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MINI-PILL IN LACTATING WOMEN

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Abstract

A non-comparative study of the progestogen-only oral contraceptive, norgestrel 0.075 mg, in breast-feeding women was conducted at the Centro de Investigaciones Regionales, Merida, Yucatan, Mexico. The study was designed to evaluate the overall acceptability and contraceptive efficacy of norgestrel in breast-feeding women. This report includes a survey of 200 women, all of whom were less than 26 weeks postpartum at admission; 113 were interval patients and 87 were postpartum. Follow-up visits were scheduled at 2, 6 and 12 months after admission. Overall, women experienced an increase in intermenstrual bleeding, amenorrhea, vaginal discharge and breast discomfort. The discontinuation rate at 12 months was 32.5 and the corresponding lost to follow-up rate was 22.5; this is a measure of acceptability. The 12-month life-table rate for pregnancy was 3.4 with a standard error of 2.0. Three women discontinued use of the mini-pill due to accidental pregnancy. One pregnancy was attributed to user failure and the woman conceived 9 months after entering into the study; the other two were attributed to method failure, one woman conceived 3 months after admission and the other conceived 6 months after admission.

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Introduction

Although breast-feeding provides a certain amount of contraceptive protection, it is not completely effective, mainly due to the fact there is no way of foretelling after delivery when the first ovulation and postpartum menses will occur. During the first 8 weeks after delivery, it is highly recommended to use more effective contraceptive methods to prevent pregnancy (1-7). In Yucatan, Mexico, it is often observed that women of lower economic status breast-feed for longer periods and, because of the greater amount of information available about contraceptive methods, they are more frequently requesting other family planning methods, preferably of the oral type. Since several studies have shown that breast-feeding can be affected with the use of combined contraceptives, even those which have minimal amounts of estrogen, the mini-pill containing only progestogen seems to be the alternative for these breast-feeding women (7-12). However, after 20 years since the introduction of the mini-pill for use as a contraceptive, it has not been widely accepted at the individual level nor at the national level in family planning programs. At this point, the mini-pill is only considered for use as a supplementary method. Likewise, there are only a few researchers who give value to the effectiveness and acceptability of this type of contraceptive, mainly during breast-feeding. Due to the above-mentioned facts, it was decided to conduct this study.

Material and Methods

In this study a total of 200 women were admitted for evaluation from May 1984 to March 1985 within the family planning program at the Centro de Investigaciones Regionales "Dr. Hideyo Noguchi". All of these women had a follow-up of 12 months postpartum as part of the study.

Of the 200 women included in the analysis, 113 women were interval patients (>42 days since last pregnancy termination, but <26 weeks postpartum) and 87 were <42 days postpartum. All women were breast-feeding on admission to the study.

To be included in this program certain requirements were needed: healthy with no contraindications for the use of oral contraceptives, such as high blood pressure, heart disease, diabetes, undiagnosed abnormal genital bleeding or history of ectopic pregnancy (due to the increased risk of irregular bleeding and possible ectopic pregnancy); to be currently breast-feeding (with or without supplementation); to have been recruited within 6 months or 26 weeks of delivery and to be 18 years of age or older.

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Upon admission a medical history was recorded and a complete medical examination was performed with priority on liver palpation, breast examination and Papanicolaou smear test for cytological examination.

The oral contraceptive administered in this study was provided in 28-day packs of 28 active steroid tablets, each containing 0.075 mg of norgestrel (Ovrette).

Follow-up visits were scheduled at 2, 6 and 12 months after admission to the study.

Data from this study were recorded on standard forms by the clinical staff and sent to Family Health International (F.H.I.) for processing and analysis.

Method of Analysis: Treatment performance was measured using life-table procedures. (The cumulative life-table discontinuation rates were calculated using the Tietze-Potter method (13)).

Results

Sociodemographic characteristics and contraceptive practice

Selected patient characteristics are presented in Table I. Women admitted to the study had an average age of 26.1 years, the education level was 3.7 years, and the total live births was 3.5, which is similar with the figures already reported (14). Table I also presents a summary of the contraceptive practices of the women studied 1 month prior to their last conception.

At admission, 138 women (69%) reported minor physical complaints (Table II). The most frequently reported complaints were headache by 93 women (46.5%), vaginal discharge by 44 women (22%) and dizziness by 34 women (17%).

Side effects

None of the women reported any serious complications during the study period. For the statistical analysis we considered 182 patients who had more than one follow-up visit during the time of the study (Tables III and IV).

None of the women reported intermenstrual bleeding upon admission. At follow-up visits, 96 women (52.7%) continued without complaints of intermenstrual bleeding, 70 women (38.5%) reported staining and spotting, 14 women (7.7%) reported moderate and 2 women (1.1%) reported severe intermenstrual bleeding. One woman reported amenorrhea upon admission but did not report the problem during her follow-up visits. Ninety women (49.5%) reported amenorrhea later

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TABLE I. SELECTED SOCIODEMOGRAPHIC CHARACTERISTICS

Characteristic	No.	%
	(n=200)	
Age (yr)		
Less than 20	40	20.0
20-24	57	28.5
25-29	55	27.5
30-34	29	14.5
35+	19	9.5
Mean		26.1
Education (yr)		
None	35	17.5
1-6	142	71.0
7-12	23	11.5
Mean		3.7
Total live births		
1	22	11.0
2	46	23.0
3	44	22.0
4	43	21.5
5	15	7.5
6+	30	15.0
Mean		3.5
Contraceptive method used in month prior to last conception		
None	77	38.5
Oral	53	26.5
Injectables	34	17.0
IUD	23	11.5
Withdrawal/Rhythm	10	5.0
Condom	3	1.5

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TABLE II. COMPLAINTS AT ADMISSION

Complaint	No. (n=200)	%
Nausea	9	4.5
Vomiting	4	2.0
Headache	93	46.5
Dizziness	34	17.0
Vaginal discharge	44	22.0
Breast discomfort	9	4.5
Total women with 1+ complaints	138	69.0

Multiple symptoms may be reported per woman.

in their follow-up visits. A summary of complaints reported at all follow-up visits is shown in Table III.

Discontinuation rates and reasons

A summary of several reasons for not continuing the study is presented in Table IV. One-hundred-and-eight women (59.3%) did not continue the study. The reasons for discontinuation given in most cases were personal reasons, and the desire for a change in method was the primary one. Three women (1.6%) discontinued the study due to accidental pregnancy. One case was attributed to user failure because the woman forgot 3 pills and conceived after 9 months in the study. The researcher attributed the other two pregnancies to method failure because the patients reported they did not miss any pills; one woman conceived 3 months after admission, and the other conceived 6 months after entering the study. The 12-month life-table rate for pregnancy was 3.4 with a

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TABLE III. COMPLAINTS SINCE ADMISSION

Complaint	No. (n=182) *	%
Nausea		
None	167	91.8
Sometimes	12	6.6
Often	3	1.6
Vomiting		
None	170	93.4
Sometimes	10	5.5
Often	2	1.1
Headache		
None	101	56.5
Sometimes	75	41.2
Often	6	3.3
Dizziness		
None	152	83.5
Sometimes	28	15.4
Often	2	1.1
Vaginal discharge		
None	119	65.4
Sometimes	61	33.5
Often	2	1.1
Breast discomfort		
None	142	78.0
Sometimes	39	21.5
Often	1	0.5
Total women with 1+ complaints	130	71.4

Multiple symptoms may be reported per woman.
*Number of women followed up

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TABLE IV. PRIMARY REASONS FOR DISCONTINUATION

Reason	No.
(n=182)*	
Accidental pregnancy	
Method failure	2
User failure	1
Menstrual problems	
Spotting	1
Bleeding	16
Amenorrhea	1
Polymenorrhea	2
Side effects	
Nausea	1
Vomiting	5
Other medical	
Fever	1
Allergy, rash	1
Diminished milk	7
Planned pregnancy	2
Other personal	
Fear of method	2
Forgetfulness	4
Desire change	48
Not needed	4
Troublesome	1
Religious reason	1
Dislike taking pills	1
Method unrelated	7
Total women who discontinued	108

*No. of women followed up

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standard error of 2.0. Gross cumulative life-table continuation and event rates are presented in Table V. The 12-month continuation rate was 32.5 with a corresponding lost to follow-up rate of 22.5. The 12-month total discontinuation rate (including those lost to follow-up) was 76.5 (Table Vi).

Discussion

The pill based on progestogen-only (mini-pill) seems to be the ideal oral method for women in the breast-feeding period since until now the information published shows that it does not interfere with breast-feeding. Even in the case when there is transfer of hormones to the child through the mother's blood, it has not been reported to affect the child's health or growing process (11). However, its use has not been widely accepted, among other reasons, because of changes in menstrual bleeding and its lesser effectiveness when compared with other oral contraceptives of the combination types (10, 15-18). At the same time it is known that the irregularities in the menstrual patterns are one of the main reasons why women abandon this method. It has been found that between 20% to 30% of mini-pill users show irregular bleeding or spotting, and two-thirds of the women who use this type of contraceptive have shown menstrual irregularities in at least one instance (10,16,17).

In our study we found a frequency of intermenstrual bleeding that is apparently higher than the figures reported in earlier studies. Although there was a large discrepancy due to the lack of standardization in the previous studies conducted, including the different types and dosages of progestogen used, with the special case of the mini-pill of 0.075 mg norgestrel, the figures published of women who experienced intermenstrual bleeding fluctuate between 21% and 28.5%. With respect to amenorrhea, since we know that it can be found with variable frequency when using the progestogen-based contraceptives, we chose in our study not to count the frequency since there are some doubts about the method of obtaining these data and their accuracy. However, we should give some consideration to those women with menstrual irregularities which apparently did not reflect in our follow-up rates since, of the 108 women who did not continue the method, only 20 (18.5%) showed menstrual problems as the primary reason for discontinuance. Likewise, contrary to studies published previously, a higher rate of complaints was found after 6 months (Table IV). This trend can be explained by the fact that the study was conducted on breast-feeding women who had physiological amenorrhea and had not re-established their ovarian cycle.

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TABLE V. GROSS CUMULATIVE LIFE-TABLE RATES

Event	Rate \pm S.E. (n=200)
Pregnancy	
2-month	0.0 \pm 0.0
6-month	0.9 \pm 0.9
12-month	3.4 \pm 2.0
Menstrual problems	
2-month	3.4 \pm 1.4
6-month	11.5 \pm 2.6
12-month	13.4 \pm 2.8
Side effects	
2-month	3.2 \pm 1.3
6-month	3.2 \pm 1.3
12-month	3.2 \pm 1.3
Other medical reasons	
2-month	0.0 \pm 0.0
6-month	5.2 \pm 1.9
12-month	8.0 \pm 2.7
Planned pregnancy	
2-month	0.0 \pm 0.0
6-month	0.0 \pm 0.0
12-month	2.7 \pm 1.9
Other personal reasons	
2-month	4.4 \pm 1.5
6-month	15.4 \pm 3.0
12-month	50.7 \pm 4.9
Method unrelated	
2-month	0.5 \pm 0.5
6-month	3.8 \pm 1.7
12-month	9.1 \pm 3.0

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TABLE VI. GROSS CUMULATIVE LIFE-TABLE RATES

Event	Rate (n=200)
Woman-months	
2-month	355.5
6-month	856.0
12-month	1264.5
Continuation	
2-month	88.9
6-month	65.5
12-month	32.5
Lost to follow-up	
2-month	70.0
6-month	15.5
12-month	22.5
Total discontinuation*	
2-month	15.5
6-month	45.5
12-month	76.5

*Includes lost to follow-up

We observed that the continuation rate after 6 months was 65.5 and after 12 months it dropped to 32.5. The highest rate of discontinuation was due to a desire to change methods during the time when the baby started to be fed other foods in addition to breast-feeding. It should be emphasized that the most beneficial effect of use of this contraceptive mainly during the first months of breast-feeding was that very few women complained of a milk decrease. In general, the contraceptive was well tolerated and it cannot be proven that the complaints from the patients were, in fact, caused by the progestogen since, if we compare Tables II and III, it is noted that the most frequent complaints were headache, dizziness, vaginal discharge, breast discomfort, etc., which were recorded upon admission to the study before starting the mini-pill intake.

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It has been established that the effectiveness of the method varies between 1 and 4 pregnancies per 100 woman-years. Although in our study we used the life-table method to evaluate the different events, we also used Pearl's formula as a means to compare our results with those previously published. We found a rate of 2.84% pregnancies, which is within the limits already mentioned (16,19,20). Likewise, it can be compared to the effectiveness of the IUD that has a rate ranging between 0.5% and 5% (21,22).

There have been few studies of continuation rates among mini-pill users. Cultural and socioeconomic differences among the groups studied make comparisons difficult; however, less than 50% of those who started mini-pills were still using them one year later (18,20). We found a continuation rate at 12 months of 32.5 and the corresponding lost to follow-up rate was 22.5. The 12-month total discontinuation rate (including those lost to follow-up) was 76.5 (Table VI).

Following 12 months of taking oral contraceptives, 151 women were still breast-feeding. These results make an indirect confirmation to previously published data that the mini-pill does not affect the quantity of milk production.

The effectiveness of the contraceptives containing progestogen only is less than those of the combined types which are not indicated during lactation. Therefore, women can only use alternative methods, such as the intrauterine device or the injectable forms. The IUDs are similar in effectiveness to the mini-pill but not well accepted for use by the Yucatecan women. The injectable contraceptives, at present, are not readily available for use and the only one advisable during lactation, medroxyprogesterone acetate, is not well accepted by the physicians because the use of this contraceptive remains controversial in Mexico (22-24). In the future it is important that further research studies be conducted to evaluate the acceptability as well as the effectiveness of this method among women in the lactation period.

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