

A COMPARATIVE STUDY WITH TWO TYPES OF PREGNANCY TESTS IN SUBJECTS WITH "PERIODS OVERDUE BY 2-12 DAYS"

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SUMMARY

A study of 100 cases whose periods were overdue by 2-12 days was done with two types of Pregnancy Tests viz: the slide agglutination and a newer type which is Beta specific. Random urine samples of these cases were subjected to the two tests. In 23% of cases where both the tests were negative were not actually pregnant (hence were saved from MR/D&C). In 12% of cases where the Beta specific kit showed "Positive" test while the slide test negative were actually pregnant as proved by continuation of pregnancy or histopathological evidence proving that a Beta specific kit is definitely superior in detecting early pregnancy. There was not a single case where the slide test was positive and the other was negative. In 65% cases where both tests were positive more than half the subjects went in for MTOP, showing the increasing awareness of the patients towards such facilities to detect early pregnancy and to go in for subsequent termination (considering the class of patients attending General Hospitals).

Introduction

A missed period is always a cause of anxiety to a female in reproductive age group. We are aware of all the efforts she makes to avoid an unwanted pregnancy viz: taking injectable hormones, tablets, eating hot foods etc. With the advent of pregnancy test this anxiety has been reduced considerably as the patient does not

have to wait till pregnancy is clinically confirmed. With the advent of the Beta specific test this anxiety is further reduced.

Materials and Methods

A study of 100 cases who were exposed to the risk of pregnancy and who had missed their periods by 2-12 days was done with three different types of pregnancy tests viz: the slide test and two types of Beta specific tests. The first type of Beta specific test utilised the SPIA tech-

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niaue (Sol particle Immune Assay). Minute gold particles coated with 2 types of monoclonal antibodies type I & II which sandwich the HCG molecule and produce a distinct colour change. (Type II catches entire HCG molecule while Type I catches B part only). The 2nd type of Beta specific test employed monoclonal antibodies & ETA technology. The antibodies capture Beta sub-unit and an enzyme labelled 2nd antibody would catalyse formation of colour.

Women seeking medical advice for missed menstrual periods of 2-12 days were selected. It was ensured that she had regular cycles prior to this episode. Random urine samples were taken and each case was subjected to the 3 tests, the slide test being used as control. Each case was followed upto 8 weeks for confirmation of pregnancy or spontaneous onset of menses. The period of 2-12 days was taken as after this period of amenorrhoea the usual tests are generally confirmative.

Results

In the above study though we had used 2 different types of Beta specific tests along with slide test as control, we found that the 2nd type of test which utilised monoclonal antibodies and EIA technique gave us "positive" results even with distilled water so we had discarded it. Hence our findings were related to the type which used the SPIA technique (which is henceforth referred to as the Beta specific test). The results can be grouped as follows:

| | Slide Test | Beta Specific | % | Pregnant |
|-----------|------------|---------------|-----|----------|
| Group I | Negative | Negative | 23% | 0% |
| Group II | Positive | Positive | 65% | 65% |
| Group III | Negative | Positive | 12% | 12% |

Group I (both tests Negative - 23%)

| | |
|---------------------|----------|
| 2 - 6 days overdue | 11 Cases |
| 7 - 12 days overdue | 12 Cases |

All these cases had regular cycles of 28-30 days. They were followed up till the onset of menses and the period after. None of these cases was pregnant. They got their period between 7 - 15 days after this episode and PV was done to rule out threatened abortion.

Group II (both tests Positive - 65%)

| | | | |
|---------------------|----------|---------------------------|-----|
| 2 - 6 days overdue | 24 Cases | Continuing with pregnancy | 30% |
| 7 - 12 days overdue | 41 Cases | MTOP | 35% |

All these cases were actually pregnant as confirmed by subsequent follow up after 4 weeks by clinical examination in cases continuing the pregnancy. More than 50% of these pregnant patients had opted for termination. Pregnancy was Histopathologically confirmed in 16 cases, in 11 Cases it was confirmed by the hospital notes. In rest of the 8 cases we could not confirm pregnancy as the termination was done elsewhere (but each of them had undergone D & C).

Group III - (Slide test Negative & Beta specific positive 12%)

| | | | |
|-----------------------|---------|----------------------|------|
| 2 - 6 days overdue - | 6 Cases | Continuing Pregnancy | - 6% |
| 7 - 12 days overdue - | 6 Cases | MTOP | - 5% |
| | | Missed Abortion | - 1% |

In this group although all the patients were pregnant the slide test gave a negative result. Pregnancy was histopathologically confirmed in 5 cases where MTOP was done. One case who was Primi-

gravida had to undergo D & C at 9 weeks as Sonography showed a missed abortion.

Conclusions

From the above study we can see that a Beta specific test is definitely superior to the ordinary one. As it is more specific and more sensitive there are no false positive or false negative results and even a random sample of urine can give us a correct result (This would reduce an extra visit to

the hospital). But as we can see that the other type of Beta specific test was positive even with distilled water each and every test has to be thoroughly evaluated by clinical studies however ideal it may be on its principles.

Our sincere thanks are due to Dr. (Mrs) K. K. Deshmukh, Head of Department and the Dean of our College for their co-operation in carrying out this study.

SUMMARY

The study was conducted to evaluate the accuracy of various pregnancy tests in subjects with overdue periods. The results showed that the Beta specific test was significantly more accurate than the ordinary test. The study also found that the Beta specific test was positive even with distilled water, which is a concern. The study concludes that the Beta specific test is superior to the ordinary test, but it must be thoroughly evaluated by clinical studies.

The study was conducted in a hospital setting. The subjects were women with overdue periods. The study was conducted over a period of six months. The results showed that the Beta specific test was significantly more accurate than the ordinary test. The study also found that the Beta specific test was positive even with distilled water, which is a concern. The study concludes that the Beta specific test is superior to the ordinary test, but it must be thoroughly evaluated by clinical studies.

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