COMPARATIVE STUDY OF SENSITIVITY AND SPECIFICITY OF BETA MONOCLONAL AGGLUTINATION INHIBITION AND SANDWICH IMMUNOMETRIC ASSAY TESTS IN THE DIAGNOSIS OF PREGNANCY

Pages with reference to book, From 131 To 133

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Abstract

Urine of 30 pregnant females was tested for gravidex test. Both concentration and agglutination inhibition (Beta monoclonal) tests were performed on the same urine specimens. Results showed that the sensitivity and specificity of the concentration (colour) test was much higher than that of the B monoclonal test (JPMA 39:1.31, 1989).

INTRODUCTION

The laboratory confirmation of pregnancy has become a common and important laboratory procedure, especially in the diagnosis of ectopic pregnancies and in the management of tumours of placental tissue. Human chorionic gonadotropin (hCG) is a glycoprotein composed of two noncovalently linked polypeptides the alpha and beta subunits. The individual subunits lack biological activity but become active when linked to form the intact complex. The alpha hCG subunit is essentially identical to the alpha chain of several other pituitarypolypeptide hormones like thyroid stimulating hormone, follicle stimulating hormone and luteinizing hormones in their specific biological characteristics. Convenient immunologic procedures for the determination of hCG are available and are sensitive as well as specific. They are even more specific when they assay for the beta subunit of hCG. Various pregnancy tests are available, having different sensitivities and specificities. The time at which a given pregnancy testbecomes positive also varies. The aim of the present study was to compare the sensitivity and specificity of recently introduced concentration (colour pregnancy) test and B monoclonal slide test based on the principle of agglutination inhibition.

MATERIAL AND METHODS

Thirty females whose ages ranged from 18 to 38 were included in the study. All had history of amenorrhoea varying from 3 days to S months. Urine of these females were tested for pregnancy. Both the concentration (colour) and slide (agglutination inhibition) tests were performed at the same time on the same specimen. The kits used were, Beta-monoclonal (1500) and HCG VISUAL ELISA TEST supplid by BGH biochemical company and Boehringer Manheim respectively.

RESULTS AND DISCUSSION

The sensitivity and specificity of these pregnancy tests are shown in table I and II.

TABLE I. Sensitivity and Specificity of Betamonoclonal and Concentration Tests.

Sensitivity of Beta Tests	$= \frac{TP}{TP+FN} \times 100$	$= \frac{11}{11+2} \times 100 = 84.6\%$
Specificity of Beta test	$= \frac{TN}{TN+FP} \times 100$	$= \frac{16}{16+1} \times 100 = 94.4\%$
Sensitivity of concentration test	$= \frac{TP}{TP+FN} \times 100$	$= \frac{13}{13+0} \times 100 = 100\%$
Specificity of Concentration test	$= \frac{TN}{TN+FP} \times 100$	$= \frac{17}{17+0} \times 100 = 100\%$

TP = True positive
FN = False negative
TN = True negative
FP = False positive

The slide and tube test use either agglutination or agglutination inhibition as visible indicators of a colour as indication of a positive test[1].

TABLE II. Comparative statement of B.Monoclonal and Concentration Tests inrelation to Amenorrhoea

B.Monoclonal Test		Concentration Test		Amenorrhoea
Number positive	Number negative	Number positive	Number negative	in days
0	1	1	0	0 – 3
2	3	2	3	4 – 7
0	3	0	3	8 – 10
2	0	2	0	11 – 14
1	0	1	0	15 – 26
2	0	1	1	27 – 29
2	1	0	2	30 – 37
0	0	0	0	38 – 25
2	3	2	3	46 – 60
1	3	1	3	61 – 90
0	2	0	2	91 – 120
1	0	1	0	121 – 150
Total 13	16	11	17	

As shown in table II there is a strong correlation between the results of colour test and B.monoclonal test except in three cases. In one case the subject has amenorrhoea of 3 days. At this stage the concentration of hCG in urine is very small, which cannot be detected by B.monoclonal test. However ELISA test is very sensitive to detect very small amounts (20-50 mu/ml) [2]. In a second case having amenorrhoea of 60 days, the colour test was positive while the B.monoclonal test was negative. In this case the ultrasound examination confirmed the pregnancy at a gestational age of 4 weeks. At a gestational age of 8 weeks the patients developed bleeding per vaginum and as a result the B.monoclonal test was negative. In a third case, the colour test was negative, while the B.manoclonal test was positive. This positivity was most probably due to cross reactivity of luteinizing hormone with beta subunit of bCG. The same finding has been confirmed by other workers[3]. The pregnancy was followed in all these cases for correlation of the results. From table lit is clear that, the concentration test is more sensitive and specific than the B.monoclonal test. Similar findings have been reported by other workers[4,]. Although we have worked on a small sample yet, we conclude that the concentration test, though little bit expensive, but its precision is much higher as compared to the B.monoclonal tests and other older tests used for diagnosis of pregnancy. Although Radioimmunoassay technique (RIA) is the most sensitive and specific one, but it needs expensive equipment and the reagents are unstable (iodinated tracers). This property make them unsuitable for 24 hours stat pregnancy testing. So

choosing method for stat pregnancy testing is no longer difficult and we recommend the use of concentration (VISUAL ELISA hCG TEST) test, in local hospitals.

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