Emergency Contraception

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Women can use emergency contraception to prevent pregnancy after known or suspected failure of birth control or after unprotected intercourse. Many patients do not ask for emergency contraception because they do not know of its availability. Emergency contraception has been an off-label use of oral contraceptive pills since the 1960s. Dedicated products, the Yuzpe regimen (Preven) and levonorgestrel (Plan B), were marketed in the United States after 1998 but had been available in Europe for years before that. A third approved method of emergency contraception is the insertion of an intrauterine device. Emergency contraception is about 75 to 85 percent effective. It is most effective when initiated within 72 hours after unprotected intercourse. The mechanism of action may vary, depending on the day of the menstrual cycle on which treatment is started. Despite the large number of women who have received emergency contraception, there have been no reports of major adverse outcomes. If a woman becomes pregnant after using emergency contraception, she may be reassured about the lack of negative effects emergency contraception has on fetal development. It may be beneficial for physicians to offer an advance prescription for emergency contraception at a patient's regular gynecologic visit to help reduce unwanted pregnancies. Advance provision of emergency contraception can increase its use significantly without adversely affecting the use of routine contraception. (Am Fam Physician 2004;70:707-14,717-8. Copyright© 2004 American Academy of Family Physicians.)

✉ See editorial on page 655.

✉ **Patient information:** A handout about emergency contraception, written by the author of this article and Melissa Place, M.A., Department of Family Medicine, Brody School of Medicine at East Carolina University, Greenville, N.C., is provided on page 717.

See page 633 for definitions of strength-of-recommendation labels.

Emergency contraception, sometimes referred to as the "morning-after" pill, is birth control that women can use to prevent pregnancy after known or suspected failure of contraception or unprotected intercourse, including sexual assault. Immediate use of an emergency contraceptive reduces a woman's risk of pregnancy to 1 to 2 percent. The effectiveness depends on the regimen used and the time between unprotected intercourse and treatment.[1] The most common reasons for seeking emergency contraception are failure of a barrier method of contraception (usually condoms) and failure to use any method.[2-5] A national survey of women conducted by the Kaiser Family Foundation in 2003 reports that two thirds of women 18 to 44 years of age are aware of emergency contraception; only 6 percent of women reported ever having used it.[6] Research analyzing abortion trends from 2000, when only 2 percent of women reported ever using emergency contraception,[7] supports estimates that 51,000 abortions were prevented by emergency contraception use that year, suggesting that increased use of emergency contraception as a back-up method may have accounted for up to 43 percent of the total decline in abortion rates between 1994 and 2000.[8]

Widespread use of emergency contraception requires familiarity with the methods, public awareness of its availability and, in all but the six states (i.e., California, Alaska, Washington, New Mexico, Hawaii, and Maine) where it can be obtained without prescription, prompt access to a health care professional who can provide a prescription. This article outlines the evidence for the methods, safety, efficacy, risks, and benefits of emergency contraception.

Methods

The U.S. Food and Drug Administration (FDA) has approved three methods of emer-

TABLE 1
Approved Methods of Emergency Contraception

Method	*Formulation and dosage*	*Cost**
Combination oral contraceptive	0.1 mg ethinyl estradiol and 1.0 mg DL-norgestrel; two doses 12 hours apart starting within 72 hours of unprotected sexual intercourse	$ 35†
Progestin-only oral contraceptive	1.5 mg of levonorgestrel once or 0.75 mg levonorgestrel twice, 12 hours apart; starting within 72 hours of unprotected sexual intercourse	$ 35†
Preven (Gynétics)	0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol; two doses 12 hours apart starting within 72 hours of unprotected sexual intercourse	$ 20
Plan B (Women's Capital Corporation)	1.5 mg of levonorgestrel once or 0.75 mg levonorgestrel twice, 12 hours apart	$ 22
ParaGard T-380A intrauterine copper contraceptive (Ortho)	—	$359

**—Estimated cost to the pharmacist based on average wholesale prices in Red book. Montvale, N.J.: Medical Economics Data, 2004. Cost to the patient will be higher, depending on prescription filling fee.*

†—Prices are approximate, varying by brand.

TABLE 2
Prescriptive Equivalents of Common Oral Contraceptives and Dedicated Products for Use as Emergency Contraception

Agent	*Pills per dose**	*Ethinyl estradiol per dose (mcg)*	*Norgestrel per dose (mg)†*
Ovral	2 white	100	1
Alesse	5 pink	100	0.50
Levlite	5 pink	100	0.50
Nordette	4 light-orange	120	0.60
Levlen	4 light-orange	120	0.60
Levora	4 white	120	0.60
Lo/Ovral	4 white	120	1.2
Triphasil	4 yellow	120	0.50
Tri-Levlen	4 yellow	120	0.50
Trivora	4 pink	120	0.50
Ogestrel	2	100	1
Low-Ogestrel	4	120	1.2
Ovrette	20 yellow	0	1.5
Dedicated products			
Preven	2 blue	100	0.5
Plan B	1 white	0	0.75

**—The progestin in Ovral, Lo/Ovral, Ovrette, Ogestrel, and Low-Ogestrel is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each tablet is twice the amount of levonorgestrel.*
†—Treatment consists of two doses taken 12 hours apart.

gency contraception *(Table 1)*. The combination oral-contraceptive method (Yuzpe regimen) uses 0.1 mg of ethinyl estradiol and 1.0 mg of DL-norgestrel (equivalent to 0.5 mg of levonorgestrel) in two doses taken 12 hours apart, starting within 72 hours of unprotected sexual intercourse.[5] The progestin-only method uses 0.75 mg of levonorgestrel in two doses taken 12 hours apart. The FDA has cleared 13 brands of oral contraceptives for safety and efficacy when used for emergency contraception *(Table 2)*.

In 1998, two prescription formulations specifically intended for emergency contraception became available: Preven and Plan B. The Preven Emergency Contraceptive Kit (Yuzpe regimen) consists of four pills, each containing 0.25 mg of levonorgestrel and 0.05 mg of ethinyl estradiol; a urine pregnancy test; and a patient information book.

The Plan B option consists of two tablets, each containing 0.75 mg of levonorgestrel.[9] (This amount differs from the 0.075-mg dose of norgestrel in certain progestin-only pills.) Detailed patient and physician labeling accompanies both methods. There is a general

consensus[10,11] that the levonorgestrel emergency contraception should be given in preference to the Yuzpe regimen where available because it is more effective and has fewer side effects. In addition, a World Health Organization (WHO) multicenter randomized trial[12] shows that the levonorgestrel dose does not have to be split but can be taken as a single 1.5-mg dose. One dose simplifies the use of levonorgestrel without causing an increase in side effects.

An alternative to the hormonal methods is insertion of the ParaGard T-380A Intrauterine Copper Contraceptive up to five days after unprotected intercourse. After insertion for the purpose of emergency contraception, this device can provide reversible contraception for up to 10 years.

Mechanisms of Action

A single mechanism of action has not been identified.[13] Inhibition or delay in ovulation and insufficient corpus luteum function have been reported in some women.[14]

Some studies have reported histologic or biochemical changes within the endometrium that may result in failure of implantation.[15,16] Another study suggests that the mechanism of action is interference with tubal transport of sperm, egg, or embryo.[17] There is no evidence that emergency contraception increases the incidence of ectopic pregnancy; however, no studies specifically focus on this issue. Although the predominant mode of action of combination hormonal contraceptives is most likely ovulation suppression, this effect is not total.[18] Breakthrough ovulation is estimated to occur in up to 10 percent of cycles.

Other mechanisms of action (changes in cervical mucus and the endometrium) are recognized and included in the prescribing information. Endometrial changes make implantation after fertilization less likely and, depending on when the hormones are taken, may be the more common mechanism. However, how often a post-fertilization effect occurs is unknown.[19]

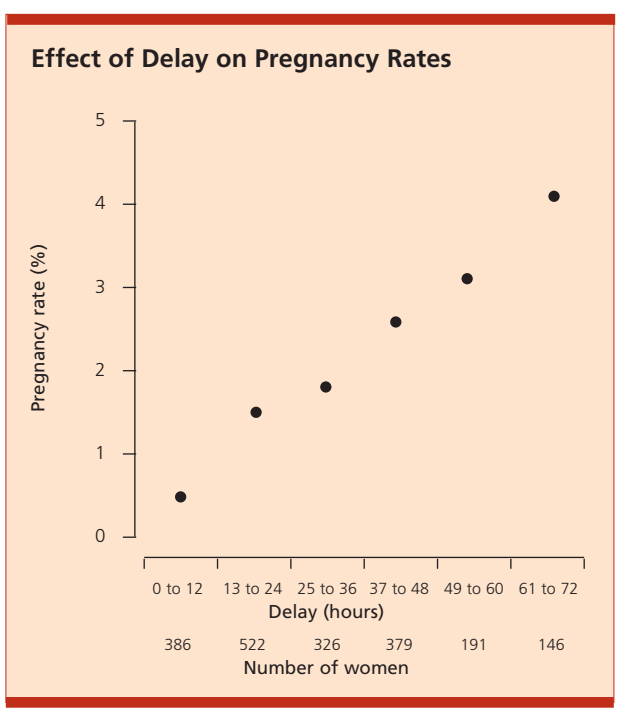

Figure 1. Effect of time of the first dose of emergency contraception on pregnancy rate.

Adapted with permission from Piaggio G, von Hertzen H, Grimes DA, Van Look PF. Timing of emergency contraception with levonorgestrel or the Yuzpe regimen. Task Force on Postovulatory Methods of Fertility Regulation. Lancet 1999;353:721.

Timing

There is an inverse relationship between prevention of pregnancy and time since unprotected intercourse *(Figure 1)*.[20] This upward gradient between 24, 48, and 72 hours is true for both hormonal methods, and particularly for the progestin-only method. In almost all studies, the first dose is administered within 72 hours after unprotected intercourse. A recent multicenter, randomized controlled study found that the sooner the first dose was taken after intercourse, the greater the effectiveness.[21] The failure rate at 72 hours (three days) after hormonal emergency contraception is approximately 4 percent. This rate increases to 10 percent at five days.[20,21]

Some authors suggest that emergency contraception may have some benefit beyond 72 hours after unprotected intercourse,[22-24] but that option should be evaluated for each patient. The data do not suggest that use of oral contraceptives can interrupt an established pregnancy. Insertion of an intrauterine device (IUD) represents an alternative that may be effective five to seven days after unprotected intercourse except in cases of known sexually transmitted infection or rape (because of the potential for sexually transmitted infection).[25]

Adverse Effects

Nausea occurs in 30 to 60 percent of patients who use combination oral contraceptives for emergency contraception. It may occur after either dose of medication and tends to last no more than two days. Emesis occurs in 12 to 22 percent of patients. The incidence and severity of nausea and vomiting decrease when antiemetic agents are taken one hour before the first emergency contraceptive dose is taken.[26,27] Antiemetic agents do not seem to

be effective if taken only after the onset of nausea and vomiting.

Compared with the combination method, the frequency of nausea and vomiting with the progestin-only method is significantly lower. This difference also is true for dizziness and fatigue.[21] There is no evidence that emesis within three hours of ingesting the dose is associated with an increased failure rate; however, none of the studies reported was designed to measure this effect. There is limited evidence on which to base a recommendation for repeating the dose if emesis occurs. If vomiting occurs within one hour after taking either dose, repeat dosing may be considered. However, it seems reasonable to infer that if gastrointestinal symptoms are estrogen-mediated secondary to an effect on the central nervous system, absorption of the dose should have occurred by the time of emesis.

Effectiveness

All three types of emergency contraception are highly effective in preventing pregnancy after unprotected intercourse. It has been estimated that widespread use of emergency contraception could reduce unintended pregnancies in the United States by one half, which translates to 1.5 million fewer unintended pregnancies. Based on this projection, the number of elective terminations also could be reduced by one half, potentially resulting in 700,000 fewer abortions.[28,29]

Two reviews[30,31] of the published literature concluded that the effectiveness rate of the combination method ranges between 55 and 94 percent, with a weighted average of 70 to 74 percent. Because the observed number of pregnancies in these studies is likely to be underestimated, the true effectiveness rate is likely to be at least 75 percent. It is important to communicate to patients that these numbers do not translate into a pregnancy rate of 25 percent. Rather, they mean that if 1,000 women have unprotected intercourse in the middle two weeks of their menstrual cycles, approximately 80 will become pregnant. Use of emergency contraceptive pills would reduce this number by 75 percent, to 20 women *(Table 3)*.

TABLE 3
Emergency Contraception Effectiveness*

Method	*Number of pregnancies*	*Reduction (%)*
No treatment	80	—
Combined	20	75
Progestin-only	10	88
Intrauterine device insertion	1	99

**—If 1,000 women have unprotected intercourse once in the second or third week of their cycle.*

The progestin-only method appears to be more effective in preventing pregnancy than the combination-pill method. In a randomized, double-blind trial,[21] the proportion of pregnancies prevented with the progestin-only method was 85 percent compared with 57 percent with combination oral contraceptives. Between the two methods, the crude relative risk of pregnancy was 0.36, a significant difference.[21] Although all of these methods reduce the risk of pregnancy, they are less effective than consistent use of methods intended specifically for routine contraception *(Table 4)*.

Teratogenic Effects

The limited data on teratogenic effects come from a relatively small number of reports in which treatment was not successful, and the woman elected to continue the pregnancy. No evidence exists of a specific syndrome of anomalies or an apparent increase in the incidence of anomalies. It is important to recognize that no studies have investigated teratogenic effects associated with the use of oral emergency contraception. Numerous studies of the teratogenic risk of conception during the routine use of oral contraceptives, including the older, high-dose preparations, found no increase in risk.[32]

Contraindications

The WHO[33] has concluded that there are no contraindications to the oral combination method of emergency contraception except pregnancy. The American

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College of Obstetricians and Gynecologists[34] states that emergency oral contraception should not be used in a patient with a known or suspected pregnancy, hypersensitivity to any component of the product, or undiagnosed abnormal genital bleeding. Adverse events associated with oral emergency contraception, such as effects listed with the known contraindications to daily use of combination birth-control pills, have not been reported in published studies using evidence-based criteria.

In addition, there is no evidence relative to increased risk or safety in women who have contraindications to the use of daily oral contraceptives. The daily dose of steroid hormones in the hormonal methods of emergency contraception is greater than that used for routine oral contraception; however, the duration of use in the latter case is short.[35] In a woman with a history of idiopathic thrombosis, the progestin-only regimen may be preferable.[36]

TABLE 4
First-Year Failure Rate of Family Planning Methods

Methods	*Lowest observed failure rate (%)*	*Failure rate in typical user (%)*
Tubal sterilization	0.3	0.3
Vasectomy	0.4	0.4
Injectable progestin (DEPO)	0.3	0.3
Progestin implant (Norplant)	0.09	0.09
Combined oral contraceptive pill	0.1	3
Progestin-only pill	0.5	3
Copper T-380A intrauterine device	0.6	0.8
Condom		
Male	3	12
Female	5	21
Diaphragm (with spermicide)	6	18
Patch	1	3
Ring	0.7	3
Cervical cap	11.5	18
Foams, creams, etc.	6	21
Coitus interruptus (withdrawal)	16	23
Fertility awareness techniques (e.g., rhythm)	2	24
Douche	—	40
Chance (no method of birth control)	85	85

Starting or Resuming a Routine Contraceptive Method

One important issue for patients following emergency contraception therapy is starting a routine contraceptive method. Patients can start hormonal contraception immediately following emergency contraception or wait until the next menstrual period. *Table 5* outlines options for beginning a family planning method following the use of emergency contraception.

After using emergency oral contraception, up to 98 percent of patients menstruate within 21 days of treatment.[5] In more than one half of patients, menses occurs at the expected time.[20] In more than 90 percent of cases, menses will be of normal (for that woman) duration. Whether the patient has a history of regular or irregular menstrual cycles does not appear to be a contributing factor.[5] If the emergency contraception treatment is given before ovulation, menstrual bleeding may begin three to seven days earlier than expected. If the treatment begins after ovulation, menstrual bleeding may come at the expected time or be delayed.[3,21] It is important for the patient to seek prompt medical care if menses has not started within 21 days.

Advance Provision

Three studies have found that advance provision results in greater use of emergency contraception. A Scottish study[37] of more than 1,000 women compared advance provision with counseling about oral emergency contraception and how to obtain it (i.e., by visiting a physician). The study found no evidence that advance provision negatively affected women's contraceptive behaviors. Most women used emergency contraception pills correctly, including many who were recruited after they had an abortion and women who had never used contraception before. Although the difference in pregnancy rates between the two groups was not statistically significant, the authors concluded that advance provision does no harm and could help prevent pregnancy.

In a San Francisco study[38] of more than 200 participants, women were systematically assigned to receive an advance prescription for emergency contraception and education (treatment group) or education only (control group). Providing emergency contraception in advance, but not education alone, increased the use of emergency contraception. Results of one study[39] found that advance provision of emergency contraception significantly increased its use without adversely affecting the use of routine contraception. The study designs and sample sizes are not adequate to demonstrate definitive impact on rates of unintended pregnancy. It may be

TABLE 5
Beginning a Family Planning Method after Emergency Contraception

Method	*Regular start*	*Jump start*	*Reminders*
Oral contraceptives (combination or progestin-only)	Use back-up contraception method until next period, then begin oral contraceptive pills according to regular patient instructions.	Start a new package of oral contraceptives the day after taking the two emergency contraception doses (use back-up contraception method for first seven days).	Perform pregnancy test if patient does not have a normal period after completing first package of pills.
Injectable contraceptives (combination or progestin-only)	Use back-up contraception method until next period, then start either injectable method according to regular patient instructions.	Start either injectable method the day after taking the two emergency contraception doses (use back-up contraception method for first seven days). Modified jump start: start oral contraceptives the day after taking the two emergency contraception doses (use back-up contraception method for first seven days); start injectable contraceptive after next period (use back-up contraception method for first seven days).	—
Combination patch	Use back-up contraception method until next period, then begin patch according to regular patient instructions.	Apply the patch the day after taking the two emergency contraception doses (use back-up contraception method for first seven days).	Perform pregnancy test if patient does not have a normal period after completing a one-month supply
Intrauterine device (IUD)	Use back-up contraception method until next period, then proceed with IUD insertion.	—	—
Diaphragm	Begin using immediately.	—	—
Condoms	Begin using immediately.	—	—
Spermicides	Begin using immediately.	—	—

beneficial for physicians to offer an advance prescription for emergency contraception to patients at regular gynecologic visits to help reduce unwanted pregnancies. Health care professionals have an important role to play in conveying information about emergency contraception *(Table 6)*.[40]

Access

In 1998, Washington became the first state to allow women to obtain emergency contraception through a pharmacist without a visit to a doctor. Washington's pilot project set up collaborative drug therapy agreements between doctors and pharmacies based on prescriptive protocols. Under the agreements, pharmacists were able to dispense emergency contraception to women who met screening criteria outlined in the protocols. The Washington program has become a model for other states.

TABLE 6
Emergency Contraception Resources

Emergency contraception hotline
888-NOT-2-LATE

Publications
Emergency contraception: client materials for diverse audiences. Seattle, Wash.: Program for Appropriate Technology in Health (PATH), 1998. Available to download from the PATH Web site at http://www.path.org/resources/ec_client-mtrls.htm.

Web sites
PATH (Program for Appropriate Technology in Health): http://www.path.org/index.htm
Emergency Contraception: http://not-2-late.com

Strength of Recommendation

Key clinical recommendation	SOR labels	References
The levonorgestrel dose does not need to be split; a single dose of 1.5 mg can be used.	A	10
The sooner the first dose of emergency contraception is taken after unprotected intercourse, the greater the efficacy.	A	19
The incidence and severity of nausea and vomiting decrease when antiemetic agents are taken one hour before the first contraceptive dose.	B	24, 25
Compared with the combination method, the frequency of nausea and vomiting, dizziness, and fatigue with the progestin-only method is significantly less.	A	19
There are no contraindications to the oral combination method of emergency contraception except pregnancy.	C	31
In a woman with a history of idiopathic thrombosis, the progestin-only regimen of emergency contraception may be preferable.	C	34

Pharmacy access to emergency contraception is now available in California, Alaska, Maine, New Mexico, and Hawaii.[41]

Advocates for women who have been sexually assaulted have been concerned about the failure of hospital emergency departments to make emergency contraception a standard practice of care. In 2001, Illinois became the first state to legislate on this issue, enhancing a law requiring hospitals to provide rape survivors with medically accurate information about emergency contraception. Six additional states now require that emergency department staff provide information about emergency contraception or offer the pills to women who have been sexually assaulted (i.e., California, New Mexico, New York, Ohio, South Carolina, and Washington).[41] A bill has been introduced in Congress (HR2527) that would require emergency departments in all states to provide emergency contraception to women in all cases of sexual assault.

On February 14, 2001, the Center for Reproductive Rights petitioned the FDA to make emergency contraception available on an over-the-counter basis. In December 2003, two FDA advisory panels endorsed switching Plan B to over-the-counter status. On May 6, 2004, the FDA denied over-the-counter status for Plan B emergency contraception. The decision was based primarily on inadequate data supporting the conclusion that Plan B can be used safely by adolescent women for emergency contraception without the supervision of a health care professional.

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