

Emergency Contraception: The Canadian Perspective

Alana Flexman, B.Sc. (OT4)
Shannon Wires, M.Sc. (OT5)

Abstract

Emergency Contraception (EC) is defined by the Society of Obstetricians and Gynecologists of Canada (SOGC) Guidelines as any method of contraception that is used after intercourse and before implantation. Two methods of EC are accessible in Canada: hormonal medications and the postcoital intra-uterine device (IUD). The hormonal EC methods commercially available in Canada are Preven® (combined ethinyl estradiol and levonorgestrel) and Plan B® (levonorgestrel alone). Emergency contraception has been shown in the research literature to have high efficacy in preventing pregnancy when used within 72 hours of unprotected intercourse. The hormonal methods are well tolerated with minimal side effects, and are not teratogenic to an established pregnancy. Given its simplicity of use and the need for timely administration, several other countries and two Canadian provinces, British Columbia and Québec, have begun to offer EC without a prescription from pharmacists. Moreover, a recent study from the University of Toronto has piloted this concept in the Toronto area with encouraging results. In conclusion, the future of emergency contraception in Canada is evolving towards improved, timely access for all women thus resulting in a probable reduction in unwanted pregnancies.

Introduction

Every year, hundreds of thousands of Canadian women are at risk for unintended pregnancy as a result of unprotected intercourse, inadequate contraceptive measures or failure of contraceptive methods. The use of emergency contraception is defined in the Society of Obstetricians and Gynecologists of Canada (SOGC) Guidelines as “any method of contraception which is used after intercourse and before implantation,”¹ and has the potential to prevent many of these unwanted pregnancies. It has been known since 1977 that a high dose of oral contraceptive (norgestrel-ethinyl estradiol) within 72 hours of having unprotected intercourse will significantly reduce a woman’s chance of becoming pregnant.² Nevertheless, commercially packaged emergency contraception (EC) has become available only recently in North America, despite growing evidence about its safety and efficacy.³ Moreover, EC is

under-utilised due to a general lack of awareness about its availability and difficulty in accessing EC within the appropriate time frame.⁴ As a result, a recent University of Toronto study established a pilot project for pharmacy access to EC and has identified a pressing need for improved access to EC.⁵

Emergency Contraceptive Options

The accepted methods for emergency contraception available in Canada consist of two hormonal methods and the insertion of a postcoital intrauterine contraceptive device (IUD). The most widely used method in Canada is the Yuzpe Method.² This hormonal method was first described in 1977 and involves a combination of 100 micrograms of ethinyl estradiol and 500 mg of levonorgestrel taken in two doses 12 hours apart.² The first dose should be initiated within 72 hours of unprotected intercourse. Several oral contraceptive pills can be used to achieve this dose if needed, although none is approved specifically for this use (Table 1). Preven®, a product containing the hormonal combination of the Yuzpe regimen in a single pill, was approved for use in Canada in 1999 by prescription specifically for use as emergency contraception. A second hormonal method, Plan B®, has also been available in Canada since February 2000. This method uses 750 mg of levonorgestrel alone taken in two doses 12 hours apart.

The postcoital copper IUD can be used past the 72-hour window following intercourse,⁶ as it is effective up to 7 days after intercourse. It is the most effective postcoital contraception as the failure rate does not exceed 0.1%.⁷ This method is most appropriate for women who meet the regular criteria for use of an IUD, as the IUD can stay in place for long term contraception following insertion.²⁰ There is currently no evidence to recommend the levonorgestrel-releasing intrauterine system, marketed under the trade name Mirena®, for emergency contraception.

In large randomised control trial of women in 1998, the crude pregnancy rate for levonorgestrel (Plan B®) was 1.1%, compared to 3.2% for the Yuzpe regimen⁸ and 0.1% for the postcoital IUD.⁷ In terms of the proportion of pregnancies prevented compared with the expected number without treatment, the levonorgestrel method prevented 85% of possible pregnancies and the Yuzpe

regimen 57% of possible pregnancies in this study. The efficacy of both treatments decreased with delay from the event of unprotected intercourse. In other studies, however, the Yuzpe regimen has been attributed efficacies as high as 75 percent.⁹ With such high efficacy, EC is thus able to reduce the number of therapeutic abortions needed due to unplanned pregnancy.

Mifepristone (RU-486), an anti-progestin, is also highly effective as emergency contraception but is currently unavailable in Canada. Several randomized, controlled trials have shown that a single oral 600 mg dose of mifepristone was more effective and had less adverse effects than the Yuzpe Method.¹⁰ Further studies have shown the efficacy of a 10 mg, 200 mg and 600 mg dose of mifepristone was similar.¹⁰ No major side effects occurred, however the delay in return of menstruation was dose-dependent and thus the dose of 10 mg is most desirable. Despite its high efficacy and favourable profile, Mifepristone is not currently available in Canada and is unlikely to be in the near future.³

Table 1

Emergency Contraceptive Doses of Dedicated Emergency Contraceptives vs. Combination Oral Contraceptive Pills

Brand	Pills/Dose	EE* (µg) Dose	LNG** (µg) Dose
Dedicated Emergency Contraceptive			
Plan B®	1 white	N/A	750
Preven®	2 blue	100	500
Combination Oral Contraceptive			
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

From: SOGC guidelines "Emergency Contraception" July 2000

Mechanism of Action

Emergency contraception is known to prevent pregnancy before it occurs. Thus, the mechanism of action is fundamentally different from the interruption of an established pregnancy. The implantation process is prevented which occurs six to seven days after fertilization.⁷ Studies of high-dose oral contraceptive pills have shown that the combined estrogen-progestin regimen (Yuzpe Method, Preven®) and the progestin-only regimen (Plan B®) will not interrupt an established pregnancy.¹¹⁻¹²

Multiple theories have been proposed to explain the high efficacy of hormonal methods of emergency postcoital contraception.¹³ Depending on the timing of administration in the menstrual cycle,

there are several ways in which this method may provide contraception. For example, when given prior to ovulation, the hormones will inhibit ovulation in some women.¹⁴⁻¹⁵ Other studies have suggested a mechanism of impaired implantation of the embryo due reduced endometrial receptivity, as histologic or biochemical alterations in the endometrium were observed following EC administration.¹⁶⁻¹⁸ Conversely, some studies have found no such effect on the endometrium,¹⁹⁻²⁰ thus the exact mechanism remains unclear. Other possible mechanisms suggested in the literature include changes to the cervical mucus and subsequent changes in the transport of sperm, egg or embryo,²¹ and impairment of corpus luteal function.²²

The mechanism of action of the postcoital IUD is also poorly understood; however it is theorised that the IUD affects tubal transport of an oocyte or embryo, changes the cervical mucus and impairs implantation of an embryo.²³

Indications and Contraindications

According to the SOGC Guidelines (2000), the indications for emergency hormonal contraception, are the desire to prevent pregnancy and unprotected intercourse 72 hours prior to seeking medical advice.¹ Emergency contraception is also considered in circumstances of high pregnancy risk that result from failure of existing contraception, such as barrier methods or missed birth control pills.¹ There is some evidence that the effectiveness of EC may last longer than the recommended 72 hour period, with a reported 72-87% efficacy 72 to 120 hours after intercourse.²⁴ As well, based on current literature on efficacy, SOGC recommendations are that a postcoital IUD be considered for women at risk of pregnancy 3-7 days after unprotected intercourse.¹ Hormonal EC is not recommended as a primary form of contraception and should be used only in emergency situations.¹ However, multiple use of EC has no known health risks and there are no contraindications for repeated use.¹

Emergency contraception is extremely safe: no deaths have been associated with EC use and there is no causal association between EC and the small number of reported adverse effects.¹³ There are no absolute contraindications to the use of emergency hormonal contraception, with the exception of pregnancy due to their ineffectiveness. As stated previously, there is no evidence of teratogenic consequences to the fetus since EC will not alter an established pregnancy and is of no utility in this situation.²⁵ The World Health Organization Guidelines indicate that breast-feeding and a history of ectopic pregnancy should not restrict access to hormonal EC.²⁶ Furthermore, in women with a history of severe cardiovascular complications, angina pectoris, migraine or severe liver disease, the benefits of EC generally outweigh the potential risks of pregnancy. Neither smoking nor age is considered a contraindication. Although some physicians are cautious about the use of estrogen-based EC in women with clotting disorders, migraine, or hormone sensitive tumours, the short-term contraceptive benefit of estrogen exceeds the risk of treatment when one considers the adverse outcomes of pregnancy in the same population.¹³

Contraindications to the use of a postcoital IUD are identical to

those for normal contraceptive use, such as pelvic infections (acute, recent or recurrent), pregnancy or a distorted uterine cavity.²⁰ Although postcoital IUD has high efficacy and few contraindications, it is not commonly administered by physicians due to the concern regarding the risk of pelvic inflammatory disease and the time required to administer the device.²⁰

Side Effects

The primary side-effects of hormonal EC are nausea and vomiting.²⁵ The Yuzpe regimen causes nausea in up to 50% of patients and up to 19% experienced vomiting.⁸ The Levonorgestrel regimen (Plan B[®]) is better tolerated with 23% experiencing nausea and 6% experiencing vomiting.⁸ Nausea and vomiting can be minimised by taking the medications with food and using anti-emetics such as dimenhydrinate (Gravol[®]) 30 minutes prior to the dose.¹ If vomiting occurs within one hour, a replacement dose is required.¹ Less common side effects with both regimens include uterine cramping, spotting, headaches and bloating.¹ Most women start their menstrual period on time or slightly early.²³ Post coital IUD is associated with complications that include bleeding, infection, perforation, cramping and expulsion.¹

Follow-Up

Follow-up after EC includes a pregnancy test if menstrual bleeding does not occur by the 21st day following EC administration.¹ In addition, arrangements for continued contraception and sexually transmitted infections (STI) testing should be done 1-2 weeks after administration.¹

Future Directions: Switch to Over The Counter Status?

Emergency Contraception is a safe medication with only one contraindication (pregnancy) and a relatively simple method of administration. Two recent studies in France and the United States found that women had little difficulty understanding how to use EC safely and effectively without a physician's assistance.²⁷⁻²⁸ Furthermore, large randomised trials have demonstrated that hormonal EC is more effective when used quickly, and the time delay in obtaining a prescription may lead to increased numbers of unwanted pregnancy due to decreased efficacy.²⁹⁻³⁰ The availability of EC without a prescription removes the clinical opportunity for physicians to provide STD and contraception counselling. While this is true, the efficacy of this counselling has not been demonstrated.³¹ In addition, some might argue that physicians should identify the woman's pregnancy status prior to EC administration and discuss side effects. However, since there is no risk to the pregnancy and the side effects are uncomplicated, this information could readily be communicated by a pharmacist.¹¹ Furthermore, some supporters of EC regulation argue that increased EC availability will lead to its use as a regular contraceptive, rather than an emergency medication.²⁹ Nevertheless, numerous studies have indicated that advance provision of EC for women at risk of unintended pregnancy does not replace traditional contraception.³²⁻³⁴

The SOGC initiated a campaign to increase awareness and availability of EC in 1998.⁴ Other Canadian supporters include the Canadian Pharmacists Association, the Royal College of Physicians

and Surgeons of Canada, the Canadian Nurses Association, the Canadian Pediatrics Society, and six provincial medical colleges.⁴ Furthermore, a cost analysis of use of EC in Canada showed that EC was cost-saving whether provided at the time of the emergency or in advance to be used as needed.³⁵

In December 2000, British Columbian Premier Ujjal Dosanjh approved the availability of EC directly from pharmacists without a prescription.³⁶ In the first 8 weeks, 800 women accessed EC from pharmacists and over half these women obtained EC on evenings or weekends when a physician is usually unavailable.³⁶ The next year, the province of Quebec made EC available from pharmacists, but required a \$30.00 consultation fee for this service.³⁷ In June 2001, a University of Toronto pilot study headed by Sheila Dunn (Professor of Medicine) and Thomas Brown (Professor of Pharmacy) was undertaken to train pharmacists in 40 pharmacies in the Scarborough, Rexdale and North York areas to dispense EC directly to women without a prescription. Preliminary results indicate that close to 7000 women obtained EC from these pharmacies over a one year period, 65% of whom indicated that they needed EC due to failure of their regular contraception and 84% indicated that it was significantly easier to get EC from the pharmacy.⁵

A recent journal article reported that Canada is lagging behind other countries in the availability of EC without a prescription.³¹ Women in the United Kingdom, Morocco, Norway, Sweden, Finland, Israel, France, Belgium, Denmark, Portugal, South Africa, and Albania can already obtain EC without a prescription.³¹ Furthermore, a large supermarket chain in England has established a pilot program to dispense EC to teenagers free of charge in order to address an alarming rate of teenage pregnancy.³⁸ In contrast, EC is only available without a prescription in three American states (Washington, Alaska, and California), despite the fact that EC is estimated to prevent 1.5 million unintended pregnancies and 700 000 abortions each year.³⁹

Conclusions

Emergency Contraception is a safe, highly effective way to prevent pregnancy in the event of unprotected intercourse or failure of regular contraceptive methods. Their effectiveness is highly dependent on their time of administration following unprotected intercourse; therefore over-the-counter availability has been proposed and widely supported by many medical organisations. Pharmacists are the most easily accessed, qualified health professionals for the distribution of EC in a timely manner. Several nations and select Canadian provinces have explored options in distribution of EC without a prescription with highly successful results. As Canada heads towards easier, more convenient access to emergency contraception, it is with clear benefit to the reproductive health of Canadian women.

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