

REDUCTION OF THE INCIDENCE OF COMPLICATIONS OF PREGNANCY¹

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It is obvious that it is impossible to perform a controlled experiment dealing with problems affecting human reproduction. In order to arrive at a reasonably accurate incidence of the various complications and abnormalities affecting both the maternal and fetal organism a large number of records must be evaluated. Such a study made with a sufficiently large number of consecutive and carefully analyzed case histories has clinical and statistical significance and should serve as an adequate substitute for a controlled experiment.

The expected incidence of the various complications of pregnancy is known. This report is made from a study of 382 consecutive private patients. Each patient was given a daily dose of wheat germ oil concentrate² throughout her entire pregnancy. Our earlier study (4) prompted this prophylactic approach. A significant lowering of the expected incidence of the various complications of pregnancy was observed.

This study shows that 30 patients or 7.8 per cent threatened to abort, and of these 16 or 53.3 per cent of those who threatened to abort went to term, and 14 or 46.6 per cent of those who threatened to abort did abort. The abortion rate of this series is 3.6 per cent. The accepted rate of threatened abortion is between 15 to 25 per cent. The actual spontaneous abortion rate in this country is reported to be at least 13 per cent (1), (2), (3), (5).

Our study also reveals a lowering of the expected incidence of toxemias of pregnancy, prematurity, still-births, and neo-natal deaths. This last condition is due to the higher survival rate among those babies who are born prematurely.

There were no gross abnormalities among either the term or premature babies. Among those who aborted only one embryo showed a gross development deficiency.

We feel that we have used the wheat germ oil concentrate in a sufficiently large number of consecutive patients to justify the belief that the incidence of the complications of pregnancy may be markedly reduced.

PATIENTS STUDIED

Three hundred and eighty-two patients were observed. Each was given three 3 minim capsules of wheat germ oil concentrate daily throughout her entire pregnancy. If complications arose, the dosage was increased.

RESULTS:

THREATENED ABORTION

Of this series of 382 patients, 30— 7.8 per cent threatened to abort. Only 14—3.6 per cent did abort, and 16 or 4.2 per cent were controlled and were delivered at term. No malformed infants were delivered and only one embryo showed a gross development deficiency.

A patient classified as having a threatened abortion exhibited vaginal bleeding with or without cramping. Bleeding from local lesions was excluded and in all patients the blood serology was negative. We made a radical departure from the accepted treatment of threatened abortion. None of the patients was put to

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²An 8 to 1 concentrate of wheat germ oil made by removing the glycerides and retaining the unsaponifiable fraction. The wheat germ oil is extracted from fresh wheat germ with ethylene dichloride by the VioBin Corporation, Monticello, Ill.

bed. Each patient was permitted to carry on her usual household duties, and her dosage of wheat germ oil concentrate was increased from three capsules daily to twenty capsules daily. This dosage was continued until all bleeding had ceased for two days and the dosage of the concentrate was then decreased one capsule daily until she was again taking three capsules per day.

RH FACTOR

Fifty patients were Rh negative. Thirty-eight were multigravida and twelve were primigravida. Ten husbands were also Rh negative. Only three of these patients threatened to abort, but all three were controlled and delivered at term. One mother delivered a baby who developed the toxic form of erythroblastosis and died on the eighth day. Her first child was normal but she lost her second child on the third day with the icteric form of erythroblastosis. It is interesting that the anti Rh antibody titer of this mother's blood never exceeded 1 : 64 and dropped to 1 : 32 just before delivery.

Wheat germ oil concentrate may be a factor in the prevention of some cases of erythroblastosis fetalis by lowering the incidence of threatened abortion and thereby preserving the integrity of the syncytial barrier.

PREMATURITY

The standards of the American Academy of Pediatrics were used in the classification of the premature infants. Twelve mothers had fourteen premature babies; there were two sets of twins. Three of these babies were still-born, two due to abruptio placenta, and one due to severe pre-eclampsia in a diabetic mother. The corrected percentage of prematurity in this series was 2.8 per cent.

CLASS 1—1000 Gms. or less—1. or 7 per cent of prematures.

CLASS 2—1000—1500 Gms.—1. or 7 per cent of prematures.

CLASS 3—1501—2000 Gms.—8. or 5.6 per cent of prematures.

CLASS 4—2001—2500 Gms.—3. or 2.1 per cent of prematures.

Two premature babies succumbed in the neo-natal period. One was a class 2 and the other a class 3 premature. Of the premature babies born alive, 9 survived. The premature survival rate for all classes of premature babies was 82 per cent.

The expected incidence of prematurity as reported by Brown et al. (5) after a study of 13,399 mothers and infants was 7 per cent. Eastman (6) reported the incidence of prematurity in a study of 28,493 deliveries to be 11.7 per cent. An analysis of 32,381 consecutive deliveries in Franklin County, Ohio, showed the incidence of prematurity to be 7.1 per cent.

It has been shown that bleeding in pregnancy doubles the incidence of prematurity (7), (8). Any agent that will aid in the prevention of uterine bleeding must necessarily be an important factor in saving infant lives. Prematurity is the largest single cause of death in the first year of life. It is also the only condition of infants which is listed among the first ten causes of death. The prevention of prematurity is probably more important than good pediatric care.

We believe the figures shown are significant. Our incidence of prematurity of 2.8 per cent (corrected) is lower and the survival rate of 82 per cent is higher than that usually reported.

TOXEMIAS OF PREGNANCY

Nausea and vomiting of pregnancy occurred in 113 patients or 29.5 per cent of the series. This was easily controlled by the intravenous administration of pyridoxine HCL (9). The early correction of nausea and vomiting may have been a factor in the reduction of late toxemias of pregnancy (10). We are unable to determine to what extent the wheat germ oil concentrate was responsible for lowering the incidence of toxemia.

The expected incidence of the pregnancy toxemias exclusive of nausea and vomiting is 10 per cent (11). In this series fourteen (3.4 per cent) patients developed some form of toxemia as shown in the table.

Nephritic Toxemia	(Group A.1) (a)	1 patient	or 0.2 per cent.
Mild pre-eclampsia	(Group B.1) (a)	11 patients	or 2.8 per cent.
Severe pre-eclampsia	(Group B.1) (b)	1 patient	or 0.2 per cent.
Eclampsia	(Group B.2) (a)	1 patient	or 0.2 per cent.

All the mothers survived and one baby was lost, a premature still-born from a non-cooperative diabetic mother.

Evaluation of the toxemias of pregnancy in this series of patients shows a definite reduction over the expected incidence.

STILL-BIRTHS

The incidence of still-births in Franklin County, Ohio, is 2.3 per cent. In our series there were four still-births—an incidence of 1 per cent. There was one avoidable still-birth from a non-cooperative diabetic mother. This baby was also premature. Three still-births were unavoidable—two due to cord accidents and one due to complete abruptio placenta.

DISCUSSION

The use of wheat germ oil concentrate in obstetrics is not new. Currie (12), Watson (13) and Vogt-Moeller (14) have reported on its value. It has been erroneously assumed that the results were due to Vitamin E. Because no one has been able to duplicate the results of these workers by the use of either distilled tocopherols or alpha tocopherol acetate, the clear cut results of Currie and Watson have been discredited.

The results obtained in this series of patients cannot be attributed to the tocopherols since the average American diet is not deficient in tocopherols. There must be a factor or factors other than the tocopherols in wheat germ oil which are of biological significance to the integrity of the reproductive mechanism.

Whatever its mode of action, wheat germ oil concentrate obtained by extraction with chlorinated solvents is of value in the reduction of the incidence of complications of pregnancy.

SUMMARY

Three hundred and eighty-two consecutive obstetric patients were given wheat germ oil concentrate in an attempt to lower the incidence of the complications of pregnancy.

The results of the administration of this substance are given.

1. Thirty patients or 7.8 per cent threatened to abort. Sixteen of these patients were delivered at term and fourteen aborted. In this series the abortion rate was 3.6 per cent.

2. The possibility for Rh incompatibility was present in forty patients or 10.4 per cent. One patient had an erythroblastotic baby which succumbed. No other patient had an increased anti-Rh antibody titer. Rh incompatibility was not responsible for any of the cases of early or late abortion, toxemia, prematurity, or still-births.

3. The corrected incidence of prematurity in this series was 2.8 per cent. The survival rate among the prematures was 82 per cent.

4. The incidence of nausea and vomiting of pregnancy was 29.5 per cent. This was controlled in every patient by the intravenous administration of pyridoxine HCL.

5. Fourteen patients or 3 per cent developed one of the toxemias of pregnancy other than nausea and vomiting. This is one-third of the expected incidence. All of the mothers survived and one baby was lost.

6. The incidence of still-births, avoidable and unavoidable, was 1 per cent.

REFERENCES

- (1) **Hudson, G. C., and Rucker, M. P.** Spontaneous Abortion, *J. A. M. A.*, 129: 542, 1945.
 - (2) *Idem.*
 - (3) **Schneider, P. F.** The Management of Threatened Abortion, *Surg. Clin. N. Am.*, 23: 21, 1943.
 - (4) **Silbernagel, W. M.** Oral Therapy in the Management of Threatened Abortion, *O. S. M. J.*, 43: 739, 1947.
 - (5) **Brown, E. W., Lyon, R. A., and Anderson, N. A.** Causes of Prematurity; Influence of Uterine Bleeding on the Incidence of Prematurity, *A. J. Dis. Child.*, 71: 428, 1946.
 - (6) **Eastman, N. J.** Prematurity From the Viewpoint of the Obstetrician, *Am. Pract.*, 1: 343, 1947.
 - (7) **Brown, E. W., Lyon, R. A., and Anderson, N. A.** Causes of Prematurity—V., Influence of Syphilis on the Incidence of Prematurity, *Am. J. Dis. Child.*, 70: 318, 1945.
 - (8) *Ibid.*, 71: 428, 1946.
 - (9) **Silbernagel, W. M., and Burt, O. P.** Effects of Pyridoxine on Nausea and Vomiting of Pregnancy. *O. S. M. J.*, 39: 1113, 1943.
 - (10) **Missett, J. W.** Relationship Between Early and Late Toxemia of Pregnancy, *Am. Obst. & Gynec.*, 27: 697, 1934.
 - (11) **Williams, J. W.** *Obstetrics*, ed. 8, New York, 1941, Appleton-Century Co., p. 623.
 - (12) **Currie, D.** Vitamin E in the Treatment of Habitual Abortion, *Brit. M. Jr.*, 2: 1218, 1937.
 - (13) **Watson, E. M.** Clinical Experiences With Wheat Germ Oil (Vitamin E), *Can. M. A. J.*, 34: 134, 1936.
 - (14) **Vogt-Moeller, P.** Treatment of Habitual Abortion With Wheat Germ Oil (Vitamin E), *Lancet*, 2: 182, 1931.
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