

The New England Journal of Medicine

© Copyright, 1998, by the Massachusetts Medical Society

VOLUME 339

JULY 2, 1998

NUMBER 1



THE EFFECTS OF SELF-ADMINISTERING EMERGENCY CONTRACEPTION

ANNA GLASIER, M.D., AND DAVID BAIRD, D.Sc.

ABSTRACT

Background Emergency postcoital contraception prevents pregnancy, but it must be prescribed by a doctor and taken within 72 hours of intercourse. It has been proposed that emergency contraception be made available without a prescription. We undertook a study to learn how women might behave if given a supply of emergency contraceptive pills to keep at home.

Methods We assigned 553 women to be given a replaceable supply of hormonal emergency contraceptive pills to take home (the treatment group) and 530 women to use emergency contraception obtained by visiting a doctor (the control group). The frequency of use of emergency contraception, the use of other contraceptives, and the incidence of unwanted pregnancy were determined in both groups of women one year later.

Results The results for 549 women in the treatment group and 522 women in the control group were available for analysis. Three hundred seventy-nine of the women in the treatment group (69 percent) and 326 of the women in the control group (62 percent) contributed detailed information at follow-up. One hundred eighty of the women in the treatment group (47 percent) used emergency contraception at least once. Among those who returned the study questionnaire, 98 percent used emergency contraception correctly. There were no serious adverse effects. Eighty-seven women in the control group (27 percent) used emergency contraception at least once ($P < 0.001$ for the comparison with the treatment group). The women in the treatment group were not more likely to use emergency contraception repeatedly. Their use of other methods of contraception was no different from that of the women in the control group. There were 18 unintended pregnancies in the treatment group and 25 in the control group (relative risk, 0.7; 95 percent confidence interval, 0.4 to 1.2).

Conclusions Making emergency contraception more easily obtainable does no harm and may reduce the rate of unwanted pregnancies. (N Engl J Med 1998;339:1-4.)

©1998, Massachusetts Medical Society.

THE widespread use of emergency postcoital contraception could prevent 1.7 million unintended pregnancies and 0.8 million abortions each year in the United States.¹ Emergency contraception has been licensed in the United Kingdom since 1984. Although many women know that it is available,^{2,3} it is underused because the method must be prescribed by a doctor and taken within 72 hours after intercourse. Medical consultation may be hard to arrange on short notice, and many women are embarrassed to ask their family doctors for emergency contraception.

Although in some countries health ministers have considered making emergency contraception available without a prescription and selling it in pharmacies,^{4,5} for several reasons this has not yet happened. Pharmaceutical companies worry about litigation. Pharmacists are concerned about requests from girls under 16 years of age (the legal age of consent to sexual relations in the United Kingdom). Many doctors and the public believe that easy access to emergency contraception would encourage promiscuity and unsafe sexual relations and discourage the use of more reliable contraception.

However, the benefits of making hormonal emergency contraception available without a prescription may outweigh the difficulties. With this in mind, we investigated how women might behave if emergency contraception were more readily available and the effect that such availability might have on the number of unintended pregnancies.

METHODS

We studied 1083 women, 16 to 44 years old, who were attending a family-planning clinic and a large hospital in Edinburgh, Scotland, from January 1994 through December 1996. Six hun-

From the Edinburgh Healthcare National Health Service Trust Family Planning and Well Woman Services (A.G.) and the Department of Obstetrics and Gynaecology, University of Edinburgh (A.G., D.B.) — both in Edinburgh, Scotland. Address reprint requests to Dr. Glasier at the Department of Obstetrics and Gynaecology, University of Edinburgh, 18 Dean Terr., Edinburgh EH4 1NL, Scotland, United Kingdom.

dred fifty women were recruited at their follow-up consultations after using emergency contraception, and 433 after therapeutic abortion. Women in whom estrogen was contraindicated (those with a history of arterial disease, venous thromboembolism, or severe migraine) were excluded.

After a routine consultation during which future contraception was discussed and contraceptive agents provided, the women who agreed to participate in the study were assigned to the treatment or control group on the basis of their dates of birth (women whose birthdays fell on even-numbered days were assigned to the treatment group). The women in the treatment group were given one packet of emergency hormonal contraceptive tablets to keep at home (four tablets, each containing 50 μg of ethinyl estradiol and 0.25 mg of levonorgestrel [Schering PC4, Schering Health Care, Burgess Hill, West Sussex, United Kingdom]), with instructions to take two tablets within 72 hours after intercourse and two tablets 12 hours later. They were also given written instructions and a telephone number to call in case they had questions. If emergency contraception was used, the women were instructed to mail a notification form to the clinic, with the time of intercourse, the time the pills were taken, and the date of the last menstrual period recorded. They also were instructed to come to the clinic within one week after the date of the expected next menstrual period, at which time the details of the emergency contraceptive use were verified and a pregnancy test was performed if indicated. If the woman was not pregnant, future contraception was discussed; if she wished to continue taking part in the study, she was given a replacement packet of emergency contraceptive pills and notification forms.

The women in the control group were simply informed of or reminded about how to use emergency contraception and where to get it and that it was safe to use it more than once. They were given a notification form to mail in if they used emergency contraception at any time during the next year.

All the women in both groups were sent a questionnaire after one year asking about the details of their use of contraception (including emergency contraception), about any pregnancies, whether they thought emergency contraception should be available without prescription, and how much they would be willing to pay for it. If the questionnaire was not returned, two additional questionnaires were sent. If we did not receive a response, we contacted the woman's family doctor to obtain information about her use of contraception and whether she had become pregnant. If the family doctor could not provide the information, the woman was deemed lost to follow-up and the information was sought from the Information and Statistics Division of the Scottish Health Department (to which all births and therapeutic abortions are reported) to determine whether she had been pregnant during the year.

The study was approved by the Lothian Research Ethics Committee with the stipulation that women using emergency contraception more than four times in four months be withdrawn from the study. All the women gave informed consent.

Statistical Analysis

Differences between the groups were tested by chi-square tests with Yates' correction for binary factors or Mann-Whitney tests for ordinal factors.

RESULTS

The results for 1071 women (549 in the treatment group and 522 in the control group) were available for analysis. One woman was withdrawn from the study because she used emergency contraception more than four times in four months. One woman in the control group died in a traffic accident, and 10 women (3 in the treatment group and 7 in the control group) dropped out of the study for

TABLE 1. CHARACTERISTICS OF THE WOMEN IN THE TREATMENT AND CONTROL GROUPS AND INFORMATION ABOUT FOLLOW-UP.*

VARIABLE	TREATMENT GROUP	CONTROL GROUP
	no. (%)	
No. enrolled in study	553	530
Recruited after use of emergency contraception	323 (58)	327 (62)
Recruited after abortion	230 (42)	203 (38)
Age		
<20 yr	132 (24)	116 (22)
20–29 yr	314 (57)	309 (58)
>30 yr	107 (19)	105 (20)
Age full-time education ended		
<16 yr	93 (17)	92 (17)
17–18 yr	127 (23)	106 (20)
19–22 yr	116 (21)	114 (22)
\geq 23 yr	54 (10)	61 (12)
Still in school full time	154 (28)	145 (27)
Educational status unknown	9 (2)	12 (2)
No. with results available for analysis	549	522
Final questionnaire returned	379 (69)	326 (62)†
Information from family doctor	136 (25)	152 (29)‡
Lost to follow-up	34 (6)	44 (8)‡

*Because of rounding, all percentages do not total 100.

† $P=0.03$ for the comparison between the groups.

‡ $P=0.12$ for the comparison between the groups.

personal reasons. None of these women had used emergency contraception before they left the study.

The characteristics of the women in the two groups were similar (Table 1). The women in the treatment group were more likely to return their final questionnaires ($P=0.03$). The women returning the final questionnaire were older ($P<0.001$) and more likely to have been recruited after use of emergency contraception than after an abortion ($P<0.01$). There was no effect of education on whether the women returned the questionnaires ($P=0.52$).

The women in the treatment group were significantly more likely to use emergency contraception on only one occasion than those in the control group (36 percent vs. 14 percent, $P<0.001$) (Table 2) but not more likely to use it more than once (12 percent [45 of 379 women] vs. 13 percent [42 of 326 women], $P=0.77$). Correct use of emergency contraception was determined from the notification forms, 91 of which were returned. The only woman who used emergency contraception incorrectly had lost the instruction sheet and did not take the second dose.

Twelve pregnancies were reported to have begun during a cycle in which emergency contraception had been used. Given that it was used on a total of 387 occasions (248 times by women in the treat-

TABLE 2. USE OF EMERGENCY CONTRACEPTION AMONG THE WOMEN IN THE TREATMENT AND CONTROL GROUPS WHO RETURNED THE FINAL QUESTIONNAIRE.

USE OF EMERGENCY CONTRACEPTION	TREATMENT GROUP (N=379)	CONTROL GROUP (N=326)
	no. (%)	
Did not use	199 (53)	239 (73)
Used once	135 (36)	45 (14)*
Used twice	27 (7)	33 (10)
Used three times	13 (3)	8 (2)
Used more than three times	5 (1)	1 (<1)

*P<0.001 for the comparison between the groups.

ment group and 139 times by women in the control group), this represents a failure rate of 3 percent, which is within the range reported in routine clinical practice.⁶ There was no report of any serious illness after the use of emergency contraception.

The condom was the most common method of contraception at the start of the study (Table 3). During the subsequent year, many women in each group abandoned condoms in favor of hormonal contraception, but there was no significant difference between the groups (P=0.07). Eighty-nine percent of the women in the treatment group said that their use of other methods of contraception was unaffected, and 8 percent reported that the availability of emergency contraception gave them "peace of mind," but 2 percent said that they took more risks.

Data on pregnancies were available from three sources — the follow-up questionnaires, the women's family doctors, and the Scottish Health Department. It was not possible to determine whether every pregnancy was intended. There were 28 pregnancies among the 549 women in the treatment group (5 percent) and 33 pregnancies among the 522 women in the control group (6 percent) during the year of follow-up (Table 4). Eight women in the treatment group and four in the control group appear to have conceived during a cycle in which emergency contraception was used; all these pregnancies were terminated, accounting for 53 percent of the abortions in the treatment group and 21 percent in the control group. A total of 18 pregnancies in the treatment group were known to have been unintended, as compared with 25 in the control group (relative risk, 0.7; 95 percent confidence interval, 0.4 to 1.2).

Among the women for whom detailed information at follow-up was available (379 in the treatment group and 326 in the control group), more of those in the treatment group (299 [79 percent]) thought

TABLE 3. PATTERNS OF CONTRACEPTIVE USE AT RECRUITMENT AND ONE YEAR LATER AMONG THE WOMEN IN THE TREATMENT AND CONTROL GROUPS WHO RETURNED THE FINAL QUESTIONNAIRE.*

METHOD OF CONTRACEPTION	TREATMENT GROUP		CONTROL GROUP	
	AT RECRUITMENT (N=350)	ONE YEAR LATER (N=350)	AT RECRUITMENT (N=336)	ONE YEAR LATER (N=336)
	number (percent)			
Oral contraception	45 (13)	169 (48)	46 (14)	171 (51)
Condom	258 (74)	108 (31)	235 (70)	94 (28)
Diaphragm	7 (2)	7 (2)	11 (3)	15 (4)
Combination	3 (1)	31 (9)	6 (2)	34 (10)
None	34 (10)	21 (6)	33 (10)	15 (4)
Other or no answer	3 (1)	12 (3)	5 (1)	6 (2)
Pregnant	0	2 (1)	0	1 (<1)

*The number of women in each treatment group is the number who responded to the question regarding the method of contraception.

TABLE 4. PREGNANCIES DURING THE YEAR OF FOLLOW-UP IN THE TREATMENT AND CONTROL GROUPS.

VARIABLE	TREATMENT GROUP (N=549)	CONTROL GROUP (N=522)
	no. (%)*	
Total no. of pregnancies	28 (5)	33 (6)
Abortions	15 (3)	19 (4)
Pregnancies despite use of emergency contraception	8	4
Childbirths	11	11
Known planned pregnancies	8	6
Known unintended pregnancies	2	4
Miscarriages	2	3
Known unintended pregnancies	1	2
Total no. of unintended pregnancies	18 (3)	25 (5)

*Percentages are shown for key outcomes.

that emergency contraception should be available without a prescription than was the case in the control group (198 [61 percent], P<0.001). This was particularly true among the women who had entered the study after having had an abortion. There was no effect of age on the women's views. Many of the women (42 percent in the treatment group and 52 percent in the control group) were willing to pay £5 (about \$8) for emergency contraception, and more than 68 percent in both groups said they would pay £3 (about \$5).

DISCUSSION

The results of this study suggest that making emergency contraception available at home is safe and may reduce the risk of unintended pregnancy. However, it is important to note that we studied a well-defined group of women who we thought were likely to use emergency contraception because they had used it previously or because they had terminated a pregnancy. Furthermore, the women were well educated (less than 20 percent had left school before the age of 16 years, and half had gone to a university or college) and were likely to have a responsible attitude toward contraception. Nevertheless, we think the study suggests what might happen if emergency contraception were made available without a prescription.

Emergency contraception is not universally available. It is not licensed, for example, in France or the United States. However, some brands of combined oral contraceptives contain the same hormones as the preparation we used, and although not licensed for such use, these contraceptives can be used as a substitute. Many clinics in the United Kingdom routinely use these oral contraceptives for emergency contraception because they are considerably cheaper than the marketed preparation we used, and many women have supplies of oral-contraceptive pills at home and could make up their own emergency contraceptive regimen if they knew how. Indeed, in 1997 the U.S. Food and Drug Administration announced that six brands of commonly used combined oral contraceptive pills are safe and effective for use as emergency postcoital contraceptives.⁷

It has been argued that if emergency contraception were available without a prescription, women would not use it correctly. We found, however, that most of the women did use it correctly, including many who were recruited after abortions and had never used such contraception before. It is also possible that women might use emergency contraception when they are already pregnant. We cannot test this hypothesis. A small number of women in our study conceived during the cycle in which they used emergency contraception, and it is possible that some of them were already pregnant when they took the tablets. Even if it was used during pregnancy, either in error or intentionally in the mistaken belief that it might cause an abortion, it would almost certainly have done no harm. The estrogen-progestin regimen of emergency contraception is ineffective after implantation, and there is no evidence that it is teratogenic.⁸

It has also been argued that if emergency contraception were more readily accessible, women might use it repeatedly and abandon more reliable methods of contraception. However, very few of the women

in the treatment group used it more than once, and they were not more likely to do so than the women in the control group who had to visit a doctor to obtain it. Nor did improved accessibility affect the pattern of contraceptive use. Few women said that they took more risks, and during the study similar numbers in each group switched from using barrier methods to using more reliable oral contraception.

Although the incidence of unintended pregnancy was lower among the women who had emergency contraception available at home than among those who had to obtain it from a doctor, the sample was small and the difference was not statistically significant. The reduction in the number of unintended pregnancies might have been greater if we had given more than one packet of pills to each woman. Although 135 women used emergency contraception once, only 74 returned to the clinic for another packet.

This study suggests that women are able to self-administer emergency contraception correctly, at the appropriate time, and without adverse effects. Given the opportunity to keep the necessary tablets at home, most of the women found emergency contraception a useful addition to their contraceptive options. Although many of the women thought that it should be available without a prescription, they did not appear to abandon more reliable methods of contraception in favor of the repeated use of emergency contraception. Making emergency contraception more accessible may reduce the rate of unintended pregnancies.

Supported by a grant from the Chief Scientist's Office of the Scottish Home and Health Department.

We are indebted to Ann Mayo and Janet Logan for assistance with data collection; to Dr. Marion Bain of the Information and Statistics Division of the Scottish Health Service for information on women lost to follow-up; to Dr. Rob Elton for help with statistical analysis; and to the staff and patients of the Dean Terrace Centre and Edinburgh Royal Infirmary for their part in the study.

REFERENCES

1. Trussell J, Stewart F, Guest F, Hatcher RA. Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. *Fam Plann Perspect* 1992;24:269-73.
2. Glasier A. Availability, accessibility and use. In: Paintin D, ed. The provision of emergency hormonal contraception. London: RCOG Press, 1995:16-20.
3. Graham A, Green L, Glasier AF. Teenagers' knowledge of emergency contraception: questionnaire survey in south east Scotland. *BMJ* 1996; 312:1567-9.
4. Should the morning after pill be OTC? *Pharm J* 1992;249:530.
5. Williams C. New Zealand doctors resist emergency contraception. *BMJ* 1996;312:463.
6. Wright DW, Thompson PM. Monitoring a post-coital contraception service. *Br J Fam Plann* 1986;12:88-91.
7. Department of Health and Human Services, Food and Drug Administration. Prescription drug products; certain combined oral contraceptives for use as postcoital emergency contraception. *Fed Regist* 1997;62(37):8610-2.
8. Glasier A. Emergency postcoital contraception. *N Engl J Med* 1997; 337:1058-64.