THE MINIPILL—A CONTRACEPTIVE FOR LACTATING WOMEN*

(A Nine-Month Follow-up Study)

by

RESHMA R. RAO
DINA N. PATEL
and
ARMIN JAMSHEDJI

SUMMARY

Contraception is essential in the post-partum period, as lactation does not always prevent pregnancy, but the method should not affect lactation or infant developmen.. This study evaluated 30 micro-gram d-norgestrol, a low dose progestogen as an oral contraceptive in the post-partum period. 250 women using the progestogen pill were compared with 250 using non-hormonal contraception.

56.1% of the study cases used the pill for a period varying from one to nine months and 18.1% used it for less than one month after detlivery. The reasons for discontinuing included various personal reasons and menstrual problems. Excessive menstrual bleeding was reported in 9.3% and moderate bleeding in 2.1% of the study cases. The alleged infant side effects included diarrhoea in 5.7% cases. The mean weight gain per month of the study infants was 471.6 gm and in the controls was 400.4 gms. The subjective assessment of milk production was reported better in the study cases, as compared to the controls.

Introduction

Since time immemorial women have nursed their newborn infants at the breast. Breast milk not only provides the mother and the infant with complete emotional satisfaction, but also excellent nutrition to the infant. In developing countries like India, where low socioeconomic and hygeinic conditions prevail, the importance of maintaining long lactational periods can hardly be emphasized. Perez, Vela *et al* (1971, 1972) have refuted the theory that women enjoy temporary immunity from pregnancy during lactation. Most women like to avoid pregnancy during breast feeding, therefore, it is an opportune time for initiating the woman to contraceptive methods. However, the contraceptive method adopted should have minimal effects

From: Nowrosjee Wadia Maternity Hospital, Ness Wadia Research Institute, and Indian Fertility Research Programme, Bombay.

**Presented at the IVth World Congress on Human Reproduction, Bombay, November 27 th December 2, 1983.*

Accepted for publication on 1-4-85.

on the maintenance of lactation and on the development of the infant.

Researchers have sought to eliminate side effects since the development of the first steroidal contraceptive in mid-1950. In the mid-60s, a significant discovery was made by Martinezo-Manatou, Rudel and colleagues in the development of progestogen-only oral contraceptives, commonly called the minipill. The minipills currently marketed are either low dosage of 19-nortestosterone group like norestisterone or low dose of 17-x hydroxyprogesterone group (megestrol and chlormadinone acetates). Minipills usually do not affect the quantity or duration of lactation. Therefore, these pills are preferred to the combined pills as oestrogen sometimes suppresses lactation (Buchanan, 1975).

The present study was undertaken to evaluate the safety and effectiveness of 30ug d-norgestrel (a low dose progestogen) as an oral contraceptive during the postpartum period.

Materials and Methods

This study was conducted at the Nowrosjee Wadia Maternity Hospital Postgraduate Institute for study and research in Gynaecology, Obstetrics and Family Planning, Bombay, from November 1979 to September 1982. Generally healthy full-term pregnant women between 20-35 years of age with a history of 2-6 live births were included in the study. These women had breast fed at least one infant in the past and planned to breast feed this infant for at least 9 months without any supplementary feeding for at least 4 months. Infants with birthweight of 2000 grams or more were included in the study.

Women fulfulling the above criteria were asked to choose between low dose progestogen-only oral contraceptive (OC) and non-hormonal contraceptives. In this study 250 women chose the progestogen-only OC (cases) and 250 women chose non-hormonal contraceptives (controls). One woman who did not fulfill the study criteria was deleted from the study.

These women were included within one week of delivery and were followed up either at home or at the hospital, once every month for 9 months. A month's supply of OC was provided to the study cases at each follow-up visit.

Results

In this series, the study cases were younger and had a lower parity than the controls. The birth interval was similar for the study cases and controls (Table I). The vast majority (96.0%) of the controls who had completed their desired family size underwent sterilisation.

TABLE I

Age and Parity

Characteristic	Cases N = 249 (Mean)	Controls N = 250 (Mean)
Age (in completed years)	25.0	28.2
Parity	1.8	2.9
Months since last pregnancy ended	26.0	27.0

While breast feeding the previous infant, the majority (94.0%) of the cases had not used any method of contraception. While 4.4 per cent had used oral contraceptives, 2 cases had used an IUD, 1 had used another method and one husband had used condoms.

On an average, 2 previous infants were breast fed by the controls and 1 by the cases. The average age when breast feeding was stopped was 15 and 13 months, respectively, for the cases and the controls. Supplementary feeding was introduced earlier by the controls than by the cases. The duration of breast feeding was similar for both the study groups (Table II).

TABLE II

History of Breast Feeding

History of Breast Feeding	Cases N = 249 (Mean)	Controls N = 250 (Mean)
Number of previous infants breast fed	1.0	2.0
Age of infants when breast feeding was stopped (Months)	15.0	13.0
Age of infants when supplementary feeding was introduced (Months)	8.0	4.0
Duration of breast feeding (Minutes)	4.0	5.0

In this analysis, only 5.6 percent of the women did not take the pill after initial acceptance, 20.1 percent were lost to follow-up and 18.1 percent had used the OC for less than one month after delivery. Thus, 140 (56.1%) of the study cases used the pill for 1-9 months (Table III).

TABLE III

Completed Months of Use before Discontinuation of the Progestogen-only Oral Contraceptive

Completed Months	Number	Per cent
Not used after initial acceptance	14	15.6
Less than 1 month	45	18.1
1	18	7.2
2	13	5.2
3	13	5.2
4	5	2.0
5	3	1.2
6	2	0.8
7	1	0.4
8	10	4.0
9	75	30.1
No follow-up contact made	43	17.3
Unknown	7	2.8

About a fourth of the women stated personal reasons for discontinuing pill usage. Husband's objection (18.6%) was the most common reason for discontinuing the pill. Medical reasons were given by 13.6 percent cases. The most frequent being excessive bleeding (9.3%). Other reasons included infant death (2.4%), stopped breast feeding (1.4%), use of other contraceptives (1.4%) and husband's death (0.7%) (Table IV).

TABLE IV
Reasons for Discontinuation

Reason	Number	Percentage
Personal Reasons		
Husband objects	26	18.6
Patient objects	5	3.6
Family doctor objects	2	1.4
Mother-in-law objects	1	0.7
Medical Reasons		
Excessive bleeding	13	9.3
Baby developed rash/diarrhoea/jaundice	3	2.4
Insufficient lactation	2	1.4
Husband unwell	1	0.7
Other		
Baby died	6	4.3
Stopped breast feeding	2	1.4
Changed method	2	1.4
Husband died	1	0.7
Changed residence	59	42.1

The study cases had a significantly higher incidence of side effects than the controls. The incidence of side effects for women in the study group was 20.0 percent and for the controls it was 2.0 percent. Spotting/staining was the commonly reported side effect for both the groups. The other side effects reported for the study cases were excessive (9.3%) and moderate (2.1%) bleeding (Table V).

TABLE V
Side Effects

Side Effect	Cases N=140		Controls N=202	
	No.	%	No.	%
Spotting/staining	12	8.6	4	2.0
Excessive bleeding	13	9.3	0	0.0
Moderate bleeding	3	2.1	0	0.0
Total	28	20.0	4	2.0

The incidence of side effects was 11.4 and 1.0 per cent for study infants and the controls, respectively. Diarrhoea was reported for 5.7 percent infants in the study group and 0.5 percent infants for the control group. Fever and gastroenteritis was each reported for 1.4 percent study infants. Other alleged side effects reported were phariangitis, jaundice, monilial infection and rash (Table VI).

TABLE VI
Side Effects Reported for Infants

Side Effect	Cases N=140		Controls N=202	
	No.	%	No.	%
Diarrhoea	8	5.7	1	0.5
Fever	2	1.4	0	0.0
Gastroenteritis	2	1.4	0	0.0
Other	4	2.8	1	0.5
Total	16	11.4	2	1.0

Mortality

There was no maternal death reported in this study.

Three (2.4%) infants died among the cases. Two infants died due to gastroenteritis and one infant died due to meningitis.

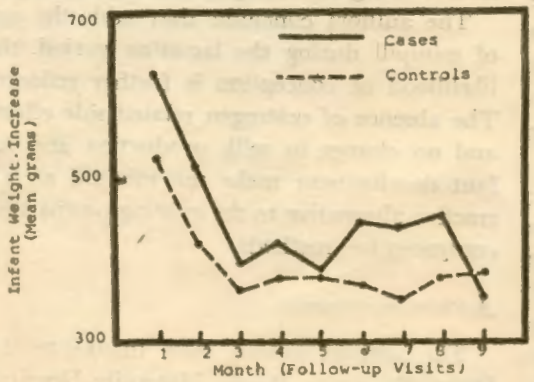

FIGURE 1

AVERAGE INCREASE IN INFANT WEIGHT BY MONTH

Except at the 9-month follow-up visit, the mean weight gain of the infants among the study cases was found to be consistently higher than the infants of the control group

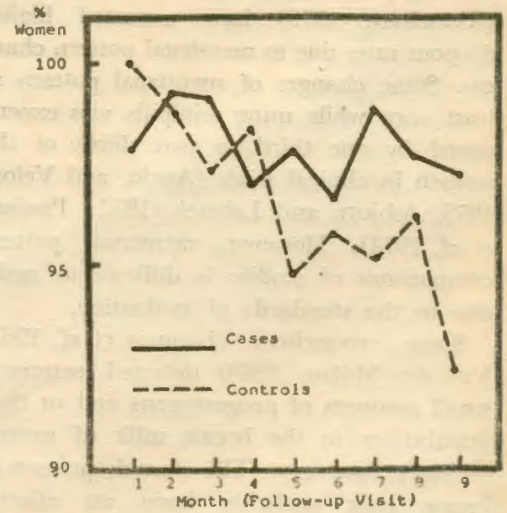

FIGURE 2

SUBJECTIVE ASSESSMENT OF SATISFACTORY MILK PRODUCTION

(Fig. 1). The mean weight gain for the study infants was 471.6 grams and for the controls it was 400.4 grams.

Milk production was satisfactory as reported by all the controls and 97.9 percent cases, at the first month follow-up visits. However, at the subsequent follow-up visits, except at 4 months, the subjective assessment of milk production was reported to be satisfactory by a higher percent of the study cases than the controls (Fig. 2).

Pregnancy

No pregnancy was reported in this study.

Discussion

The results of the present study show that the minipill is a safe and effective contraceptive for lactating women. Neither lactation nor infant development was found to be adversely affected.

Side effects mainly bleeding problems were reported for 6.4 percent cases. Only 5.2 percent of the cases discontinued from this study for this reason. Other studies (Rhinehart, 1975) have reported higher dropout rates due to menstrual pattern changes. Some changes of menstrual pattern at least once while using minipills was experienced by one third to two thirds of the women in clinical trials (Apelo, and Veloso 1973, Asbjorn and Leberch 1972; Paulson *et al,* 1974). However, menstrual pattern comparisons of studies is difficult to make due to the standards of evaluation.

Some researchers (Laumas *et al,* 1967; Van der Molan, 1969) detected extremely small amounts of progestogens and/or their metabolites in the breast milk of women taking progestogen. The steroids present in breast milk probably have no adverse effects on nursing infants. At higher dosage, Wong *et al* (1971) suspected steroids in milk contributing to neonatal jaundice. In this analysis only I (0.4%) infant was reported to have had jaundice. The other side effects reported are not attributable to the use of minipills. Only one infant died due to gastroenteritis.

Studies have found that most minipills have no significant adverse effect on breast feeding whether lactation performance is evaluated on the basis of infant weight (Abdel-Kader *et al,* 1969; Virkar *et al,* 1968), milk volume (Tejuja *et al,* 1974; Virkar *et al,* 1968) or duration of lactation (Guiloff *et al,* 1974). The present series shows that infants among the cases had higher weight gain than the controls at all the follow-up visits except at the 9-months visit. The infant weight gain followed a similar pattern for the cases and the controls. The subjective assessment of milk production was found to be satisfactory for both the cases and the controls.

No pregnancy was reported in this study. However, high to low failure rates have been reported in literature. Rinehart (1975) attributed the high rate to irregular use of the minipill or to low absorption due to vomiting or diarrhoea.

The discontinuation rate for this study was 51.2 percent. The continuation rates of various minipill users is less than 50 percent after starting the minipill (Rinehart, 1975).

The authors conclude that with the use of minipill during the lactation period, the likelihood of conception is further reduced. The absence of oestrogen related side effects and no change in milk production and infant development make the minipill an attractive alternative to the existing postpartum contraceptive methods.

Acknowledgements

The authors extend their thanks to the Dean, Nowrosjee Wadia Maternity Hospital, and to Dr. C. L. Jhaveri, Chairman, Indian Fertility Research Programme for allowing the use of this data.

References

1. Abdel-Kader, M. M., Abdel-Hay, A., El-Safouri, S., Abdel-Azia, M. T., Saad El-din, J., Kamal, I., Hefnawi, F., Ghoneim, M., Talaat, M., Younis, N. and Abdalla, M.: Am. J. Obstet. Gynec. **105**: 978, 1969.
2. Apelo, R. and Veloso, I.: Fertil. Steril. **24**: 191-197, March 1973.
3. Asbjorn, O. and Leberch, P. E.: Danish Medical Bulletin, **19**: 154-156, July 1972.
4. Buchanan, R.: Population Reports, J(4), July 1975.
5. Guiloff, E., Ibarra-Polo, A., Zanartu, J. Toscanini, G., Mischler, T. W. and Gomez-Rogers, C.: Am. J. Obstet. Gynec. **118**: 42, 1978.
6. Laumas, K. R., Malkani, P. K., Bhatnagar, S. and Laumas, V.: Am. J. Obstet. Gynec. **98**: 411, 1967.
7. Perez, H., Vela, P., Masnick, G. S. and Potter, R. G.: Am. J. Obstet. Gynec. **114**: 1041, 1972.
8. Perez, A., Vela, P., Marnick, G. S.: Population Studies. **25**: 491, 1971.
9. Paulsen, M. L., Varaday, A., Byron, B. W. and Kalman, S. M.: Contraception. **9**: 497, 1974.
10. Rinehart, W.: Population Reports, A(3), September 1975.
11. Tejuja, S., Saxena, N. C., Choudhury, S. D. and Malhotra, U.: Contraception. **10**: 385, 1974.
12. Van der Molen, N. J. Hart, P. G. and Wijmenga, H. G.: Acta. Endocrinol. **61**: 255, 1969.
13. Virkar, K. D., Kore, S. J. and Dikshit, S. S.: Sixth All India Conference on Family Planning. Report of the Proceedings, Chandigarh, November 30 to December 5, 1968.
14. Wong, Y. K. and Wood, B. S. B.: Brit Med. J. **4**: 403, 1971.