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Evaluation of a Plasma hCG Method for Point of Care Testing with the Aim of Shortening Test-Turnaround-Times

Anna-Karin Wikström[1], Magnus Hagmar[1], Göran Ronquist[2], Anders Larsson[2*]

[1]Department of Women's and Children's Health, Uppsala University, Uppsala, Sweden
[2]Department of Medical Sciences, Section of Clinical Chemistry, Uppsala University, Uppsala, Sweden
Email: *anders.larsson@akademiska.se

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Abstract

Objective: To examine the correlation between plasma hCG results obtained with the new i-STAT® hCG point of care test with those concomitantly obtained from the central hospital laboratory utilizing the same patient samples. Methods: Prospective cross-sectional laboratory test evaluation. We compared plasma hCG results obtained with the i-STAT® hCG test (Abbott Point of Care, Princeton, NJ, USA) with Architect Ci8200 (Abbott Laboratories, Abbott Park, IL, USA). We also calculated the total coefficient of variation (CV) for the i-STAT® method. Results: The two methods showed a good linear correlation (R^2 = 0.994; slope 1.03) and CV for the i-STAT® method was 2.1% - 5.2%. Conclusion: We suggest that the i-STAT® hCG blood assay could be used as a complement to urine hCG assays in clinical situations when rapid test results are needed and urine is not available.

Keywords

Human Chorionic Gonadotropin, Pregnancy, Method Evaluation, Point of Care Test

1. Introduction

Pregnancy tests utilizing antibodies for detection of human chorionic gonadotropin (hCG) in urine have been used for half a century. The antibody based tests are cheaper and much faster than the older bioassays. HCG is a dimer made up of two subunits, α and β [1]. The α subunit is also present in other proteins and in the 1970s the specificity of the assay was further improved by using β subunit specific antibodies [2]. This founded the basis

*Corresponding author.

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for the home pregnancy urine tests that are used around the world. These tests are accurate and affordable and are used in large numbers. Due to their accuracy, pregnancy tests are now used within the healthcare system to confirm or rule out pregnancies. These may involve acute situations such as women with abdominal pains where an ectopic pregnancy or a hydatidiform mole may be possible causes. Since pregnancy is not compatible with risk-taking like certain clinical investigations, it is important to be able to rule out pregnancies in e.g. the X-ray department. In such situations it is not always possible for the women to quickly provide urine samples on request that certainly will cause a delay in the overall process. An alternative to minimize such a delay in a health care setting is to measure hCG in blood plasma close to the patient. Blood samples may be obtained more rapidly than urine samples. Another advantage with blood tests is that these tests are usually quantitative in contrast to urine tests that usually only are qualitative. Also, there are reports of false negative results with the urine tests [3].

If the HCG test is performed at the central laboratory the transport may cause a significant delay. We were thus interested in evaluating plasma hCG methods that could be performed locally in the outpatient emergency units, X-ray department or primary care.

The aim of the current study was to evaluate the i-Stat hCG method as a complement to our urine based pregnancy tests. The i-Stat hCG method was compared with the current central laboratory method.

2. Methods

2.1. Study Population

Lithium heparin plasma samples (n = 53) were collected in LH PST II vacutainer tubes (366,567, Becton, Dickinson, Franklin Lakes, NJ, USA). The samples used were from routine requests for plasma hCG at the Department of Clinical Chemistry and Pharmacology, Uppsala University Hospital, Uppsala. All HCG tests were performed on fresh samples. The local Ethical Committee (01-367) approved the collection of samples. The work was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki).

2.2. Plasma hCG Assays

The central laboratory plasma hCG measurements were performed on an Architect Ci8200 (Abbott Laboratories, Abbott Park, IL, USA). The total coefficients of variation (CVs) for the hCG method were 8.1% at 3 U/L and 4.9% at 312 U/L.

Plasma hCG was also analysed with the i-STAT® system (Abbott Point of Care, Princeton, NJ, USA) using plasma hCG cartridges from the same supplier.

2.3. Statistical Analyses

The measuring range for the i-STAT® instrument was 5 - 2000 U/L. Results < 5 U/L was set to 5 U/L and results > 2000 U/L was set to 2000 U/L for both instruments in the statistical analysis. The correlation between the methods was evaluated with linear regression analysis and CV was calculated using Excel 2007 (Microsoft, Seattle, WA, USA).

3. Results

3.1. Coefficient of Variation (CV) for the i-STAT® Assay

A total of 10 measurements during 5 days were used to calculate the total CV for each level. CVs were measured at three different levels. The total CVs were 5.2% at 22 U/L, 2.7% at 950 U/L and 2.1% at 1474 U/L.

3.2. Correlation between the Two Plasma hCG Assays

The equation for the correlation between the two methods was plasma $hCG_{i\text{-}STAT}$ = 1.03∗plasma $hCG_{Architect}$ + 10.56 and a R^2 = 0.994 (**Figure 1**).

4. Discussion

The i-STAT® had in this study CVs similar to the central hospital laboratory analyser. There was also a strong

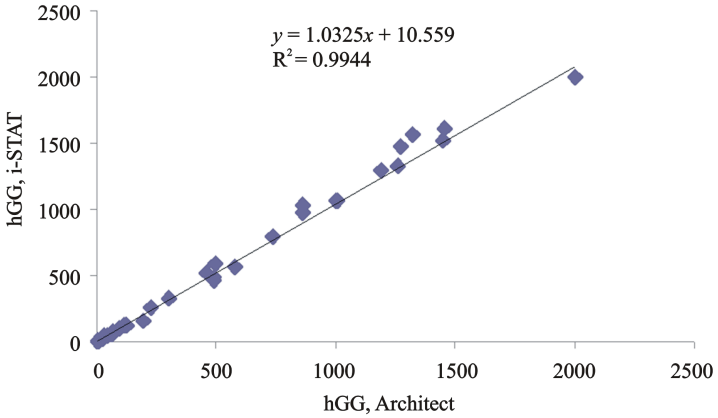

Figure 1. Linear correlation between human plasma chorionic gonadotropin (hCG) samples analysed with architect (x-axis) and i-Stat (y-axis).

correlation between the two methods. The i-STAT® gave slightly higher values but the small differences between the two instruments permitted the use of identical reference intervals. A point of care instrument is often used to make rapid clinical decisions based on a single test result rather than continuous monitoring of results or the same instrument is used for repeated measurements. HCG also has a large dynamic range. The slightly higher values from the i-STAT® should therefore not cause any serious clinical problems even if the two assays were occasionally used in parallel for daily monitoring of hCG levels.

The i-STAT® is a handheld cartridge based system and there is no direct blood contact with the instrument. The total assay time is 10 minutes, which will reduce the test-turnaround time in comparison with sending the samples to the centralized laboratory. The traditional urine hCG method can only be used to confirm/rule out pregnancy while the i-STAT will provide quantitative plasma data that will be valuable in the emergency unit for patients with suspected ectopic pregnancies.

5. Conclusion

In conclusion, the results of this study show that the i-STAT® hCG assay could be used as a complement to urine hCG assays when rapid test results are needed and urine is not readily available.

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Conflict of Interest

The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.

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