

## AOGS MAIN RESEARCH ARTICLE

# Emergency contraception in a country with restricted access to contraceptives and termination of pregnancy, a prospective follow-up study

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Contraception, levonorgestrel, treatment effectiveness, adverse effects, pregnancy, Poland

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**Conflict of interest**

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**Introduction**

Within the last 15 years, the profile of women requesting emergency contraception (EC) in specific countries has been examined in several studies (1–3). In the majority of countries throughout the world, abortion laws are less

**Abstract**

**Objective.** Poland has a restrictive abortion law. Emergency contraception (EC) is expensive and available only on prescription, which is not easily obtainable in public health care. We aimed to identify the main reasons for EC requests, observed failure rates and the type and incidence of adverse effects. **Design.** Prospective single-center observational study. **Population.** A cohort of women living in Warsaw, who requested EC. **Methods.** Data were collected via a questionnaire completed by healthcare providers prescribing EC, and included age, date of the request, previous EC use, time from intercourse to clinic visit and day of menstrual cycle on which intercourse took place. **Main outcome measures.** Reason for EC request, time lapse between unprotected intercourse and EC use, age of women requesting EC, reported cases of pregnancy. **Results.** A total of 4655 women requested EC. Of these 62.9% ( $n = 2928$ ) were  $\leq 25$  years old. During follow up, 0.75% (31 individuals) became pregnant. Adverse effects of hormonal EC were rare and mild. The main reason for requesting EC was problems associated with condoms (63.2%,  $n = 2609$ ). The mean interval between unprotected intercourse and EC use was 21.2 h, but 26.7 h when EC failed (n.s.). Considering intake within and after 24 h, the difference was significant ( $p < 0.05$ ). **Conclusions.** Women living in Warsaw seeking EC used the EC product very soon after unprotected intercourse, and this was probably one of the most important reasons for the low pregnancy rates in the studied population.

**Abbreviations:** EC, emergency contraception; LNG, levonorgestrel.

**Key Message**

In Poland, the use of emergency contraception is the only legal way to avoid unwanted childbearing after unprotected intercourse. The great majority of patients living in Warsaw sought and used emergency contraception very soon after intercourse. This probably explains the high effectiveness of levonorgestrel emergency contraception in the study population.

restrictive than in Poland. With restrictive legislation the pressure to avoid unintended pregnancy and to use EC is strong.

The most popular contraceptive methods in Poland are those with the lowest or questionable effectiveness, such as coitus interruptus and periodic abstinence (4). In recent years, the use of hormonal contraception and condoms has increased, but this has been a slow process and is often limited to those living in the largest towns and cities (5,6). With the low use of modern contraception in Poland, high abortion rates and many deliveries might be expected. However, the total fertility rate in Poland (7) is very low (total fertility rate for 2008 1.39), and number of legally induced abortions were 225 and 322, respectively, in 2005 and 2007. There are no reliable data to reflect the number of illegal abortions performed in Poland.

For over 20 years, EC drugs [both as levonorgestrel (LNG) only and as LNG in combination with ethinylestradiol] have been available on prescription only. Insertion of a copper intrauterine contraceptive device is available as an EC method, but is not popular because of its cost (over €100, and not reimbursed by the social security system). The current social and political decision-makers in Poland are in general reluctant to promote modern contraceptive methods, especially EC drugs. Previous lack of clarity about the mechanism of action of EC drugs, with possible obstruction to endometrial implantation of a blastocyst, was a cause for the scepticism voiced by some experts in medical sciences (7). As a result, it has been extremely difficult to promote EC drugs in Poland (8). However, the results of several studies (9,10) show that LNG EC is not an abortifacient and it has recently been proven that it prevents pregnancy only when taken before ovulation (11).

The majority of contraceptives and EC drugs are relatively expensive and not refundable from the Polish National Health Fund (a pack containing one tablet of 1.5 mg LNG costs approximately €10–12). Prescriptions for EC drugs are difficult to obtain. Generally patients are unlikely to be provided with such prescriptions at public healthcare institutions, especially if there is any time pressure, such as within 72 h after unprotected intercourse. The use of LNG EC within 72 h after unprotected intercourse has been estimated to reduce the risk of pregnancy by between 74 and 93% (12,13). However, this high rate of reduction of pregnancy after LNG EC use is not widely accepted by all authors (14,15). Recently the pregnancy rate of LNG EC was reported to be as low as 2.6% (16,17). There is evidence (11) that the use of LNG EC neither alters endometrial receptivity nor impedes implantation. This may help to put to rest at least some of the controversy surrounding the use of hormonal EC in Poland.

The aim of this study was to identify the main reasons for EC requests, the observed failure rates in clinical practice, and factors that may affect the effectiveness of EC, as well as to identify adverse effects.

## Material and methods

The study was designed as a prospective single-center observational study (Out-Patient Clinic of Fertility and Sterility Research Centre in Warsaw) of a cohort of 5000 women who attended this Clinic and requested an EC prescription, starting on 1 January 2004. The product (LNG, two tablets of 750 µg each) was withdrawn from the market on 31 August 2008 so recruitment was lower than anticipated. Between 1 January 2004 and 31 August 2008, 4655 women asked for an EC prescription. All were asked to have an initial urine pregnancy test (sensitivity 10 mIU/mL). Those women with a negative pregnancy test and regular menstrual periods (every 26–31 days) were informed about the study. Eleven women had a positive pregnancy test result and were not eligible, leaving 4644 who were invited to participate and given written information about the study. All agreed and signed a written consent. The data were collected via a questionnaire completed by each healthcare provider prescribing EC, and included the following parameters: age, date and day of week when the request was submitted, previous use of EC drugs, the time interval from the pregnancy risk in hours, day of menstrual cycle on which intercourse took place and the reason for requesting EC.

Routine patient counseling took place and the packet containing two pills, each of 750 µg LNG, were prescribed (the first one was supposed to be taken as soon as possible and the second one after a time interval of 12 h). The women were asked to abstain from sexual intercourse until the onset of the next menstruation or until the follow-up telephone call. Each woman was given an additional pregnancy test and instructed on how and when to carry out the test. The women were told to expect a phone call from the study personnel in 1 month's time. The effectiveness of EC was reviewed during the follow-up telephone call. If a woman failed to answer the first call, three more attempts were made every other day using all available telephone numbers. If this failed, the woman was classified as "lost to follow up." A negative result of the urine pregnancy test reported during follow up was taken as indicating that there was no pregnancy. During the same call, the women were asked about any adverse effects experienced after taking EC. The results of the follow-up telephone calls were entered into the respective medical records. The study was approved by the Mazovian Bio-Ethics Committee in February 2002 (Protocol 212/02).

### Statistical analysis

The study results are expressed in absolute values, percentages, means, standard deviations and medians. The Mann–Whitney *U*-test for the comparison of two means from independent samples in the case of equal variances, and the Cochran–Cox test to compare two means from independent samples if the variances were unequal, were used. A chi-squared test was used for qualitative variables. Statistical significance was considered at  $p < 0.05$ .

### Results

The mean age of subjects was  $24.2 \pm 5.9$  years, with 62.9% being  $\leq 25$  years and 12.0%  $< 18$  years. Most (92.0%) women were using EC pills for the first time and none had used the method more than once before. The main reason (63.2% of women) for requesting EC was having problems with a condom (broken or retained), followed by unprotected intercourse (34.6%). Problems with hormonal contraception led to only 1.7% of requests. Saturdays and Mondays were the days of the week on which EC was most often requested. The majority of women (69.6%) requested EC within 24 h of a risk, whereas 21.6% did so on the second day (25–48 h) and 8.4% on the third day. When asked about the last

menstrual period, all but three women were able to provide the exact date.

Despite several attempts at contacting them, 515 (11.1%) women were lost to follow up. No significant differences were identified in terms of age, time interval between intercourse and EC use, or the day of the menstrual cycle on which EC was requested between these and other women (Table 1).

Emergency contraception failed in 31 (0.75%) women. Failure was reported more frequently in those women who used “no birth control methods” (13/1437; 0.9%) compared with “condom failure” (18/2609; 0.7%), although the difference was not significant (Table 2). The pregnancy rate was slightly higher in older women. The mean age of women with effective EC was 24.1 years; that for non-effective EC was 25.6 years. In 56.4% of the women intercourse took place between days 10 and 20 of the cycle whereas in women in whom EC failed, unprotected intercourse had taken place on days 10–20 in 90.3% of instances (not significant). Pregnancy was reported more frequently (1.2%) in the latter group than in the general study population (0.75%).

The mean interval between intercourse and the use of EC was  $21.2 \pm 17.1$  h (median 18.0 h). In the group in which EC failed, this interval was  $26.7 \pm 18.6$  h (median 25.2 h), but the difference was not significant ( $0.05 < p < 0.10$ ).

**Table 1.** Comparison of the group of patients “available for the follow up” with the group “lost for follow up.”

The group of patients	Number of patients	Mean age (years)	Mean lapse of time between the intercourse and EC use (h)	Mean day of the menstrual cycle when EC was required
Lost to follow up	515	$24.4 \pm 5.8$	$22.1 \pm 16.8$	$15.4 \pm 7.1$
Available for follow up	4129	$24.1 \pm 6.0$	$21.2 \pm 16.8$	$15.4 \pm 7.1$
<i>p</i> -value <sup>a</sup>	–	NS	NS	NS

<sup>a</sup>In Mann–Whitney *U*-test.

**Table 2.** The reason for requesting emergency contraception (EC) and EC “effectiveness” in the group of patients available for follow-up.

The reason for the EC request	EC “effectiveness” in the group of patients available for follow-up						<i>p</i> -value <sup>a</sup>
	Total number of follow-up patients <i>n</i> = 4129		No pregnancy after EC use <i>n</i> = 4098		Pregnancy occurred in spite of EC use <i>n</i> = 31		
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	
Condom failure	2609	63.2	2591	63.2	18	58.1	NS
No methods used	1437	34.8	1424	34.7	13	41.9	
Not perfect use of hormonal contraception	72	1.7	72	1.8	0	0.0	
Other methods used	11	0.3	11	0.3	0	0.0	

<sup>a</sup>In chi-squared test.

**Table 3.** Emergency contraception (EC) "effectiveness" in the group of patients available for follow up and the lapse of time between unsecured intercourse (in h) and EC use.

The lapse of time between unsecured intercourse and EC use	EC "effectiveness" in the group of patients available for follow up						
	Total number of follow-up patients <i>n</i> = 4129		No pregnancy after EC use <i>n</i> = 4098		Pregnancy occurred in spite of EC use <i>n</i> = 31		<i>p</i> -value <sup>a</sup>
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%	
≤24 h	2730	66.1	2715	66.2	15	48.4	<0.05
>24 h	1331	32.3	1315	32.1	16	51.6	
No data	68	1.6	68	1.7	0	0.0	

<sup>a</sup>In chi-squared test.

When the women requesting EC were divided into those requesting EC ≥24 h and <24 h after unprotected intercourse, the difference was significant (Table 3). Adverse effects (the most common adverse effects were headache 4.0%, drowsiness 3.4% and abdominal pain 2.4%) of EC were rare and mild and no adverse effects were reported in 82.9% of the women. The majority of the adverse effects occurred in the group of women aged ≤30 years.

## Discussion

In a country with a very restrictive abortion law, contraception (including EC) is the only method available to avoid unplanned parenthood. Hormonal EC is the only available post-coital method of contraception in Poland (the intrauterine device EC is available, but in practice – due to high costs – is not used). The study results give an indication of who was using EC and for what reasons, and also the effectiveness of the method. Condom failure was the most common reason for EC use among the women in the study, and every third woman had used no protective measures at all. The majority of the women attempted to take EC as soon as possible, which confirms that women requesting EC were afraid of the risk of unintended pregnancy and were ready to take all available measures to avoid it. Knowledge of the existence and effectiveness of EC is therefore of importance for sexually active individuals (5,6).

The definition (18) of EC effectiveness is imprecise, and because of that the data about EC effectiveness presented in various studies may not be conclusive. The results obtained in this study suggest good LNG EC effectiveness, but could be affected by pregnancies among those women with whom we lost contact. However, even if the same number of failures had occurred among the women lost to follow up, the failure rate would only have increased to a minor degree, and would have remained within the range of LNG EC failure rates established by the World Health Organization (12). Some women in the

group that we could not follow may also not have used the EC provided or used it in the wrong way. The rate of women who were missed for failed follow up may not be considered as too high (19).

The sooner EC drugs are taken, the lower the failure rate (14,20). In this study the average interval was 26.7 and 21.1 h in the EC-failure and EC-effective groups, respectively. The estimated probability of pregnancy after a single instance of random unprotected intercourse is 3.1% (21). In this study, the number of pregnancies among women who used EC was very low, which raises the question of the estimated rate of pregnancies after a single instance of sexual intercourse and if EC was used by some women who were in fact at no risk of pregnancy. It may be necessary to consider that in some cases the women use EC because of a clear risk of unintended pregnancy but in some other cases, the EC product is taken only because of fear (anxiety/panic) of possible pregnancy of the women and/or their partners (21). As shown by Ekstrand et al. (22) the advance provision of EC pills to teenage girls shortened the time from unprotected intercourse to pill intake and did not jeopardize future regular contraceptive use.

Due to local circumstances, fear and anxiety may be more common among women in Poland when compared with other countries where abortion laws are less restrictive and EC pills are widely available (23). These circumstances may influence the use of EC, but this phenomenon needs further evaluation. EC may also have a socio-political dimension, related to the question of the right to wide accessibility to EC (24). In Poland, this right cannot be assumed to exist.

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