

PN-ABF-797

67634

A Study of a Progestogen-Only Oral Contraceptive
for Lactating Women in
Bamako, Mali

Prepared for
Ministry of Public Health
and Social Sciences
Bamako, Mali

Center: 0440
Study: 8876

April 1989

Family Health International
Research Triangle Park, NC 27709
USA

I. Introduction

A non-comparative study of a progestogen-only oral contraceptive (Ovrette) was conducted at the PMI Centrale, a public MCH center, in Bamako, Mali as a part of a multicenter trial. This trial was designed to evaluate the discontinuation rate, the reasons for discontinuation, the frequency of selected symptoms contributing to discontinuation and the contraceptive efficacy of Ovrette in breastfeeding women.

Several studies have shown that lactation may be impaired by combined estrogen-progestogen oral contraceptives, including those with relatively low doses of estrogen. Progestogen-only OCs offer an alternative to combination OCs for lactating women who desire steroidal contraception. Progestogen-only OCs may minimize a reduction in milk volume and length of lactation, and may have a lower incidence of and less severe non-menstrual, estrogen-related side effects usually associated with combined OCs. Progestogen-only OCs have been associated with disrupted menstrual cycles--with a higher incidence of both intermenstrual bleeding and amenorrhea.

II. Study Design

Oral Contraceptive Evaluated

The OC administered in this study, Ovrette, was provided in packages of 28 active steroid tablets. Ovrette has a composition of 0.075 mg of the progestin, norgestrel.

Study Procedure

A total of 98 women were admitted to the study from August 1984 to November 1985. Follow-up visits were scheduled at two, six and twelve months after admission to the study. Of the 98 women included in the analysis, 97 women were at least 42 days but within 26 weeks postpartum; 1 woman was less than 42 days postpartum. All women were breastfeeding at admission.

Each women admitted to the study had to meet the following criteria: be 18 years of age or older, be in good physical health with none of the standard contraindications for use of steroid contraceptives, be currently breast-feeding (with or without supplementation), be recruited within six months (26 weeks) of delivery, be accessible for regular follow-up visits for at least 12 months. Due to the increased risk of irregular bleeding and possibly ectopic pregnancy among progestogen-only pill users, undiagnosed vaginal bleeding or a history of ectopic pregnancy were also considered contraindications for admission into the study.

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

III. Results

Sociodemographic Characteristics

Selected patient characteristics are presented in Table I. Women admitted to the study had a mean age of 27.2 years. The mean education level was 7.0 years, and the mean total live births was 3.3.

Contraceptive Practice

Table I also presents a summary of the contraceptive practices of the women, one month prior to admission to the study for interval patients and one month prior to conception for postpartum patients. Sixty-six women (67.3%) reported having used no contraception immediately prior to admission or conception. The predominant method employed was oral contraceptives--by 25 women (25.5%). Twenty-nine women (29.6%) reported ever having used oral contraceptives prior to the study.

Preexisting Medical Conditions and Complaints

None of the women reported a preexisting medical condition at admission. At admission, 68 women (69.4%) reported minor physical complaints (Table II). The most frequently reported complaints were vaginal discharge by 53 women (54.1%) and headache by 37 women (37.8%).

Regularity of Use

Regularity of pill use data were collected at two, six and twelve months after beginning oral contraceptive use. Data were assessed by self-report and from the date last pill taken prior to the date of follow-up visit contact. Follow-up visit data indicate that 5 women (5.9%) reported missing at least one pill during the study period.

Side Effects

Serious complications were reported by 2 women during the study period. One woman reported severe headache, palpitations and dizziness. She was referred to a cardiology specialist. The complication was deemed to be "method related" as the patient had not suffered from these complaints prior to the study and the patient was discontinued from the study for this reason. The other woman also complained of severe headaches and of ringing in her ears. She was also referred to a cardiology specialist, and was discontinued from the study. Serious complications are based on the clinicians' interpretation as to problem severity.

A summary of menstrual problems and complaints ever reported at all follow-up visits is shown in Table III. In general, the women who reported complaints at follow-up visits were not the same as those reporting the problem at study admission. Intermenstrual bleeding was reported by 2 women (2.0%) at admission; neither of the women reported any intermenstrual bleeding at follow-up. Fourteen additional women reported intermenstrual bleeding at follow-up who did not report it at admission. At admission 14 women (14.3%) reported dysmenorrhea, 9 women (9.2%) reported amenorrhea, 8 women (8.2%) reported scanty menses, one woman reported menorrhagia and one woman reported intermenstrual pelvic pain. At follow-up an additional 49 (57.6%) women reported amenorrhea, 4 women (4.7%) reported scanty menses, 2 women (2.4%) reported dysmenorrhea, 2 women reported menorrhagia and one woman reported intermenstrual pelvic pain, who did not report these complaints at admission.

A summary of other complaints ever reported at follow-up visits is presented in Tables IV and V; and changes in complaints since admission in Table VI. Fifty-five women (64.7%) reported other less common complaints (Table V), the most common of which was general fatigue reported by 10 women (11.8%). Twenty women (23.5%) who had not reported nausea at admission reported the complaint at follow-up. Thirty-three women (38.8%) reported vaginal discharge at follow-up who had not reported the problem at admission (Table VI). Other new reports included twenty-three women (27.1%) who reported headaches, 14 women (16.5%) who reported dizziness, 6 women (7.1%) who reported breast discomfort and 4 women (4.7%) who reported vomiting.

A summary of significant changes in the percentage of women reporting complaints at admission and during follow-up is presented in Table VII. There were statistically significant increases at the $p < 0.01$ level in reports since admission for intermenstrual bleeding ($\chi^2 = 7.6$), other menstrual complaints ($\chi^2 = 29.1$), nausea ($\chi^2 = 9.4$), dizziness ($\chi^2 = 9.6$) and vaginal discharge ($\chi^2 = 17.3$).

Discontinuation Rates and Reasons

A summary of all reasons for discontinuation is presented in Table VIII. Thirty-seven women (43.5%) discontinued from the study. The reason for discontinuation provided most often was personal reasons, with method not needed, forgetfulness (patient discontinued for having missed 3 or more consecutive pills) and desires change of method most often cited, followed by other medical reasons. There were no pregnancies reported during the study period.

Gross cumulative life table discontinuation and event rates are presented in Table IX. The twelve month total discontinuation rate was 71.4 including a lost-to-follow-up rate of 36.7.

IV. Summary

A non-comparative study of the progestogen-only oral contraceptive, Ovrette, in breastfeeding women was conducted at the PMI Centrale, Bamako, Mali. The study was designed to evaluate the discontinuation rate, reasons for discontinuation and contraceptive efficacy of Ovrette in breastfeeding women. This report includes an analysis of 98 women, all of whom were less than 26 weeks postpartum at admission; 97 were interval patients and 1 was postpartum. Follow-up visits were scheduled at two, six and twelve months after admission. Overall, women experienced increases in amenorrhea, vaginal discharge, headaches, nausea, dizziness ($p < .05$) and intermenstrual bleeding. The total discontinuation rate at 12 months was 71.4 including the lost-to-follow-up rate which was 36.7 at 12 months. There were no accidental pregnancies reported during the study period.

Table I
Selected Sociodemographic Characteristics

Characteristic	No. (N=98)	%
Age (years)		
Less than 20	10	10.2
20-24	23	23.5
25-29	38	38.8
30-34	19	19.4
35+	8	8.1
Mean		27.2
Education (years)		
None	20	20.4
1-6	18	18.4
7-12	48	49.0
13+	12	12.2
Mean		7.0
Total Live Births		
1	20	20.4
2	23	23.5
3	17	17.3
4	13	13.3
5	13	13.3
6+	12	12.2
Mean		3.3
Contraceptive method used in the month prior to admission or conception		
None	66	67.3
Orals	25	25.5
IUDs	5	5.1
Foam/diaphragm/jelly	1	1.0
Condoms	1	1.0

Table II
Complaints at Admission

Complaint	No. (N=98)	%
Intermenstrual Bleeding		
Staining/spotting	1	1.0
Moderate	1	1.0
Severe	0	0.0
Menstrual Complaints		
Dysmenorrhea	14	14.3
Amenorrhea	9	9.2
Scanty menses	8	8.2
Menorrhagia	1	1.0
Intermenstrual pelvic pain	1	1.0
Nausea	7	7.1
Headaches	37	37.8
Dizziness	5	5.1
Vaginal discharge	53	54.1
Total women with 1+ complaints*	68	69.4

* Multiple symptoms may be reported per woman.

Table III
Menstrual Complaints Since Admission

Complaint	No. (N=85) *	%
Intermenstrual Bleeding		
None	71	83.5
Staining/spotting	1	1.2
Moderate	11	12.9
Severe	2	2.4
Other menstrual complaints		
Amenorrhea	55	64.7
Dysmenorrhea	6	7.1
Scanty menses	5	5.9
Menorrhagia	2	2.4
Intermenstrual pelvic discomfort or cramps	1	1.2
Postcoital bleeding	1	1.2
Heavy bleeding (period lasts for 1 week)	1	1.2
Total women with 1+ menstrual complaints **	73	85.9

* N represents number of women followed up.

**Multiple symptoms may be reported per woman.

Table IV
Other Complaints Since Admission

Complaint	No. (N=85)	%
Nausea	22	25.9
Vomiting	4	4.7
Headaches	45	52.9
Dizziness	17	20.0
Vaginal Discharge	74	87.1
Breast Discomfort	6	7.1
Total women with one or more of above complaints	80	94.1

Multiple symptoms may be reported per woman.
N represents number of women followed up.

Table V
Other Complaints Since Admission

Complaint	No. (N=85)	%
Weight loss	3	3.5
Weight gain	2	2.4
Weight change	1	1.2
Decreased appetite	1	1.2
Increased appetite	2	2.4
Decrease in lactation	3	3.5
Increase in lactation	1	1.2
Hypogalactia	1	1.2
Cessation of lactation	1	1.2
General fatigue	10	11.8
Nervousness	2	2.4
Palpitation	4	4.7
Mild pelvic pain	6	7.1
Continuous pelvic pain	3	3.5
Pelvic pain preceding menses	1	1.2
Pelvic pain on last day of menses	1	1.2
Mild abdominal pain	2	2.4
Needle-like pain in abdomen	1	1.2
Pruritus vulva	4	4.7
Vulvovaginitis	4	4.7
Decreased libido	1	1.2
Back pain	2	2.4
Hypertension	2	2.4
Constipation	1	1.2
Heartburn	1	1.2
Varicose veins	1	1.2
Migraine (in the evening for 1 week)	1	1.2
Cystitis	1	1.2
Cervicitis	1	1.2
Acne	1	1.2
Combination of light pelvic pain, constipation and nausea	1	1.2
Combination of pelvic pain and weight gain	1	1.2
Combination of malaria and general fatigue	1	1.2
Combination of general fatigue and palpitations	1	1.2
Combination of fever during period and general fatigue	1	1.2
Baby has diarrhea	1	1.2
Baby has decreased appetite	1	1.2
Total # women with 1 + of above complaints	55	64.7

Table VI
Changes in Complaints Since Admission

Complaint	No. (N=85) *	%
Intermenstrual Bleeding		
Never reported	69	81.2
No change	0	0.0
Decrease	2	2.4
Increase	0	0.0
New reports	14	16.5
Nausea		
Never reported	59	69.4
No change	2	2.4
Decrease	4	4.7
Increase	0	0.0
New reports	20	23.5
Vomiting		
Never reported	81	95.3
No change	0	0.0
Decrease	0	0.0
Increase	0	0.0
New reports	4	4.7
Headaches		
Never reported	29	34.1
No change	15	17.6
Decrease	13	15.3
Increase	5	5.9
New reports	23	27.1
Dizziness		
Never reported	67	78.8
No change	2	2.4
Decrease	1	1.2
Increase	1	1.2
New reports	14	16.5
Vaginal Discharge		
Never reported	5	5.9
No change	30	35.3
Decrease	7	8.2
Increase	10	11.8
New reports	33	38.8

* N represents number of women followed up.

Table VI Cont'd
Changes in Complaints Since Admission

Complaint	No. (N=85) *	%
Breast Discomfort		
Never reported	79	92.9
No change	0	0.0
Decrease	0	0.0
Increase	0	0.0
New reports	6	7.1

* N represents number of women followed up.

Table VII
Significant Changes in the Percentage of Women Reporting
Complaints at Admission and Since Admission

Complaint	Ovrette	
	At Admission (N=98) %	Since Admission (N=85) %
Intermenstrual bleeding	2.0	16.5*
Other menstrual complaints	33.7	83.5*
Nausea	7.1	25.9*
Dizziness	5.1	20.0*
Vaginal discharge	54.1	87.1*

* p<.01 using McNemar's non-parametric test

Table VIII

Primary Reasons for Discontinuation

Reason	No. (N=85) *	%
Menstrual Problems		
Amenorrhea	1	1.2
Polymenorrhea (continuous bleeding)	1	1.2
Side Effects		
Headaches	1	1.2
Weakness	1	1.2
Other Medical Reasons		
Epigastric pain	1	1.2
Cardiologic consultation	1	1.2
Hypertension	2	2.4
Malaria	2	2.4
Trauma from a fall	1	1.2
Sore throat	1	1.2
Heartburn (gastric)	1	1.2
Cervicitis	1	1.2
Planned Pregnancy	1	1.2
Personal Reason		
Forgetfulness (missed more than 3 consecutive pills)	3	3.5
Desire change	3	3.5
Not needed	4	4.7
Other personal		
Interruption in pill use for 1 month during Lent (34 days)	1	1.2
Child was hospitalized for malaria	1	1.2
Method Unrelated Reason		
Travel, Moving	8	9.4
Relative ill (child was hospitalized with meningitis)	1	1.2
No supply	1	1.2
Total women who discontinued	37	43.5

N represents number of women followed up.

Table IX

Gross Cumulative Life Table Rates

Event	Rate \pm S.E. (N=98)
Menstrual problems	
2 month	2.7 \pm 1.9
6 month	2.7 \pm 1.9
12 month	2.7 \pm 1.9
Side Effect	
2 month	1.3 \pm 1.3
6 month	3.0 \pm 2.1
12 month	3.0 \pm 2.1
Other Medical Reasons	
2 month	4.6 \pm 2.3
6 month	10.8 \pm 3.7
12 month	15.6 \pm 4.8
Planned Pregnancy	
2 month	0.0 \pm 0.0
6 month	0.0 \pm 0.0
12 month	2.4 \pm 2.4
Other Personal Reasons	
2 month	3.8 \pm 2.1
6 month	9.9 \pm 3.6
12 month	18.4 \pm 5.2
Method Unrelated Reason	
2 month	2.7 \pm 1.9
6 month	5.5 \pm 2.7
12 month	14.2 \pm 4.9
Lost-to-Follow-up Rate	
2 month	15.3
6 month	21.4
12 month	36.7
Total Discontinuation Rate*	
2 month	20.4
6 month	44.9
12 month	71.4
Woman Months	
2 month	168.5
6 month	418.0
12 month	647.0

*Total discontinuation rate includes all women discontinuing from the study including those women lost-to-follow-up.