

The Most Common Side Effects, Concerns and Discontinuation Patterns of Oral Contraceptive Pills Among Polish Women: A Cross-Sectional Study

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Abstract

Objective: Over the decade, variety and effectiveness of contraception methods have greatly improved, resulting in increased popularity of oral contraceptive pills (OCPs). However, hormonal contraception carries the risk of multiple side effects. The lack of sufficient knowledge often leads to the development of health concerns, which can affect patient's adherence. The aim of our research was to describe a side effect profile of OCPs and assess the most frequent concerns and discontinuation reasons in Polish women. The survey included questions regarding OCPs utilization patterns, side effects, health concerns and attitudes of the responders.

Materials and methods: This cross-sectional study was based on a survey, which was distributed online and open from 29 April to 15 May 2022. The survey included questions regarding OCPs utilization patterns, side effects, health concerns and attitudes of the responders.

Results: Out of 1699 respondents, the current OCPs intake was reported by two thirds of women and 22% had a history of using them in the past. Seventy-nine percent of all OCPs users experienced adverse effects while 9% reported having concerns about safety and potential adverse effects. Decreased libido and weight gain were the most significant reasons for ceasing hormonal contraception. Moreover, the most common concerns and the most unfavorable side effects varied in different age groups. The occurrence of anxiety depended on age and education.

Conclusion: Healthcare professionals prescribing OCPs should provide their patients with comprehensive counseling. Understanding and addressing concerns of young women can improve their compliance and reduce the number of unintended pregnancies.

Keywords: Hormonal Contraception; Adverse Effects; Reproductive Behavior; Family Planning

Introduction

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Following cultural and socio-economic transformations that have started in 20th century, as well as recent trends and constantly changing pace of life, there is a fundamental need for effective family



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planning. Advances in medicine resulted in a great variety of easily accessible contraceptive measures facilitating birth control and leading to revolution in reproductive health (1). Depending on a classification, contraceptive methods can be assigned to certain groups: modern or traditional, long lasting or short lasting, reversible or irreversible and, most importantly, hormonal or non-hormonal (2-4). According to data from 2019, combined oral contraceptives (a modern, short-lasting, reversible and hormonal method) were the most popular choice among Polish women (38%), preceding even the exclusive use of condoms (24% of women). However, 33% used more than one prevention measure and only 38% continuously used the method they had originally chosen (5). That may point to a hypothesis that despite general recognition of hormonal contraception, there is a limited trust and a primarily inadequate choice of birth control option. Moreover, another study from 2019 showed that the main sources of knowledge about sex behaviors for Polish teenagers and young adults were friends and mass media (6). It may be the explanation for growing disinformation and controversies regarding the safety and side effects of oral contraceptive pills (OCPs). The occurrence of this phenomenon on a massive scale may contribute to lower satisfaction or even discontinuation of this method of contraception. At the same time, potential OCPs users should be aware of the actual adverse effects and contraindications of hormonal therapy as well as its benefits. Therefore, a comprehensive and evidence-based contraceptive counselling should be provided and physicians should be actively involved in decision-making process (7). Moreover, depending on the patient, there are different motivations for OCPs intake and health professionals are entrusted with the task of taking them into consideration when adjusting the therapy. Factors such as attitude towards contraception, belief, financial situation, sexual self-scheme, body image perception and reproductive plans also should be taken into account to ensure individual approach (8). Fear of adverse effects and concerns about health consequences are common reasons for OCPs discontinuation or rejecting the possibility to start using them in the first place. Any reliable evidence does not support the majority of those concerns and it is especially important to recognize them and address directly (9). OCPs users are a heterogeneous group and comprise women who take them for medical indications other

than birth control. Hormonal therapy is a well renowned treatment for dysmenorrhea, heavy or irregular menstrual bleeding and conditions resulting from hyperandrogenism (3).

The purpose of our research was to describe a side effect profile of OCPs and to assess the most frequent concerns and reasons for discontinuation in Polish hormonal contraception users. We aimed to determine the current state of knowledge and recognize the most pressing needs of Polish women. Additionally, this study was created to raise awareness of reproductive health and fight disinformation concerning hormonal contraception.

Materials and methods

A cross-sectional, survey-based study was designed establish the occurrence of the most common side effects, concerns, attitude and utilization patterns in Polish oral hormonal contraception users. We aimed to address and include into our study women who took or had a history of OCPs intake, excluding individuals below 15 years old. Our survey was intended for respondents whose sex was designated as female at birth. The self-administered questionnaire in Polish language was created using the survey administration software Google Forms and was shared online in eight Facebook groups dedicated to Polish women. The survey consisted of both close-and open-ended questions regarding OCPs utilization patterns, side effects, health concerns and attitude of the responder. Accuracy and validity of the questionnaire were checked with specialists in gynecology and endocrinology from the Clinical Hospital of Duchess Anna Mazowiecka in Warsaw. The data was collected from 29 April 2022 to 15 May 2022. Additionally, the questionnaire enclosed an information about the survey, stating its objectives, the way of personal data processing and ensuring anonymity and confidentiality of the participants. The completion of the survey form was synonymous with providing consent to being included in the study. The minimal sample size (calculated with G*Power Version 3.1.9.6 software) was reached and the achieved power of the test exceeded 0.95. We presented the acquired data as a percentage of female respondents indicating a given statement. To describe quantitative variables, the mean with standard deviation was used. The assessment of dependence between the qualitative variables was developed using the Pearson Chi-Square test. T-Student test or Mann-Whitney U test were used to compare

quantitative variables. Statistica™ 13.1 software was used to conduct statistical analysis. The study was prepared in accordance with the Strengthening the Reporting of Observational Studies Epidemiology (STROBE) guidelines (10), The Sex and Gender Equity in Research (SAGER) guidelines (11) and the Declaration of Helsinki (12). It was approved by Bioethics Committee affiliated to Medical University of Warsaw (ID number: AKBE/170/2021, date of approval: 4 October 2021).

All procedures performed in studies involving human participants were in accordance with the ethical standards of the Ethics Committee of Medical University of Warsaw (ID number: AKBE/170/2021, date of approval: 4 October 2021) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Results

The total survey sample consisted of 1700 respondents who completed the online questionnaire. One person was excluded from the statistical analysis due to young age (below 15), resulting in 1699 respondents eventually included in the study. The participants were then divided into 3 age groups: 15-19 years old, 20-25 years old and 26 or more years old. This division was based on the approximate age of graduating from high school (19 years) and finishing university (25 years) in Poland. Table 1 shows basic sociodemographic features of the respondents. The majority of them (58.0%) were aged between 20 and 25 years. The ages of the interviewed women ranged from 15 to 57 with the mean value of 22.7 ± 5.22 years. Nearly one-third (30.4%) of oral contraceptive pills users lived in the city with over 500 k citizens ($p > 0.05$). Approximately 70.9% of all current users were also university students ($p > 0.05$).

67.1% (1139) of women who completed the survey declared taking oral hormonal contraceptives and 22.0% (373) admitted to taking it in the past. 85.3% of the total group of 1512 participants who had any experience with OCPs used it to avoid pregnancy. The other reasons for choosing this contraceptive measure were dysmenorrhea (39.9%), irregular bleeding (29.4%) and acne (17.6%).

Adverse side effects: In total, adverse effects of OCPs were reported by 1197 out of 1512 women (79.2%). The most frequent side effects included respectively: mood swings (58.4%), decreased libido (51.1%), depressed mood (41.9%), headaches, irritability, breast enlargement and weight gain.

Prevalence and comparison of the most common complaints in different age groups are presented in Table 2. Flatulence, vaginal dryness, bleedings, feeling of heaviness and increased appetite also proved to be relevant as they were mentioned by about 25-30% of all participants. Unfavorable side effects were less common in respondents below 25 years old (above 80%) than in older women (75%).

Table 1: Demographic characteristic of responders

Variables	No. (N=1699)	%
Age		
15-19	426	25.1
20-25	985	58
≥26	288	17
Place of residence		
Countryside	335	19.7
Small village (< 50 k residents)	302	17.8
Town (50 k–100 k citizens)	165	9.7
City (100 k–500 k)	359	21.1
City (> 500 k)	538	31.7
Level of education		
Primary	108	6.4
Secondary	501	29.5
Vocational	25	1.5
Studying	726	42.7
Higher	339	20
Marital status		
Single	277	16.3
Informal relationship	1254	73.8
Married	158	9.3
Divorced	10	0.6
Number of pregnancies		
0	1511	89
1	98	5.8
2	48	2.8
3	30	1.8
>3	12	0.7
Number of deliveries		
0	1546	91
1	82	4.8
2	52	3.1
3	18	1.1
≥4	1	0.1
Currently having a sexual partner		
Yes	1462	86.1
No	237	13.9
Currently taking hormonal contraceptive pills (OCPs)		
Yes	1139	67
No	560	33

Moreover, we observed that the reported side effects might depend on the composition of taken OCPs.

Table 2: Side effects as per different age group

Adverse effect/Age group	15-19 years (N=341)	20-25 years (N=894)	26+ years (N=277)	All (N=1512)
Decreased libido	N=149 (43.70%)	N=457 (51.12%)	N=167 (60.29%)	N=773 (51.12%)
Weight gain	N=130 (38.12%)	N=321 (35.91%)	N=121 (43.68%)	N=572 (37.83%)
Mood swings	N=229 (67.16%)	N=539 (60.29%)	N=115 (41.52%)	N=883 (58.40%)
Headaches	N=152 (44.57%)	N=361 (40.38%)	N=107 (38.63%)	N=620 (41.00%)
Depressed mood	N=170 (49.85%)	N=385 (43.06%)	N=78 (28.16%)	N=633 (41.87%)
Irritability	N=157 (46.04%)	N=356 (39.82%)	N=83 (29.96%)	N=596 (39.42%)
Breast enlargement	N=182 (53.37%)	N=336 (37.58%)	N=56 (20.22%)	N=574 (37.96%)

Our study revealed that breast tenderness occurred more often among women who took combined estrogen-progesterone pills (37.5% of combined pills users), compared to those who took progesterone-only pills (28.1% of minipills users, $p=0.022$). The same correlation was discovered in case of breast enlargement, which occurred in 41.1% of all combined pills users and 21.3% of minipills users, $p<0.001$. The frequencies of the other side effects according to the type of OCPs did not prove to be statistically significant.

Given the duration of OCPs intake, side effects were observed by 82.5% of the respondents who took the pills for less than one year, 78.3% in case of 1-5 years, and 76.6% when OCPs were used for 5-10 years and 53.3% when the time exceeded 10 years. We concluded that the adverse effects were rarer in females whose time of OCPs intake was longer

($p<0.001$). This dependence may be possibly explained by the willingness to continue this method by women who initially experienced fewer side effects.

In regard to serious health conditions, deep vein thrombosis was reported by 23 participants which accounted for 1.4% of the whole study group. In two cases, it was also accompanied by pulmonary embolism.

Positive effects: Except for unfavorable side effects, positive effects were also observed by 97.1% of women. The most common positive effects reported by the respondents were: regular bleeding (74.1%), less painful bleeding (65.4%), reduction of stress related to fear of unwanted pregnancy (64.6%), less heavy bleeding (61.2%), improvement of the complexion/skin condition (43.7%) and reduction of premenstrual syndrome (PMS) (29.3%). The frequency of particular positive effects depending on the age group is showed in Table 3.

Table 3: Positive side effects as per different age group

Positive side effects	15-19 years (N=341)	20-25 years (N=894)	26+ years (N=277)	All (N=1512)
Regular bleeding	N=235 68.91%	N=682 76.29%	N=203 73.29%	N=1120 74.07%
Reduction of stress related to fear of unwanted pregnancy	N=226 66.28%	N=585 65.44%	N=165 59.57%	N=976 64.55%
Less painful bleeding	N=207 60.70%	N=619 69.24%	N=162 58.48%	N=989 65.41%
Less heavy bleeding	N=195 57.18%	N=557 62.30%	N=174 62.82%	N=927 61.21%
Improvement of the complexion/skin condition	N=156 45.75%	N=399 44.63%	N=104 37.55%	N=660 43.65%
Reduction of PMS symptoms	N=101 29.62%	N=255 28.52%	N=86 31.05%	N=443 29.30%
No positive side effects	N=12 3.52%	N=19 2.13%	N=13 4.69%	N=44 2.91%

The statistical analysis indicated that there was no significant relationship between the age of women or the duration of OCPs use and the occurrence of positive effects ($p>0.05$).

Concerns: Nine percent of respondents admitted to having concerns associated with safety and potential adverse effects of taking oral hormonal contraception. Among the general study group, the most commonly reported were respectively: fear of weight gain (reported by nearly 74% of women who had concerns), fear of hormonal disorders (66%) and fear of loss of libido (54%). The mentioned concerns slightly varied across different age groups (Table 4). Moreover, age proved to be related to the occurrence of anxiety ($p<0.05$), showing tendency to decrease with years (Figure 1).

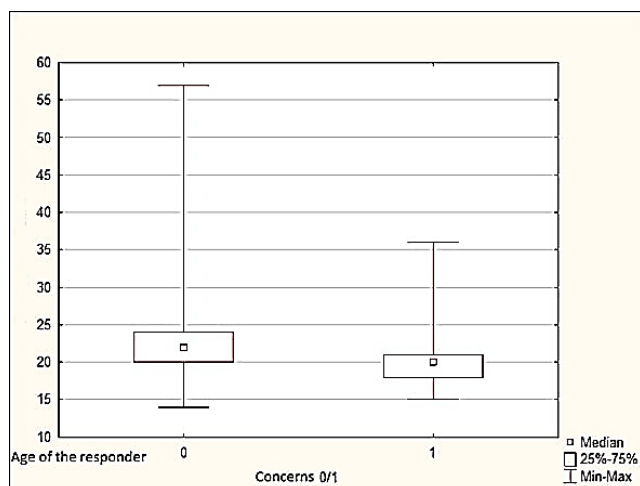


Figure 1: Boxplot showing the correlation between age and prevalence of concerns (Mann–Whitney U test, $p<0.05$)

Our study also revealed the inverse correlation between the occurrence of concerns and the level of education ($p<0.05$). Anxiety was the lowest among women with higher education (4%) and the highest in those with primary education (19%). The

relationship seems linear (Figure 2), however, it should be marked that the representation of women with vocational education accounted only for 1.5% (25) of the participants.

Discontinuation and the least accepted side effects: Out of the total number of 1699 participants, 560 (32.9%) stated that they did not take oral hormonal contraceptives at that time. However, 373 (66.6%) of them took OCPs in the past.

The main factors that led to the cessation of OCPs were unacceptable side effects (45.3%), change or willingness to change the method of contraception (18.2%), occurrence of health contraindications (10.7%), trying to get pregnant (9.4%) and loss of sexual partner (5.6%). Unacceptable side effects were the most frequent reason for resignation in all the age groups.

In 320 cases, the adverse side effects were also the motivation to seek the alternative contraceptive methods. Most usually dissatisfied women switched to condoms (44%). Vaginal rings and contraceptive patches were the second (17%) and the third (14%) most common choices. The other mentioned methods were hormonal intrauterine devices (7%), copper intrauterine devices (4%) and subdermal implants (4%).

Additionally, the questionnaire contained a question regarding the least acceptable effects (one participant could choose up to three answers). The results of the study showed that the least tolerable symptoms were psychological ones: loss of libido (30.8% of women experiencing any adverse effects), mood swings (20.7%) and depressed mood (15.1%). It should be noted that those three least acceptable side effects coincided with the most prevalent negative side effects in the general study group. Table 5 depicts the differences in the frequency of unacceptable effects between the age groups, given all the respondents who reported side effects. Conditions such as vaginal infections and inter-monthly bleeding or spotting were also occasionally reported.

Table 4: Concerns profile as per different age group

Reported concerns (N=153)	15-19 years (N=74)	20-25 years (N=70)	≥ 26 years (N=9)
Weight gain	81.1% (60)	72.9% (51)	77.8% (7)
Hormonal Disorders	70.3% (52)	67.1% (47)	66.7% (6)
Loss of libido	58.1% (43)	52.9% (37)	66.7% (6)
Fertility problems after discontinuation of oral hormonal contraception	41.9% (31)	31.4% (22)	44.4% (4)
Neoplasms	12.2% (9)	18.6% (13)	33.3% (3)
Costs	37.8% (28)	14.3% (10)	11.1% (1)

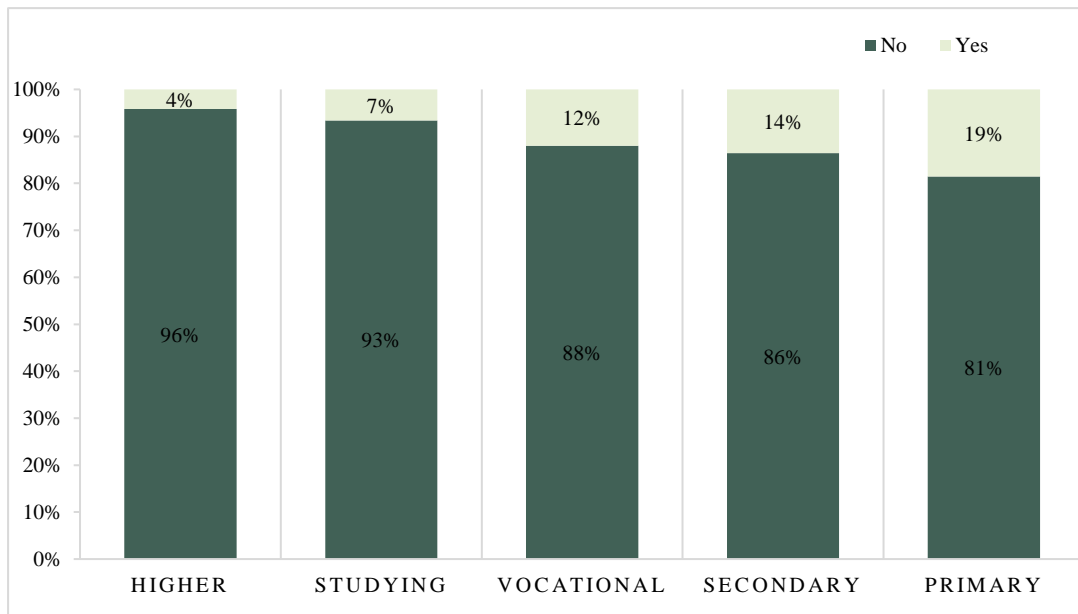


Figure 2: The rate of anxiety in women with different education levels

Discussion

According to World Family Planning 2020 Highlights by the United Nations Department of Economic and Social Affairs, between 2000 and 2020, the number of women using modern contraceptive methods increased by about 30% (from 663 million to 851 million) and an additional 70 million women are projected to be added by 2030 (13). The other source data suggest that the pill is used by over 20% of women of reproductive age in 27 countries worldwide, with the highest prevalence in European countries (14). The latest official data from Poland were collected by Statistics Poland in

2019 and revealed that 29.8% of women using any method of birth prevention chose hormonal contraception including pills (15). The research conducted in 2020 presented that the most frequently Polish females used condom as a method of contraception (63.2%), while hormonal agents were used by 34.2% of them. It is worth noting that according to the mentioned study, 30.4% of women used intermittent intercourse. Higher education, good financial situation and being a non-believer were factors associated with higher frequency of using effective methods, such as condoms or hormonal agents (16).

Table 5: The least accepted side effect as per different age group

Positive side effects	15-19 years (N=341)	20-25 years (N=894)	26+ years (N=277)	All (N=1512)
Decreased libido	N=83 24.30%	N=267 29.90%	N=116 41.90%	N=466 30.82%
Mood swings	N=89 26.10%	N=191 21.30%	N=33 11.90%	N=313 20.70%
Depressed mood	N=59 17.30%	N=145 16.20%	N=24 8.70%	N=228 15.08%
Increased appetite	N=52 15.20%	N=86 9.60%	N=26 9.40%	N=164 10.85%
Weight gain	N=37 10.90%	N=102 11.40%	N=104 37.50%	N=243 16.07%
Headaches	N=37 10.90%	N=120 13.40%	N=50 18.00%	N=207 13.69%
Vaginal infections	N=32 9.40%	N=19 2.13%	N=24 8.70%	N=75 4.96%

Due to the still increasing oral hormonal contraception utilization, resulting in constantly growing controversies, doubts and circulating myths or disinformation, our aim was to assess concerns, the most common and the most undesirable side effects among Polish females.

Data derived from research recently conducted in Poland suggest that 71.1% of Polish female respondents found oral contraceptives as one of three most effective contraceptive methods (6). Apart from this, 1700 females filled out our online survey, which indicates that there is a huge interest in this topic among the Polish. However, frequency and intensity of OCPs side effects may contribute to usage discontinuation. Our study underlines that 45.3% resignations were due to unacceptable symptoms. These results are coherent with the other analysis - problems related to physical side effects, mental health, sexuality and concerns about future fertility were in the group of the main reasons for rejecting hormonal contraception (17).

Unlike other studies, we also investigated Polish women's concerns about taking oral contraceptives. Fear of weight gain, decreased libido or hormonal disturbance (including infertility), which affected 14% of our respondents, may have serious impact on choice and continuation of that method (18). Arising from social-media disinformation, the phenomenon of "hormonophobia" may also contribute to women's fears (6). Since the Internet and doctors are the most common sources of Polish females' knowledge about contraception (5), there is a need to provide patients with accurate information about oral contraception, especially in case of adolescents and young women. Apart from complex and individualized counselling in physicians' offices, evidenced-based medicine should be widespread in social media to fight popular myths and disinformation. Activity in mass media may increase adolescents' reproductive health awareness. We believe it is especially important in case of the youngest women as our study revealed the link between young age and the most prevalent occurrence of concerns. A serious need to implement convenient solutions to improve people's knowledge about contraception was also underlined by other authors (16, 19, 20).

This is the first cross-sectional study to analyze the most common and the most disruptive side effects of using oral contraception among such a large and age-ranged population of Polish females. Our aim was to compare different experiences with using oral

contraception among different age groups, taking into account especially adolescents. We focused on a combined or one-ingredient oral contraception, not only as one of the methods of preventing unintended pregnancy, but also as a solution used in several medical conditions. This study revealed that side effects are similar among women using oral contraceptives for different reasons. The most common side effect reported by our respondents was mood liability, which differs from data arising from the other analysis, where the most frequent undesirable effect was decreased libido (16). Our results are also different from the study, where headache was the most common side effect of using oral contraception (with 40% of respondents encountered headache) (21). Additionally, our research covered younger women's experience and they were the group, which complained about mood liability more often than 26+ age group. In the 15-19-year-old group, it was also the least acceptable side effect. It should be marked that mood changes seem the most consistent in women with medical history of depressive disorders (22). All these factors should increase physicians' vigilance and result in contraception counselling based on individual risk. Moreover, other common adverse effects, like decreased libido, headaches or weight gain, require doctors' attention. Recognition of the most disruptive symptoms and detailed interview as well as adjusting dosage, administration mode and type of a drug are essential for effective collaboration between health provider and a patient. We believe that it may have an impact on women's usage pattern, effectiveness, tolerance, lower risk of rejection and general satisfaction from using particular oral hormonal contraceptives. Receiving sufficient information during medical visits also improves overall satisfaction with family planning services (23).

Basing on the participants' answers we concluded that focusing on the most annoying and prevalent side effects was more common than identifying conditions that are life-threatening but less frequent. However, the possibility of potential dangerous events, such as venous thromboembolism (VTE), should be underlined as well. Our respondents reported both deep venous thrombosis and pulmonary embolism. A great prospective controlled cohort study PRO-E2, published in 2021, compared the incidence of VTE in patients taking 17 β -estradiol (1.5 mg) and norgestrel acetate (2.5 mg) to taking ethinylestradiol and levonorgestrel agents in different

proportions. This research revealed that the incidence of VTE among the first group was 2.5 per 10,000 WY (woman-years) (95% CI: 1.3–4.3) and among the second group it was 3.7 per 10,000 WY (95% CI: 2.3–5.7). The incidence in the group taking other combined contraceptive pills amounted to 6 per 10,000 WY (95% CI: 2.0–14.1) (24). In case of our study VTE occurred in 23 of the participants, which can be assessed as a relatively high outcome. Nevertheless, in the light of the most up to date studies, the levonorgestrel-based pills are having relatively high safety profile for venous system (25). For a long time, the only type of estrogenic component in combined oral contraception was ethinyloestradiol, which has a well-documented cardiovascular risk. Different types of progestins have been used to modulate this risk. Nowadays, besides the possibility to adjust progestin type for patient's needs, also synthetic estradiol or estetrol-based formulas are available on the market. Promising research data for estetrol (a natural steroid produced by human fetal liver) suggest that it may be the safest estrogen in terms of reducing thrombosis risk and potentially breast cancer risk. These days clinicians may choose different types of products based on the properties of particular components (26).

Uniqueness of our study includes taking into account positive effects of oral contraception. Any recent publications about mentioned positive aspects are hard to find. Regular, less painful bleeding and reduction of stress related to the fear of unwanted pregnancy were the most common factors reported by our respondents that could have an impact on increased users' satisfaction. Moreover, hormonal contraceptive therapy is one of the recommended treatment options in acne vulgaris. The use of hormonal pills may result in a significant reduction of skin lesions and seborrhea (27), which was commonly reported by our respondents. These beneficial effects should be underlined in conversations with patients to provide them with a full spectrum of information and facilitate the choice of a contraception method. Although our study is focused on negative effects and concerns about oral contraceptives, our aim was to emphasize the need for finding balance between adverse effects, which could be reversible, and advantages of using that kind of method. We could find publications about oral hormonal contraception's positive impact on some particular aspects, such as cognitive functions (28), but further research is needed.

According to the WHO recommendations, physicians should offer evidence-based, comprehensive contraceptive information, education and counselling to ensure informed choice (29). Our research highlighted the growing need to improve communication with Polish patients in order to provide them with high-quality care. Leaving them alone with concerns or unacceptable adverse effects of oral contraception could lower their overall satisfaction from OCPs use. Although most side effects encountered by Polish women are not life-threatening or dangerous, daily life comfort should definitely be taken into account to adjust a convenient and proper method of contraception.

Our online survey was fully anonymous. One of the advantages of this research design was the wide access to a representative population of young Polish women, which was obtained with the use of the Internet. Apart from that, our study is at the moment the most up to date analysis of experience and attitude towards oral hormonal contraception among Polish population.

This study has several limitations including characteristics of the study group and method of online survey. Data derived from this research apply to 15-26 or more year-old Polish-speaking females using specific Facebook groups and may not refer to other populations, different in terms of sociodemographic characteristics. There is a huge disproportion in number of women in particular age groups, which can be explained by age-related tendencies in the use of social media and in the need to be a part of internet societies. Moreover, due to the survey construction, we do not know the exact numbers of years of OCPs intake by each of the participants. Potential sources of bias were tried to be minimized through ensuring anonymity, audience diversity and inclusion of closed-ended questions. Authors are aware of the risk of bias as a consequence of self-composed online form. Further research on the topic should be conducted, encompassing a wider study group with equal representation of women from different backgrounds and of different age.

Conclusion

Hormonal contraception carries the risk of multiple side effects, which may affect patient's adherence or lead to a complete resignation. Our study showed a significant correlation between the prevalence of concerns and both age and level of education, which points to a need to target certain groups and provide

them with more accurate guidance. Especially the group of the youngest women (15-19 years old) requires more time and effort spent on early explanation of their concerns and counselling by health professionals.

Conflict of Interests

Authors declare no conflict of interests.

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