

# Emergency Postcoital Contraception

*These guidelines have been reviewed and approved by the Clinical Practice Gynaecology, Public Education Committee, Social and Sexual Issues Committees of the Society of Obstetricians and Gynaecologists of Canada, and approved as a Policy Statement by the SOGC Council*

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### Abstract

**Objective:** unintended pregnancies occur because of both failure to use a contraceptive method and failure of or incorrect use of a method. Unintended pregnancy could be substantially reduced by improving both the public's and the profession's awareness about emergency contraception, and by developing strategies to ensure its accessibility. The purpose of this article is to review the literature on emergency postcoital contraception (EC), to determine its efficacy and safety, and to develop guidelines for its appropriate and effective provision.

**Method:** a MEDLINE search was performed to find relevant publications between 1976 and 1999. The search was restricted to articles in English with original research given priority, followed by meta-analyses and review articles. Studies were reviewed and evaluated for quality according to the method

outlined in the *Canadian Task Force on the Periodic Health Examination* (Table I).

**Results:** according to several level II-3 studies and a large level I study, emergency postcoital contraception with combined estrogen and progestin or levonorgestrel alone prevents 75 and 85 percent of pregnancies respectively when initiated within 72 hours of unprotected intercourse. Level I evidence supports that early use of hormonal EC increases its efficacy, and that women given a prescription in advance of need use it appropriately (not as on going contraception). The Yuzpe regimen (100 µg ethinyl estradiol and 500 µg levonorgestrel, two doses 12 hours apart) is associated with a substantial risk of nausea and vomiting but not serious adverse events (I and II-3). The levonorgestrel only regimen is associated with significantly less nausea and vomiting than the combined

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estrogen and progesterone regimen (Level I). Hormonal EC may be somewhat effective up to five days after the act of intercourse (II-3). The postcoital insertion of a copper bearing intrauterine device (IUCD) is associated with a failure rate of less than one percent and can be used up to seven days after the act of intercourse (multiple level II-3 studies).

**Conclusion:** emergency contraception can safely reduce the number of unintended pregnancies. Reproductive health care providers should ensure that their patients are knowledgeable about emergency contraception and develop a strategy, such as in advance of need prescription, to ensure its availability when required.

## INTRODUCTION

It is well established that many unintended pregnancies occur as a result of unprotected intercourse, inadequate contraceptive measures, or failure of a method. Effective methods of postcoital or emergency contraception (EC) can prevent many of these pregnancies, as well as the health and social consequences associated with them. Availability of emergency contraception depends on both education of health care providers and patients, as well as the development of a means for facilitating access to emergency contraception in a timely fashion. Postcoital contraception is intended as an emergency method, not a form of ongoing contraception.

### WHAT IS EMERGENCY CONTRACEPTION?

Emergency contraception is any method of contraception which is used after intercourse and before implantation. As these methods work prior to implantation they are not abortifacients.

### WHAT ARE THE METHODS?

There are two accepted methods for emergency contraception: hormonal methods and insertion of a postcoital intrauterine

contraceptive device (IUCD). The most widely used method in Canada is the Yuzpe Method (a combination of 100 µg ethinyl estradiol and 500 µg levonorgestrel two doses 12 hours apart).<sup>2</sup> This method should be initiated within 72 hours of intercourse. Ovral<sup>®</sup> is the most commonly used product because two tablets are equivalent to one dose of the regimen. Other products can be substituted if they are more readily available (Table II), although they may not deliver an exactly equivalent dose. None has been approved in Canada specifically for use as emergency contraception.

In 1999, Preven<sup>®</sup>, a product containing the Yuzpe regimen of hormones, was approved in Canada, by prescription only, for emergency contraception. Packets of Preven<sup>®</sup> initially contained a home pregnancy kit intended to exclude preexisting pregnancy. The pregnancy test has since been removed from recently produced product, but can still be found in some packets. Although EC should not be given if the woman suspects she is pregnant (only as it is ineffective), a menstrual history is usually all that is required to exclude this possibility. There is no evidence that EC or other hormonal contraception is teratogenic if inadvertently taken during pregnancy.<sup>3</sup>

Based on one comparative study, conducted by the World

| TABLE 1 <sup>20</sup><br>QUALITY OF EVIDENCE ASSESSMENT  | CLASSIFICATION OF RECOMMENDATIONS   |
|--|---|
| <p>The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.<sup>20</sup></p> <p>I: Evidence obtained from at least one properly randomized controlled trial.</p> <p>II-1: Evidence from well-designed controlled trials without randomization.</p> <p>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.</p> <p>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940's) could also be included in this category.</p> <p>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p> | <p>Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.<sup>20</sup></p> <p>A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.</p> <p>D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.</p> <p>E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.</p> |

| Brand              | Pills/Dose | EE* (µg)/Dose    | LNG** (µg)/Dose |
|--------------------|------------|------------------|-----------------|
| Ovral®             | 2          | 100              | 500             |
| Allesse®           | 5          | 100              | 500             |
| Triphasil®         | 4 yellow   | 120              | 500             |
| Triquilar®         | 4 yellow   | 120              | 500             |
| Minovral®          | 4          | 120              | 600             |
| *Ethinyl estradiol |            | **Levonorgestrel |                 |

Health Organization (WHO), using levonorgestrel alone in a dose of 750 µg compared to levonorgestrel 500 µg and ethinyl estradiol 100 µg, it was suggested that levonorgestrel alone had improved efficacy over the combination of levonorgestrel and ethinyl estradiol.<sup>4</sup> More large scale comparative studies will be required to determine if this finding is valid. It was approved by Health Canada in February 2000 under the name "Plan B".

The antiprogestin mifepristone (RU-486) has been shown to be a highly effective postcoital contraceptive,<sup>5</sup> but this product is unlikely to be available to Canadian women in the near future.

Alternative hormonal methods suggested for EC, such as danazol or high dose estrogens, have either questionable efficacy or an unfavourable side effect profile.<sup>6,7</sup> They offer no advantage to the options discussed above.

A copper-bearing intrauterine contraceptive device (IUCD) can be used up to seven days after intercourse to prevent conception in women who have no contraindications to its use. It can remain in place to provide ongoing contraception.<sup>8</sup>

#### MECHANISM OF ACTION

Multiple mechanisms of action have been suggested to account for the efficacy of hormonal methods of postcoital contraception. These include the suppression or delay of ovulation, ovarian steroid changes with corpus luteum disruption, and endometrial asynchrony.<sup>9,10</sup>

There is no good scientific literature on the mechanism of action responsible for the efficacy of the postcoital IUCD. Further research is needed to address this question.

#### EFFICACY

The Yuzpe regimen of emergency contraception is often stated to be 97 to 98 percent effective, since studies indicate that two to three percent of women who use it for an isolated act of unprotected intercourse will become pregnant.<sup>4,6</sup> This may be somewhat misleading for the individual woman, as the rates apply to the population of women who are treated after intercourse at various points in their menstrual cycle, not just at their most fertile time. The risk of failure for an individual woman who has intercourse at her most fertile time may be considerably higher. It is more correct to consider that the Yuzpe Method

| Time Since Coitus              | Strategy              |
|--------------------------------|-----------------------|
| 0-3 days                       | Yuzpe Method or IUCD  |
| 3-5 days                       | Yuzpe Method* or IUCD |
| 5-7 days                       | IUCD                  |
| *Evidence for efficacy limited |                       |

prevents about 75 percent of the pregnancies which would have occurred were EC not used.<sup>11</sup> The levonorgestrel regimen has been found to prevent 85 percent of expected pregnancies.

Although hormonal postcoital contraception has been shown to be effective when used up to 72 hours after intercourse, the earlier the treatment begins, the more effective it is. In the WHO Task Force study, the world's largest randomized controlled trial, delaying the first dose from 12 to 24 hours after intercourse increased the odds of pregnancy by up to 50 percent.<sup>12</sup> These increased odds apply to both the Yuzpe and levonorgestrel regimens, providing support for the provision of hormonal EC in advance of need to avoid delays in the first dose. This finding should not discourage the use of hormonal EC if the first dose is delayed, but rather encourage its early use.

The postcoital insertion of an IUCD is a very effective means of preventing pregnancy. In the largest review (8,300 postcoital IUCD insertions), the failure rate in all studies did not exceed 0.1 percent.<sup>13</sup>

#### INDICATIONS

Emergency hormonal contraception should be considered for any woman wishing to avoid pregnancy who has had unprotected intercourse within the 72 hours prior to seeking medical advice. EC should be considered for other pregnancy risks that result from multiple missed birth control pills, failure of a barrier method, ejaculation on the external genitalia, and sexual assault. Breast-feeding is not a contraindication to hormonal EC. As long as the woman is not pregnant, neither the total number of times unprotected intercourse has occurred, nor the cycle day(s) of exposure is directly relevant to the decision to use EC.<sup>4</sup> Hormonal EC will not affect an established pregnancy and there is no evidence that it is teratogenic, but its administration may prevent an unintended pregnancy.<sup>3</sup> As hormonal EC has a significant failure rate, it is not recommended as an ongoing form of contraception. However, repeated use poses no known health risks and should not be a reason for denying women access to treatment. There is evidence that hormonal EC may be somewhat effective past the 72-hour window, even up to 5 days after intercourse, and so may be considered in circumstances where there are contraindications to IUCD use (Table III).<sup>14</sup>

All contraceptive methods are fallible, and human factors

may lead to imperfect use of a chosen contraceptive method. Women given hormonal EC in advance of need have been shown to use it appropriately (only for emergency situations and not as ongoing contraception).<sup>15</sup> At the present time, access to hormonal EC is limited by the need for a prescription. Timely use of EC appears to be more efficacious; therefore, consideration should be given to providing a prescription for EC in advance of need to any woman in the reproductive age group who is not sterilized. Detailed information must be given about how and when to use it.

A postcoital IUCD insertion can be offered to women who have no contraindications to its use up to seven days after intercourse. Although there is no evidence to suggest that the short-term use of estrogens is associated with the adverse events of long-term use, the postcoital IUCD may be preferred for the rare woman who has strong contraindications to exogenous estrogens (i.e. stroke, myocardial infarction, thromboembolic disorder) until the levonorgestrel pill becomes available.

#### CONTRAINDICATIONS

There are no absolute contraindications to the use of emergency hormonal contraception aside from pregnancy, and this only because it is ineffective. According to WHO, "there are no known medical contraindications to the use of emergency contraceptive pills."<sup>16</sup> In the United Kingdom over 13 years of use of the Yuzpe regimen, on more than four million occasions, there were only six serious adverse events (three venous thrombosis and three cerebrovascular events); in none of these was the relationship between the administration of the hormonal EC and the event clearly determined.<sup>17</sup> The hypothetical risk of adverse events associated with the use of oral contraceptive pills is unlikely to pertain to the short duration of use for EC. No substantial increased risk for developing venous thromboembolism has been found with combined hormonal EC.<sup>18</sup> Pregnancy poses a much higher risk of these events. Any theoretical risk associated with estrogens should not apply to the levonorgestrel regimen.

If the IUCD is selected as the most appropriate method, care must be taken to exclude those women who are not suitable candidates (history of recent pelvic inflammatory disease, or multiple partners, especially during the exposure period in question). At the time of insertion, endocervical cultures should be taken and consideration given to the use of antibiotics to reduce the risk of inducing pelvic infection.

#### ASSESSMENT

Very little work-up is required aside from determination of the last menstrual period and previous unprotected acts of intercourse during that cycle to establish if an existing pregnancy is a concern. Rarely will a urine pregnancy test be necessary to rule out pregnancy.

When seeing women for emergency contraception, health care providers should use the opportunity to discuss broader

sexual health concerns, such as whether the unprotected act was coerced, risks for sexually transmitted infections, and need for ongoing birth control. Women should be informed about potential side effects and advised that hormonal EC will not protect them from unprotected intercourse in the days or weeks following treatment. A barrier method such as the condom can be used for the remainder of the cycle and a different method initiated at the beginning of her next cycle if the woman desires.

#### FOLLOW-UP

Women should be informed that they should obtain a pregnancy test if they do not experience menstrual bleeding by the 21st day following treatment. Arrangements should be made to provide continued contraception if not done at the initial visit. If it is a concern, testing for sexually transmitted infections should be done 1-2 weeks after exposure.

#### SIDE EFFECTS

The main side effects of hormonal methods of EC are gastrointestinal. The Yuzpe regimen causes nausea in up to 50 percent of recipients and as many as 19 percent experience vomiting.<sup>4</sup> Taking each dose with food and using anti-nausea medications (such as dimenhydrinate 50 µg) thirty minutes prior to the dose may reduce nausea. Since the pills are completely absorbed within one hour, replacement dosing is unnecessary if vomiting occurs after this time.<sup>19</sup> The levonorgestrel regimen is significantly better tolerated, with nausea in 23 percent and vomiting in six percent.<sup>4</sup> Other uncommon side effects with both the Yuzpe and levonorgestrel regimens are headache, bloating, and uterine cramps. Although some women may experience spotting, the majority of women have their menstrual period on time or slightly early.<sup>5</sup>

The postcoital IUCD is associated with potential complications such as cramps, bleeding, infection, perforation, and expulsion.

#### ACCESS

From a public health perspective, the promotion of emergency contraception can be seen as primary prevention for the serious problem of unintended pregnancies. In order to accomplish this, women at risk of pregnancy and their partners need to be knowledgeable about EC before they need it and be able to access it when needed. Improved access can be achieved by the provision of a prescription in advance of need, with instructions for use. Another option, supported by the SOGC and other major medical organizations, is to make hormonal EC available through a pharmacist without prescription, after counselling regarding follow-up with a health care professional if menstruation does not occur and for ongoing sexual health care.

#### CONCLUSION

Emergency contraception is a safe and effective means of reducing the number of unintended pregnancies and abortions. The

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effective use of EC is dependent on increasing both public and professional awareness and improving access to this important therapeutic intervention. Health care providers can encourage the appropriate use of EC by discussing it with their patients and by providing them with a prescription for hormonal EC in advance of need. Those involved in the promotion of women's health must become advocates for emergency contraception, locally and nationally.

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