Original Investigations

The efficacy, acceptability and continuation of postpartum, post-abortive progestin-only pill: a pioneering prospective multicentric study from Turkey

Dilbaz et al. Progestin-only pill in postpartum

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Abstract

Objective: The aim of this study was to evaluate the efficacy, side-effects and continuation rate of the desogestrel-progestin-only-pill (POP) in postpartum and post-abortive Turkish women its relation with breast-feeding**.**

Material and Methods: In this prospective multicentric study women who delivered (or had surgical abortion) and wanted to receive POP for contraception were recruited to the study. The follow-up visits were scheduled at 3rd, 6th and 9th months.

Results: Overall 7468 women (66.5% postpartum, 33.5% post-abortive) participated in the study. According to the previous visit, the percentage of women who came for a follow-up visit at 3rd, 6th and 9th month was 944(12.6%), 406(43%) and 121(29.8%) respectively. Out of the 7468

women recruited only 6% continued with the method at the end of the 9th month. There was a statistically significant increase in Hb level at the 3rd month when compared to the initial values. The incidence of breastfeeding at all visits was between 54.8% and 68.4%. Oligomenorrhea, spotting and headache were the three leading side-effects. There was no pregnancy among the patients who were followed up.
Conclusion: This study demonstrates that POP is an effective postpartum and post-abortive contraceptive method that has no negative impact on breast-feeding and the change in bleeding patterns is the most common side-effect. However, the possible causes of low contraceptive maintenance rates need to be investigated.
Keywords: Breast-Feeding, contraception, progestin-only pill, postpartum, postabortive

Introduction

Out of 211 million pregnancies that globaly occur each year, 87 million are unintended and 46 million of these might end in induced abortion while unintended pregnancies constitute 40% of all pregnancies in 2012 (1,2). Unintended pregnancies and shorter pregnancy intervals result in maternal and fetal morbidity and mortality besides causing social and economic burden (3-5). In various studies, short interval between pregnancies were found to be associated with increased maternal risks such as gestational diabetes, placental abruption, uterine rupture and fetal problems such as preterm delivery, low-birth wieght or small for gestational age infants (6) and thus birth-spacing is strongly advised. While World Health Organization (WHO) recommends an interpregnancy interval (time between delivery and conception of subsequent pregnancy) of 24 months, American College of Obstetricians and Gynecologists (ACOG) emphasises the importance of avoiding an interpregnancy interval less than 6 months and advising an interpregnancy interval longer than 18 months (7,8).

Postpartum contraception is a life-saving issue for women who opt to delay the subsequent pregnancy. Traditionally contraceptive service delivery is delayed until the routine postpartum 6th week visit. However, this practice is criticized as most women experience sexual activity before this initial postpartum visit and might even ovulate especially if they are not breast-feeding (9). The other problem related to postpartum 6th week visit is the low uptake as women might skip this visit due to various structural, social and economic problems (10). Although the context of the postpartum visit covers postpartum contraception in some settings, the Cochrane Review reported that two-thirds of postpartum women have unmet needs for contraception (11).

Immediate postplacental and early postpartum intrauterin device insertion is a convenient and reliable contraceptive method but expulsion rate is higher than the interval insertion and immediate postplacental intrauterine device (IUD) insertion requires a trained practitioner (12). Progestin-bearing hormonal contraceptives (PHC) are effective without any negative impact on lactogenesis, breastfeeding rates, and milk supply during the postpartum period (13). Progestin-bearing contraceptive implants can also be used during the early postpartum period but insertion and removal requires a visit to a qualified health center, similar to the intrauterine devices (14). Progestin-only contraceptive pills (POP) are safe and effective. POPs are currently under utilized although they are a good choice for almost any women but especially for postpartum and breastfeeding women and women with a higher risk of thromboembolism such as diabetic, obese and smoking women who chose to use a hormonal method (15). Postabortion contraception is an essential component of comprehensive abortion care in women who do not want to get

pregnant immediately after abortion as return of fertility is much shorter after surgical abortion and POP can be started at the time of abortion (16).

While traditional POP provides contraception through thickening of the cervical mucus and endometrial atrophy and therefore must be taken within 3 hours of the same time every day, the new generation desogestrel POP inhibits ovulation besides these effects and has a range of 12 hours delay within the same day without jeopardizing its contraceptive efficacy (17).

Desogestrel POP was licensed in 2011 in Turkey and it was procured for the first time by Ministery of Health (MOH) and distributed to the study sites for evaluation of the efficacy, acceptability and safety of this method among Turkish postabortive and early postpartum women. In this pioneering study in our country, this contraceptive drug was distributed free of charge to all postabortive / postpartum women who had consented for POP use for the first time as a part of the Ministery of Health Reprosductive Health and Woman's Health Programme.

The aim of this study was to evaluate the efficacy, side-effects and continuation of the new generation desogestrel POP initiated in the early postpartum and postabortive period and its relation with breast-feeding.

Material and Methods

This multicentric prospective study was conducted in three centers; Ministry of Health ********** Health Research and Training Hospital, Ministry of ********** Health Research and Training Hospital and ******* University Hospital Department of Obstetrics and Gynecology between March 2016 and March 2017 in Collaboration with the Ministry of Health Reproductive and Woman's Health Department after obtaning approval from the Ethics Committee (Approval Number 57536863-231.02.01). Intrauterine device, depot-medroxprogesterone injections, oral contraceptives and Desogestrel POP (Cerazette® 75 µg, Merck Sharp & Dohme Pharmaceuticals Co.Ltd.) are procurred and delivered free of charge to women by the MOH. All women who delivered vaginally or had a cesarean section or had a surgical abortion (manual vacuum aspiration) for termination of pregnancy on demand up to 10 weeks of pregnancy -which is legal in ******- were counselled for all methods of postpartum, postabortive contraception before discharge as a part of the hospitals's routine practice. Women who wanted to receive desogestrel POP (Cerazette® 75 µg, MSD) and gave a written informed consent were recruited to the study. All the women received counselling for full-breast-feeding and POP at each visit. Women started using POP immediately after abortion and 21 days postpartum. Not wanting to receive a contraceptive method or prefering another contraceptive method or having a stillbirth or having a contraindication for POP use according to WHO medical eligibility criteria and unwillingness to take part in the study were the exclusion criteria for recruitment to the study (18).

The patient's demographic characteristics and obstetric histories were recorded. They were given 3 packs of POP and the intitial follow-up was scheduled 3 months after their discharge. The follow-up visits were scheduled for 3 follow-ups, at 3rd, 6th and 9th months. The women who attended to the follow-up visits had their vital signs and weight measured and were inquired about the contraceptive method continuation, method satisfaction, side-effects and breast-feeding by filling in the questionnaire. Among them women who opted to continue the method were given another three months supply during each follow-up. The study flow-chart is shown in Figure 1. Contraceptive method continuation, method satisfaction side-effects and the incidence of full breast-feeding during each visit were recorded and analyzed.

Statistical analysis

SPSS (Statistical Package for Social Science version 21; IBM Corporation, Armonk, NY) was used for statistical analysis. Paired Samples T test was used for continous variables and the values were given as mean ± standart deviation. The categoric variables were evaluated using Pearson Chi-Square test. The statistical significance was accepted as $p<0.05$ and the confidence interval was taken as 95%.

Results

Out of the 21924 women from three centers who were counselled about contraception during the study period, 7468 women (34.1%) who met the inclusion criteria were recruited to the study. Out of 7468 women 66.5% were postpartum (n=4963), while the remaining 33.5% were postabortive. The average age of the patients was 30.03±6.76 years, the median number of pregnancies and number of children were 3 (eange: 0-18) and 2 (range: 0-10) respectively. The body mass index (BMI) was 26.8±4.7 kg/m^2, the systolic blood pressure was 110.4±11.4 mmHg and diastolic pressure was 70.9±8.8 mmHg. The average hemoglobin and hematocrit values were 12.08±1.58 g/dl and 36.58±4.65 respectively. The percentage of women with systemic disease was 4.8%, 134 (1.8%) women had hypertension, 21 (0.3%) had diabetes mellitus, 201 (2.7%) had gestational diabetes. When the contraceptive use prior to the last pregnancy was questioned 24.1% were on a modern contraceptive while 63.8% were not using a method. The demographic and medical features of the women recruited is shown in Table 1.

The percentage of women who came for a follow-up visit at 3rd, 6th and 9th month was 944 (12.6%), 406 (406/944, 43%) and 121 (121/406, 29.8%) respectively. Out of the 7468 women recruited only 6% continued with the method at the end of the 9th month (Table 2). Out of 944 women attending to the initial 3rd month visit, 37/944 wanted to discontinue, while this figure was 2/406 at 6th month and 16/121 at 9th month. The average weight at 3rd month was statistically significantly lower than the initial average weight ($p<0.001$), however there was no statistically significant difference between the 3rd, 6th and 9th month follow-up weight and sistolic and diastolic blood pressure measurements ($p>0.05$). The percentage of women who lost weight during method use was high most probably due to the expected postnatal weight loss. There was a statistically significant increase in Hb level at the 3rd month when compared to the initial (Postpartum / Post Abortion) values (12.08±1.58g/dL vs 13.19±1.07 g/dL $p<0.05$), with no significant change during the follow-up visits. The incidence of breast-feeding during the three consecutive visits were 68.4%, 54.8% ve 58.5% respectively.

Although the discontinuation was high, method satisfaction was also high among the women who continued to use the method. The main reason for method discontinuation according to the limited number of patients (n=55) who attended to the follow-up visits and answered the questionnaire was side-effects and unsatisfaction. Oligomenorrhea, spotting and headache were the three leading side-effects and the incidence of these decreased at the 9th month follow-up. Apart from the vaginal discharge the incidence of almost all the side-effects expressed by the women subsided gradually (Figure 2). None of the patients had method failure during POP use or had an adverse event. The percentage of women who resumed normal mensturation increased from 7.2% at third month to 14.9% at 9th month. Incidence of amenorrhea increased from 46.4% to 57% at 9th month, while the incidence of oligomenorrhea decreased from 43.2% to 24.8 %.

Discussion

POP prevents pregnancy through making cervical mucus impermeable to the sperm, inducing endometrial changes that interfere with implantation, inhibiting ovulation and changing tubal motility. These contraceptive actions vary according to the dose and type of the progestin involved. Desogestrel, a 3rd generation progestin that inhibits ovulation (in addition of the thickening of the cervical mucous and reduced tubal

motility) with a dosage of 75 µg when taken continously without a break unlike the older oral formulations containing Levonorgestrel and Norethisterone that are not able to supress ovulation effectively (19,20). As these pills are estrogen-free, they can be used in various conditions that are contraindicated to combined hormonal contraceptive use such as early postpartum women, lactating women, women with cardiovacular risks (obesity, smoking) thromboembolic risks (family history, thrombophilia) and specific arterial risks (valvular heart disease, past ischemic heart disease)**.** They have a limited number of contraindications, mainly being breast cancer, active liver disease, benign and malignant liver tumors. Desogestrel POPs should be taken continously. With a crude Pearl index of 0.41 its efficacy is similar to combined oral contraceptives and the incidence of ovulation inhibition is 97% when a 75 µg dose/day is used (21,22). None of the patients followed up in our study experienced pregnancy during the use of desogestrel POP.

The disturbance of menstrual bleeding patterns effects the compliance of women on progestin-only contraceptives. In natural ovulatory cycles, estrogenic effect leads to endometrial proliferation in the first phase prior to ovulation and this is followed by a secretory transition of the estrogen-primed endometrium due to the progestagenic activity (20). At the end of the menstrual cycle, mensturation is triggered by progesteron withdrawal. In women on progestin-only contraceptives, breakthrough bleeding is thought to arise from the fragile vascular structures adjacent to the uterine lumen that have lost their integrity and the change in angiogenic factors (23,24). In a double-blind, randomized, multicenter trial comparing desogestrel-POP with levonorgestrel-POP a higher incidence of amenorrhea and infrequent bleeding was encountered in the desogestrel-POP group but there was also a higher incidence of lessened bleeding in time in this group (22). In a study comparing Desogestrel-POP with Drospirenone-POP, women on Desogestrel-POP experienced a higher proportion of different bleeding pattern such as amenorrhea, infrequent bleeding, frequent bleeding and prolonged bleeding however, from cycle 2 to 9 subjects who had no bleeding or spotting increased from 26.0 to 54.7% in the Desogestrel group (25). In our study group the women who were amenorrheic increased as the duration of Desogestrel POP use increased. Zigler & McNicholas pointed out that the high incidence of discontinuation with the method might be related to the high incidence of unscheduled bleeding that occurs in 20% of the women using progestin only contraceptive methods although method satisfaction is high (26). In our study group, the women who came for an initial follow-up visit and stated that they were satisfied with the method is relatively high, the number coming for a second and third follow-up for continuation of the method decreased and this can be speculated to be related with the change in bleeding patterns.

There are few studies on the metabolic effects of desogestrel-POPs. In a systemic review and meta-analysis conducted by Glisic et al, POPs were found to demonstrate no effect on blood pressure and moreover oral progestin-only contraceptives did not increase the risk of developing cardiometabolic syndrome unlike the injectable progestin-only contraceptives (27). In our series there was no statistically significant change in the blood pressure measurements at the 3rd, 6th and 9th month follow-ups.

The most frequent side effects related to progestagens are acne, mild hirsutism, depressive mood, sexual pain, and weight gain (20). Vaginitis is also one of the side-effects reported by a colloborative study (22). In our patient group, none of the women complained of acne, hirsutism, depressive mood changes. Vaginal discharge was also one of the side-effects reported by the women in the study and the incidence did not change in the follow-up visits. The studies on the effect of POPs on sexuality is very scarce. In a double-blind placebo-controlled study the effect of combined oral contraceptives on well-being and sexuality was compared with women on progestin-only pill and no advers effect of POP was

found on sexuality while some improvement in well-being was noted (28). In our study the incidence of loss of libido was 9.4 % but decreased to 4.1% at 9th month. In a study from Germany, 403 women who experienced estrogen-related symptoms during combined oral contraceptive use and 403 women with dysmenorrhea received 5 µg/d Desogestrel POP and remarkable resolution or improvement of the estrogen–related symtoms mainly nausea, breast-tenderness, estrogen-related head-ache and oedema was noted in 70%of the women (29). However, in the presented study group 13.1% of the women experienced head-ache while this incidence decreased to 4.1% at 9 th month follow-up. Merki-Feld et al reported improvement in migraine frequency, migraine intensity and use of pain medication for migraine in women on Desogestrel 75 µg/d POP (30). This finding was supported by the meta-analysis conducted by Warhurst et al (31). None of the women in the presented group was diagnosed as having migraine nor were recieving any treatment for migraine.

POP is a good choice for lactating patients like the other progestin-only contraceptive methods. In a Cochrane review, analysis of published trials comparing combined oral contraceptives with POPs showed no difference in duration of breast-feeding, milk volume or composition (32). Goulding et al reported that the women using POPs were most likely to breast-feed when compared to using combined hormonal contraceptives even at 9th month (33). In our patient group the incidence of breast-feeding did not change among the group who continued with the contraceptive method.

In our study, we found the follow-up rate at the first visit (third month) to be 12.6%. This high loss rate is the most important limitation of our study. As this is a hospital-based study women's transportation to the hospital besides the difficulties in obtaining a suitable appointment from the hospital for a breast-feeding mother are obstacles that might cause the lower follow-up rate. In the second phase of the project in order to improve the service delivery for the women, the reproductive health service providers working at the primary health care facilities were trained by the Ministry of Health Reproductive Health and Woman's Health Division and the POPs were made available for use in the primary health services.

Conclusion

Progestin-only contraceptives are safe, effective methods of contraception and can be used by most of the women as the contraindications for their use are very few. Progestin-only intrauterine systems and implants are long-acting contraceptive methods but their cost and the need for medical services for initiation and discontinuation is a burden for some women. New generation progestin-only pills are very effective due to their inhibitory effect on ovulation, however the awareness of the availability and advantages of this is method is still low. The menstrual changes related to progestin-only contraceptive methods might lead to higher incidence of discontinuation so the counselling sessions need to be improved by emphasising the possibility of this side-effect in detail. This sudy also demonstrated that progestin-only pills could be a good choice for breast-feeding women.

According to the latest ***** Demographic Health Survey (TDHS 2018) (34), out of the 70% of currently married women using a method of contraception 49% are using a modern method. The unmet need for family planning among currently married women has reached to 12%. Percentage of women using the pill is 5% and has not changed since 2013. The Desogestrel-POP use at the end of the 9th month is still higher than the over all pill use reported by the TDHS 2018. Increasing awareness about POP will provide women a choice especially if they have contrindications for combined hormonal contraceptives and are breast-feeding.

Ethics committee approval: This study was carried out with the permission of the Ministry of Health, Reproductive and Women's Health Department (57536863-231.02.01).
Informed Consent: Written consent was obtained from all participants.
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Conflict of Interest: The all authors declare that there is no conflict of interests regarding the publication of this paper.
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Table 1. The demographic and medical features of the patient group		
n=7468		
Name of the center n (%)	ADYU	2798 (37,5)
	EZH	2425 (32,5)
	ZTB	2245 (30,0)
Age (Mean ± SD)		30,03±6,76
Age distribution n (%)	<19 years	155 (2,1)

	20-34 years	5737 (76,8)
	35-39 years	1000 (13,4)
	>40 years	576 (7,7)
Method use prior to the last pregnancy n (%)	No	4763 (63,8)
	CI	905 (12,1)
	Condom	553 (7,4)
	COC	319 (4,3)
	IUD	837 (11,2)
	Injection*	59 (0,8)
	POP	32 (0,4)
Height (cm) (Mean ± SD)		161,1±6,1
Weight (kg) (Mean ± SD)		69,5±12,5
BMI (Mean ± SD)		26,8±4,7
SBP (mmHg) (Mean ± SD)		110,4±11,4
DBP (mmHg) (Mean ± SD)		70,9±8,8
Hemoglobin (Mean ± SD)		12,08±1,58
Hematocrit (Mean ± SD)		36,58±4,65
Number of vaginal birth (Median, Range)		1 (0-10)
Number of cesarean sections (Median (min-Max))		1 (0-6)
Gravidy (Median, Range)		3 (0-13)
Parity (Median, Range)		2 (0-18)
Number of living children (Median, Range)		2 (0-10)
Number of abortions (Median, Range)		0 (0-11)
Number of voluntary termination of pregnancies (Median, Range)		0 (0-7)
Ectopic pregnancy (Median, Range)		0 (0-3)
Disease history n (%)	Hypertension	134 (1,8)
	Diabetes mellitus	21 (0,3)
	Gestational diabetes mellitus	201 (2,7)
SD: Standart deviation, ADYU: Adiyaman University Research and Training Hospital, EZH: Etlik Zubede Hanım Women's Health Research and Training Hospital, ZTB: Zekai Tahir Burak Women's Health Research and Training Hospital, CI: Coitus interruptus, COC:		

combined oral contraceptive, IUD: Intrauterine device, POP: Progestin-only contraceptive pills, SBP: Systolic blood pressure, DBP: Diastolic blood pressure, BMI: Body mass index. *: All injection types (Progesterone Injections, Depot injections and DMPA)

Table 2. Findings of Desogestrel Progestin-only pill users at the 3rd, 6th and 9th month follow-ups

		3rd Month	**6th Month**	**9th Month**
		n=944	**n=406**	**n=121**
Weight Kg (Mean±SD)		67.83±12.47$^{\beta}$	67.55±12.89	68.61±13.55
Systolic Blood pressure mmHg (Mean±SD)		112.53±10.89	113.54±10.59	112.89±12.68
Diastolic Blood Pressure mmHg (Mean±SD)		71.35±8.19	72.43±8.08	70.23±8.39
Hemoglobin g/dl (Mean±SD)		13.19±1.07*****	13.31±1.40$^{\Omega}$	13.28±1.23
Cycle charactheristics n (%)	Amenorrhea	438 (46.4)	185 (45.6)	69 (57.0)
	Oligomenorrhea	408 (43.2)	164 (40.4)	30 (24.8)
	Normal mensturation	68 (7.2)	42 (10.4)	18 (14.9)
	Menorrhagia	30 (3.2)	15 (3.7)	4 (3.3)
Breast-feeding n (%)		511 (68.4)	172 (54.8)	48 (58.5)

Method satisfaction n (%)	Very satissfied	248 (26.3)	84 (20.7)	27 (22.3)
	Satisfied	677 (71.7)	313 (77.1)	84 (69.4)
	Not satisfied	19 (2.0)	9 (2.2)	10 (8.3)
Reason for method discontinuation n (%)	Side-effects	10 (1.1)	1 (0.3)	4 (3.3)
	Not happy with the method	14 (1.5)	1 (0.3)	7 (5.8)
	Forgets taking pills	8 (0.9)	0 (0.0)	1 (0.8)
	Friends, -neighbours do not approve of the method	5 (0.5)	0 (0.0)	0 (0.0)
	Wants to get pregnant	0 (0.0)	0 (0.0)	4 (3.3)
Side-effects n (%)	Mastodynia	73 (7.7)	28 (6.9)	3 (2.0)
	Head-ache	124 (13.1)	57 (14.0)	5 (4.1)
	Oligomenorrhea	408 (43.2)	164 (40.4)	30 (24.8)
	Spotting	253 (26.8)	135 (33.3)	23 (19.0)
	Menorrhage	30 (3.2)	15 (3.7)	4 (3.3)
	Vaginal discharge	75 (7.9)	35 (8.6)	13 (1.7)
	Loss of libido	89 (9.4)	43 (10.6)	5 (4.1)
	Difficulty in swallowing the pill	4 (0.4)	0 (0.0)	0 (0.0)
	Nausea	4 (0.4)	2 (0.5)	0 (0.0)
	Dizziness	3 (0.3)	1 (0.3)	0 (0.0)
	Hirsutism	1 (0.1)	0 (0.0)	0 (0.0)
	Itching, and rash	1 (0.1)	0 (0.0)	0 (0.0)
	Pelvic pain	3 (0.3)	0 (0.0)	0 (0.0)
Weight change n (%)	Weight lossn	481 (50.9)	263 (6.8)	84 (69.4)
	Weight gain	463 (49.1)	143 (35.2)	37 (30.6)

$^{\beta}$ the **average** weight at 3rd month was statistically significantly lower when compared to the initial avarage weight ($p<0,001$). * There is a statistically significant increase compared to the first hemoglobin ($p<0,001$). $^{\Omega}$ 6th month Hb value was higher than the 3rd month ($p=0,008$).

Women who received postpartum/ post abortive contraception training between 10.03.2016 - 27.03.2017

Adiyaman University RTH
4344 vaginal birth
3396 cesarean section
486 abortion

Etlik Zubede Hanım Women's Health RTH
2745 vaginal birth
2452 cesarean section
1987 abortion

Zekai Tahir Burak Women's Health RTH
3219 vaginal birth
2155 cesarean section
1140 abortion

2798 women
- 1318 vaginal birth
- 1087 cesarean section
- 393 abortion

2425 women
- 462 vaginal birth
- 313 cesarean section
- 1650 abortion

2245 women
- 717 vaginal birth
- 1067 cesarean section
- 461 abortion

Excluded women
14393 women refused to use POP.
63 women were in the risky group.
2 Undiagnosed genital mass
2 Malignancy
1 Stroke
45 Migraine with aura
4 Previous myocardial infarction
1 Previous DVT / PE
2 Liver cancer
2 Breast cancer
2 Antiepileptic drug use
1 APLS
1 SLE

7468 women were included in the study.
(4964 postpartum, 2504 post-abortive)

3rd month follow-up — 944 women (747 Postpartum, 197 post-abortive) — 6524 women did not come for control.

6th month follow-up — 406 women (314 Postpartum, 92 post-abortive) — 538 women did not come for control.

9th month follow-up — 121 women (82 Postpartum, 39 post-abortive) — 285 women did not come for control.

Figure 1. Study flow-chart
RTH: Research and Training Hospital, POP: Progestin-only contraceptive pills, DVT: deep vein thrombosis, PE: Pulmonary embolism, APLS: antiphospholipid antibody syndrome, SLE: systemic lupus erythematosus

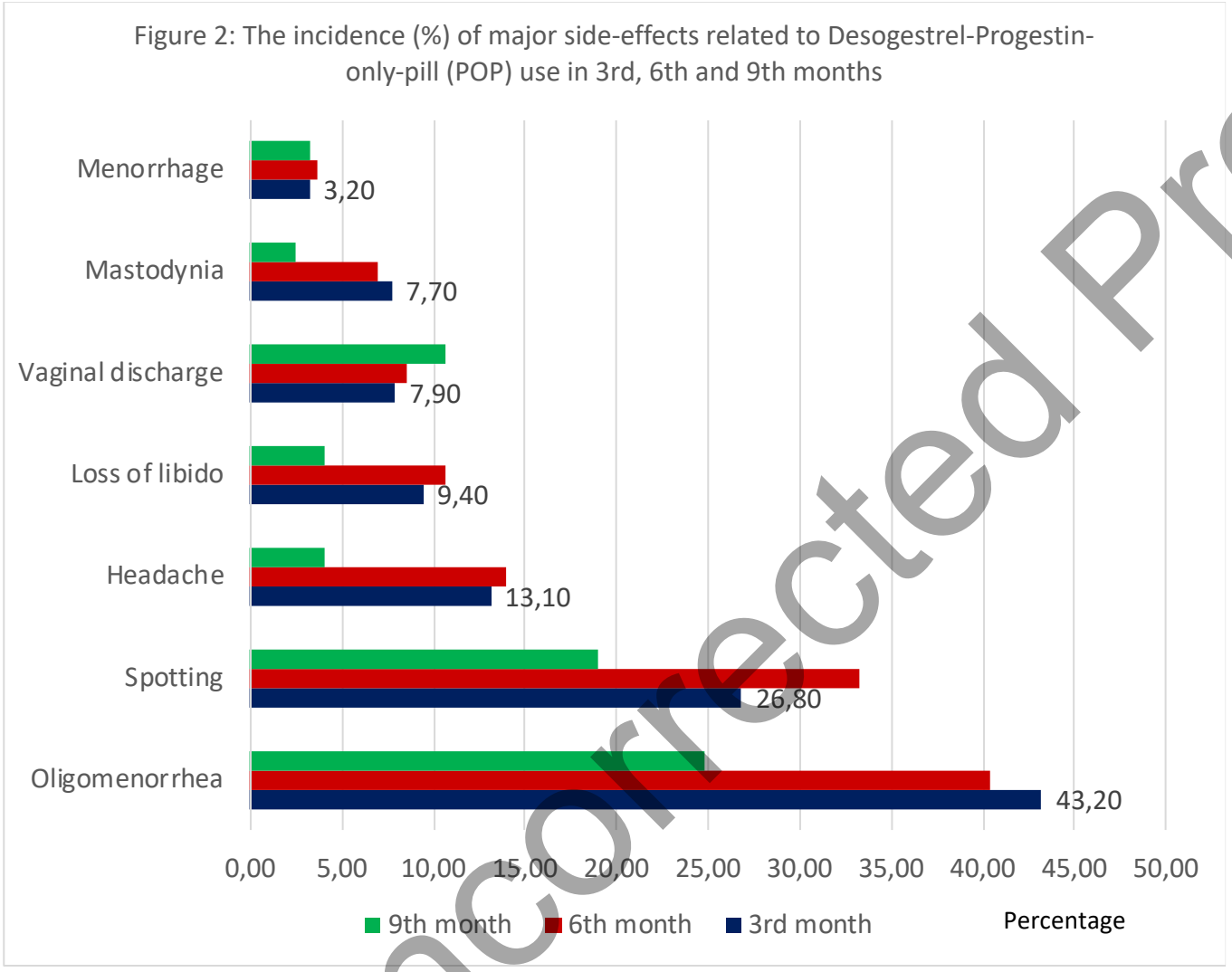

Figure 2. The incidence of major side-effects related to Desogestrel-Progestin-only-pill use in 3rd, 6th and 9th months