The progestin-only oral contraceptive – its place in postpartum contraception

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Abstract

The progestin-only oral contraceptive (POC) is not a widely-used method of contraception, possibly due to competition from other contemporary contraceptive methods or misunderstanding and prejudices among clients and/or service providers. Because of its underuse, the POC, as a contraceptive method, is under-studied.

This article evaluates the general merits of the POC and its disadvantages relative to combined oral contraceptives (COCs) and other contraceptive methods, specifically during the postpartum period and particularly for breastfeeding women. We find that the POC appears to be a safe and acceptable contraceptive method for postpartum women who are fully or nearly fully breastfeeding at six months postpartum or when menstruation returns. The POC could be considered for use at any time by non-breastfeeding postpartum women. The need for empirical studies of the POC is also discussed.

Introduction

A short birth interval (e.g. less than two years) imposes harmful effects on both the mother and the infant, especially for those in less-developed countries (LDCs) [1]. Besides providing important nutrients to infants, lactation is known to have an important contraceptive effect by prolonging birth intervals, as well as by enhancing the contraceptive effect of other contraceptive methods used after delivery [2].

In LDCs, 30-40% of the women of reproductive age are estimated to be breastfeeding at any one time [3]. Since the progestin-only oral contraceptive (POC), or the minipill, has no known adverse effects on lactation or on infant development [4], it should have a special place as a contraceptive modality during the postpartum period. Nevertheless, it is a much underused contraceptive method.

This article evaluates the merits and disadvantages of the POC, compared with combined oral contraceptives (COCs) and other current contraceptive methods, and it gives special attention to the postpartum period. It is hoped that an understanding of the POC's attributes will maximize its use-effectiveness, minimize its risks both to mothers and to their infants, and position it appropriately in the spectrum of currently available contraceptive methods.

Advantages of the POC

Unlike combined OCs, POCs contain no estrogen; thus, they can be used by women who prefer oral contraception but have contraindications to estrogen, such as thromboembolic disposition, hypertension, and diabetes. Because of their reduced association with cardiovascular side-effects, POCs may be more appropriate for women who smoke or women who are age 35 or older. The amount of progestin in POCs is also reduced compared with COCs. Thus, POCs are associated with a lower incidence of side-effects such as nausea, vomiting, headache, high blood pressure, and breast tenderness [4–6]. Non-menstrual side-effects are also reported to occur less frequently during POC use than during the cycles preceding treatment [4]. The return of fertility in previous POC users may be more rapid than in those taking the COC [7] but somewhat slower than in women discontinuing the diaphragm [5].

Perhaps the most important advantage is that the POC does not adversely affect lactation; therefore, it is frequently recommended for postpartum use. Numerous studies have shown that the quantity and quality of breast milk or the length of lactation are not affected by POC use [8–12]. Among the 35 studies reviewed by Howie and McNeilly [13], all except one have shown that POCs have either no effect or a beneficial effect on lactation. In contrast, 21 of 28 studies reported some adverse effects of COCs on lactation [3]. Recent comparative studies similarly reported that women who initiated POCs within a week after delivery had either no association or a positive association with breast milk production [14,15].

A Bangladesh study showed that early postpartum use of a COC may, paradoxically, increase a woman's risk of pregnancy rather than decreasing it, as intended. This risk arises because COC use leads to reduced milk production, which is followed by the mother prematurely discontinuing COC use [16]. The somewhat lower contraceptive efficacy of the POC, compared with that of the COC, can be offset in breastfeeding women whose fecundity is reduced during the postpartum period [9,17].

While most of the commonly used nonsteroidal contraceptive methods also do not interfere with lactation, the POC's primary advantages over them are as follows: it is more effective than withdrawal or the rhythm method; it does not interfere with spontaneity in intercourse (hence compliance should be better) when compared with barrier methods and spermicides; it requires no surgical training or equipment in delivering the method and thus has no risk of uterine perforation, cervical laceration and/or other insertion-related problems when compared with the IUDs (which may also have high expulsion rates when they are inserted within six weeks after delivery); and it is easily reversible when compared with male and female sterilization [17,18].

Disadvantages of the POC

Most service providers are of the opinion that for the POC to be as effective as the COC, preferably it should be taken at the same time each day. Its efficacy is also more likely to be adversely affected by diarrhea and/or vomiting, because of reduced absorption, or by interaction with antibiotics and antituberculosis drugs [7].

Reported use-effectiveness of the POC differs widely among studies. A World Health Organization (WHO) multicenter study of a 0.03 mg levonorgestrel minipill [19] reported a pregnancy rate of 4.9 per 100 woman-years in one center, and 16.0 in another. Graham and Fraser cited in their review paper [7] various studies of different formulations with pregnancy rates ranging from 0.9 to 4.0; these rates are comparable to most other reversible methods, except the COCs. Vessey *et al.* [6] reported a low overall pregnancy rate of 0.9 per 100 woman-years with 3303 woman-years of observation from the prospective Oxford Family Planning Association Contraceptive Study in England. The pregnancy rates per 100 woman-years reported in this study were 3.1 pregnancies in women aged 25–29 years and 0.3 pregnancies at age 40 or more. This strong negative trend in the pregnancy rate with age is consistent with results reported from other studies [5] and suggests that older women in particular can use the method with confidence [3]. None of the above studies specifically reported women's breastfeeding status at admission or during follow-up.

Even lower pregnancy rates have been reported from centers with good counseling systems. Postlethwaite [20] reported a Pearl Index (PI) of 0.52 per 100 woman-years for 127 women using Femulen (0.5 mg of ethynodiol diacetate), a rate close to the reported failure rates for COCs. Bisset *et al.* [21] reported a PI of 1.01 for all ages (and a PI of 0.43, when adjusted for patient failure) among 1042 cases using POCs (among them, 11% were lactators). He suggests that the POC is a much more effective contraceptive method than it is generally thought to be. Broome and Fotherby [22] reported a PI of 0.2 per 100 woman-years in 358 nonlactating women followed for 150 months. POCs in the studies by Bisset and by Broome and Fotherby are those currently in use in the United Kingdom: Femulen, Micronor, or Microval/Neogest.

The POC is probably also less effective in preventing accidental pregnancies than other progestogen-releasing contraceptives such as Norplant, Depo-Provera, the Progestasert IUD, and the levonorgestrel-releasing IUD - all of which have the advantage of being long-acting and not requiring the strict compliance that the POC does. Norplant has not been studied in women earlier than four weeks postpartum. However, in studies in Chile [23], Egypt [24] and Indonesia [25] comparing Norplant and IUD use among acceptors inserted with the devices between 4 and 6 weeks postpartum, there were no differences in infant growth patterns, maternal weight or breastmilk production between the two groups. Some of these methods are not as easily reversible as the POC, however. The progestogen-releasing vaginal ring has the advantage that reversibility is under the woman's own control, as is the case with the POC, but the ring's efficacy and continuation rates are probably comparable to, if not lower than, those of the POC. The pregnancy rate in the WHO international study on the vaginal ring releasing 20 μ g levonorgestrel per day has been reported to be 3.7 per 100 woman-years of use; the one-year discontinuation rate, including loss to follow-up, was 50% [26].

POC users also appear to have a higher risk than COC users for an accidental pregnancy to be ectopic. While the percentage of ectopic pregnancies among pregnancies in US women using no contraceptive method is estimated to be between 0.3 and 3.0%, about 2.8 to 4.1% in every 100 pregnancies occurring in POC users are

ectopic – a proportion nearly as high as that for IUD users (4.3%) [7]. The explanations offered for this increased ectopic pregnancy risk among POC users, according to Fotherby [5], are that progestogens are less effective in preventing ectopic pregnancies than intrauterine pregnancies and that progestogenic changes in tubal motility, secretions and cilia may decrease the rate of transport of the blastocyst down the fallopian tube. Fotherby has pointed out, however, that a generally increased incidence of ectopic pregnancies has occurred during the past decade. It should be made clear that the chances of conceiving an ectopic pregnancy per woman (rather than per pregnancies occurring in women) using POCs remain less than those of a woman who uses no contraception and therefore faces a far greater risk of pregnancy [4].

Also, because of the low progestin dose and absence of estrogen in POCs, a much higher incidence of intermenstrual bleeding or spotting (20-30%) occurs among users [3] compared with women who use COCs [27] which generally tend to regulate menstruation. In POC users, duration (either longer or shorter) and volume of menstrual flow (increase or decrease) may change, and the length of cycles may vary widely. Breakthrough bleeding or amenorrhea may be more common. These menstrual problems are usually responsible for the lower continuation rates associated with POC use [6,28]. On the other hand, bleeding irregularities that may accompany POC use may cause less concern in postpartum women than in women at other stages [11]. Hatcher *et al.* [29] warned about the risk of abnormal bleeding in POC users, which in some instances may delay the diagnosis of a significant uterine pathology, such as hyperplasia, if this bleeding is incorrectly attributed to the use of POCs.

The low prevalence of POC use

In 1983, only 2.5% of English women of reproductive age were using the POC [6]. According to Graham and Fraser [7], the POC accounts for just 4% of the total oral contraceptive market in Australia, whereas in the USA the corresponding figure is 0.2%. Worldwide, only several hundred thousand women use the POC out of approximately 50 million oral contraceptive users.

The above-mentioned disadvantages – including a generally deemed lower efficacy, the required stringent compliance regimen, and the adverse menstrual pattern changes – all tend to lower POC acceptability among women as well as among the providers. Administrative and logistical reasons that may hinder widespread use of POCs include the manufacturers' lack of active promotional efforts due to fear that POCs will compete with their own COCs, reluctance of LDCs to include POCs in their family planning programs, and the resultant hesitation of international donors to distribute them [3]. Some programs have been warning women not to use 'the pill' while breastfeeding. Program administrators, especially those in LDCs, may perceive the difficulties of making women understand that another kind of pill is available that has no adverse effect on breastfeeding, and can be used at that time. According to *Population Reports* [11], the US Agency for International Development has joined other donor agencies in offering the POCs in its assistance program. The US Food and Drug Administration labeling, which continues to list any oral hormonal contraceptive as being contraindicated for lactating women, may also cause concern to providers and potential POC users [17]. To our knowledge, this is also the licensing situation in Australia.

Programmatic considerations for postpartum POC use

Compared with COCs, the POC is an understudied method of contraception. Most previous studies were descriptive in nature, and randomized comparative studies have been rare. The life-table method has been used infrequently to examine the complaints, complications, and events that lead to POC discontinuation. Mills' criticism [30] is well-taken that most of the recommendations for POC use are based on scientific theory rather than on data derived from clinical trials. Several practical issues warrant empirical studies and are listed below.

1. Safety

Studies have suggested that POC use causes few changes in most hematological factors, and that the metabolic effects of POCs are likely to be safer than COCs [3]. Vessey *et al.* [6] reported only two POC users receiving hospital treatment for venous thromboembolism during 3303 woman-years of observation. Fotherby [31] also remarked on the absence of cardiovascular disease in his POC trials. No evidence links POC with cancer of the breast, cervix, or endometrium [7].

POC users have a higher incidence of functional ovarian cysts, as do users of other progestogen-releasing contraceptive methods. These cysts invariably spontaneously resolve after POC discontinuation, according to Tayob *et al.* [32] and Fraser [17]; they pointed out the importance of not subjecting these women to unnecessary surgical intervention.

Because of the life-threatening nature of ectopic pregnancy, service providers should increase their index of suspicion when a POC user shows signs of pregnancy.

Exposure to high-dose progestins early in pregnancy could have teratogenic effects and may occasionally cause congenital defects, such as masculinization of female infants [33]. Although no cases of congenital abnormalities have been reported and no adverse effects on the health or growth has been demonstrated in babies born to mothers who were taking POCs at the time of conception [4], caution is required to avoid POC use during pregnancy.

Transmission of the steroid to the infants through breastfeeding is also of concern, but studies have shown that only a very small fraction (0.1%) of the maternal POC dose is transmitted in the milk and absorbed by the infants. Also, studies showed that the health and growth of these infants were not affected [34,35].

The issues of the long-term risks and benefits of POC use on mothers and infants

could be answered with more confidence with prospective epidemiologic studies. In the case of functional ovarian cysts, a follow-up study beyond POC discontinuation is needed to confirm the asserted transitory nature of these cysts. However, unlike the COC, the low POC use in women, in general, renders such studies much more expensive and less feasible.

2. Timing in initiating POC use and changing to other contraceptives

Theoretically, initiating contraceptive use during the postpartum period should be based on the estimated time of the return to ovulation. This timing, however, differs among women and depends on a number of factors, including the woman's breastfeeding and menstrual status; it is difficult to predict on an individual basis.

Recent findings suggest that for a woman who is fully or almost fully breastfeeding, lactational amenorrhea is an effective contraceptive during the first six months postpartum [36-40]. Short *et al.* further showed in their prospective study that the lactational amenorrhea method can also give good protection for women who continue to breastfeed up to 12 months postpartum [38]. However, all the women (n=101) in their study resumed normal ovulation while still breastfeeding. This finding led investigators to conclude that once menstruation returned, other forms of contraception were essential to prevent pregnancy.

Jellife and Jellife [41] proposed that contraceptive methods are needed on a community basis no later than about two months prior to the usual time of return of menses. For nonlactating women, ovulation generally resumes about four to six weeks after delivery; Gray *et al.* [37] suggest that, for these women, contraception should be initiated three to four weeks postpartum.

Regarding POC use in particular, as a general principle, it is safest not to expose infants to the hormone in the first three or four months of development [11]. Initiation of POC use immediately or within seven days after childbirth has been suggested on the grounds that (a) it would not enhance the risk of thrombosis, (b) return of ovulation may precede return of menses, and (c) women may not return for subsequent follow-up visits, and hence may become pregnant early in the postpartum period [42]. Wilson *et al.* [43] suggested that POC use be initiated three to four weeks after delivery to avoid the increased risk of puerperal breakthrough bleeding and any possible undesirable effect on the very young infant being breastfed.

The International Planned Parenthood Federation (IPPF) argues against using any hormonal methods earlier than six weeks postpartum on similar grounds [44]. Laukaran [45] advocated administering hormonal contraceptives no earlier than three months postpartum, deeming that this schedule will reduce the risk to infants without affecting the risk of pregnancy. These variations in timing suggested for initiating postpartum POC use reflect the complexity of predicting incipient ovulation. Considering POC's somewhat lower efficacy relative to COCs, the strict requirement of compliance, and adverse menstrual pattern changes, there are likely to be a number of postpartum POC users who might switch to COCs or other contraceptive methods when their breastfeeding status changes and/or menses resumes. Unfortunately, the literature gives few guidelines on the desirable time for switching, and the guidelines are usually vague and confusing. However, women who want an oral contraceptive but have contraindications for COC use (e.g. older women, women who smoke, and/or women who are hypertensive, diabetic, or with thromboembolic predisposition, etc.) can be encouraged to continue to use the POC.

3. Compliance and use-effectiveness

The importance of compliance in oral contraceptive use has been emphasized by Potter and Williams-Deane [46]. To a great extent, the differences in reported use-effectiveness among POC studies, as described above, probably reflect differences in compliance. Service providers and researchers generally recommend a stricter compliance regimen for POC use than for COC use, and warn that even slight negligence could lead to an increased risk of accidental pregnancy [5]. Other researchers [3,27], however, criticize this as being unnecessarily stringent, and think that this may actually make POCs less acceptable to consumers or that some consumers may use POCs, ignoring some of the guidelines. This advice, according to Howie [3], is based on the assumption that the contraceptive effect of the POC is mainly to render the cervical mucus hostile to sperm penetration; however, the POC's effects on ovarian function may also play an important role. Compliance may be especially problematic in postpartum women who are aware of their reduced fecundity.

Empirical studies are thus warranted to examine whether occasional irregularity of POC use is indeed a risk factor for accidental pregnancy for users, taking into account the three major and easily observable factors in predicting pregnancy risks during the postpartum period: the woman's breastfeeding status, menstrual status, and the length of interval after delivery [2]. An epidemiological case-control study may be a feasible, less time consuming, and less expensive approach to ascertain whether such a relationship exists and to delineate the risk factors affecting active patient compliance. The study should be designed carefully, to avoid selective recall bias and put the related events in correct temporal sequence.

4. Reasons for discontinuation and effects of client counseling on improving compliance

POC discontinuation is high. According to a *Population Report* [4], fewer than 50% of POC users are still using it a year later. Rosman [47] presented a similarly high one-year POC discontinuation rate of 51.6% (including those lost to follow-up) in a pooled dataset of 4088 postpartum women from 22 centers in 14 countries. Menstrual irregularities (e.g. intermenstrual bleeding or spotting, or amenorrhea) are reported to be the side-effects most often responsible for POC discontinuation [5,6,22,28]. A study by West in Scotland [48] on lactating women using the POC, however, revealed that, at six months postpartum, the primary reason for discontinuation was cessation

of breastfeeding (42%), and only 9% of the cases discontinued POC use because of side-effects, including irregular bleeding. Canto *et al.* [12] reported similar findings in Mexican women who were lactating at the time of study admission.

Different needs of women in the studies with regard to their menstrual and lactational status at admission and at follow-up were probably the reasons for these seemingly conflicting findings. Discontinuation of POC use because of amenorrhea, for instance, may be due to a rational suspicion of an unwanted pregnancy. Cessation of lactation, on the other hand, diminishes the POC's main advantage over other contraceptive methods; namely, it does not affect lactation. In both situations, the woman may want to switch to a contraceptive method that is deemed more effective. Service providers also need to be careful to differentiate amenorrhea caused by POC use and amenorrhea that may be due to pregnancy because of POC failure, especially if and when breastfeeding is stopped.

According to Graham and Fraser [7], the frequency of breakthrough bleeding is greatest among POC users in the first three or four months of use. When adequate counseling was given, however, the discontinuation rates of POC use due to this reason at the end of 13 months were not significantly different from those of COC users. Whether this was due to the woman's cycles acclimating to POC use or due to a selection process that those women who experienced irregular and frequent bleeding were more likely to withdraw from the trial, as suggested by Foss and Fotherby [49], or both, needs to be studied.

5. Baseline studies

Issues that are also warranted for study of POC use include those issues related to important baseline information such as studies (a) on the understanding of the POC's mechanism of action; (b) suggesting ways to minimize dual coverage provided by lactational amenorrhea and contraception; (c) evaluating the demographic effectiveness of postpartum contraception using the POC; (d) measuring POC demand and supply in regions where more women are breastfeeding, and/or breastfeed for longer intervals; and (e) evaluating women's attitudes toward menstrual pattern changes, especially amenorrhea.

Conclusions

The POC is a contraceptive option for use at any time by postpartum women who are not breastfeeding. Additionally, the POC appears to be a safe and acceptable contraceptive method for postpartum women who are breastfeeding. Howie [3] urged that POCs be readily available to mothers in LDCs, as 30-40% of women of reproductive age in these countries are breastfeeding at any given time. Adequate counseling, based on empirical findings and local, cultural, and traditional practices, should help to increase user acceptability and decrease the relatively high rates of discontinuation that are often associated with POC use. However, contraceptive counseling should not be focused on only one contraceptive method, especially during the postpartum period when a woman's fecundity changes with her breastfeeding and menstrual status, and with time elapsed since delivery. As Kennedy has commented: "The health care provider who is assisting the lactating mother should be thoroughly familiar with how lactation, fertility, sexuality, and contraception are intertwined threads in the cord of life's experience in order to best serve the breastfeeding family" [50]. Thus, each woman's total contraceptive needs should be addressed, and recommendations should be based on considering a spectrum of available contraception options.

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Resumé

La méthode de contraception par les produits ne contenant que de la progestine (POC) administrés par voie orale n'est pas largement utilisée, sans doute en raison de la concurrence que lui font d'autres méthodes modernes ou à cause de malentendus, voire de préjugés, de la part des clientes et/ou de ceux qui offrent ce service. Etant peu utilisé en tant que méthode contraceptive, le POC est aussi moins étudié.

L'article présenté évalue les mérites généraux de ces produits et leurs inconvénients en les comparant à des contraceptifs oraux combinés (COC) et à d'autres méthodes de contraception, et cela spécifiquement durant la période du post-partum et plus particulièrement chez les femmes qui allaitent. On a constaté que les POC semblent constituer une méthode de contraception sûre et acceptable après le post-partum chez les femmes qui allaitent entièrement, ou presque, six mois après l'accouchement ou lorsque la menstruation reprend. On pourrait envisager l'utilisation des POC à n'importe quel moment après l'accouchement chez les femmes qui n'allaitent pas. L'article examine également la nécessité de conduire des études empiriques sur les POC.

Resumen

El método anticonceptivo oral con productos que contienen sólo progesterona (POC) no se utiliza en gran medida, sin duda debido a la competencia de otros métodos modernos o a causa de malentendidos y prejuicios de parte de las clientas y/o de los proveedores de este servicio. Debido a su escaso uso, el POC ha sido poco estudiado.

Este artículo evalúa los méritos generales del POC y sus inconvenientes en comparación con los anticonceptivos orales combinados (COC) y otros métodos anticonceptivos, específicamente durante el período de posparto y, en particular, en las mujeres que amamantan. Se ha determinado que el POC parece constituir un método anticonceptivo seguro y aceptable en el posparto para las mujeres que amamantan exclusivamente, o casi exclusivamente, seis meses después del parto o cuando se reanuda la menstruación. Se podría considerar el uso del POC en cualquier momento después del parto entre las mujeres que no amamantan. Este artículo examina asimismo la necesidad de realizar estudios empíricos relativos al POC.