

Advantages and disadvantages of over-the-counter availability of emergency contraception

Elzbieta BUMBUL¹, Magdalena STAREK¹, Iwona SZYMUSIK², Bronislawa PIETRZAK², Zana BUMBULIENE³, Katarzyna KOSINSKA-KACZYNSKA², Mirosław WIELGOS²

¹ Students' Research Group at the 1st Department of Obstetrics and Gynecology, Medical University of Warsaw, Poland

² 1st Department of Obstetrics and Gynecology, Medical University of Warsaw, Poland

³ Clinic of Obstetrics and Gynaecology, Vilnius University Faculty of Medicine, Vilnius, Lithuania

Correspondence to: Iwona Szymusik
1st Department of Obstetrics and Gynecology, Medical University of Warsaw
Plac Starynkiewicza 1/3, 02-015 Warsaw, Poland.
TEL: +48 22 5021430; FAX: +48 22 5022157; E-MAIL: iszymusik@aol.com

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Abstract

OBJECTIVES: To compare usage patterns, accessibility and knowledge about over-the-counter (OTC) emergency contraception (EC) in comparison to prescription-only EC.

DESIGN AND SETTING: Self-designed, paper-based validated questionnaires containing 26 questions were distributed among students and high school pupils in Poland (PL) – 1000 questionnaires and in Lithuania (LT) – 650. In Lithuania EC is available OTC, whereas in Poland EC is a prescription-only drug. Statistical analysis was performed using SAS software with $p < 0.05$ considered significant.

RESULTS: 74.01% of Poles and 70.89% of Lithuanians reported a history of sexual activity. About one third of the respondents in both countries used EC at least once in a lifetime (PL: 29.01%, LT: 32.2%; $p > 0.05$). The main reason for EC usage in both countries was a broken condom (PL: 60.63%, LT: 57.66 %; $p > 0.05$). In case of emergency more than half of the questioned women in both countries would use EC pill. The knowledge about EC was significantly lower in Poland (PL median – 8 out of 16; LT – 10 out of 16 true/false statements; $p < 0.01$).

CONCLUSIONS: Over-the-counter availability of EC does not cause repetitive or increased usage. Moreover, an easier access to EC improves patients' knowledge about the drug.

INTRODUCTION

Emergency contraception (EC), also called post-coital, is a method of prevention from unintended pregnancy after an unprotected intercourse. The EC pills appeared on the market in 1960s for the first time – it was a 5-day course of diethylstilbestrol (25–50 mg per day) or ethinyl estradiol (0.5–5 mg per day (McGuinness 1983). Yuzpe method was

the next step (100 mg ethinyl estradiol and 0.5 mg levonorgestrel (LNG) in two doses (Lee *et al.* 1999). In 1980s a regimen of progesterone-only emergency contraception (POEC) was established and proved to be better tolerated and more effective than Yuzpe method (Task Force 1998). Nowadays, there are two types of POEC available with a regimen of one dose of 1.5 mg LNG or 2 doses of 0.75 mg LNG taken within 72 hours. The shorter

the time between an unprotected sex and the first pill, the higher the effectiveness (Lee *et al.* 1999). In terms of World Health Organization's factsheet N244, there are no contraindications for EC with LNG (WHO 2012). LNG prevents fertilization primarily by suppressing LH surge, but also by changing the density of the cervical mucus. However, it is proved to have no influence on implantation (Medard & Ostrowska 2010; Baird 2009).

In 2009 the new hormonal EC method was marketed in Europe: a selective progesterone receptor modulator – ulipristal acetate (UPA) available in one dose of 30 mg. The latest surveys show that UPA is at least as effective as LNG. Moreover, it has a high effectiveness within 120 hours from an unprotected intercourse (Glazier *et al.* 2010a; Glazier 2013).

In the '70s, copper intrauterine device (IUD) was described as the first non-hormonal EC method that could be placed into the uterus up to 5 days after sexual intercourse. IUD impedes fertilization, because copper released from the device changes the permeability of the cervical mucus for the sperm cells (WHO 2012).

At least one EC pill brand is available in 144 countries. In nearly 60, including Lithuania, it is available over-the-counter (OTC), whereas in the rest of the countries, such as in Poland, it is a prescription only drug (ICEC). All the above mentioned methods of EC are marketed in both countries.

Although EC has been on the market for a few decades, the level of knowledge of that particular contraception method is still unsatisfactory. The recognition of a risk of unintended pregnancy and the knowledge about the method are essential for its proper usage. A lot of women consider EC a way of an induced abortion, thus they do not even consider using it because of ethical reasons. The majority of women are unaware of the mechanism, in which EC really works (Olszewski *et al.* 2007). The objective of the study was to compare the usage patterns and the level of knowledge about EC with regard to the accessibility to that particular contraception – either OTC or a prescription-only.

MATERIAL AND METHODS:

The paper-based self-prepared questionnaire was designed for this study. It consisted of 26 questions, therein 23 of multiple choice. The questionnaire was translated and adjusted to the countries: Poland and Lithuania. Lithuanian Bioethics Committee gave the consent for this study in 2013 (no 158200-07-516-152). In Poland such permission for questionnaire-based surveys is not necessary. After an initial validation, 1000 forms were dealt among female students and high-school pupils in Warsaw (PL group) and 650 in Vilnius (LT group).

The questionnaire was divided into 3 parts: general information for all participants (demographic data, knowledge about EC, general opinion about EC), questions dedicated only to women, who had had a sexual

intercourse (the age of the first sexual intercourse, the number of partners, preferred contraception method, etc.) and questions only for those who had used EC (the reason for usage, the time between the sexual intercourse and the pill administration).

There were differences in 3 questions between PL and LT groups. The Polish form included questions about the time frame between the sexual intercourse and medical consultation, the doctor's specialty and the type of information provided. Women were also asked whether any difficulties were encountered with getting a prescription. In Lithuania questions regarded the time frame between an unprotected intercourse and getting to a pharmacy, the information given by a pharmacist and whether the respondents knew that EC was an OTC drug. In both countries there was also a special question regarding the knowledge about EC, consisting of 16 true or false statements. The questionnaires were collected, verified and correctly filled out forms were analyzed and compared between countries.

Statistical analysis was performed with the use of SAS software 9.3. Exact Fisher's test, Kruskal-Wallis test and multiple variation were used to compare the results. The *p*-value of <0.05 was considered significant.

The exclusion criteria were as follows: incomplete questionnaires, participants younger than 16 and older than 35 years old and medicine students. Finally, 788 Polish and 578 Lithuanian questionnaires were analyzed.

RESULTS

The response rate to the distributed survey reached 83% in Poland and 89% in Lithuania. There were significant differences between Polish and Lithuanian groups with regard to age (mean age PL: 22.0±2.9 vs. LT: 20.5±1.7; *p*<0.01). Most of the respondents (>70% in PL and LT) were single and lived in big cities. The age at the first sexual intercourse was also similar in both countries (mean PL: 18.4±2.0 years, LT: 17.8±1.7 years; *p*>0.05), while the duration of sexual life was longer in the Polish group (PL: 4±2.8, LT: 2.9±2; *p*<0.01). According to the questionnaire there were 74.01% sexually active students in Poland and 70.86% in Lithuania (*p*>0.05). Figure 1 illustrates contraception methods applied by the respondents in both countries, with condoms being the most popular regardless of the nationality.

Emergency contraception was used at least once by 29.01% of Poles and 32.2% of Lithuanians with similar indications (regardless of the fact that EC is a prescription-only drug in Poland and an OTC in Lithuania). A broken condom was the main reason for EC usage in both countries (PL: 60.63%, LT: 57.66%; *p*>0.05), followed by no contraception (PL: 28.13%, LT: 25.55%; *p*>0.05) and mistakes in regular hormonal contraception (PL: 6.25%, LT: 6.75%; *p*>0.05). Rape was the cause for administration in 3.13% of cases in Poland and 0.73% in Lithuania (*p*>0.05).

In case of emergency, the majority of Poles scheduled a doctor's appointment – in 89.1% of cases a gynecologist. However, 74% of Poles did not know that EC can be prescribed by any doctor, regardless of the specialty. 12.35% of Polish respondents encountered problems with obtaining the prescription. In Lithuania 70.87% of women sought pharmacists' advice. The pharmacists informed the women about usage regimen in 64%, about side effects in 28% and only in 3.7% of cases asked about the last menstrual period (LMP). There were no leaflets about regular contraception provided and no separate rooms for consultation at the Lithuanian pharmacies.

The presented data clearly show that EC is administered earlier when available OTC. Lithuanians applied EC pill within 12h in 79.26% of cases, while only 39.41% of Poles managed to do so ($p < 0.001$). However, no case of unintended pregnancy occurred. Figure 2 illustrates the time frames of EC administration in both countries.

EC was used only once by 68.21% of Poles and 69.63% of Lithuanians ($p > 0.05$). Repeated usage (2–5 times in a lifetime) was reported by 30.06% of Poles and 29.63% of Lithuanians ($p > 0.05$).

EC was an acceptable method of contraception for more than half of the respondents in both countries. Poles, who did not accept such method of contraception, found it contradictory to their religious beliefs (22% vs. 14% in Lithuania; $p < 0.01$). Lithuanians were more anxious about side effects (21.5% vs 11% of Poles; $p < 0.01$). Moreover, sexually active women in both countries were more likely to consider administering EC in case of emergency (PL: 61.95% vs. only 38.05% of non-sexually active respondents, $p < 0.001$; LT – 61.95% vs. 42.01%, respectively; $p < 0.001$).

Polish EC users were younger than Lithuanians at their first sexual intercourse and were more likely to have a risky sexual behavior (defined as having 5 or more sexual partners): 30.6% vs. 9.56% ($p < 0.001$). They also more often had a history of sexually transmitted disease (10.84% vs. 2.64%; $p < 0.001$).

In order to evaluate the knowledge about EC, the question consisting of 16 true or false statements was constructed. It was concluded that the knowledge was significantly lower in Poland: median of correct answers was 8 among Poles in contrast to 10 among Lithuanians ($p < 0.001$). Table 1 shows the statements and percentages of correct answers in both countries.

Internet was the only source of information that increased the knowledge about EC in Poland. Although the knowledge was higher in Lithuania, no single source of knowledge responsible for that positive influence was identified.

The necessity of prescription for acquiring EC is supported by 63.7% Poles and only 16.1% of Lithuanians ($p < 0.001$). Poles, who do accept EC usage, more often believe it should be available OTC in comparison to Poles declining such a possibility (45.56% vs. 23.84%; $p < 0.001$).

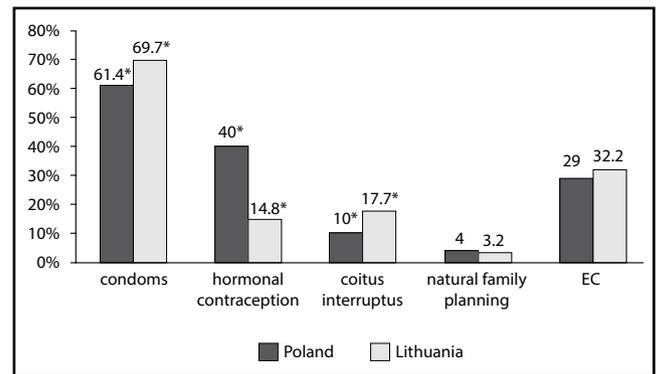


Fig. 1. Contraception methods used by the respondents in Poland and Lithuania. * – significant difference between the countries with $p < 0.05$

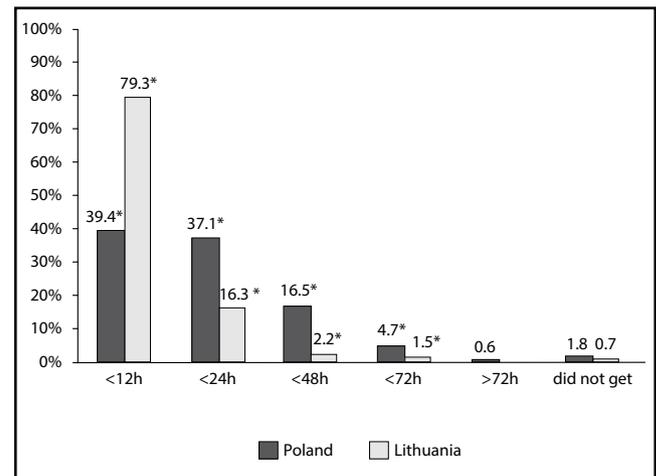


Fig. 2. Time frames of EC administration after unprotected sex in both countries. * – significant difference between the countries with $p < 0.01$

DISCUSSION

Over-the-counter availability of EC obviously results in an earlier administration and increasing effectiveness of the method (Lee *et al.* 1999; von Hertzen *et al.* 2002). The results of the above study show that easier access to EC does not cause the abandonment of regular contraception or the repetitive usage of the method. These results are in agreement with the literature – neither British nor Canadian data, nor French study showed the repetitive usage of EC when available without prescription (Marstonet *et al.* 2005; Leung *et al.* 2008). In 2003 Camp *et al.* underlined that removing prescription requirement for EC in the US would help in the reduction of unintended pregnancies and abortion and presented no serious safety issues – health consequences appeared to be minimal. According to their study there was no evidence suggesting that American women would abuse an OTC product (Camp *et al.* 2003). Moreover, the increased usage of modern contraceptive

Tab. 1. Evaluation of the knowledge about emergency contraception (EC).

Statement	True or False	Percentage of correct answers		p-value
		Poland	Lithuania	
EC drugs cause abortion	False	40.68%	58.12%	<0.001
EC drugs are teratogens	False	33.75%	41.26%	0.004
What is the time frame for EC usage	72h or 120h depending on drug	85.25%	79.90%	0.009
After EC administration the woman can still get pregnant in the same menstrual cycle	True	66.12%	73.33%	0.004
Several contraceptive pills can serve as EC	True	9.7%	23.33%	<0.001
Copper IUD inserted within 5 days from unprotected intercourse prevent from unwanted pregnancy	True	8.82%	20.45%	<0.001
EC drugs are meant for regular usage	False	83.88%	79.9%	0.057
What is the effectiveness of EC:				
• Less than 50%	False	59.7%	79.47%	<0.001
• About 70%	True	28.21%	28.95%	0.76
• Over 90%	False	37.28%	40%	0.3
After EC administration menstruation can start earlier or later than usual	True	86.4%	88.77%	0.19
EC drugs available over-the-counter*	True		87.06%	-
Any doctor regardless the specialty can prescribe EC **	True	20.40%		-

*- question appeared only in Lithuanian questionnaires; **- question appeared only in Polish questionnaires

methods generally resulted in a significant decrease in the rate of induced abortions – for example in Czech Republic the total abortion rate fell from 1.54 abortions per a woman in 1990 to 0.34 in 2007 (Kocourkova & Fait 2009).

In the above study, over 28% of sexually active Poles had a history of EC usage. This number is twice as high as previously published. In 2007 Olszewki *et al.* reported the rate of 14% of sexually active students to have used EC and Folwarczny *et al.* – 12.7% in 2009 (Olszewski *et al.* 2007; Folwarczny *et al.* 2009). The above might be explained by the fact that EC users are mainly young, educated, unmarried citizens of large cities. The same characteristics of EC users were identified in France and in Great Britain (Moreau *et al.* 2006; Black *et al.* 2006). On the other hand, it probably illustrates an increasing usage of EC in general.

Due to the conscience clause physicians in Poland can refuse prescribing contraception, including EC, if they find it incompatible with their conscience. However, another source of prescription should be indicated (Ustawa 1996). The conscience clause for pharmacists is now being widely debated in Poland. The above mentioned law allows medical employees to act according to their beliefs, thus causing difficulties and delays in EC administration. According to the presented research 12.6% of Poles encountered obstacles with obtaining the prescription for EC. Although EC pills can be prescribed by any physician regardless the specialty, only a quarter of the respondents were aware of that fact. This shows the insufficient level of knowledge about EC.

According to the WHO Standards of Sexuality Education in Europe, Sexual Education should provide an age-appropriate, scientifically accurate, realistic, non-judgmental and not fear based information about sex and relationships (WHO standards). According to the presented research, the information provided in schools did not increase the level of knowledge about EC neither in Poland, nor in Lithuania. This might be due to the fact that there are no established programs of public sexual education in these countries. The abstinence-only programs are sometimes incorporated into religion or preparation for marriage and family classes. However, the experience of abstinence-only programs in the USA showed no positive influence of such education on sexual behaviour or reduction in the risk of teenage pregnancy (Kohler *et al.* 2008).

Although neither in Poland, nor in Lithuania sexual education is the standard part of the curriculum, the level of knowledge was higher in Lithuania. This could be explained by the previous scientific findings showing the significant improvement in the level of knowledge about EC after a well performed advertising campaign (Trussell *et al.* 2001). It is worth emphasizing that the drug can be advertised only when available OTC, thus is forbidden in Poland at the moment.

However, when EC is available OTC, pharmacists are responsible for providing information not only about the regimen of EC, but also about regular contraception options. In order to make sure that a woman is not already pregnant, the question about the date of LMP should be asked. According to Mystery Shopper

Study in Great Britain 70% of pharmacists asked about LMP (Glasier *et al.* 2010b). The information provided in Lithuanian pharmacies should be improved. If no consultation on contraception and sexually transmitted infections is available, at least leaflets should be available.

In a country such as Poland, where approximately 90,000–180,000 illegal abortions take place each year, the high level of knowledge and easy access to EC are crucial (Raport 2007). There are conflicting reports about the reduction of pregnancy terminations after the introduction of OTC EC. Glasier *et al.* showed that even advanced supply of EC does not cause reduction in abortion rate (Glasier *et al.* 2004). However, the study was conducted in the country where abortions are legal.

It is important to introduce the accurate, scientific, not fear based sexual education in schools and discuss the legal actions in order to introduce over-the-counter EC in Poland. Teenagers and young adults should know the time frame of EC effectiveness. Moreover, young women should be aware that levonorgestrel does not influence implantation and is not teratogenic (Zhang *et al.* 2009; De Santis *et al.* 2005).

CONCLUSIONS

Over-the-counter availability of EC does not cause repetitive or increased usage. Moreover, an easier access to EC improves patients' knowledge about the drug. Removing prescription requirement for EC should be encouraged in countries like Poland.

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