

IMMUNOLOGIC DIAGNOSIS OF PREGNANCY IN MINIABORTION

by

R. RAJAN,* M.D., D.G.O.

L. USHA DEVI,** M.B.,B.S.

S. VENKITAKRISHNAN,*** M.B.,B.S.

and

ROSAMA JOHN,† M.B.,B.S., D.G.O.

Endometrial aspiration continues to be the most elegant procedure for termination of pregnancy, and in simplicity, safety, efficacy and patient convenience no known method can surpass this procedure. Nevertheless, when performed within 21 days of missed menstrual period, endometrial aspiration is an unnecessary invasion of uterus in upto 32% of cases in the absence of pregnancy (Rajan and Kaimal, 1977). In an attempt at minimising the incidence of the non-pregnant women undergoing the procedure, in a subsequent series of 600 cases, we elected to delay the aspiration until the patient was at least more than 10 days past the expected menses. By performing the aspiration between 15th and 21st day of a missed period, even though blood loss was minimal (27.20 ml) and complications were negligible (1.20 per cent), the incidence of invasion of non-gravid uterus could not be reduced below 14 per cent (Rajan *et al* 1978). To further improve the results in this

group (in women who were atleast more than 10 days past the expected menses), we tried to eliminate the non-pregnant women by employing immunologic method of pregnancy diagnosis. This schedule yielded gratifying results, and the incidence of aspiration in non-pregnant women was reduced to 4 per cent.

In this communication we intend to point out the benefits of doing the pregnancy test at least 10 days past the expected menses, and if found positive performing endometrial aspiration not later than 21 days past the expected menses. This formula, without sacrificing the simplicity and efficacy of the procedure, ensures a very high pregnancy termination rate nearing 100 per cent. Admittedly, there are some short-comings such as patient inconvenience and false negative results, which will be further discussed.

Patient Selection

Women reporting with short period of amenorrhoea, ranging from 10 to 21 days past the expected menstrual period, and desiring endometrial aspiration were considered for the evaluation. The period of study extended from March 1977 to December 1977, and the number of patients registered were 105. All were parous women, with majority in the low parity group.

*Assistant Professor.

**Senior Research Fellow, Indian Council of Medical Research.

***Family Planning Medical Officer.

†Postgraduate Student.

Department of Obstetrics & Gynaecology,
Medical College Hospital, Kottayam-686 008.

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Urine Test for Pregnancy

A careful pelvic examination was performed to elicit the early pregnancy changes in the uterus. As a routine urinary pregnancy test was done in all the patients. The test was performed in the Contraceptive Testing Unit of the ICMR with Pregnosticon haemagglutination-inhibition tube test. Eventhough it was not a quick test and took 2 hours for interpretation, results were anticipated to be more accurate because the test was adjusted to detect concentrations of HCG at 1000 I.U./Liter. A positive test was indicated by a specific sedimentation pattern in the form of a clearly defined ring.

Aspiration Procedure

If the pregnancy test was positive, subsequently endometrial aspiration was done in the outdoor. Modified Karman Syringe and 5 mm plastic cannulae were employed for this purpose. The quantity aspirated was carefully measured, and sent for histopathological confirmation of pregnancy. After resting for 30 minutes the patient was allowed to go home, with advice to report for check-up after one week.

Where the pregnancy test was negative, the patient was advised to report after one week for reassessment and repeat pregnancy test. If the patient desired, a hormone withdrawal bleeding was induced. If the amenorrhoea continued and the pregnancy test became positive subsequently, or the pregnancy symptoms developed, pregnancy interruption was carried out at that stage. Except in one occasion, where suction curettage was required, endometrial aspiration could be performed successfully in all the other cases.

Contraceptive Therapy

The patients were encouraged to accept concurrent post-abortal contraceptive therapy. In those who showed an inclination a copper device was inserted following the completion of the aspiration procedure.

Follow-up

At the time of follow-up visit after one week, a careful pelvic examination was made for evidence of any complications such as excessive blood loss, incomplete abortion, sepsis or continuation of pregnancy. In cases of IUD users the position of the device was ascertained.

Analysis

In 105 women early diagnosis of pregnancy was attempted with immunological test, as a preliminary to endometrial aspiration. In the presence of a positive pregnancy test the aspiration was carried out. Of the 64 women who had a positive pregnancy test, 61 were documented to be pregnant by histopathological examination of the aspirate. The total aspiration in the pregnant women ranged from 15 ml to 50 ml, with a mean of 29 ml. The non-pregnant women recorded less than 15 ml aspiration. None of the patients in this series had any complications. Copper IUDs were inserted for 60% of these women, as a post-abortal contraceptive.

In 41 women the pregnancy test was negative. However, 8 of them were subsequently proved to be pregnant and underwent pregnancy termination. In 7 patients endometrial aspiration could be performed successfully, and 1 patient required cervical dilatation with laminaria tent and suction curettage. Except for the delay of one week and the inconvenience, there were no complications in this group.

A final analysis (Table I) revealed that a positive pregnancy test had 96% reliability, whereas a negative test is less reliable (80%). Since the pregnancy test was employed, endometrial aspiration could be avoided in 33 of the 36 non-

From these observations our inference is that, if endometrial aspiration is performed between 10 and 21 days past the expected menses, proportion of documented pregnancy will be only 86 per cent, which can be improved to 90 per

TABLE I
Immunological Test for Pregnancy Diagnosis
(Total Patients: 105)

Positive test for pregnancy					Negative test for pregnancy				
Total Cases	Preg. confirmed		Not pregnant		Total Cases	Not pregnant		Preg. confirmed	
	No.	Percentage	No.	Per cent		No.	Per cent	No.	Per cent
64	61	96	3	4	41	33	80	8	20

False Positive results: 4%

False Negative results: 20%

pregnant women, but the procedure was delayed by a week in 8 of the 69 pregnant women. The overall results appeared to be satisfactory because the incidence of non-pregnant women undergoing uterine aspiration was minimised to 4 per cent.

A parallel analysis was as follows: In all the 105 patients a clinical diagnosis of pregnancy was elicited by pelvic examination, and the same was confirmed subsequently. Of the 72 patients who were clinically pregnant, 65 had documented histological evidence of pregnancy, which gave an accuracy of 90% for positive findings. In the meanwhile, of the 32 patients who had no clinical evidence of pregnancy, 24 were proved to be not pregnant, giving a diagnostic accuracy of only 75% for negative findings. (Table II).

cent by careful consideration of clinical diagnosis. Nevertheless, the best results are obtained (96 per cent) when endometrial aspiration is performed after immunological diagnosis of pregnancy. (Fig. 1).

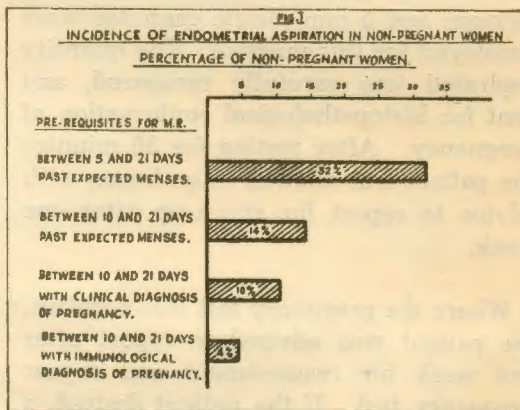


TABLE II
Clinical Diagnosis of Pregnancy (105 Cases)

Positive Evidence of Pregnancy					No Clinical Evidence of Pregnancy				
Total Cases	Preg. confirmed		Not pregnant		Total Cases	Not pregnant		Preg. confirmed	
	No.	Percentage	No.	Per cent		No.	Per cent	No.	Per cent
72	65	90	7	10	33	24	75	8	25

False positive results: 10%

False Negative results: 25%

Discussion

It has to be accepted that, due to lack of a method of early and specific diagnosis of pregnancy, suction aspiration has been performed in a significant number of non-pregnant women with a possibility

developed, which proves to be a rapid, reliable and specific test for early diagnosis and management of pregnancy (Landesman and Saxena, 1976). Evolution of pregnancy diagnosis methods is given in Table III.

TABLE III
Evolution of Pregnancy Tests

Type of test and Author	Year	Time to perform	Specificity	Days of detection after ovulation
Biologic (Aschheim and Zondek)	1927	2 to 5 days	95%	25
Immunologic (Wide and Gemzell)	1960	2 mnt. to 2 hrs.	90%	25
Radioimmunoassay (Kossasa et al.)	1972	24 to 72 hrs.		7 to 9
Radioreceptorassay (Landesman and Saxena)	1974	1 hr.	99%	6 to 8

of uterine infection occurring in 2 per cent of them. This unnecessary intrauterine manipulation in non-pregnant subjects can eventually result in uterine synechiae and infertility (Landesman and Saxena, 1974). But, in combination with reliable diagnosis of pregnancy, endometrial aspiration or miniabortion is an ideal technique for termination of early pregnancy.

Biologic tests for the diagnosis of pregnancy usually require more than 24 hours and are reliable only after 2 weeks past the expected menses. Immunological tests for pregnancy are more rapid; however, there is little improvement in the sensitivity. These tests showed a 95% reliability only when used after 45 days of amenorrhoea (Brenner *et al* 1973; Dawn, 1975). The radioimmunoassay detected HCG as early as 7 to 9 days after conception (Mishell, *et al* 1974), but required an incubation period of 72 hours (Goldstein, 1976). Recently radioreceptorassay for HCG has been

If radioreceptorassay is available, pregnancy diagnosis as early as 6 to 8 days after conception will be possible, and the aspiration procedure can be undertaken as early as possible. This obviously eliminates the need for delaying the procedure for 10 days past the expected menses. This being a quick test (interpreted in one hour), it adds to the convenience of the patient.

Since radioreceptorassay is not readily available, we have to make use of the presently available methods of pregnancy diagnosis. Among the immunological methods, the two-hour pregnosticon haemagglutination-inhibition tube test (used in our series) seems to be more accurate because it is adjusted to detect concentrations of HCG at 1000 I.U./liter. It is reliable from the 10 day of the missed menses (Dawn, 1975).

In the previous report Rajan *et al* (1977) have established that by just delaying the aspiration procedure until

the patients were atleast 10 days past the expected menses, a pregnancy termination rate of 86 per cent could be obtained. In the present study, where the immunologic pregnancy test was performed after the 10th day of missed period as a preliminary to endometrial aspiration, we feel that we could improve the termination rate by 96 per cent. Certainly, this is a step towards perfection and is due to the meticulous and calculated use of immunologic test. Moreover, since the procedure is limited to 21 days past the expected menses, we could minimise the blood loss (means aspiration 29 ml), and avoid any complications. All these factors establish endometrial aspiration as the most ideal method of pregnancy termination.

Nevertheless, since this method involved a delay of 2 hours for interpretation of the test there was some amount of patient inconvenience and quite often necessity for a second visit. Yet another drawback was the unreliable negative results. Twenty per cent of the women who recorded a negative immunologic test were pregnant, and in these patients the termination procedure was unnecessarily delayed due to the false negative reports.

Conclusion

1. None of the readily available methods for pregnancy diagnosis can detect pregnancy until the woman is atleast 10 days past the expected menstrual period. Endometrial aspiration performed within this period becomes a poor and interim procedure of pregnancy termination, with as many as 50 per cent remaining non-pregnant.

2. Immunological test for pregnancy (Pregnosticon-tube test), performed after the 10th day of expected menses ensures

a diagnostic accuracy of 96 per cent for positive results. However, negative results are unreliable and carry an error of 20 per cent.

3. Endometrial aspiration performed between 10th and 21st day of expected menses, without a preliminary immunologic diagnosis of pregnancy, ensures a pregnancy termination rate of 86 per cent.

4. In combination with a preliminary immunologic test greater perfection can be obtained with a high pregnancy rate of 96 per cent, and endometrial aspiration can be considered as the most ideal method for termination of early pregnancy.

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