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Review article

What some women want? On-demand oral contraception ★,★★★,★

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Abstract

Objective: To summarize evidence regarding current demand for on-demand oral contraception.

Study design: We used Medline and collegial contacts to find published and unpublished studies conducted or reported in the past 15 years with information assessing women's interest in using any oral drug preparation, including emergency contraceptive pills, in a coitus-dependent manner either repeatedly or as a primary or planned pregnancy prevention method.

Results: We found 19 studies with relevant information. The studies were conducted in 16 countries. Eight studies provided data on women's attitudes regarding a coitus-dependent oral contraceptive; all suggested substantial interest in using it. Nine studies assessed actual use of oral tablets on demand for primary contraception. In these studies, 9–97% of women in the analysis populations reported using the pills on demand as main method, although frequency and consistency of use varied. Reported reasons for interest in or use of this contraceptive approach included convenience, ease of remembering, ability to conceal use, lack of coital interruption, and infrequent sexual activity. Three studies were clinical trials of investigational on-demand oral contraceptives which reported Pearl indices ranging from 6.8 to 53 pregnancies per 100 woman-years.

Conclusion: Data from a variety of settings suggest that demand for an on-demand oral contraceptive may be widespread. The effectiveness of this potential method is not established, however. Considering the seriousness of the unmet need for contraception, further development research into the public health benefits and risks of such a method would be worthwhile.

Implications: Demand for an on-demand oral contraceptive may be widespread. Efforts should be made to further explore the possibility of developing such a method.

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1. Introduction

Decades ago, an oral contraceptive product containing 4 or 10 tablets of levonorgestrel 0.75 mg was commercially marketed in several countries in Eastern Europe and Asia.

This product differed from current oral contraceptives in that women were instructed to take the pills only "on demand"—that is, only when they had sex, shortly before and/or after the act—rather than daily. Ten clinical trials of the regimen that together included more than 2600 women who used the pills over a period of 1–16 months found a combined pregnancy rate of 5.1 pregnancies per 100 woman-years, approximately comparable to the rates observed among typical users of other coitus-dependent contraceptives such as condoms and diaphragms [1]. No serious adverse effects occurred in the trials, although bleeding irregularities, nausea, and other symptoms associated with progestin-based contraceptives were not uncommon. Despite the side effects, participants in the trials generally liked the method and used it continuously for more than 6 months on average. The product reportedly sold quite well for at least 10 years [2].

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Nevertheless, marketing of this product was discontinued during the 1990s, in part because of concerns about overuse [2] and also because of the conviction that women should use more effective methods with fewer side effects [3]. The manufacturer introduced a new product that contained only two tablets per package and that was explicitly indicated for emergency treatment after unplanned contraceptive mishaps or failure to use contraception during sex. Levonorgestrel-based emergency contraceptive pills (ECPs) are now widely available worldwide.

However, recent studies suggest that the original concept of on-demand oral contraception as an ongoing family planning approach continues to have appeal, at least to some women in some settings. This information is of interest to researchers working on the development of new contraceptive methods and may also be relevant to clinicians and program managers needing to advise women about frequent use of ECPs. In this paper, we summarize evidence regarding current demand for on-demand (also called “pericoital”) oral contraception.

2. Materials and methods

We aimed to find published and unpublished studies conducted or reported in the past 15 years (since 1998) with information assessing women's interest in using any oral drug preparation, including ECPs, in a coitus-dependent manner either repeatedly or as a primary or planned pregnancy prevention method. To locate these reports, we performed multiple PubMed searches including the following terms either alone or in various combinations: *on-demand*, *pericoital*, *postcoital*, *visiting pill*, *repeat*, *contraception*, *oral*, *emergency contraception*, *levonorgestrel* and *mifepristone*. We supplemented these searches by reviewing reference lists of the papers identified in primary searches and by consulting with experts working on issues related to emergency contraception. We used our judgment to determine whether each report included pertinent information.

3. Results

We found 19 studies that met the above criteria. All of these were either previously known to us through our work on emergency contraception over many years or were identified through contacts with colleagues. Despite our best creative efforts, our Medline search strategies did not find additional information about this method, which is yet nonexistent and has no standard name. The studies were conducted in a total of 16 countries. We grouped the 19 studies into three categories.

3.1. Studies that assessed women's attitudes about an on-demand oral contraceptive

Eight of the studies provided direct data on women's attitudes about routine coitus-dependent oral contraceptive

use (Table 1). In three of these studies, researchers described a hypothetical on-demand oral contraceptive pill to convenience samples of subjects drawn from clinics, schools and the community, and they ascertained subjects' thoughts about it. Two of the studies were surveys conducted in the United States [4] and Kenya and Nigeria [5], and the third was a set of focus groups and in-depth interviews with women and men in Uganda and India [6]. The descriptions of the imaginary pill included basic instructions for on-demand use. The United States and Uganda/India studies provided further detail: that the pill would be intermediate in efficacy between condoms and daily oral contraceptive pills, that it probably would cause irregular bleeding and that it would not protect against sexually transmitted infections.

All 3 studies found favorable reactions to the on-demand pill. In the United States, Kenya and Nigeria, 58%, 48% and 40% of women, respectively, said that they were interested in using it [4,7]. In Kenya and Nigeria, 39% and 37%, respectively, indicated that they were likely to adopt the pill as their primary contraceptive method, and among women who had ever previously used ECPs, these figures were even higher: 66% and 79%, respectively. Interest was associated with various subject characteristics: Black race, difficulty obtaining prescription contraceptives, recent unprotected sex, recent abortion in the United States, and higher education, prior ECP use and prior use of other short-acting family planning methods in Kenya and Nigeria. In each of these African countries, more than 20% of women who had never used modern contraceptives said that they would be likely to adopt the imaginary pill as a main method (D. Chin-Quee, personal communication). The study in Uganda and India did not provide quantitative results but reported that women were generally enthusiastic, especially younger unmarried women [6].

Across all three studies, perceived advantages of the hypothetical method included ease of remembering, applicability for women who have infrequent sex, requirement to use only when needed, potential for use before or after sex and female control. Women in Uganda also highlighted the possibility of taking the pill without their partners' knowledge. In the United States, India and Uganda, some respondents cited superior efficacy to condoms. Some women in each study noted concerns about the method, including insufficient efficacy, fear of forgetting and side effects. Mechanism of action was not specifically cited as an issue by women in any of the studies.

A fourth study asked abortion clients at six clinics in the United States about the importance of 18 features of contraceptives, such as effectiveness, side effects, ease of use, control and effect on enjoyment of sex [8]. The authors concluded that an on-demand oral pill would have at least 64% of the features considered by the women to be extremely important. This method would thus have more highly desirable features than almost any other currently available method, including daily oral contraceptives (60%), intrauterine devices (56%), injectables and implants (51%)

Table 1

Studies with information on women's interest in using an on-demand oral contraceptive

Lead author	Location, year of data collection	Population	n	Study design
Foster [4]	9 states, United States, 2011	Women in abortion and family planning clinics	1616	Self-administered questionnaire
Chin-Quee [5]	Nairobi, Kenya and Lagos, Nigeria, 2011	Women in busy shopping areas	6165	Interviewer-administered questionnaire
Cover [6]	Kampala, Uganda and Lucknow, India, 2012	Women and men sampled through communities and clinics.	241 women, 40 men	Focus groups and in-depth interviews
Lessard [8]	6 states, United States, 2010	Female clients at six large abortion clinics	574	Self-administered questionnaire
Arowojolu [9]	Lagos, Ogun and Oyo states, Nigeria, 1997	Female students at 7 post-secondary schools	1072	Self-administered questionnaire
Ezebialu [10]	Nigeria, 2009	Survey of female university students	675	Interviewer-administered questionnaire
Neustadt [11]	Chicago, United States, 2006	EC users recruited by advertisements	30	In-depth interviews
Teixeira [12]	Senegal, Burkina-Faso and Ghana, 2005–2007	Personal acquaintances of interviewers	149 women, 77 men	In-depth interviews

or condoms (42%). If it could be obtained over the counter, the on-demand pill was judged to be a perfect or good match for 27% of women, more than any available method except the vaginal ring.

Four additional studies questioned women about their knowledge and attitudes regarding currently available contraceptives. Two were surveys of Nigerian university students. One found that 37% would like to or planned to use ECPs in the future (presumably not only for emergencies) because they perceived ECPs as more convenient, safer and/or more effective than regular methods [9]. In the other, 59% of respondents felt that emergency contraception should be

used routinely after every sexual intercourse as long as the woman does not want to be pregnant [10]. A qualitative study interviewed 30 prior ECP users in the United States. Respondents who reported infrequent intercourse felt that ECPs were a preferred method of contraception. For these women, a postcoital contraceptive may be a “first-line contraceptive strategy” rather than a backup method [11]. Finally, a qualitative study in three countries in West Africa found that routine planned postcoital contraception is a familiar concept and is commonly practiced using traditional substances or ECPs [12]. Along with the previously mentioned advantages, respondents in that study expressed

Table 2

Studies with information on use of post-coital oral hormones as primary contraceptive

Lead author	Location, year of data collection	Population	n	Use of tablets as primary on-demand contraception
Lerkiatbundit [13]	Hadyai, Thailand, 1999	Women in shopping malls or purchasing EC who had previously used EC at least once	100	97% used ECPs as a prospective planned contraceptive
Addo [14]	Kumasi, Ghana, 2005	Sexually active female university students	225	8.8% used ECPs as main contraceptive method
Keesbury [15]	5 towns in Kenya, 2007	Women purchasing ECPs in pharmacies	147	48% used ECPs every time or most times they had sex in past 6 months
L'Engle [16]	Accra, Ghana, 2008	Women purchasing ECPs in pharmacies	24	“Almost all” considered ECPs to be main contraceptive method
Chin-Quee [17]	Accra Ghana, 2008	Women purchasing ECPs in pharmacies	232	35% were using ECPs as main contraceptive method
Chin-Quee [5]	Lagos, Nigeria and Nairobi, Kenya, 2011	Women in shopping areas	Women who had ever used ECPs: 526 in Nigeria, 547 in Kenya,	41% in Nigeria and 15% in Kenya considered ECPs to be main contraceptive method
Morgan [18]	5–6 cities in Nigeria and Kenya, 2010–2011	Sexually experienced women in representative households	Weighted 12,487 Nigeria, 7785 Kenya; women who had used EC in past year 300 Nigeria, 420 Kenya	Of those who used ECPs in past year, 38% in Nigeria and 12% in Kenya considered it to be their main method.
Gold [19]	Ethiopia, 2011	Young women purchasing ECPs in pharmacies	46	“Many” used ECPs repeatedly, including at every sex act or as main contraceptive method

a fear of using hormones continuously over a long time period and felt that intermittent use of contraceptives represented freedom and autonomy.

3.2. Studies that quantified actual on-demand use of oral tablets for primary contraception

We identified eight studies, including one of those mentioned above [5], that included quantitative data on women's reported use of marketed hormonal tablets either as a primary contraceptive or at most or all coital acts (Table 2). One was conducted in Thailand [13], and 7 were conducted in Africa [5,14–19]. The sample sizes ranged from 24 to more than 1000 women. Only one of the studies used a population-based sampling frame [18]; of the others, one intercepted a convenience sample of women in shopping areas [5], one surveyed university students [14] and the rest surveyed women who were purchasing ECPs. The Thai study was performed only 2 years after the previously mentioned commercially marketed on-demand oral contraceptive product had been taken off the market. In six of the studies, the hormone tablets used were ECPs, but in two studies, both conducted in Ghana, some women reported using other drugs, particularly norethindrone tablets that were officially labeled for treatment of irregular menses and other gynecologic disorders but not for contraception [14,16].

In the eight studies, the reported proportion of the analysis population who were using the hormone tablets on demand as a primary contraceptive ranged from 9% to 97%. The lowest figure came from a study that included women who had never used ECPs; [14] the other studies that all excluded such women from the analysis population not surprisingly reported higher prevalence of the practice. As we explained in an earlier publication [20], studies that enroll women who are actively purchasing ECPs should be expected to oversample frequent users and thus will tend to overestimate the use of ECPs as a primary method. However, the two most recent studies, which were also the largest, were deliberately designed to prevent this bias by recruiting women in venues other than ECP outlets. Both found that in Nigeria, quite high proportions of prior ECP users — 41% in one study [7] and 38% in the other [18] — were using the pills as their main contraceptive method.

The frequency and consistency with which the admitted on-demand oral contraceptive users actually took the tablets varied among studies. In the Thai study, in which almost all subjects were using ECPs as a primary method, 39% took them more than once a week [13]. In one study in Kenya, 48% of the total population purchasing ECPs claimed to use these pills most or all the times they had sex, and even more — 58% — had used them at least once previously in that same month [15]. In contrast, in a study in Nigeria, although more than 66% of recent ECP users had sex at least once a week and 41% considered ECPs to be their main method, at least half the population used the tablets four or fewer times

in the prior 6 months. Similarly, a study in Ghana found that many women using ECPs as a main method used them very inconsistently: among those who reported sex twice a week or more, 77% purchased ECPs at most six times in the prior year [17].

None of the reports provide data on characteristics of the subgroup of women who claimed to be using the ECPs or hormone tablets in an on-demand fashion. In Thailand, where nearly the entire study population was in that subgroup, the women were demographically diverse: ages spanned from younger than 20 years to older than 35 years, 59% had education beyond high school and 53% were neither married nor cohabiting [13].

Several of the studies reported the reasons that women chose to use the pills in an on-demand manner as their primary contraceptive. These included convenience, ease of remembering, ability to conceal use from male partner, lack of coital interruption and infrequent sexual activity [13,15,16]. In some studies, women reported side effects such as menstrual cycle disturbances, nausea and dizziness and were aware of contraceptive failures, but they apparently did not find these problems excessively troublesome [13,16]. In one study, most subjects had no experience with other contraceptive methods and were manifestly ignorant about their benefits and risks; they also overestimated the efficacy of ECPs compared to other methods [16]. In comparison, in the Thai study, most women had used at least one other modern method [13]. One study reported use of the on-demand pills in conjunction with other methods, including condoms, periodic abstinence, withdrawal and traditional herbs [17].

A ninth study, conducted in family planning clinics in Utah in the United States, found that 7% of 1038 women purchasing ECPs reported having used the pills six or more times in the prior year [21]. The authors speculated that some of these “extensive users” may have been using ECPs as “more than Plan B” (i.e., not just for emergencies). However, the study did not investigate use of the pills as an explicit main contraceptive method. The extensive users were not statistically different demographically from occasional users, but they were more likely to have had multiple sexual partners currently and in the past and also to have used alcohol or illicit drugs at their last sex act. They were also more likely than other women to overestimate ECP efficacy.

3.3. Clinical trials of efficacy and safety of an on-demand oral contraceptive

Three clinical trials met criteria for this review. Two were designed to assess the efficacy and safety of an investigational product consisting of 0.75-mg tablets of levonorgestrel taken around the time of each sex act. The first study, conducted by the World Health Organization in the 1990s, enrolled 295 women at six sites in China, Pakistan, Slovenia, Cuba and Russia. Over all sites combined, the Pearl index was 6.8 pregnancies per 100 woman-years [95% confidence

interval (CI)=3.1–12.9] [3]. The second trial was conducted in 2010–2011 in the United States and Brazil [22]. Only 72 of the planned 300 subjects were enrolled before the trial was terminated in part because of slow recruitment. Whether the problem was aversion to the method itself or some other factor related to the trial was undetermined. The primary analysis showed a Pearl index of 22.4 pregnancies per 100 woman-years (95% CI=4.6–65.4). No serious adverse events occurred in either study. In the earlier study, 66% of participants expressed favorable opinions of the method. In the later study, 81% stated that they would be interested in using the method in the future if it were found to be effective.

The third trial included 23 women who were asked to take mifepristone 10 mg as soon as possible after each intercourse act but no more often than every 5 days. In 68 months of follow-up, the Pearl index was 53 pregnancies per 100 woman-years. Women had difficulty implementing the 5-day limit, and 2 of the 3 pregnancies occurred in women who were noncompliant with the instructions [23].

4. Discussion

Data from 19 studies conducted in 16 countries suggest that demand for an on-demand oral contraceptive may be widespread. Across these studies, not only did substantial proportions of women like or support the concept in theory, but some were actually using it, having created the method for themselves with available products. In two large surveys [5,18], a sizeable proportion of women (at least 38% in Nigeria and 12% in Kenya) who had recently or ever taken ECPs considered the pills to be their primary contraceptive method. This behavior seems particularly noteworthy since currently in those countries and throughout the world, ECPs are promoted and explicitly labeled for emergency use only.

Women's cited reasons for interest in this approach to family planning were consistent across the disparate study settings. For some women, particularly those who have infrequent sex, an on-demand pill seemed intuitive: since they incur the risk of pregnancy only intermittently, they should not need to take pills every day. The link between pill ingestion and the sex act was felt to aid in compliance, a notorious problem with daily pills [24]. Women also appreciated the ability to use the method after sex and without the cooperation or even the knowledge of their partners. Concealing contraceptive use from men is one strategy recommended for women in relationships affected by violent or nonviolent forms of reproductive coercion [25].

Although these data are intriguing, we advise caution in using them to anticipate the potential public health impact of an on-demand oral contraceptive. Many of the 19 studies surveyed women who had previously used ECPs or were about to do so; in most of the world, such women are a small minority of the general population. The women in these studies may have had greater interest in the on-demand method than the general public, who may be better informed

about other contraceptive options. These data obviously thus are not generalizable to the full spectrum of women in need of contraception. In addition, most studies were conducted in developing country settings where knowledge and availability of standard contraceptives may be relatively limited and where misunderstandings about both ECPs and other contraceptives abound. Indeed, a 28-month demonstration project in Lothian, Scotland apparently found essentially no routine use of ECPs among nearly 18,000 women who received five free packages of the drug [26]. Clinical trials conducted in the United States in which women had free and easy access to ECPs also found low incidence of repeated use [27,28].

Furthermore, the studies reviewed here do not address potential problems that might arise among women who did adopt on-demand oral contraceptives. Substitution for other contraceptives might limit the benefit of the new method in reducing unintended pregnancy rates, and if the on-demand pills replaced condoms, risk of sexually transmitted infections might increase. Some reassurance on this point was provided by the findings of one study conducted in Nigeria and Kenya suggesting that a substantial proportion of women who had never used contraception would consider using a hypothetical on-demand oral contraceptive, whereas interest was relatively low among users of highly effective contraceptives [5]. However, data from actual use trials would be valuable. Another concern is the difficulty of recognizing pregnancy due to method failure given that bleeding disturbances, including amenorrhea, are an expected side effect of the method. New approaches to manage this and other service delivery issues would need to be developed as part of the introduction of the new method.

Finally, the effectiveness of on-demand oral contraception used over a prolonged interval has not been established. In theory, even a moderately efficacious method could be quite effective in actual use if women like and use it more consistently than they would available alternatives. Trials of levonorgestrel conducted many years ago had promising results and convincingly demonstrated the safety of repeated use of levonorgestrel in doses as high as 1 mg [1]. However, the only recent trial of tablets containing levonorgestrel 0.75 mg, although small, found a pregnancy rate higher than most currently recommended contraceptive methods [22]. Until more definitive data are obtained, the routine use of ECPs as a prospective strategy for ongoing contraception is not recommended.

Nevertheless, the available evidence of demand for on-demand oral contraception has sparked interest on the part of pharmaceutical companies and nonprofit organizations in developing a marketable product. The process would be challenging. This method would likely not meet typical regulatory expectations regarding the efficacy of systemic hormonal contraceptives. Furthermore, it would undoubtedly raise objections: in a recent study in Uganda and India, although some health providers and key opinion leaders recognized that the potential method would fill a

demonstrated need, others expressed concern that the method would cause excess side effects, encourage promiscuity and deter use of more effective contraceptives and condoms [29]. But given the magnitude and seriousness of the unmet need for contraception, especially in high-risk populations such as those where many of the 19 studies were conducted, and the hope that this method could fill an obvious gap in the current array of methods, making some effort to meet those challenges would be worthwhile. Certainly as ECPs are now readily available in many countries without prescription, research is needed to clarify for women the risks and possible benefits of using them repeatedly for routine pregnancy prevention [30].

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