

Field Trial of Billings Ovulation Method of Natural Family Planning

Indian Council of Medical Research Task Force on Natural Family Planning

There are couples with unmet family planning needs and couples who do not use any modern method, yet they desire to space or avoid pregnancies. Many of them look for safe and effective options like the natural family planning methods. The Billings Ovulation Method based on single index cervical mucus parameter is one such option. The present multicentre trial conducted in India has shown an encouraging use-effectiveness of the method, indicating method failure as low as 1.5 ± 0.3 and use-failure 15.9 ± 0.8 per 100 users at 21 months. The method continuation rates have also been as high as 88.3/100 users at 6 months and 52.0/100 users at 21 months. CONTRACEPTION 1996; 53:69-74

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Introduction

India's quest to facilitate its family welfare programme (FWP), thereby attaining the demographic goal of a net reproduction rate (NRR) of one by the turn of the century, has resulted in an appreciation for the spacing methods among both the providers and users. This could be witnessed through the improved overall couple protection rate (CPR) from 22.8 per cent (2.7% spacing and 20.1% sterilization) in 1980-81 to 37.5% (9.6% spacing and 27.9% sterilization) in 1986-87 around the conduct of the present field trial. However, the improvement in the CPRs could not influence appreciably the crude birth rate of the country and it remained stagnant during these years.¹

On the other hand, 7.2% and 5% of eligible couples

were not using any modern method of family planning (MMFP), instead they were practicing traditional/natural methods of FP during 1980-81 and 1988-89, as observed in the 2nd and 3rd round All India FP surveys, respectively.^{2,3} Also, a sizable proportion of eligible couples, 15.0% and 18.3%, respectively, were found in these surveys with unmet FP needs. Further, there are couples who have discontinued the use of modern spacing methods of FP due to side effects and inconveniences or other reasons.⁴⁻⁷ In studies carried out in India, one year discontinuation rates of IUDs and OC were reported to be 22-50% and 30-60%, respectively.⁴ Similarly, there are couples who do not desire additional children, yet do not want to use any MMFP. The women in these couple aggregates remain exposed to the risk of pregnancy. Our existing FP cafeteria and underlying efforts of expanding contraceptive choice seem to benefit these couples only to some extent. The option of non-barrier, non-chemical and culturally compatible natural family planning methods remains dormant, despite their intrinsic quality, efficacy and acceptability.

The Billings Ovulation Method (BOM) is one such method of natural family planning (NFP) based on a single index⁸ cervical mucus parameter that enables the woman to recognize her potential fertility. It also enables her to recognize infertility after ovulation and in the pre-ovulatory phase of the cycle. During the time of infertility in the pre-ovulatory phase of the cycle, the level of ovarian oestrogens is low and the hormonal pattern is reflected in the cervical mucus. Billings refers to this pattern as the basic infertile pattern. Any variation in the cycle length occurs in the pre-ovulatory phase. The presence of mucus which produces a distinctive slippery sensation as it leaves the vagina indicates the time when intercourse has the best chance of resulting in conception. For postponing the pregnancy, Billings established the early day rules, i.e., i) avoid intercourse on days of heavy bleeding during menstruation, ii) alternate evenings are available for coitus, when these days have been recognized as infertile, and iii) avoid coitus on any day of mucus or bleeding which interrupts the basic in-

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fertile pattern. Allow 3 days of basic infertile pattern afterwards before coitus is resumed. There must be avoidance of all genital contact until the beginning of the fourth day following the peak of the mucus.⁹⁻¹¹

During the last two decades, a number of trials of this method have been carried out in several developed and developing countries, e.g., the Pacific, Australia, Korea, India, Ireland, USA, New Zealand, the Philippines, El Salvador, Africa, etc. All these trials have shown very low rates of method-related failures and consistently high continuation rates. However, a few earlier trials carried out in India¹²⁻¹⁴ were confined to a particular area, atypical of our larger socio-culturally, heterogeneous population that is aimed to be reached with additional effective and acceptable methods of contraception. The duration of teaching the rules of the method was quite long [generally 3 cycles, extending in one multinational study to a further 3 cycles]. The observations and follow-up in these studies were based on small numbers of cycles. The women were select subjects, taught to learn and master the method before they were included in the trial. The observations made in the earlier studies, under similar conditions, were not deemed beneficial to the Indian family planning programme envisaged to promote a cafeteria approach to ensure informed choice and voluntarism to prospective users.

Although the results from these trials did qualify the Billings Ovulation Method and establish its merits for achieving or avoiding pregnancies, they could not succeed in influencing the national health and family welfare policy to consider it for the programme, especially when controversies about the NFP methods persisted at the level of professionals, research scientists and programme managers about its efficacy and acceptability. The fallback of this controversy could have contributed to the disappearance of the rhythm calendar and the withdrawal and abstinence methods from the national FP programme between the late 60's and early 70's.

On the other hand, the Church and non-government agencies (NGOs) continued their efforts to advocate NFP and provide related training and services through their channels and claimed success of the method in the country. This could not be ignored for long by the professionals and research scientists who believe in expanded contraceptive choice for users and want to help women in meeting their unmet family planning needs. In view of these circumstances, the need of a field trial with optimum duration for assessing the use-effectiveness and acceptability of this method among a culturally non-comparable large population that could be exposed to the learning of the rules of the BOM for a minimum number of days [one cycle] was felt imperative by

ICMR. A Task Force of NFP comprised of experts from interdisciplines like natural family planning, public health, social sciences, obstetric/gynaecology, and health management was thus formed to this effect, and the present field trial of BOM was planned and conducted. Thus, the present study, quite different in design and methodology, included women volunteers both from the urban and rural areas of different states, keeping in view the existing FP programme conditions and needs. The purpose was to study a larger population of the country in order that its results could attract a discrete policy decision.

Methods and Materials

The present non-comparative field trial was carried out in five self-selected states in India; Uttar Pradesh (UP), Bihar, Rajasthan, Karnataka and Pondicherry. About 500 healthy women volunteers, aged 15-35 years, with regular menstrual cycles (26-31 days \pm 5 days), enjoying their husbands' support for participating in the trial were enrolled at each centre between January 1987 and September 1987. They were from both the urban and rural areas, with the exception of the Bihar state centre that included a slum area characterized more or less like the contiguous rural area. Each woman received information and counselling about the spacing methods available in the family planning cafeteria and the BOM. They were taught about changes during the menstrual cycle, feeling or sensation of secretion of mucus or dryness felt at the site of the vulva, identification of the changes in the mucus, the peak day of mucus, the rules of the method, and recording/markings of daily changes observed in the cycle on the menstrual chart/diary. The charts provided to them were 6x8" cards, each with provision for recording the observations for 3 consecutive menstrual cycles. To help them chart their observations easily and correctly, they were told to use the alphabet and symbols (in the case of even low and illiterate women), like B = bleeding, S = spotting, O = thin mucus, * = thick mucus, X = stretchy mucus, and # = the peak day of mucus (ovulation). Their observations recorded on the above charts were transcribed by the trained teachers and social workers onto separate charts for each cycle during the follow-up and appended with the follow-up interview forms. These two documents were then cross-checked and the accuracy and inaccuracy of the practice of the BOM was established.

The women monitored the onset of their menses, fertile and infertile days, and peak day of cervical mucus symptoms in the cycle regularly, and abstinence practiced during all the fertile days. They were told about the importance of complete abstinence to be

adhered to strictly during the first cycle (the period of learning the method and identification of cervical mucus pattern to understand the fertile/infertile days and peak day of mucus). They were to avoid sexual intercourse on the fertile days in the subsequent cycles. No modern methods of FP were used by these women during the trial period, either as a backup or combination method.

A total of 32,957 woman-months of use was observed over a period of 21 months for 2059 women volunteers. The cut-off period for analysis of data was 21 months. Those women who were not available for the follow-up interviews for 3 consecutive months were considered as lost to follow-up.

During the first month of learning the BOM and during the next two months, fortnightly contacts were established with the women in the field and at the centres providing the BOM services for the trial. This was done in order to monitor the women's comprehension of the rules of the method, review charting of the changes occurring in the mucus pattern and reinforce their motivation and spousal support. From the fourth month and onwards when they started achieving autonomy,¹⁵ monthly follow-up was performed.

The women were discontinued from the trial due to various reasons. The date of discontinuation was decided for each reason as follows:

- Discontinuation due to switching over to other methods (MMFP)—the date on which the other contraceptive was started.
- Discontinued due to husband's non-cooperation, planning for pregnancy, and other personal reasons—the date on which following the rules of the BOM stopped.
- Discontinuation due to lack of comprehension of the method, i.e., incorrect charting of observations for 3 consecutive cycles—the date of last follow-up visit.
- Discontinuation due to lost to follow up, i.e., no contact with the woman for 3 consecutive months—the date of the last contact.

The pregnancies were classified into two categories. First, *theoretical or method failure*, i.e., pregnancies occurring while using the method correctly and consistently [*perfect use*]. Second, *user failure*, i.e., pregnancies occurring due to departure from the rules of the BOM due to failure to obtain and/or lack of identification of mucus pattern [*imperfect use*].

Net cumulative probabilities were computed using daily life table technique. The test of significance was calculated by chi-square with one degree of freedom using log rank method.

For computing the theoretical or method failure

rates, all segments with correct and consistent use were considered as the denominator, women with imperfect use were considered as re-entry into the study for this purpose after deleting the segment of imperfect use.

For computing actual use-failure rates, total pregnancies (method failure and user failure) that occurred while using the method (correctly or incorrectly) were considered. The complete duration of use until the date of discontinuation was used as the denominator.

For computing the discontinuation rates due to other reasons also, complete duration of use was considered for the denominator.

Results

Profile

The mean age of the acceptors of the BOM was 26.2 ± 4.8 years. The average monthly coital frequency was 6.7 ± 1.2 . Of the total acceptors of the method, 32.2% were illiterate and 7.5% were just able to read and write. The majority of women (87.7%) were housewives or non-working. As regards the family types, a large proportion of these women (57.2%) belonged to nuclear families, with the mean number of

Table 1. Socio-cultural profile of BOM adopters

Characteristic	Mean \pm SD
No. of women	2059
Age of women (yrs)	26.2 ± 4.8
Age of husband (yrs)	30.5 ± 5.9
Age at marriage (yrs)	17.6 ± 3.5
Age at consummation (yrs)	17.9 ± 3.0
Coital frequency (per month)	6.7 ± 1.2
No. of living children	2.2 ± 1.5
Nulliparous	percent
Education of women	7.5
Illiterate	32.2
Read and write	7.5
Up to standard VIII	24.0
IX-X	17.6
XI and above	18.7
Occupation	
Housewife	87.7
Labourer	4.7
Teacher	2.7
Others	4.9
Type of family	
Nuclear	57.2
Joint	42.8
Religion	
Hindu	87.8
Muslim	9.6
Christian	1.8
Sikh	0.5
Others	0.3

Table 2. Obstetric history of adopters

Characteristic	Mean \pm SD
Age at menarche (yrs)	14.1 \pm 1.2
Length of menstrual cycle (days)	28.5 \pm 3.2
Length of menstrual flow (days)	4.4 \pm 1.2
No. of pregnancy	2.5 \pm 1.8
No. of live births: Male	1.2 \pm 1.1
Female	1.1 \pm 1.1
Total	2.3 \pm 1.7

living children being 2.5 \pm 1.5. A sizable proportion (7.5%) of them was nulliparous (Table 1). The average length of menstrual cycle and menstrual flow was 28.5 \pm 3.2 and 4.4 \pm 1.2 days, respectively (Table 2).

Awareness/Ever Use of FP Methods

Though a large proportion of women were aware that FP methods were being offered through the national family welfare programme, only about one-fourth reported ever having used any type of spacing methods. Some of the women (2.4%) had used traditional/natural methods. Also, a sizable proportion reported their husbands having used condoms (Table 3).

Continuation Rate

A high rate of continuation (88.3 per 100 users) was seen at 6 months. The continuation rate at 12 months was observed to be 76.0 per 100 users. A substantial fall in the continuation rate was observed after 12 months, especially in rural areas. Significantly higher rates were observed at all intervals of use in the urban areas as compared with the rural areas ($P < 0.01$, Table 4).

Table 3. Awareness and practice of family planning

Awareness/Use Status	Percent
Aware of FP methods	77.0
Spacing methods ever used	23.8
IUD	5.2
OC	5.0
Condom	11.2
Other conventional/traditional	2.4

Method Failure Rate

There were 21 women who had unplanned pregnancies during the trial while following the method correctly. The rate of method failure among the perfect users of the BOM was found as low as 1.1 \pm 0.3 per 100 users at 12 months of use and 1.5 \pm 0.3 per 100 users at 21 months of use (Table 4).

Use-failure Rate

As observed in the trial, while counting all involuntary pregnancies occurring during perfect or imperfect use of the method, the cumulative pregnancy rate was observed to be 10.5 \pm 0.7 per 100 users at 12 months of use and 15.9 \pm 0.8 per 100 users at 21 months of use (Table 4).

Use-failure by Residence and User Characteristics

The failures resulting in pregnancies at 21 months of use of the method (13.4 \pm 1.0 per 100 users) in the urban areas were found to be significantly lower when compared with the failures in the rural areas (19.6 \pm 1.4 per 100 users, $P < 0.01$, Table 5).

The women aged <25 years showed a failure rate of 18.6 \pm 1.3, indicating a statistically significant differ-

Table 4. Continuation and failure rate per 100 users and woman-months of use of BOM

Observation	Period of Observation (Months)			
	0-6	7-12	13-18	19-21
No. of women entering				
Urban	1179	1047	912	781 (600)*
Rural	880	768	630	467 (267)*
Pooled	2059	1815	1542	1248 (867)*
Woman-months of use				
Urban	6600	12521	17485	19526
Rural	4909	9058	12382	13431
Pooled	11509	21579	29867	32957
Continuation rates				
Urban	89.0	79.0	77.0	59.5
Rural	87.3	72.0	54.0	41.1
Pooled	88.3	76.0	62.0	52.0
Failure rates				
Method failure	0.7 \pm 0.2	1.1 \pm 0.3	1.2 \pm 0.3	1.5 \pm 0.3
Use failure	4.1 \pm 0.4	10.5 \pm 0.7	14.1 \pm 0.8	15.9 \pm 0.8

*Figures in parentheses indicate number completing 21 months of use.

Table 5. Total failure rates at 21 months by place of residence and user characteristic

Total Failure	No. of Adopters	Rate per 100 Users \pm SE
Residence		
Urban	1179	13.4 \pm 1.0*
Rural	880	19.6 \pm 1.4
Age (yrs)		
≤ 25	1090	18.6 \pm 1.3*
> 25	969	11.9 \pm 1.1
Living children		
≤ 2	1258	16.3 \pm 1.1
> 2	801	14.1 \pm 1.3
Education		
Illiterate	663	16.8 \pm 1.6
Literate	1396	14.8 \pm 1.0

* $P < 0.01$

ence ($P < 0.01$) as compared with the failure rate of 11.9 \pm 1.1 in the women aged >25 years (Table 5).

There appeared to be no association between the use-failure rates and either the number of living children that the women had or the educational status of the users (Table 5).

Discontinuation Rate Due to Other Reasons

It was observed in the study that about 24% of the users could not continue the practice of the BOM between 0-12 months and an almost similar proportion during the later periods. The discontinuation of the use of the method during the trial was attributed to several reasons (Table 6). However, the most prominent among them was the switching over to other methods of FP (20.1 \pm 1.0 per 100 users), followed by pregnancy (16.0 \pm 1.0 per 100 users). The rate of discontinuation due to these two reasons was found to be significantly higher ($P < 0.01$) in the rural areas compared to the urban areas. Besides, the rate of lost to follow-up in the study was 16.3 \pm 1.0 per 100 users at 21 months.

Discussion

The present trial studied acceptability and use-effectiveness of the BOM during the trial period of 21

months with sustained standard follow-up after only one cycle of teaching of the rules of the BOM to women volunteers. The learned and sustained ability of women to follow the method correctly and maintain diaries for mucus pattern and coital frequency in interpretable manner, testified in the trial that they could master the practice of the method to the extent that the majority of them could identify the peak day of mucus correctly.

The cumulative failure rate of 15.9 per 100 users at 21 months does not seem disturbing as most of the reasons are user-related. Since these relate to user's behavioural pattern, to a great extent, these reasons could be minimized by further improvement in the training, motivation, and better spousal cooperation. Considering a relatively high method efficacy (failure rate of 1.5 per 100 users) and continuation rate (52.0 per 100 users), the method establishes its immediate relevance to the Indian family planning programme.

The low method failure rate compares well with the rates found in other studies of the BOM (2.8, 1.3 and 2.9 per 100 users) conducted in India (multinational study), USA, and Australia at 1, 2 and less than 2 years of use.^{13,16,17}

The use-failure rate (15.9 per 100 users at 21 months) found in the present trial was considerably lower than reported rates of 19.6, 22.7 and 32.1 per 100 users at 1, 2, and little over 2 years of use, respectively, in some studies of the BOM.^{13,16,18}

Analysis of discontinuations reveals that switching over to other methods of FP appears to be the major reason. This seems to be a normal practice among spacers and those who wish to avoid pregnancies but do not desire to opt for any permanent method, and thus the present rate (20.1 \pm 1.0) during a period of 21 months may not, in fact, undermine the significance of the BOM to serve as an additional choice in the Indian FP cafeteria as well as the initial choice of millions for regulating their fertility without any drug or barrier/surgical device.

In India, since the outreach of contraceptives is poor due to several programmatic and psycho-social factors, and about 17% of the couples have unmet

Table 6. Discontinuation rate per 100 adopters of BOM at 21 months by reason

Reason	Urban Rate \pm SE	Rural Rate \pm SE	Total Rate \pm SE
Husband not cooperative	1.5 \pm 0.4	5.0 \pm 1.0	3.0 \pm 0.4
Low level of comprehension	0.4 \pm 0.2	0.2 \pm 0.2	0.3 \pm 0.1
Planning pregnancy	4.0 \pm 1.0	7.0 \pm 1.1	5.0 \pm 1.0
Pregnancy	13.4 \pm 1.0	20.0 \pm 1.4	16.0 \pm 1.0
Switching over to other MMFP	17.3 \pm 1.2	24.3 \pm 2.0	20.1 \pm 1.0
Others	0.4 \pm 0.2	1.1 \pm 0.4	1.0 \pm 0.2
Lost to follow-up	12.0 \pm 1.1	23.5 \pm 2.0	16.3 \pm 1.0

family planning needs, a wide scope for variety of family planning methods is envisaged for improving accessibility. The Billing Ovulation Method of natural family planning could be safely considered for service provision along with the existing MMFP. Because this method's high efficacy is closer to the failure rates (theoretical) of some of the modern methods of contraception, like the intrauterine device (1-3 per 100 users), condom (1-2 per 100 users), and diaphragm (2 per 100 users), it appears as an immediate option. Its use-failure rate (in practice) is comparable with those observed with condom (3-15 per 100 users) and diaphragm (4-25 per 100 users).¹⁹ Also, its continuation rate, as observed in the present trial, is considered favourable from the programme angle.

Thus, the Billings Ovulation Method of natural family planning appears a feasible and acceptable option to couples belonging to different socio-cultural milieu. Besides the training period, the method does not incur cost either to the provider or user. The method is not associated with fear or any side effect. It is a user-controlled, behavioural and culturally compatible method. It, therefore, promises good programme benefits to developing countries, in general, and to India, in particular.

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References

1. Government of India. Year Book 1986-87. Ministry of Health & Family Welfare, Dept of Family Welfare, 1988.
2. Operations Research Group. Family Planning Practices in India—Second All India Survey (unpublished), Baroda, 1983.
3. Operations Research Group. Third All India Family Planning Survey (unpublished), Baroda, 1990.
4. Indian Council of Medical Research. Task Force Study. Psychosocial Factors Affecting Continuation and Discontinuation of Intrauterine Device and Oral Pill in Urban India. New Delhi, 1986.
5. Centre for Research, Education, Service and Training. Documented Scientific Hazards & Medical Complications of Contraception, Sterilization and Amniocentesis, A Monograph, Bangalore.
6. World Health Organization. Oral Contraceptive: Technical & Safety Aspects. Geneva:WHO Offset Publication, 1982:64.
7. The Alan Guttmacher Institute. Making Choices: Evaluating the Health Risks and Benefits of Birth Control Methods. New York, 1983.
8. Klaus H. The Role of the Clinicians in Natural Family Planning. Health Education Bulletin. National Clearing House for Family. Bureau of Community Health Services, Rockville, MD. 1982;27:25-9.
9. Billings EL, Billings JJ, Catarinich M. Atlas of the Ovulation Method, 4th Ed. Melbourne, Australia: Advocate Press, 1980.
10. Billings EL, Westmore Ann. The Billings Method Controlling Fertility without Drugs or Devices. World Organization/Ovulation Method/Billings, revised ed. Australia: Penguin Books Ltd, 1992.
11. Wilson, MA. Love & Fertility: The Ovulation Method, the Natural Method for Planning Your Family. Louisiana: Family of the Americas Foundation, Mandevilla, 1986.
12. Holiburn CB. The Impact of Natural Family Planning in Six Dioceses in Tamil Nadu: A study. In: Muloof GE, Billings JJ, Taylor RS, eds. Proceedings of the World Organization of the Ovulation Method—Billings, USA. Portland, OR: Natural Family Planning Teachers, 1980.
13. World Health Organization. A prospective multicentric trial of the ovulation method of natural family planning. II. The effectiveness phase. Fertil Steril 1981;36: 591-8.
14. Mascarenhas MM, Lobo A, Ramesh AS. The use-effectiveness of the ovulation method in India. Trop Doc 1979;9:209-11.
15. Klaus H. Natural Family Planning: A Review. Obstetrical and Gynaecological Survey. Baltimore, MD: Williams & Wilkins Co, 1982;37:128-50.
16. Klaus H, Goebel JM, Muraski M et al. Use-effectiveness and client satisfaction in six centres teaching the Billings Ovulation Method. Contraception 1979;19:613-29.
17. Ball M. A prospective field trial of the ovulation method. Europ J Obstet Gynaeco Repro Biol 1976;6:63-6.
18. Johnston JA, Roberts DB, Spencer RB. Continuity—Discontinuity in the Sydney Survey. In: Proceedings of the 1st International Conference for Family Life Promotion. Cali, Columbia, 1977.
19. Population Crisis Committee. A guide to modern contraceptive methods, Washington DC, 1985. In: Natural Family Planning—A guide to provision of services. Geneva:WHO, 1988.