

CLINICAL PRACTICE

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Emergency Contraception

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This Journal feature begins with a case vignette highlighting a common clinical problem. Evidence supporting various strategies is then presented, followed by a review of formal guidelines, when they exist. The article ends with the authors' clinical recommendations.

A 19-year-old woman calls your office for advice. She does not want to have a baby for several years but has trouble remembering to refill her prescription for birth-control pills and often misses pills. She finished her last pack of birth-control pills 2 weeks ago, and last night she and her boyfriend had sex without using any contraception. What can you recommend to reduce her risk of pregnancy?

THE CLINICAL PROBLEM

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Unintended pregnancy is common; in 2008, the most recent year for which data are available, half the 6.8 million pregnancies reported in the United States were unintended.¹ In theory, unintended pregnancy can be almost completely avoided through the use of contraception before or during sex. Current methods of contraception are highly efficacious: in 1 year of consistent and correct use, hormonal methods and intrauterine devices (IUDs) are estimated to fail in at most 0.5% of women, and condoms in about 2%.² However, for various psychological, educational, financial, and social reasons, achieving perfect adherence to contraception can be challenging. The vast majority of unintended pregnancies in the United States — at least 95% — occur among the one third of women who use contraception inconsistently, incorrectly, or not at all.³

Emergency contraception provides a second chance to prevent pregnancy, after unprotected or inadequately protected sex. Situations in which emergency contraception may be indicated are listed in Table 1. In this article, we summarize evidence regarding the clinical use of emergency contraception and discuss several unresolved issues associated with the available methods.

STRATEGIES AND EVIDENCE

ORAL EMERGENCY CONTRACEPTIVE PILLS

Oral emergency contraceptive pills are the most commonly used form of emergency contraception. Two regimens are currently marketed in the United States: ulipristal acetate (30 mg) and levonorgestrel (1.5 mg). In 39 clinical trials that included a combined total of more than 18,000 women, rates of pregnancy after use of one of these two regimens ranged from 0 to 6.5%.⁵ Interpretation of these numbers is problematic because the likelihood of pregnancy in the absence of emergency contraception was not directly assessed; estimates that were based on the days of the menstrual cycle on which the participants had sex suggest that use of each of these regimens reduces the risk of pregnancy after a single sex act by 40 to 90%.⁵ These regimens have largely replaced regimens consisting of combined oral contraceptive pills, which are less effective and more likely to cause nausea.⁵

A meta-analysis of the two randomized trials that directly compared ulipristal with levonorgestrel indicated that ulipristal was significantly more effective; how-

KEY CLINICAL POINTS

EMERGENCY CONTRACEPTION

- Emergency contraception is indicated to prevent unintended pregnancy after unprotected sex.
- Two oral emergency contraceptive regimens are available. Ulipristal is reported to be more effective than levonorgestrel, although the absolute difference is small. Both regimens should be used as soon as possible after sex but appear to have some efficacy through at least 4 to 5 days after sex. Neither regimen has any contraindications. In the United States, ulipristal requires a prescription and currently is not carried by many pharmacies, whereas levonorgestrel is available over the counter.
- Some but not all data suggest reduced efficacy of the levonorgestrel regimen in obese women.
- The most effective method of emergency contraception is the copper intrauterine device, which almost eliminates the risk of pregnancy resulting from recent unprotected sex and can be used for ongoing contraception for at least 10 years.
- Initiating a method of ongoing contraception after the use of emergency contraception is critical for continued pregnancy prevention.

ever, the absolute difference was small.^{6,7} For example, through 72 hours after sex, the incidence of pregnancy was 1.4% among women who took ulipristal and 2.2% among women who took levonorgestrel. Although the adjusted odds ratio was 0.58 (95% confidence interval, 0.33 to 0.99), the absolute difference was only 0.8 percentage points.

The levonorgestrel regimen is effective for at least 4 or 5 days after sex but may be more effective the sooner it is taken; data on the ulipristal regimen have not indicated a decrease in efficacy through 120 hours after sex.⁵⁻⁸ However, since both regimens work largely by delaying or inhibiting ovulation,⁹ and since women are usually unaware of whether ovulation is imminent, prompt use is prudent.

Neither of these two oral emergency contraceptive regimens has any recognized contraindications. No deaths or serious complications have been causally linked to either regimen. The two randomized trials comparing the regimens showed similar incidences of adverse effects, most commonly headache (19%), dysmenorrhea (13 to 14%), nausea (11 to 13%), and menstrual disturbances ($\geq 24\%$).⁷ These symptoms cannot be directly attributed to use of the medications because the trials were not placebo-controlled.

Previous studies over the past decades have not revealed adverse effects of levonorgestrel exposure during pregnancy on either the woman or the conceptus. Two studies that compared a total of 357 women who had used levonorgestrel emergency contraception during the conception cycle with unexposed women showed no significant differences in pregnancy outcomes.^{10,11} Two-year follow-up in one of these studies of babies identified no differences in physical or mental development between those who had been exposed to

levonorgestrel and those who had not.¹² A review of 136 studies showed that, when this regimen failed, the likelihood of the pregnancy implanting ectopically was not greater than that in the general population.¹³ Data on ulipristal exposure during pregnancy are limited, but combined data from postmarketing surveillance and clinical trials showed that among 232 pregnancies with a known outcome in which the woman and conceptus were exposed to ulipristal, no teratogenic effects were seen.¹⁴

No specific data are available regarding the interaction between oral emergency contraceptives and other drugs, but agents that can reduce the efficacy of other hormonal contraceptives may reasonably be assumed to affect the efficacy of emergency contraceptives in a similar way. In addition, because ulipristal is an antiprogesterin, it could interact with progestins in other contraceptives; therefore, if a woman who has taken ulipristal concurrently uses a contraceptive containing progestin, the efficacy of both the ulipristal and the other contraceptive could be reduced. Use of the two oral emergency contraceptive regimens together may thus be unwise, and whether initiation of hormonal contraceptives should be delayed after ingestion of ulipristal has not been established.

The levonorgestrel regimen is available without a prescription in many countries. In the United States, products containing 1.5 mg of levonorgestrel in one tablet may legally be sold over the counter to women and men of all ages. Although the ulipristal regimen was recently approved for nonprescription sale in Europe, it still requires a prescription in the United States; consequently, use of this regimen in the United States is limited.

Oral emergency contraceptive pills are clearly useful in reducing the risk of pregnancy after a

Table 1. Situations in Which Emergency Contraception May Be Indicated in a Woman Using Routine Contraception.*

Method of Routine Contraception	Situations
Oral contraceptive pills, patch, or vaginal ring	Contraception was started later in cycle than instructed and backup form of contraception was not used, contraception was not used consistently during the menstrual cycle, or drugs that may reduce effectiveness of contraception were used
Progestin-only injection or implant	Contraception was started later in cycle than instructed and backup form of contraception was not used, or period of protection has ended†
Intrauterine device	Device has been expelled, string cannot be located by the user, or period of protection has ended‡
Condoms	Condom broke or slipped during sex, or male partner did not put on the condom before sex
Diaphragm or cap	Device dislodged before or during sex, or device was not inserted before sex or was removed earlier than instructed
Spermicide	Spermicide was not inserted before sex as instructed, or spermicide tablet or film failed to melt before use
Fertility-awareness methods	Woman was in the fertile period when she had sex, or woman is uncertain about whether she was in the fertile period when she had sex
Withdrawal	Ejaculation occurred in the vagina or on the external genitalia

* Recommendations are adapted from *Emergency Contraceptive Pills: Medical and Service Delivery Guidelines*, 3rd edition.⁴

† The periods of protection for standard progestin-only injections or implants are as follows: 3 years for the Nexplanon etonogestrel implant, 13 weeks for the Depo-Provera depot medroxyprogesterone acetate injection, and 14 weeks for the Depo-SubQ Provera 104 depot medroxyprogesterone acetate injection. These periods of protection are taken from the Food and Drug Administration (FDA)-approved package labels for each product. The actual periods of protection may be longer than indicated.

‡ The periods of protection for standard intrauterine devices are as follows: 10 years for the ParaGard copper intrauterine device, 5 years for the Mirena levonorgestrel-releasing intrauterine system, and 3 years for the Skyla and Liletta levonorgestrel-releasing intrauterine systems. These periods of protection are taken from the FDA-approved package labels for each product. The actual periods of protection may be longer than indicated.

single unprotected sex act, but a substantial body of experimental and observational data suggests that, as a public health intervention, increasing the availability of oral emergency contraceptives is unlikely to produce a measurable decrease in the rate of unintended pregnancy.^{15,16} Even with immediate, free access to the medications and previous counseling, women do not use oral emergency contraceptives every time they are indicated. An analysis of one trial suggested that some women who were provided with unlimited, free access to emergency contraception in advance of need may have had more frequent sex or substituted emergency contraception for more effective methods.¹⁷ However, randomized trials have shown no evidence that increased access to oral emergency contraceptives increases the rates of either unintended pregnancy¹⁵ or sexually transmitted infections.¹⁸⁻²¹

COPPER INTRAUTERINE DEVICE

The most effective form of emergency contraception is the copper IUD. A review of 42 studies showed that, of 7034 women who received IUDs up to 10 days after unprotected sex, only 0.09% subsequently became pregnant.²² Recent analyses

suggest that the IUD is effective for emergency contraception throughout the menstrual cycle and can be inserted at any point if pregnancy is ruled out.²³ A key advantage of the IUD over oral emergency contraceptive pills is that the IUD can provide ongoing contraception for at least 10 years.^{24,25} This benefit may be substantial; a recent study showed that for 1 year after the use of emergency contraception, the rate of pregnancy among women who chose the IUD for emergency contraception was half the rate among women who used oral emergency contraceptives.²⁶

Almost all women can safely use an IUD for emergency contraception; the only recognized contraindications are pregnancy, cancer of the genital tract, uterine malformation preventing device placement, copper allergy, mucopurulent cervicitis, current pelvic inflammatory disease, and known current cervical infection with chlamydia or gonorrhea.²⁷ These conditions can be reasonably ruled out on the basis of interview, examination, and, if indicated, pregnancy test; routine testing for cervical infection is not necessary. The incidence of pelvic inflammatory disease after IUD insertion is less than 5% even when the device is inserted through an infected cervix; whether IUD

insertion itself increases this incidence has not been definitively established.²⁸ In the two published studies of the use of IUDs for emergency contraception that included a combined total of 2160 women, no cases of pelvic inflammatory disease were detected.^{29,30}

Surveys of women seeking emergency contraception in the United States have shown that 12 to 15% would be interested in using an IUD if it were available.^{31,32} However, the method has substantial drawbacks. Insertion can be uncomfortable, and some women have vaginal bleeding and cramping after insertion. In the one published study of IUD insertion for emergency contraception, which was conducted in community clinics, the IUD insertion attempt was unsuccessful in 18% of women; this proportion is higher than that reported in clinical trials of IUD insertion for routine contraception.²⁶ The explanation for this unexpectedly high proportion of unsuccessful insertions and whether it might apply to other clinical settings remains to be determined. Historically, the high up-front charge for IUDs has been a major barrier to obtaining this form of contraception³²; the out-of-pocket cost of an IUD insertion can be approximately \$975,³³ whereas the mean charge for levonorgestrel is \$40 to \$50 and the charge for ulipristal is approximately \$50 plus consultation fees.³⁴ In the United States, the Affordable Care Act should mitigate the cost of IUDs for women with health insurance. The key remaining obstacles to the use of IUDs for emergency contraception are lack of awareness among both women and providers about this option^{31,35} and the requirement that IUDs must be inserted by trained clinicians in medical settings.

The levonorgestrel-releasing intrauterine system has not yet been evaluated for use as a method of emergency contraception.

AREAS OF UNCERTAINTY

BODY WEIGHT AND THE EFFICACY OF ORAL EMERGENCY CONTRACEPTIVE PILLS

Recent regulatory decisions have brought attention to the potential effect of body weight on the efficacy of oral emergency contraceptive pills. In November 2013, European regulatory authorities approved a request from one manufacturer of levonorgestrel to change the drug label to state that, “efficacy was reduced in women weighing 75 kg or more, and levonorgestrel was not effective in women who weighed more than 80 kg.”³⁶ Health

Canada approved a similar request in March 2014.³⁷ These decisions were based on data from two randomized efficacy trials in which women who had had unprotected sex during the previous 3 to 5 days were given either levonorgestrel or ulipristal emergency contraceptives.^{6,7} The combined analysis of the 1731 women who took levonorgestrel showed a significant trend toward a substantial increase in the rate of pregnancy with increased weight; the rate among women who weighed less than 65 kg was less than 1.5%, and the rate among women who weighed at least 75 kg was about 6%.³⁸ The rate of pregnancy among women who weighed at least 75 kg was similar to the estimated rate among women who do not take emergency contraceptives (5.4%).

In contrast, data from four other trials conducted by the World Health Organization (WHO) that studied the use of the levonorgestrel regimen and included more than 6800 women in 16 countries showed no association between weight and pregnancy rate (Festini M, WHO: personal communication). The reasons for the discrepancy are unclear. In one of the trials submitted to the European authorities and possibly in some of the WHO trials, the weight of each participant was not verified by measurement. In three of the WHO trials, pregnancy was self-reported,³⁹⁻⁴¹ and the fourth trial had an unusually low pregnancy rate, raising concerns about underascertainment.⁴² The data analyses in both sets of trials were adjusted for known potential confounders, but the possibility that women with a lower weight had a different risk of pregnancy than women with a higher weight or used the medications differently (e.g., by taking them closer to the time of intercourse) could not be definitively excluded. Furthermore, because the risk of pregnancy in the absence of treatment could not be precisely known, the validity of the conclusion reached by the European regulatory authorities that treatment was “not effective” in obese women is questionable.

In July 2014, the European Medicines Agency completed a review of both sets of data and concluded that “the data available are too limited and not robust enough to conclude with certainty that contraceptive effect is reduced with increased bodyweight” and that reference to such statements should be deleted from the labels that had been changed.⁴³ The U.S. Food and Drug Administration (FDA) is currently conducting its own review.

Analysis of the data from women who took ulipristal showed a higher pregnancy rate among

those who were obese than among those who had a normal weight or were underweight, but the difference was not significant.⁴⁴ The pregnancy rate was substantially lower among obese women who took ulipristal than among obese women who took levonorgestrel.

ORAL EMERGENCY CONTRACEPTIVE PILLS FOR ROUTINE CONTRACEPTION

Emergency contraception is intended to be used as a backup form of contraception after unprotected or inadequately protected sex. However, some women may be interested in using pericoital oral contraceptives as their primary form of contraception because they are easy to remember, are taken only when needed (a particular benefit for women who have infrequent sex), can potentially be used before or after sex, and can be controlled entirely by the woman and hidden from the male partner, if necessary.⁴⁵ Research conducted several decades ago suggested that routine ingestion of 0.75 mg of levonorgestrel shortly before or after each coital act may be moderately effective in reducing the risk of unintended pregnancy.⁴⁶ In 10 trials investigating this strategy, the combined pregnancy rate was 5.1 pregnancies per 100 woman-years. This rate is similar to the rate among women who use other coitus-dependent methods of contraception (e.g., condoms, diaphragms, and spermicides), although direct comparative trials have not been done.² In contrast, a recent trial investigating the use of pericoital levonorgestrel (0.75 mg) as a form of routine contraception showed a much higher pregnancy rate of 22 pregnancies per 100 woman-years.⁴⁷ This trial included only 72 women but was more rigorously conducted than the older studies. The mean number of pills taken per month by women in these trials was approximately four. No serious adverse events related to levonorgestrel were reported in any of the trials; the primary side effect was menstrual irregularities. The WHO has recently completed another trial investigating the pericoital use of levonorgestrel (1.5 mg) as a form of routine contraception (WHO International Controlled Trials Registry Platform number, ACTRN12611001037998); results are expected within the next year.

PROMOTING THE USE OF ROUTINE CONTRACEPTION

Additional unprotected sex shortly after the use of oral emergency contraceptives is common and associated with a risk of pregnancy.^{39,44} Prompt

initiation or resumption of contraception is thus critical; recommendations are shown in Table 2. Because most women who use emergency contraception obtain levonorgestrel over the counter, strategies for promoting uptake of routine contraception are needed that do not involve a face-to-face encounter with a clinician (Table 2). A few pharmacy-based approaches have been studied; in one trial, distributing a coupon for daily oral contraceptive pills along with the emergency contraceptive pills was ineffective,⁴⁸ but in another trial, directly providing daily oral contraceptive pills along with the emergency contraceptive pills or offering rapid access to a family-planning clinic significantly increased the use of effective contraception 6 to 8 weeks later.⁴⁹ Further research is needed to evaluate strategies for increasing the use of routine contraceptives after the use of oral emergency contraceptives and for simplifying access to IUDs for emergency contraception. In addition, data on the potential interaction between ulipristal and other progestin-containing contraceptives would be useful to guide recommendations about initiating such methods after ulipristal without decreasing the effectiveness of either method.

GUIDELINES

Guidelines about emergency contraception have been published by the International Consortium for Emergency Contraception,⁵⁰ the Faculty of Sexual and Reproductive Healthcare,⁵¹ and the American College of Obstetricians and Gynecologists.⁵² The information in this review is generally consistent with these guidelines.

CONCLUSIONS AND RECOMMENDATIONS

Because the woman described in the vignette recently had unprotected sex and does not wish to become pregnant, we would counsel her about the full range of options for emergency contraception. The copper IUD is the most effective method and may especially appeal to this patient because of her desire to avoid pregnancy for several years and her difficulty with adhering to a regimen of oral contraceptive pills. The IUD would almost eliminate the risk of pregnancy resulting from the recent unprotected sex act and would continue to provide protection for at least 10 years. Moreover, once the device is inserted, it requires

Table 2. When to Initiate Routine Contraception after the Use of Oral Emergency Contraceptive Pills.*

Method of Routine Contraception	When to Initiate
Condoms or other barrier methods	Start using immediately
Hormonal methods (oral contraceptive pills, patch, vaginal ring, injection, implants, levonorgestrel-releasing intrauterine system)	If using after the levonorgestrel regimen, start the same day or the following day but use a barrier method for the first 7 days; alternatively, start after the next menstrual period and use a barrier method in the interim If using after the ulipristal regimen, start after the next menstrual period and use a barrier method in the interim Before insertion of implants or the levonorgestrel-releasing intrauterine system, pregnancy should be ruled out on the basis of history, pregnancy test, or other appropriate means
Copper intrauterine device	Some guidelines recommend that the intrauterine device be inserted for emergency contraception within 5 days after unprotected sex; however, evidence shows that it is effective throughout the menstrual cycle Pregnancy should be ruled out on the basis of history or pregnancy test before insertion of the device
Fertility-awareness methods	Initiate after the first normal menstrual period after the use of emergency contraception (note that the first bleeding episode after taking emergency contraception may not be a normal menstrual period); use a barrier method in the interim
Sterilization	Perform the procedure after the start of the next menstrual period; use a barrier method in the interim

* Data are adapted from *Emergency Contraceptive Pills: Medical and Service Delivery Guidelines*, 3rd edition.⁴

virtually no attention. If the patient does not want or cannot obtain an IUD or if an IUD is contraindicated, she should consider oral emergency contraceptive pills. A meta-analysis of the two trials comparing the ulipristal and levonorgestrel regimens⁷ showed that the ulipristal regimen is more effective, at least for women who are not obese, but that the absolute difference is small. In the United States, ulipristal requires a prescription and is not available in many pharmacies, but it can be obtained by mail through a reputable online prescription service (see the Supplementary Appendix, available with the full

text of this article at NEJM.org). In contrast, levonorgestrel is readily available over the counter; for many women, the convenience of obtaining levonorgestrel locally may outweigh its modestly lower efficacy. If this woman chooses to take one of the oral emergency contraceptives, she should take it as soon as possible and then begin using a method of routine contraception before further intercourse.

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