VALUE OF PROGESTATIONAL AGENT NOR-ETHINDRONE@ IN THE DIAGNOSIS OF AMENORRHOEA*

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Establishment of the diagnosis of early pregnancy and secondary amenorrhoea of recent onset is one of the constantly posing problems for the gynaecological out-patient. There are several tests designed to establish the diagnosis of pregnancy, their basis being chemical, biochemical, biological and smear examination. Of all these tests the biological test still holds the line of a fair degree of reliability and accuracy of about 98%. The test, however, is cumbersome and needs well-established laboratory, and, therefore, can not be utilised with usefulness in common practice. An attempt recently, therefore, has been made to find an easy and reliable test in the use of progestational agents.

The earliest pregnancy test dates back to four hundred years. In Egypt it was believed the germination of gram seeds could take place by the urine of pregnant women. In 1928, Aschheim and Zondek made the sensational discovery of finding gonadotrophic hormones in urine of pregnant women.

Studies on hormonal assay and the physiological basis of menstruation has opened a new chapter. It has been found that withdrawal bleeding can be induced by adequate doses of oestrogen and progesterone practically in every patient of child-bearing age with intact uterus and endometrium. Depending upon this rationale, Zondek devised the test for withdrawal bleeding by injection of a combination of 2.5 mg. oestradiol benzoate and 25 mg. progesterone. The bleeding followed within 24 to 74 hours.

Hady and Gedije, in 1945, utilised oestrone for this purpose and later progesterone combination to establish the diagnosis of functional amenorrhoea. Hayden, in 1955, used progesterone injection for pregnancy test with high accuracy. Later, in 1958, Hayden utilised newer progestins for pregnancy test with a similar success.

The present study aims at finding the value of Nor-ethindrone (a progestational agent) as a diagnostic test for early pregnancy. This drug was first developed and utilised by

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Dr. Gayeski of Parke Davis Company in 1959. It has been claimed that Nor-ethindrone can produce withdrawal bleeding in oestrogen primed endometrium in non-pregnant women and maintains the decidua in pregnant women.

Material and Methods

The material used for clinical evaluation consisted of 26 cases attending the gynaecological out-patient department of S. N. Hospital, Agra, who presented for doubt and/or confirmation of pregnancy. Before including the patients in the series, a detailed clinical history was taken. Internal examination to note the size and the consistency of the uterus, as well as speculum examination to see the condition of the cervix, was done. Examination of breasts was made as a routine. After giving the drug the patient was kept for follow up, for appearance of withdrawal bleeding or any other change.

Incidentally the series under study included two types of cases.

A. Women who had regular periods without missing.

B. Women who were in lactational amenorrhoea and who doubted that they had conceived.

Nor-ethindrone in 5 mg. tab. form was given after breakfast for two consecutive days. The patient was asked to report every 15 days or the day of withdrawal bleeding if any was recorded.

Observations

A total of 26 cases was studied for doubtful pregnancy and for confirmation of pregnancy.

Table 1 above shows the number of patients and their parity. They ranged from 1st to 7th parae.

Table 2 shows the period of amenorrhoea which varied from 5th week to 28th week. There were three cases who were in lactational amenorrhoea and had doubted that they had conceived.

TABLE 3
Results

Pregnancy test	No. of patients	Percentage
Negative	20	76.92%
Positive	4	15.3%
False positive	2	7.6%
False negative	Nil	Nil

TABLE 1
Parity

Parity	1	2	3	4	5	6	7	Total
No. of patients	5	8	3	2	4	3	1	26

TABLE 2
Period of Amenorrhoea

Period in weeks	5	6	8	10	22	Lactational	Total
No. of patients	5	11	5	1	1	3	26

Results and Comments

Table 3 shows the results at a glance. A total of 26 cases were studied. Out of 26 cases 6 had withdrawal bleeding within a period of 3-7 days. On the follow-up, out of these 6 cases 4 proved non-pregnant, while the remaining two were found to be pregnant thus giving a false positive result of 33.3%. On further follow-up both these cases aborted. One may offer a physiological explanation for these false positives. Possibly the ovum was already separated or dead and it might be due to this that these two cases had withdrawal bleeding. If that be so, these two false positives would have to be regarded as pseudopositive. It might even be inferred that when the test is positive (with withdrawal bleeding), it could be presumed that the lady was either non-pregnant or if at all an early pregnancy was present, the pregnancy would not continue. From a clinical angle therefore, if we accept this explanation for positives, then test has 100% value.

In the remaining 20 cases no withdrawal bleeding occurred and all these cases on follow up proved to be pregnant. This would imply that when the test is negative, it was again of 100% value.

Conclusions

1. Withdrawal bleeding by Norethindrone could be utilised as a safe test for excluding amenorrhoea due to early pregnancy.
2. There were two cases who were pregnant, yet the test was positive. These cases, however, aborted within the next few days.
3. There are no side effects by Norethindrone, when utilised as pregnancy test.
4. The clinical value of the test with present series was found to be 100%.

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