Objectives: Our primary objective was to assess the agreement between urine pregnancy tests done in the emergency department (ED) and those done by the Calgary Laboratory Services (CLS). Our secondary objective was to compare turnaround times for tests done in the ED and those done in the laboratory.

Methods: This prospective study enrolled a convenience sample of ED patients who required a pregnancy test at 1 of 3 urban Calgary EDs. Using the same urine sample from each patient, testing was done in both the ED and by the CLS using the Abbott TestPak Plus (Abbott Laboratories, Mississauga, Ont.) urine pregnancy kit. The ED data included time of urine collection, β-hCG (human chorionic gonadotropin) result, urine specific gravity, and the time the ED nurse reported the result. The CLS data included the time sample was sent to the laboratory, time of laboratory reporting, time ED nurse was aware of the result, the urine β-hCG result and uring specific gravity. When the ED result and CLS result differed, a serum β-hCG assay was performed and used as the diagnostic "gold standard."

Results: There was a high level of agreement between the CLS and the ED, as indicated by a kappa value of 0.97 (95% confidence interval [CI], 0.95–0.98). The ED was significantly faster in time to initial report and time to availability on the chart, with mean differences of 25 minutes (95% CI, 22–27) and 60 minutes (95% CI, 56–64), respectively.

Conclusions: ED nurses can perform urine pregnancy tests as accurately as laboratory technicians, and can provide results on which to base care much faster than the laboratory can. Point-of-care urine pregnancy testing may expedite the ED management of patients who require pregnancy tests.

RÉSUMÉ

Objectifs : Dans un premier temps, notre objectif était d'évaluer la concordance entre les tests de grossesse effectués à l'urgence et ceux effectués par les Calgary Laboratory Services (CLS). Dans un deuxième temps, notre objectif était de comparer les délais d'obtention des résultats des tests effectués à l'urgence avec ceux effectués au laboratoire.

Méthodes : Cette étude prospective incluait un échantillon de commodité de patientes nécessitant un test de grossesse dans l'un des trois départements d'urgence urbains de Calgary. En utilisant le même échantillon d'urine de chaque patiente, le test fut effectué à l'urgence et aux CLS à l'aide de la trousse de test urinaire de grossesse Abbott TestPak Plus (Laboratoires Abbott, Mississauga, Ont.) Les données à l'urgence comprenaient l'heure de la collecte d'urine, le résultat du dosage de la β-hCG (gonadotrophine chorionique humaine), la densité urinaire et l'heure à laquelle l'infirmière de l'urgence remit le résultat. Les données des CLS comprenaient l'heure à

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laquelle l'échantillon avait été envoyé au laboratoire, le délai pour recevoir le résultat, l'heure à laquelle l'infirmière avait été mise au courant du résultat, le résultat du dosage de la β-hCG urinaire et la densité urinaire. Lorsque les résultats à l'urgence et les résultats des CLS différaient, un dosage de la β-hCG urinaire était effectué et utilisé comme l'«étalon-or» diagnostique.
Résultats : Le niveau de concordance entre les CLS et l'urgence était élevé, comme l'indique la valeur kappa à 0,97 (intervalle de confiance [IC] à 95 %, 0,95–0,98). L'urgence était nettement plus rapide en termes de délai pour le rapport initial et le délai de disponibilité au dossier, les écarts moyens étant de 25 minutes (IC à 95 %, 22–27) et de 60 minutes (IC à 95 %, 56–64), respectivement.
Conclusions : Les infirmières à l'urgence peuvent effectuer des tests de grossesse de façon aussi précise que les techniciens de laboratoire et donner les résultats permettant d'orienter les soins beaucoup plus rapidement que le laboratoire. Les tests urinaires de grossesse sur les lieux des soins (POC) pourraient permettre d'accélérer la prise en charge à l'urgence des patientes qui nécessitent un test de grossesse.

Key words: emergency department, urine pregnancy testing, point-of-care testing

Introduction

Women frequently present to emergency departments (EDs) with abdominal pain, vaginal bleeding, syncope or shock — conditions that may be pregnancy related. During pregnancy, many common medications are contraindicated, and diagnostic imaging is avoided if possible. It is often necessary to determine rapidly whether women are pregnant, and the menstrual history alone is not reliable.[1] For these reasons, EDs require a rapid, accurate, noninvasive and cost-effective pregnancy test.

Qualitative urine pregnancy tests performed by lab technicians are accurate and cost effective when compared to serum β-hCG (human chorionic gonadotropin) assays.[2] At the time this study was conceived, only 1 of 3 adult EDs in Calgary was approved to do point-of-care (POC) pregnancy testing. The investigators felt that laboratory pregnancy testing was unnecessarily time-consuming and that moving this function to the ED could improve efficiency. Unfortunately, a review of the medical literature and local quality assurance data revealed no studies comparing ED to laboratory urine pregnancy testing and no data to support pregnancy testing in the ED.

Our objective was to demonstrate that ED nurses could perform POC pregnancy tests with a high level of accuracy. Our hypothesis was that urine pregnancy tests performed in the ED would be as accurate as those performed by laboratory technicians, and that ED results would be available more rapidly than laboratory-based tests.

Methods

Design and setting

This prospective study enrolled a convenience sample of patients who required pregnancy testing in 3 urban Calgary EDs. It was approved by the Calgary Regional Health Authority Ethics Committee.

Patients

Female patients between the ages of 18 and 50 years were eligible if they had a pregnancy test ordered in association with any of the following presenting complaints: abdominal pain, abdominal mass, nausea, vomiting, syncope, hypotension, vaginal bleeding or amenorrhea, or if there was a need for radiographic studies. Patients with a previous hysterectomy or known gynecologic or endocrine malignant disease were excluded, as were patients who did not have concurrent blood tests performed. The latter exclusion criterion was at the request of the research ethics committee and was intended to avoid additional venipunctures when there was a discrepancy between the laboratory and ED urine test results.

Urine testing

All urine pregnancy tests in the ED and laboratory were performed using the Abbott TestPack Plus hCG Urine (Abbott Laboratories Ltd., Mississauga, Ont.). This test kit is a POC immunoassay designed for the qualitative determination of HCG in urine. The test kit employs monoclonal antibodies to the beta subunit of HCG and has a β-HCG detection threshold of 25 mIU/mL.

After acquisition of the urine sample, 3 drops of urine are placed in the device's sample well. A positive test is indicated by the appearance of a pink or red colour in the assay window within 5 minutes. To increase reliability, ED nurses were trained to perform the test the same way as the laboratory technicians, using the laboratory procedure manual. Nurses and technicians were advised that pregnancy tests may be falsely negative when urine specific

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gravity is less than 1.015, and that this should prompt additional testing if clinically indicated.

Study procedures

Eligible patients were approached by ED nurses for informed verbal consent to be enrolled into the study. After urine was acquired, samples were divided into 2 aliquots. One was analyzed by an ED nurse; the other was sent by porter to the hospital laboratory (Calgary Laboratory Services [CLS]) for standard analysis. To facilitate prompt laboratory reporting to the ED, laboratory results were transmitted to the ED by fax and placed on the patient's chart by the ED staff. At the time of phlebotomy, nurses drew 1 extra tube of blood, which was labelled and stored in the laboratory. This tube was used for serum β-HCG analysis whenever the ED and laboratory urine pregnancy results differed. In such cases, a serum value of less than 25 mIU/mL was defined as a negative test, and a value equal to or greater than 25 mIU/mL was defined as a positive test.

Data collection

Nurses collected and recorded study data on standardized collection forms derived from the CLS procedure manual. The data forms documented time of urine collection, time urine was sent to the laboratory, time of reporting, and time that clinical staff received test results. The data form also documented urine specific gravity and β-HCG result (positive, weakly positive or negative). In cases of disagreement between laboratory and ED results, the treating physician was notified and assured the performance of a serum β-HCG, which was used as the diagnostic "gold standard."

Time definitions

Lab "testing time" was defined as the time elapsed between sending the sample to the laboratory and receiving the result on the ED patient chart. An additional time, lab "report time" was calculated, and was defined as the time elapsed between sending the sample to the laboratory and the time the laboratory reported that the test was completed.

Statistics

Cohen's κ statistic was used to evaluate agreement between laboratory and ED test results. Partial data were used in the analysis when either the times or urine pregnancy results were complete. Elapsed times using mixed-effect analysis of variance were used to allow the inclusion of patients with partial data. Since the application of the simpler paired *t*-test and associated confidence intervals (CIs) (to compare data cases) yielded essentially identical results we report the latter. The comparative box plot (Fig. 1[3]) was constructed using a logarithmic scale to show the degree of skewness of the data. Statistical computations were done in SPSS and S-Plus.

Results

During the 6-month study period, ED nurses prospectively enrolled 498 patients. Of these, 476 (95.6%) had complete data and 22 (4.4%) had 1 or more missing data points. Laboratory and ED results agreed in 471 (98.9%) of the 476 cases. Using the serum hCG as the "gold standard," with a cut-off value of 25 mIU/mL, laboratory urine pregnancy test results were incorrect twice (1 false negative and 1 false positive) and ED results were incorrect 3 times (all false negative). Overall laboratory–ED test agreement was high, with a κ value of 0.97 (95% CI, 0.95–0.98).

Figure 1 shows testing times for laboratory versus ED urine pregnancy results. Mean testing times, reflecting time to result availability on the ED chart, were 7.6 minutes for the ED and 67.4 minutes for the laboratory, with a difference of 60 minutes ($p < 0.0005$; 95% CI, 54–64 min).

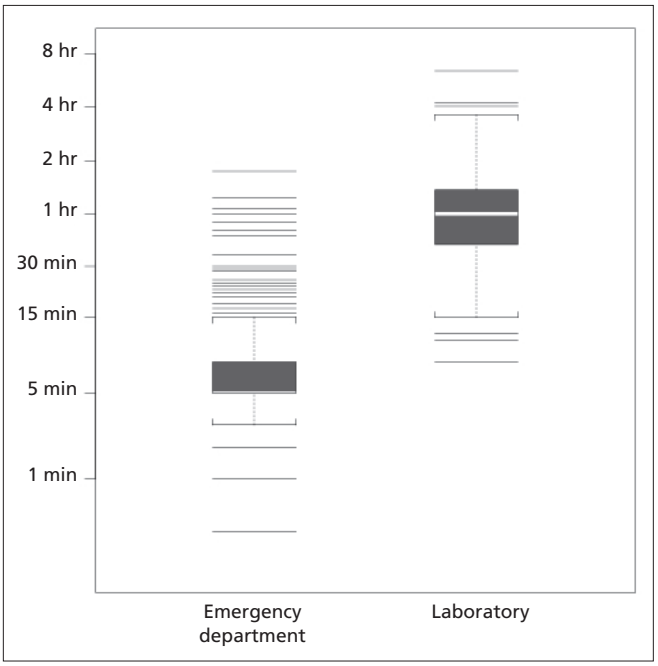

Fig. 1. Emergency department and laboratory test times on a logarithmic scale. The upper and lower ends of the boxes represent upper and lower quartiles, the white bars represent median values. The broken lines extend to minimum and maximum values, excluding outliers. Outliers, represented by horizontal lines, are defined as observations beyond the quartile values by more than 1.5 times the interquartile range.[3]

Mean laboratory report time was 32.6 minutes, 25 minutes longer than corresponding ED time ($p < 0.0005$, 95% CI, 22–28 min).

Discussion

These data support our study hypothesis that ED nurses can perform urine pregnancy tests as accurately as laboratory technicians and can provide results on which to base care much faster than the laboratory.

Urine pregnancy tests, such as the one used in this study, use monoclonal antibodies specific to the hCG beta subunit. They become positive at an hCG level of 25 mIU/mL or greater, which is typically reached before or at the time of expected menses. Previous studies have confirmed the accuracy of urine pregnancy testing relative to serum testing, demonstrating at least 99.63% concordance.[2,4,5] At the time of the study, the cost of a urine pregnancy test in our setting was $1.65, whereas a serum test cost approximately $10. For these reasons, most physicians in our region do not routinely order serum pregnancy tests.

This study demonstrates excellent but not perfect accuracy. Laboratory technicians generated 1 false-negative and 1 false-positive result, and ED nurses generated 3 false-negative results. We believe these low error rates are within the expected range for human error. One of the ED false-negative results occurred because of a faulty test kit, in which the assay control window did not turn positive and the ED nurse did not repeat the test.

Study limitations

Cost concerns prevented us from performing concurrent serum hCG assays on all enrolled patients; therefore, we did not compare urine to serum β-hCG results. Therefore, although we can conclude that ED urine testing is as accurate as laboratory urine testing, we cannot conclude that urine testing is as accurate as serum testing. The implication of a 1-hour time advantage for ED testing is that patients who undergo this form of testing can be discharged or have critical decisions made more rapidly. Because patients waited for both results, we could not determine the impact of more rapid test availability on actual clinical outcomes. Finally, this study evaluated only 1 POC pregnancy kit, and these results cannot necessarily be generalized to other available kits.

Conclusions

ED nurses can perform urine pregnancy tests as accurately as laboratory technicians and can provide results on which to base care much faster than the laboratory can. POC urine pregnancy testing may expedite the ED management of patients who require pregnancy tests.

Competing interests: None declared.

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