

POSTCOITAL CONTRACEPTION WITH
DIETHYLSTILBESTROL - UPDATED

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Abstract

This paper represents an updating of a previous manuscript. It summarizes the author's experience and brings the material up to 90% plus follow-up, still with no pregnancies in patients who met the criteria of the successful treatment plan.

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Introduction

This paper is an updating of "Postcoital Contraception with Diethylstilbestrol", published October, 1971 (1). In April, 1971, with the completion of the follow-up of 1000 females of child bearing age at the University of Michigan Health Service who met the criteria of one unprotected or inadequately protected sexual exposure since their last normal menstrual period, came in for treatment within 72 hours of exposure and who completed the medical treatment of 25 mg of stilbestrol, twice daily for five days, there were no pregnancies. However, there were 1410 women who received this therapy from the fall of 1967 through April, 1971, the cut-off time for the study. In patient interest and for scientific validity, it was important to make an effort to complete the follow-up of the women who had not been contacted.

Methods

An inquiry form was filled out at the time of the first visit, on which was recorded the patient's name, address, phone number, age, last menstrual period, usual cycle, hours between exposure and taking DES, any other unprotected exposures since last menses, prophylaxis, contraindications to estrogen therapy, and the amount of medication and directions for taking. It was explained to the patient that stilbestrol was not a new drug but this was a new use and a follow-up was expected. The possibility of failure was explained, and it was only given to consenting women. Possible side reactions to estrogen were discussed. Also, it was emphasized that this was an emergency type of treatment, and should a continuing need for contraception exist, other means should be sought. A return visit was requested after their next menses, or sooner if they were having any problem. At that time they were questioned as to the character of the menses, any side reactions, a physical examination done if indicated, and counseling offered. This information was also recorded on the inquiry form. Actually by the time a number of the patients were contacted, two or more menses had occurred.

The Health Service Pharmacy was very helpful by recording a copy of each prescription number and patient name, on a separate record. Thus, one could check the returned inquiry forms from the physicians with the prescription numbers and names, and if a form was lacking, the medical record was pulled to see if the patient had returned as requested, and the information was there. If not, the patient was contacted. The women filled this type of prescription virtually 100% at the Health Service Pharmacy or Health Service Emergency Room.

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This therapy was carried out under the direction of Jan Schneider, Associate Professor of Obstetrics and Gynecology, from the University of Michigan Medical Center.

Results

Of the 1410 patients, completed data was obtained on 1298 by July, 1972. In spite of great efforts on the author's part, 112 women could not be reached as they had moved, married, etc. Efforts to reach this group were discontinued in July, 1972.

Of the 1298 patients contacted, 1217 met the criteria of the 1000 stated earlier in this paper, and there were no pregnancies.

There were 81 women who did not meet the criteria for various reasons, such as: different medication dose schedules, coming in later than 72 hours after exposure, multiple exposures without treatment since last normal period then finally coming in, and there were some who did not complete the medication as prescribed. There was a 100% follow-up of this group of 81; probably because most of these cases were seen in the early part of the study. There were six pregnancies in this group of 81. They had each had sexual relations at other times since their last normal period without coming in for treatment, and two of the six, in addition to multiple exposures, came in over 72 hours after the last unprotected sexual relations to get treatment. Each of the six chose to terminate the pregnancy by abortion.

Tables are presented showing data on the 1217 who met the previously stated criteria. When the word, UNKNOWN, is listed, this means the patient did not note the information in her correspondence or the physician did not record it on the inquiry form.

Table I shows the time of exposure in relation to the menstrual cycle and the expected time of ovulation.

Table II shows the per cent not using contraception, plus those using some, and the methods used.

Table III shows the incidence of side reactions. One might note that 45% had virtually none. Although the medication was usually prescribed one tablet after breakfast and one after the evening meal to decrease possible gastric irritation, the nausea, if it occurred, did so usually about six to eight hours after ingestion of the DES tablet. This was interpreted as a systemic reaction to estrogen. The various antiemetics available seemed helpful at times if indicated.

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TABLE I

TIME OF EXPOSURE IN RELATION TO THE MENSTRUAL CYCLE

	<u>No. of patients</u>	<u>Percent</u>
*Midcycle	849	69.76
Not midcycle	224	18.41
Irregular	75	6.16
Recently discontinued oral contraception	12	0.99
Post-abortion and before first menses after abortion	4	0.33
Unknown	53	4.35

*Midcycle includes exposures to sexual intercourse 3 days before or 3 days after expected time of ovulation.

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TABLE II

USE OF PROPHYLAXIS

	<u>No. of patients</u>	<u>Percent</u>
*None	1089	89.48
Coitus interruptus	66	5.42
Condom alone	17	1.40
Contraceptive foam or jelly alone	20	1.64
Ejaculation on external genitalia	9	0.74
Birth control pills forgotten several days or had been on them the first time for only 2-3 days	4	0.33
Miscellaneous as tampon, douche after intercourse, condom and foam but use preceded by foreplay, diaphragm with very little jelly	8	0.66
Unknown	4	0.33

Huhner tests were not done on any of the above patients.

*None includes cases where condom came off intravaginally or condom broke intravaginally.

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TABLE III

SIDE REACTIONS TO DIETHYLSTILBESTROL

	<u>No. of patients</u>	<u>Percent</u>
*None	407	33.44
Nausea, slight, hardly noticeable	157	12.90
Nausea without vomiting	277	22.76
Nausea and vomiting, intermittent 1 day	162	13.31
Nausea and vomiting, intermittent more than 1 day	37	3.04
Headache	15	1.23
Vaginal spotting while taking DES or soon after finishing course	13	1.07
Dizziness	12	0.99
Diarrhea	10	0.82
Bloated or swollen condition	10	0.82
Miscellaneous as breast tenderness, increased vaginal secretions, mild lower abdominal cramps, etc.	44	3.61
Unknown	117	9.61

Note: As some patients had more than one side reaction, the total number of side reactions was 1261 in the 1217 patients.

*Includes 43 patients with only tired feeling.

Table IV describes the character of the first menses after the therapy, and it is particularly important to emphasize that about 12% had late periods. Should delayed menses occur, the patient's knowledge of this possibility reduces unnecessary anxiety.

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TABLE IV

CHARACTER OF FIRST MENSES FOLLOWING THE COURSE OF STILBESTROL

	<u>No. of patients</u>	<u>Percent</u>
Normal time and flow	543	44.62
Normal time and lighter flow	81	6.66
Normal time and heavier flow	30	2.47
Early onset (usually few days only)	67	5.50
Late onset (1-7 days)	75	6.16
Late onset (more than 7 days)	71	5.83
Irregular	45	3.70
Unknown	305	25.06

Discussion

To evaluate the benefit of treatment, one wants to know what the incidence of pregnancy with one unprotected exposure would have been with about 70% of the patients coming in at the expected time of ovulation. Udry of the University of North Carolina at Chapel Hill, applying the work of his colleagues there on fertility and timing, especially that of Lachenbruch, indicated to Family Planning Digest that the risk of pregnancy from a single coital act has been estimated for each part of the menstrual cycle. On the basis of these calculations, he believes that the overall premedication risk among Dr. Kuchera's patients was about one in ten, making 100 probable pregnancies a 'reasonable estimate' (2). His evaluation was done on the initial 1000 patients.

Morris and van Wagenen, at Yale, published a paper on this type of therapy and arrived at a pregnancy rate of 0.03% (3). They have done the pioneering work on this type of therapy for humans in this country (4).

There appears to be no serious side effects to the women receiving DES for postcoital contraception. However, long term effects to the baby, in the event of failure, and in the absence of abortion, are unknown. Because it is known that normally 2-6% of all children born have congenital defects, and because there is a definite link between carcinoma of the genital tract in the female offspring of women who received stilbestrol while pregnant, should the morning-after pill fail, the mother should be offered the choice of an abortion.

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Comments

Points to emphasize when prescribing this therapy:

1. It is very important to establish by whatever means necessary, that the patient desiring the treatment is NOT pregnant, as stilbestrol is CONTRA-INDICATED in pregnancy.
2. Possible side reactions to the medication should be discussed.
3. The patient should be advised that this will not bring on a period.
4. She should be told she is not protected against pregnancy in further sexual relations while on the medication, and should this be desired, she should use adequate contraceptive protection.
5. Repeated use should be discouraged. When it was explained to the patient that there is as much estrogenic activity in these 10 tablets of stilbestrol totalling 250 mg as in a ten month supply of some of the oral contraceptives currently used, this seemed to be quite an effective deterrent.
6. Stress the emergency nature of this treatment, and should a continuing need for pregnancy prevention exist, other contraceptive means should be used.
7. Offer counseling, as many times this is a first time experience for the patient.

Summary

This paper represents an updating of a study done at the University of Michigan Health Service from the fall of 1967 through April, 1971. Of the 1410 women of child bearing age who received the morning-after pill, diethylstilbestrol, 1298 have received follow-up, or a total of 92.1%. Of the 1217 patients who met the criteria of having had one unprotected or inadequately protected sexual exposure since the last normal menstrual period, who came in for therapy within 72 hours of the fact, and completed the course of 25 mg of DES twice daily for five days, there were no pregnancies, or 100% effectiveness. One would have to conclude, with a follow-up of 90%+ that this therapy is highly efficacious.

REFERENCES

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