

A COMPARATIVE STUDY AMONG ONE STEP HCG TEST STRIP, DIRECT AGGLUTINATION TEST AND ELISA FOR DETECTION HCG⁺

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Abstract:

One hundred suspected pregnant women were included in this study . Direct latex agglutination test and one step HCG test strip as well as ELISA for determination HCG were performed in all suspected pregnant women .

70% of suspected pregnant women showed positive results in each of direct agglutination test , one step HCG test strip and ELISA but 85% of results showed agreement between one step HCG test strip and ELISA (15% negative + 70% positive) based on a dependable quantitative ELISA , the specificity and sensitivity for one step HCG test strip were 100% , 99% respectively while the specificity and sensitivity for direct latex agglutination were 43% , 82% respectively and the HCG test strip was sensitive to 10mIU/ml also this study indicated that HCG test strip can be yielded positive result after two days from first missed menstrual period in contrast with direct latex agglutination test which need at least 7 day after the first missed menstrual period to give positive result.

Finally, this study has confirmed that the one step HCG test strip is the best qualitative method for detection the early pregnancy.

المستخلص

شملت الدراسة مئة امرأة من المتوقع ان تكون نساء حوامل ولكل امرأة أجريت ثلاث اختبارات هي اختبار التلازن المباشر للحمل وشريط اختبار هرمون الحمل بالاضافة الى اختبار (ELISA) وذلك لغرض التحري عن هرمون الحمل (HCG) .

٧٠% من النساء المتوقع حملها اعطت نتائج موجبة لهرمون الحمل في كل من اختبار التلازن المباشر وشريط اختبار هرمون الحمل وكذلك (ELISA) . وان ٨٥% من النتائج كانت متوافقة لكل من شريط اختبار هرمون الحمل وطريقة (ELISA) .

كانت (١٥% من النتائج سالبة + ٧٠% من النتائج موجبة) تم تحديد الخصوصية والحساسية لكل من اختبار شريط هرمون الحمل واختبار التلازن المباشر للحمل بالاعتماد على طريقة (ELISA) حيث اشارت الدراسة بان الخصوصية والحساسية لشريط هرمون الحمل كانت ١٠٠% ، ٩٩% على التوالي بينما الخصوصية والحساسية لاختبار التلازن المباشر للحمل كانت ٤٣% ، ٨٢% على التوالي كما اشارت الدراسة ايضاً بان شريط اختبار هرمون الحمل من الممكن ان يعطي نتيجة موجبة للحمل بعد يومين من

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فقدان الدورة الشهرية المعتادة على عكس اختبار التلازن المباشر للحمل الذي يحتاج ما لا يقل عن ٧ أيام بعده فقدان الدورة الشهرية لكي يعطي نتيجة موجبة .
وأخيرا أكدت الدراسة بأن اختبار شريط هرمون الحمل هو أحسن طريقة نوعية للتحري عن الحمل مبكراً .

Introduction :

We think that we are in a great need to resolve some complications and controversies which comrades the early pregnancy tests such as false positive and negative results therefore; this study will focus on the specificity and sensitivity for each of a commercially available one step HCG test strip (Acon laboratories) and direct latex agglutination test for qualitative detection of HCG based on a quantitative ELISA test which is reference method [1] .

Human chorionic gonadotropin (HCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization [2] , HCG can be detected in both urine and serum as early as 7 days after conception in normal pregnancy .

HCG levels continue to rise very rapidly , frequently exceeding 100mlu/ml by the first missed menstrual period [3,4] . The appearance of HCG in both urine and serum soon after conception , and its rapid rise in concentration makes it ideal indicator for detection and confirmation of the pregnancy [5] .

Materials and methods :

One hundred suspected pregnant women were included in this study, sufficient serum sample was taken for each women to detect HCG by both one step HCG test strip (Acon laboratories company) and quantitive ELISA test (Biocheck company). Also urine sample was taken for each women to detect HCG by a direct latex agglutination test (Omega company).

All procedures were achieved by following the manufacture's directions. The study started from October 2006 until February 2007.

$$\text{Sensitivity} = \frac{\text{No of true positive}}{\text{No of true positive} + \text{No of false negative}} \times 100$$

$$\text{Specificity} = \frac{\text{No of true negative}}{\text{No of true negative} + \text{No of false positive}} \times 100 \quad [6]$$

Results:

70% of results showed agreement among direct latex agglutination test , one step HCG test strip and ELISA but 85% of results showed agreement between one step HCG test strip and ELISA (15% negative + 70% positive) .Only 1% of women showed positive results in ELISA but negative for each direct agglutination test and one step HCG test strip .

Table (1): Comparison among direct latex agglutination test, one step HCG test strip and ELISA .

No of women	Direct agglutination test	HCG test strip	ELISA cut-off = 2mlu/ml
15	-	+	+
70	+	+	+
8	+	-	-
6	-	-	-
1	-	-	+
Specificity	43%	100%	100%
Sensitivity	82%	99%	100%

Conc. concentration.

ELISA: Enzyme linked immunosorbent assay.

Table (2) illustrated that pregnant women who gave positive results in HCG test strip but negative for direct agglutination test had HCG concentration between 10-50 mlu/ml.

Table (2): HCG concentration In ELISA for each pregnant women who gave positive results in one HCG test strip but negative for direct agglutination test .

HCG conc. In ELISA (mlu/ml)	Number of pregnant women	%
10-20	4	27
21-30	2	13
31-40	3	20
41-50	6	40
Total	15	100

The data represented in table (3) showed that one step HCG test strip is capable of detection HCG in serum of pregnant women after two days from first missed menstrual period.

Table (3): The duration per days after first missed menstrual period for pregnant women who gave positive results in one step HCG test strip but negative for direct agglutination test .

The duration per days after first missed menstrual period	Number of pregnant women	%
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2-	2	13.3
3-	2	13.3
4-	3	20
5-	4	26.7
6-	4	26.7
Total	15	100

Discussion :

The study has showed that 70% of suspected pregnant women gave positive results in each of a direct agglutination test, one step HCG test strip and ELISA but 85% of results showed agreement between HCG test strip and (reference method) ELISA (15% negative + 70% positive) .

Data in this study also reported that 8% of suspected pregnant women gave positive in a direct agglutination test but negative for each HCG test strip and ELISA to interpret these results ,we can say that all positive results in direct latex agglutination which are not confirmed by HCG test strip and quantitative ELISA may be account as false positive results belong to across reactivity which is possible with agglutination test [7,8] , because it is not specific for beta HCG and react with another reasons other than HCG[9,10],in addition to some complications behind the technique which is used in agglutination test [11] , in contrast with one step HCG test strip which depend on the immunological specificity (chromatographic immunoassay) permitting virtually to eliminates a cross reactivity interference from structurally related glycoprotein hormones such as LH, FSH and TSH [12,13] .

We should remember that the minimum detectable concentration of HCG by reference method ELISA is 2.0mIU/ml [14]. Based on a dependable quantitative ELISA the sensitivity and specificity for each of a direct agglutination test and HCG test strip were obtained. The specificity and sensitivity for HCG test strip were 100% , 99% respectively while the specificity and sensitivity for a direct latex agglutination were 43% , 82% respectively and the HCG test strip was sensitive to 10mIU/ml , also this study has illustrated that 27% of pregnant women who give positive results in HCG test strip but negative for a direct agglutination test have serum HCG concentration 10-20mIU/ml , this may confirm that HCG test strip is capable of detection fewer concentration of HCG in serum of pregnant women near to concentration that can be detected by quantitative ELISA 2.0mIU/ml . Also data in this study have represented that HCG test strip is able to detect HCG in serum of pregnant women within two days after first missed menstrual period in contrast with a direct agglutination test which need at least 7days after first missed menstrual period to give positive results .

The high sensitivity and reliability of HCG test strip for detection fewer concentrations of serum HCG $\geq 10\text{mIU/ml}$ make it a good test for detection the early pregnancy at any time of day and do not need a first morning specimen or specimen

collected 48 hours later which are very necessary for a direct latex agglutination test [14] .

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