

EllaOne – students' knowledge and opinions – part one

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SUMMARY

Introduction. The medical product ellaOne contains an active substance, ulipristal acetate, an oral synthetic selective modulator of a progesterone receptor. Its effect results from its influence on a woman's natural hormonal cycle. EllaOne inhibits or delays ovulation.

Study objective. Presenting a level of knowledge and opinions of students of the University of Silesia in Katowice about effects, use and availability of ellaOne tablets.

Material and methods. The study covered 418 students, of which 85.5% were women (N=358), and 14.5% were men (N=60), of mean age 25.2 years. Participants completed a proprietary questionnaire consisting of 8 questions concerning effects, use, distinguishing from an abortion pill, availability, and own opinion about the specified medicine. Statistical analyses were conducted in the IBM SPSS Statistics package.

Results. 55% of participants are against changes in the legal status of ellaOne. However, when asked about an emergency situation, in which they would have to make a decision about using ellaOne or not, 46% women declares they would not use this medicine, and 34% men would advise their partners against taking it.

In the study, five questions were asked concerning participants' awareness about effects and use of ellaOne, 9.6% of respondents gave 4 or 5 correct answers, 70% indicated two or less correct answers, and 13.2% were able to give a correct answer to a question how ellaOne works.

Conclusions. Students of the Medical University of Silesia in Katowice do not have knowledge about ellaOne. The results indicate there is high demand for education in this area.

Key words: post-coital contraception, ulipristal acetate, ellaOne, knowledge and opinion

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INTRODUCTION

Emergency contraception is an emergency measure preventing unplanned pregnancy after an unprotected sexual intercourse or contraceptive failure. Post-coital contraception prevents pregnancy by inhibiting or delaying ovulation. They can be divided into measures containing 1.5 mg of levonorgestrel (LNG) or 30 mg of ulipristal acetate (UPA). Emergency contraception does not terminate pregnancy, because it works before a blastocyst implants in endometrium, and it does not affect embryo development [1–4].

Levonorgestrel (LNG) is a synthetic progestagen administered orally at a dose of 1.5 mg. LNG used within 72 hours of an unprotected intercourse may reduce a risk of unwanted pregnancy by 75% to 95%. When more than 72 hours but less than 120 hours elapsed from an unprotected intercourse, use of a pill containing 30 mg of ulipristal acetate may be effective [5,6].

Ulipristal acetate (UPA) (EllaOne) is a 19-norprogesterone derivative from the 4-N group and it is an oral, synthetic, high-affinity, selective modulator of a progesterone receptor. A single oral dose of UPA influences maturing and rupture of a pre-ovulation follicle; its pharmacodynamic mechanism is based on inhibiting or delaying ovulation by inhibiting the luteinizing hormone (LH) surge, depending on a moment when the pill is taken. When the pill is taken before the LH surge, ovulation is prevented, while after the LH surge but before its peak levels are reached, the ulipristal acetate can delay rupture of follicles by at least 5 days. Use of this medicine after the peak LH level is reached is ineffective [7–11].

Safety of use of the medicinal product ellaOne containing 30 mg of ulipristal acetate was described in the Summary of Product Characteristics. Adverse effects were described accor-

ding to the classification of systems and organs. Within each group with a specified frequency of occurrence, possible adverse effects are listed in order of decreasing frequency. The most commonly reported adverse reactions include: headaches, nausea, stomach ache and painful menstrual periods [9,10–12]. The medical product EllaOne does not terminate existing pregnancy, it is not intended to be used during pregnancy and should not be taken by women suspecting pregnancy or pregnant [3,4,11]. Ulipristal acetate is a lipophilic compound and it is distributed in woman's milk, therefore breastfeeding is not recommended for one week after taking orally the ellaOne pill [11].

The medicinal product ellaOne (30 mg of ulipristal acetate) was approved for marketing as a medicinal product for human use under the Commission K (2009) Decision No. 4049 of 15 May 2009. [12]. Currently, this medicinal product in form of an oral pill is available in 70 countries. On 7 January 2015, with a decision of the European Commission, the legal status of the ellaOne medicinal product was changed from a prescription medication to an over the counter (OTC) medication. This means that in the EU countries this medicine is available without a prescription, unless those countries have separate regulations prohibiting or limiting sale or use of contraceptive medicinal products. In Poland this access was restricted for people under 15 years of age with the Minister of Health Regulation amending the Regulation concerning issuing medicinal products and medical devices from a pharmacy of 2 April 2015 [Journal of Laws, 2015, No. 0, item 477] [12, 13]

STUDY OBJECTIVE

The aim of this study was to evaluate knowledge and study opinions concerning the medicinal product ellaOne of students of the Faculty of Health Sciences in Katowice, Medical University of Silesia in Katowice, and to analyse relationships between their knowledge and the opinion.

MATERIAL AND METHODS

The research was based on questionnaires. It was conducted using a proprietary questionnaire distributed amongst students of the Faculty of Health Sciences in Katowice, Medical University of Silesia in Katowice in the first quarter of 2015.

The proprietary questionnaire contained 8 questions, five of which concerned knowledge about ellaOne, and the remaining three questions concerned opinions on legal changes associated with this medicine and its possible use in a private life. A group of 418 students were examined, including 358 women and 60 men. A difference in the number women and men in the study results from specificity of studies at the Faculty of Health Sciences in Katowice; in majority those courses are dominated by women. Amongst the respondents, the largest group were students of physiotherapy (165 - 39.5%), followed by nursing (128 - 30.6%) and midwifery (125 - 29.9%). The mean age of participants was 25.2 years (SD = 6.38, min. 19; max. 55), with the largest group being participants within an age interval of 20–25 years (334 - 79.9%). The respondents most commonly lived in cities above 100 000 inhabitants (172 - 41.2%) and villages and towns up to 15 000 inhabitants (105 - 25.1%). The obtained data was analysed statistically using the IBM SPSS Statistics application.

RESULTS

55% of participants are against allowing purchases of the medicinal products ellaOne without a prescription (55% of women and 53% of men). The majority (77% of women, 68% of men) supports introduction of an age limit of 15 years for a medical product available over the counter. More than half (54%) of interviewed women said that they would use post-coital contraception in an emergency situation in their private life (e.g., contraceptive failure), while 66% of men would support their partner in such decision. The answers to the questions discussed above were classified as „in favour” and „against”, and the total score of points assigned for individual answers formed a classifying variable determining the opinion level (from 0 - totally against to 3 - totally in favour); the results distribution is shown in Figure 1.

In the knowledge part, the respondents were asked whether ellaOne has a negative effect on woman's health, is the same as an abortion pill, how many hours after an unprotected or risky intercourse should ellaOne be taken, can ellaOne be used as a regular method, and how ellaOne works in contraception. The results are shown in Figure 2. The answers to above questions were used to determine a classifying variable determining a level of knowledge, which was a sum of correct answers; the varia-

ble assumed values ranging from 0 - no knowledge to 5 - very good knowledge. A small percentage (9.6%) of respondents received 4 or 5 points in a five point scale, 20.1% obtained 3 points, and the largest group consisted of participants who received 0–2 points (70%). The detailed information is shown Figure 3.

The mean result for the whole group was 2.1; the same mean was achieved in the group of women and of men. Of the analysed students, the physiotherapy students obtained the highest mean of 2.3, midwifery students obtained the mean of 2, and the nursing students had the lowest mean of 1.9. The result obtained for knowledge about ellaOne is positively, but very weakly correlated with a studied course ($r=0.13$; $p<0.01$). The question concerning the way in which ellaOne works was a semi-closed question with a multiple answer; with a choice of answers and an answer „other” possible to indicate and provide own answer.

The correct answer, „delays ovulation”, was selected by 13.2% of respondents (N=55), the majority of students selected the answer „prevents embryo implantation in the uterus” (N=182; 43.5%) and „prevents fertilisation of an egg by sperm” (N=101; 24.2%). The remaining respondents selected the answer „causes expelling of the implanted embryo from the uterine cavity” (N=32; 7.7%), many incorrect answers (N=29; 6.9%), „delays ovulation” and other incorrect answer (N=14; 3.3%), and 5 people (1.2%) selected the answer „other”.

For the question concerning time of taking ellaOne after an unprotected intercourse, only 9.3% (N=39) of respondents indicated a correct answer, i.e., 120 hours, the other answers included 72 (N=236; 56.5%) or 24 hours (N=124; 29.7%).

There was a significant moderate correlation ($r=0.3$; $p<0.01$) between a level of participants’ knowledge and their opinion about ellaOne legal status.

Fig. 1. Opinion about ellaOne

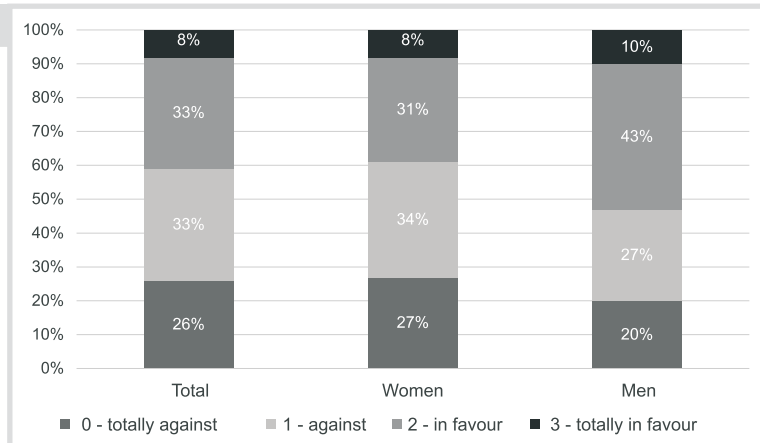
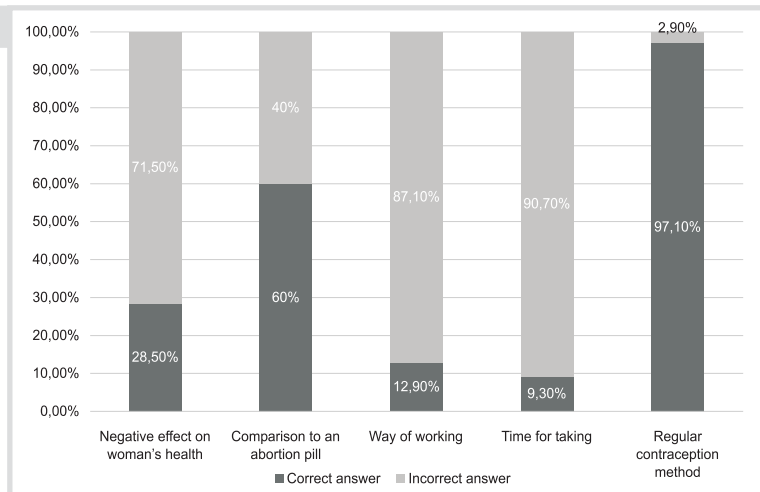


Fig. 2. Knowledge about ellaOne



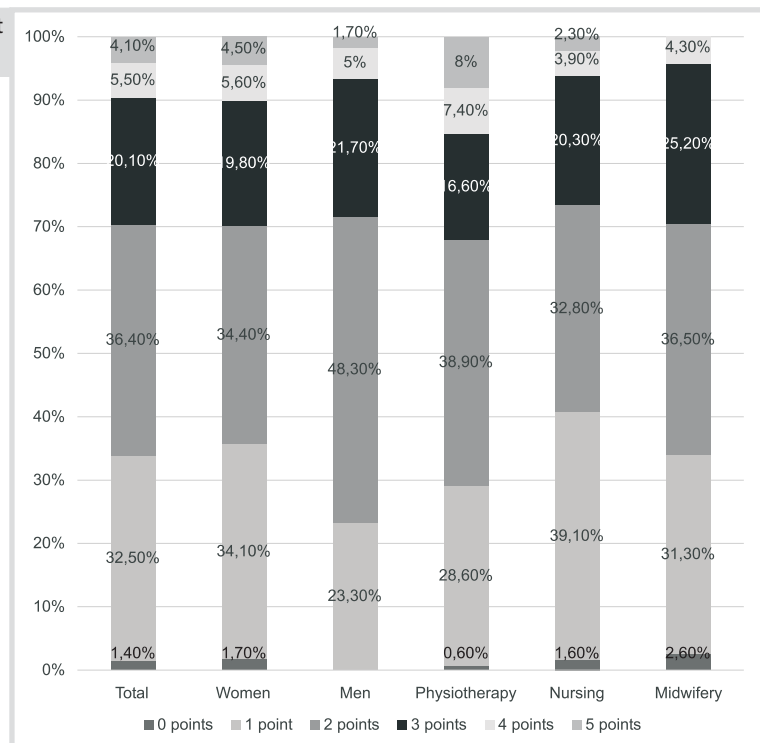
DISCUSSION

The results of the study indicate that the majority of the analysed students is against ellaOne being available without a prescription, and is of the opinion that limiting its availability to people below 15 years of age is a correct approach. These rates are reversed for women when their private life is analysed, and 54% of respondents declares that in an emergency situation they would use post-coital contraception. The same answer was given by 66% of men, and when compared to men's answer to the question concerning availability without a prescription (53% men against) it may suggest that men's opinions become more liberal where their private situation is considered. However, it should be indicated that for men this question concerned support for their partner making a decision to use post-coital contraception, and this may explain differences between the groups of women and of men concerning the discussed question. The results of own studies show that knowledge about the medicinal product ellaOne of studied people was low (a mean score of 2.1 points in a five point scale for knowledge). The lowest number of correct answers concerned the way in which ellaOne works and the time from an unprotected intercourse within which the medicine should be

taken. The most common answer was that the medicine prevents the embryo implantation in the uterus, and that it prevents fertilisation of the egg by sperm. The correct answer, conforming to a specification of the ellaOne manufacturer [11], was given by 13.2% of the respondents. The participants had a significant problem to indicate the time when ellaOne should be used after an unprotected or a risky intercourse. The majority (56.5%) indicated 72 hours, and 24 hours (29.7% of the respondents). According to the literature data [8,9] ellaOne taken as recommended does not have a negative effect on woman's health. In the studied population of students, 71% were of the opinion that it has an adverse effect on woman's health. Knowledge about ellaOne correlates positively with an attitude to availability of this medicine as an OTC product. This means that the greater the knowledge, the more frequently the respondents were in favour of the medicine availability as an OCT product.

In Poland, the change in the ellaOne legal status was an issue widely discussed in media and information about discussions and positions were widely published in traditional and in social media channels. However, this extensive media interest in the subject did not result in an increased level of knowledge of students at the Faculty of Health Sciences in Katowice.

Fig. 3. Level of knowledge about ellaOne



CONCLUSIONS

1. The level of knowledge about the medicinal product ellaOne amongst the students at the Faculty of Health Sciences in Katowice, Medical University of Silesia in Katowice is low.
2. The majority of participating students is against availability of the ellaOne medicinal product as OTC medicine and supports the additional limitation that makes purchase of this product impossible for people below 15 years of age.
3. Every second student declares they would use post-coital contraception in an emergency in their private life.
4. The knowledge level of analysed students is moderately correlated to their opinion on a change in the ellaOne legal status.
5. There is a high demand for education in post-coital contraception.

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