Prospective evaluation of immunological urinary pregnancy test using SPIA technique

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UMMARY: This is a prospective evaluation of 618 consecutive pregnancy tests done by SPIA technique (Pregcolour st ~ Intercare).We found that the test has a sensitivity 94.5%,specificity of 89.6 % and a positive predictive value 98.6%.It was least reliable giving low sensitivity (83.8 %) and specificity (77.4 %) at or before 35 days of enstrual age. However it was most reliable at or after 50 days of menstrual age,in subjects who were suspected to pregnant.

ntroduction

mmunological urinary pregnancy tests have not only ade the clinical practice of obstetricians and fertologists mfortable,but have also rendered decision making ster and precise.Many pregnancy tests are commercially ailable. Cole and Kardana (1992) found that in USA, out 50 serum based pregnancy tests were available mmercially.O'Conner et al in 1994 as well as Tyrey in 995 identified different methods used for immunological egnancy test for detecting HCG. These involve inciples of agglutination inhibition, ELIZA,immuno~ romatography,radio immunoassay,immuno radiometric say (IRMA), etc.One such immunological test for tecting HCG in urine is SPIA technique (Manufactured Intercare Ltd.~Calcutta)popularly known as egcolour test.

this prospective study we present our results of aluation of this urinary pregnancy testing method.

laterial and Methods

his is a prospective evaluation of 618 urinary pregnancy sts.These were consecutive tests done.This study was rried out in Unit III of the Dept.Of Obst.& nec.,Medical College and S.S.G.Hospital Baroda.This inary pregnancy test (popularly known as Pregcolour st)is manufactured by Intercare Ltd. (Calcutta) under ense from Organon Teknika N.V.Belgium. This study neither sponsored nor funded in any form by the anufacturers /marketing agency.It uses SPIA technique and is based on change of colour.In presence of urinary HCG,test solution prepared changes its colour from purple to colourless.As mentioned in the information literature of the company was only morning specimen of urine not insisted upon. Only freshly voided samples of urine were taken.The results of these 618 consecutive tests performed was over long period of time exceeding five years are presented. The change in colour from purple to colourless within 5 minutes.was considered as positive.

If the time taken was more than 5 minutes.it was noted as delayed positive. Those tests where the colour got converted from dark purple to light pink but not completely colourless was noted as weak positive. The results so obtained were evaluated using standard statistical tests and counter checked on computerised SPSS software for such evaluations.

Results

In all , 618 consecutive pregnancy tests were analysed in this study.

This Table I shows the distribution of tests which gave expected results.By expected results it is meant that if a woman's pregnancy test was positive, she should be pregnant and if negative, she should not be pregnant. As shown in Table I, 448 out of 618(72.5%) tested positive and indeed had an intra~uterine pregnancy. Ectopic pregnancies are not included in this study. On the other hand,129(20.9%)out of 618 tested negative and indeed did not have pregnancy.

Table :I

(Expected Results)

Positive test : Pregnancy present

	No.	%
Upto 35 days M.A.	88	19.6
36~42 days M.A.	130	29.01
43~49 days M A.	132	29.5
50~56 days M.A.	98	21.9
Total	448/618	72.5

Negative test: Pregnancy absent

Upto 35 days M.A.	24	18.6
36~42 days M.A.	35	27.1
43~49 days M.A.	39	30.2
50~56 days M.A.	31	18.2
Total	129/618	20.9

(M.A.= Menstural Age)

Table II

(Unexpected Results)

Positive test : No. Pregnancy

	No.	%
Upto 35 days M.A.	07	46.6
36 -42 days M.A	05	33.3
43~49 days M A	03	20.0
50~56 days M.A.	Nil	Nil
Total	15	

Negative test : Pregnancy present

	No.	%
Upto 35 days M.A.	17	65.3
36~42 days M.A.	07	26.9
43~49 days M.A.	02	7.7
50~56 days M.A	Nil	Nil
Total	26	

(M.A.= Menstrual Age)

This Table II shows distribution of false positive and false negative tests. There were 15 false positive and 26 false negative cases. Maximum false negatives were when the tests were done upto 35 days of menstrual age.

Table III

Menstrual Age wise~sensitivity,specificity, etc.,

	Menstrual Age in days				
	Overall	35	36~42	43~49	50~56
Sensitivity	94.5	83.8	94.9	98.5	100
Specificity	89.6	77.4	87.5	92.8	100
False +ve	5.5	16.1	5.1	1.5	Nil
False -ve	10.4	22.5	12.5	7.1	Nil
Positive Predictive value	96.8	92.6	96.3	97.7	100
Negative Predictive value	83.2	58.5	83.3	95.1	100
No Tested	618	136	177	176	129

As shown in table III, Pregcolor test had a sensitivity of 94.5% and a specificity of 89.6%. This test has a positive predicitive value of 96.8% and a negative predictive value of 83.2%. When these statistical indices are applied as per the Menstrual age of suspected gestation interesting results emerge. This test becomes very efficient and competent as the Menstrual age advances. Thus the sensitivity of only 88.8% at 35 days soars to 100% at 50 days. Similarly the specificity of this test which is only 77.4% at 35 days of Menstrual stage reaches it's peak of 100% by 50 days. Similar behaviour is found for other statistical indices as shown in table III.

Discussion

Immunological pregnancy tests are very valuable aids in day to day practice of obstetricians and fertologists.Originally evolved as serum pregnancy tests now even urinary pregnancy tests have become popular.The basic aim of these tests is to detect HCG in urine. Levels of HCG in urine of pregnant women are closely parallel to levels in serum (Williams, 1993). A good rule of thumb is that the amount of HCG contained in 1 liter of maternal plasma is equivalent to that contained in 24 hours of urine.

Urinary pregnancy tests use various technologies for detecting HCG.The present test uses SPIA technique.Most tests claim that they are sensitive enough

to pick up HCG levels at or beyond 200 i.u/ml. Admittedly ,we did not expect such a clear and consistent correlation getting established from the results.The efficiency of the test is least when tested at or before 35 days of Menstrual age and reaches its peak of efficiency by the time it reaches 50 days.This indeed correlates with the behaviour of HCG which has increasing levels upto 70 days and then it plateaus (Williams, 1993).We were having a feeling of lesser reliability of this test when employed in very early days of pregnancy during the prolonged period of documentation.The end results have ultimately given a clear verdict on the matter.On basis of these results we agree with Jovanovic et al (1987)who proved that routine tests could reliably detect pregnancy only after the missed period.

For this test, the earliest a clinician could get good reliable results is when the test is positive between 36 to 42 days i.e.6 to 12 days after the date of last missed period.Before that the test is likely to be less reliably specific and having a poor negative predictive value.The reason for inability of the test to pick up a pregnancy very early is understandably ,the low levels of HCG.On the other hand,a high false positive of 16.1% at 35 days could be due to some degree of cross reactivity with high levels of LH.These were invariably cases of P.C.O.D. who missed their period, checked for pregnancy,tested positive(usually weak positive) while the subjects were not pregnant.Though we did catalogue cases as weak positive and delayed positive also, it is not an aspect aimed to be highlighted in this paper.

We would also like to devote a couple of lines to the claims made in literature hand out of this test by the company concerned. Most of their claims seem to be correct and sustainable. But a couple of them require to be disputed. We did not find a 99.0% positive and 99.5% negative predictive value of the test as claimed in the said literature. Also,its relability will be low if really done at 2nd day of missed period,as recommended in their literature.

The question as to whether this test can be recommended for home testing is also important. Doshi (1986)found that when women conducted their own pregnancy tests at home the predictive value of a negative result was a low 56%. From the results of our study and those of Doshi(1986)we could recommend this test for home testing only at or after 56 days of Menstrual age of suspected pregnancy.

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