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Evaluation of the Effectiveness of a Natural Fertility Regulation Programme in China

By Shao-Zhen QIAN, De-Wei ZHANG, Huai-Zhi ZUO, Ren-Kang LU, Lin PENG, Chang-Hai HE and the Chinese Billings Ovulation Method Collaboration Programme*‡

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1. Introduction

Natural fertility regulation (NFR) methods could provide family planning (avoiding or achieving pregnancy) naturally through conforming to the women's reproductive cycle without the use of drugs or devices. NFR originated about 60 years ago from the rhythmic method, but this method was not scientifically based. Its deadly shortcoming is the prediction of the coming events on the basis of the past rhythm and is therefore destined to be inaccurate with a failure rate of more than 20%. A milestone in the NFR study is the discovery of the intrinsic relationship between the cervical mucus, the hormonal balance and the fertility status of women by the Billings group. It was shown that the changes in the cervical mucus correlated with the sex hormone levels in the women,^{1,2} thus the fertile status could be determined by observing the characteristics of the cervical mucus at the vulva.^{3,4} In this way the Billings Ovulation Method (BOM) overcomes the fatal weakness of early natural family planning methods in predicting the current events on the basis of past happening, and lays the foundation of scientific NFR research.

There have been many reports on BOM field trials all over the world.^{5–11} They all reached a common conclusion, i.e. the BOM had a very low method-related pregnancy rate and a consistently high continuation rate. Since the preliminary trial of the BOM in China in 1990 and the official introduction of the method by the Chinese Ministry of Health in 1995, the method has been widely used in China both for avoiding and achieving pregnancy with promising results.^{12–16}

2. Design and Methodology

In China the BOM has been used in more than 156,400 fertile couples for avoiding pregnancy and 3,268 infertile couples for achieving pregnancy. In well-designed

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field trials we studied the acceptability and use-effectiveness of the BOM and the comparative efficacy of the BOM and an intrauterine device in avoiding pregnancy. In these trials we paid much attention to the following items:

2.1 Qualified Teachers. The Billings teachers (nurses or midwives) had themselves been trained and examined by authenticated Chinese and Australian (during site visits) doctors. Only those who obtained good scores were awarded the certificate of "Billings teacher". In the majority of cases, the teachers were married young women with a long experience of using the BOM for the avoidance of pregnancy.

2.2 Competent Teaching Course. All women accepting the BOM were trained by weekly interviews for 1 month under the supervision of Billings teachers. In the training, in addition to the principal BOM knowledge, the following key points were stressed:

(a) *Mucus Symptoms.* The identification of mucus depends mainly on the vulval sensation and to a lesser extent on its appearance; in some women no mucus may be seen and the only signs of the fertile days or the beginning of the fertile days are a wet/slippery sensation and a soft and swollen vulva.

(b) *The Early Day Rules and the Peak Rule* should be strictly observed. If the Peak symptoms are not clear (no slippery/lubricative sensation at the vulva), one should continue to follow the Early Day Rules.

2.3 Subject-screening Procedure. After the training, every subject was interviewed to see whether she could proficiently master the BOM. Those who could not identify the mucus symptoms were either allocated a special tutor to help them or screened out. This measure was intended to ensure everybody participating in the study mastered the BOM.

2.4 On-the-Spot Guidance and Regular Follow-up Visits. During the trial a teacher was assigned to take care of 20 women as their on-the-spot guide. Arrangement was made so that women could get in touch with the teacher at any time they wished. The responsible teacher should be clearly aware of the cycle pattern, in particular the fertile days of every woman they guided. The principal investigator of the centre interviewed the volunteers biweekly (every other visit as arranged by the responsible teacher) in the first 2 months and then monthly (at the time of changing mucus symptoms) to check their personal record, monitor the women's comprehension of the rules, and reinforce their motivation and spousal support (husbands were invited to participate in every other visit). At the end of the 2 months the responsible teacher and the principal investigator could decide that the couples were now autonomous. The woman not available for follow-up interviews for three consecutive times was considered lost to follow-up.

It is generally accepted that the acquisition of BOM knowledge by the participants, the women's motivation and the husbands' cooperation are the key points for the successful implementation of the BOM. Our programme not only imparted scientific knowledge but also provoked and maintained the initiative of the women

and their husbands. Thus the result of the present study is highly rational and reflective of the scientific essence of the BOM.

Table 1. Base-line characteristics of subjects

	TCu220c (n = 662)	BOM (n= 992)
	(mean \pm S.D.)	(mean \pm S.D.)
Age (years)	27.8 \pm 3.2	28.0 \pm 3.1
Gravidity (number)	1.5 \pm 0.6	1.5 \pm 0.6
Parity (number)	1.0 \pm 0.2	1.0 \pm 0.2
Education	No. of subjects (%)	No. of subjects (%)
0 - 6 years	199 (30.1)	316 (31.9)
7 - 9 years	212 (32.0)	297 (29.9)
10 - 12 years	132 (19.9)	198 (20.0)
>12 years	119 (18.0)	181 (18.2)
Occupation	No. of subjects (%)	No. of subjects (%)
Peasant	403 (60.9)	626 (63.1)
Labourer	154 (23.2)	216 (21.8)
Intellectual	105 (15.9)	150 (15.1)

3. Acceptability

Due to its high efficacy, low expenditure and extreme safety incomparable by any other contraceptive methods, the BOM is well accepted by the Chinese couple of different cultural and economical backgrounds.⁵⁻⁷ Lower reproductive tract infection (vaginitis and cervicitis), quite common in the low cultural stratum in China, does not influence the observation of the mucus symptoms.

It is interesting to note that in one field trial, most failure cases had a relatively high cultural level (two university graduates and two lecturers). They all felt sorry and admitted that since they considered the method was simple and easy to master, they had paid less attention to the teaching course and had not strictly followed the rules. The consequence was use-related failures. On the contrary, the illiterate women were generally very attentive to BOM teaching and rigidly stuck to the rules, and failures were very rare. This experience gives us the following elicitation:

3.1 The BOM is simple and easy to comprehend; almost all the women, including the illiterate, can successfully learn the method and identify their own mucus symptoms.

3.2 During the training, special attention should be paid to the intellectuals and professionals. The method seems to be too "simple" to them and they could not get hold of it without strict supervision.

Interim conclusion: BOM is well accepted and by the Chinese women of different cultural and economical backgrounds; illiteracy and lower reproductive tract infection are not incompatible with the use of the Method.

4. Comparative Study on BOM and IUD

1,654 healthy women of proven fertility (having at least one live birth), aged 24–35 years, with regular menstrual cycles (3–7/24–35 days), to be cohabiting and enjoying their husbands' support for participation in the trial, were enrolled. The participants were mostly peasants and also workers and white collars with different

**Table 2. Gross cumulative 12-month life table (Tietze) event rates
(per 100 women)**

	BOM (rate ± S.E.)	IUD (rate ± S.E.)	<i>P</i>
Pregnancy	0.5 ± 0.2	2.0 ± 0.6	<0.01
Expulsion		2.6 ± 0.7	
Medical removal		6.3 ± 1.0	
Use-related			
discontinuations	0.5 ± 0.2	10.6 ± 1.2	<0.001
Non-medical			
discontinuations	3.1 ± 0.9	0.5 ± 0.3	
Loss to follow-up	1.0 ± 0.3	1.1 ± 0.3	
Continuation rate	96.4 ± 0.6	89.3 ± 1.2	< 0.01
Continuation: case			
number	966	587	
Women-months of use	9,870	6,299	
Total number of cases	992	662	

educational levels (Table 1). They were randomly divided according to the ratio 3:2 into two groups (the BOM group, 992 subjects, and the IUD group, 662 subjects). The observation was continued for 12 months.

Results showed that in the BOM group five women became pregnant (all use-related), the pregnancy rate being 0.5%, while in the IUD group there were 12 pregnancies (2%), the difference being highly significant ($P < 0.01$). From Table 2, it was also seen that the discontinuation due to medical reasons was significantly lower ($P < 0.001$) in the BOM than in the IUD group. Besides, in the IUD group, there were 15 expulsions and 38 removals due to severe pain/bleeding; thus the total use-related discontinuations amounted to 65 cases (12 pregnancies, 15 expulsions and 38 medical removals). Nothing particular was seen in the BOM group and only five pregnant cases were medically discontinued.

5. Achieving Pregnancy

The BOM has also been employed widely in many Infertility Clinics in China to achieve pregnancy. Women wishing to be pregnant were subject to a brief training course, the main purpose of which was to identify the fertile days, the Peak and the BIP. The BIP (Basic Infertile Pattern) enables the woman to define days of infertility before the fertile phase begins. Besides, teachers would help them to determine the days for centralized intercourse. The schemed intercourse protocol was as follows: (1) during the BIP, intercourse every 3 days or more in order to clearly identify the mucus symptoms and to reserve enough sperm for the fertile days; (2) during the fertile days, intercourse every other day in order to identify the elapse of the fertile phase and to reserve more sperm for the next intercourse; (3) no more restrictions on the days after the Peak.

According to an incomplete survey, in 3,268 couples using the BOM for infertility without apparent cause, 1,032 got live babies after 2–5 cycles, the live baby rate being 31.6%. Many couples had been infertile for more than 5 years, and became pregnant after the schemed intercourse. The people affectionately called these babies the Billings babies and the doctors in charge of the Billings Infertility Clinics (established in many localities in China) have been given the title of Baby-Provider by the common folk.

Interim conclusion: the BOM is effective in achieving pregnancy in infertile couples.

6. Conclusion

6.1 The BOM is well accepted and by the Chinese women of different cultural and economical backgrounds; illiteracy and lower reproductive tract infection are not incompatible with the use of the method.

6.2 The use-effectiveness of the BOM is much higher than that of TCu220c, one of the most popular IUDs used in China.

6.3 The BOM is effective in achieving pregnancy in Chinese infertile couples.

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