

## The Use-Effectiveness of Combining Three Contraceptive

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**Abstract:** A total of 240 women, age 17-40 years, in rural areas in the west of Tabriz city, with self-reported cycles of 26-32 days, desiring to delay pregnancy at least one year were admitted to the study. After teaching the method to the subjects, they followed-up for 12 months to complete the study or dropped out from the study. Only 8 pregnancies occurred during the study and a total of 1956 months were contributed by the 240 study participants. So first-year pregnancy rate was 4.91% and percentage of protection of unplanned pregnancy was 95.09 without considering the correct or incorrect use. Results indicate that this combined method is able to provide a significant protection from unplanned pregnancy and is acceptable to the couples.

**Key words:** Standard days method, contraceptive, fertility awareness, family planning, condom

### INTRODUCTION

Natural Family Planning (NFP) has been defined as those methods that take advantage of the fact that women are at most times infertile throughout their reproductive lives (Wade *et al.*, 1981). During such times, sexual intercourse can take place without risk of conception. A couple wanting to avoid or achieve pregnancy by timing intercourse needs to know when during her menstrual cycle the woman is most likely to become pregnant. They can do so by using a fertility awareness-based family planning method. The fertile window of the woman's menstrual cycle consists of approximately 6 days-the 5 days before ovulation and the day of ovulation, with variable probabilities of pregnancy for each day (Wilcox *et al.*, 1995, 1998). However, the timing of ovulation is variable both among women and across cycles of same women, with some women experiencing much greater variability than others (Wilcox *et al.*, 2000). A fertility awareness-based method that takes into account this variability could be viable option for many couples. The Institute for Reproductive Health, Georgetown University, proposed a fixed formula in which women who typically have menstrual cycles of 26 to 32 days consider themselves fertile during Days 8 through 19 (12 days) of their cycles. To prevent unplanned pregnancy, they avoid unprotected intercourse on those days (Arevalo *et al.*, 1999). Arevalo *et al.* (2002) developed Standard Days Method (SDM), in which a woman considers herself potentially fertile on Days 8 through 19 of her menstrual cycle. If she does not want to become pregnant, she avoids unprotected intercourse on those days.

An efficacy trial (Arevalo *et al.*, 2002) found that the SDM was more than 95% effective with correct use and more than 88% with typical use among women who reported regular cycles of 26-32 days. These effectiveness rates are similar to those of a number of other user-dependent methods (Hatcher *et al.*, 1998). Most users of the SDM rely on CycleBeads, a color-coded string of beads that was designed by Arevalo *et al.* (2002) to help them track their cycle and identify the days when pregnancy is most likely.

In this study the combination of the SDM, condom and Emergency Contra Ceptive Pills (ECP) is defined as a combined method. In this combined method women with regular menstrual cycles between 26 and 32 days long, in days 8 through 19 (12 days) should use condom and when condom was breaks or slippages, they should use ECP. I also designed another device, a card with 32 color circles (Marking Card), to help women to identify the days cycle. The aim of this study was to determine the use-effectiveness of this combined method in the rural women.

### MATERIALS AND METHODS

A prospective, non-randomized study was conducted to test the use-effectiveness of the combined contraceptive method among rural women. Participants were enrolled from four village in west of Tabriz city (northwestern region of Iran). A total of 240 women were admitted to the study. Eligibility requirements included:

- Age between 17-40 years.
- Willing to delay pregnancy at least one year.
- At least to able to read and write.

- Have stable sexual relationship with husband (Have exposure to pregnancy).
- Have a desire to this method.
- Not pregnant at the beginning of study (women were entered to the study by beginning of menses).
- Have regular menstrual cycles between 26 and 32 days long.
- To have no contraindications of contraceptive pills.
- In breast feeding mothers have at least 3 menstrual cycles after delivery.
- In present time use condom (lower than 2 years long) or natural family planning or none of the family planning methods.
- Husband willing to use condom in 12 consecutive days every cycle.

In each village, 2 health workers were trained (service providers) in the combined method and in study procedures. Method provision involved a counseling session in which the woman was given the instruction in the combined method and given the consultation on the importance of following the method recommendations to avoid pregnancy. They were invited to contact the provider with questions. To assist women in using this method we gave them a card (one card for each cycle), a string of 32 circles in which each circle represents a day of the menstrual cycle. The first circle is red, representing the first day of menses; the next 6 circles are green, representing the additional non-fertile days preceding the fertile window; the next 12 circles are yellow, representing days that should be considered fertile (8-19) and must use condom in intercourse and the remaining 13 circles are green, again representing non fertile days. Women were instructed to mark the red circle on the day their menses began and to mark per day one of other circles until their menses returned. In addition to marking the circles of missed days (forgotten days), the date of this day was written on the box on the top of red circle. They also were told in order to avoid pregnancy, they should use condom on the days the mark was on a yellow circles and when condom was broke or slippaged, they must use ECP according to the instructions. ECP must be taken within 72 h and the sooner it is taken the better. Two pills are taken immediately and then two more are taken 12 h later. If they had menstrual bleeding before day 27 (darker green circle) of the cycle (i.e., a cycle shorter than 26 days), or if their menses had not occurred by the day after they completed all 32 circles (i.e., a cycle longer than 32 days), they were educated to contact their provider for further assessment and advice. Women who had two cycles out side the 26 through 32 day range during the study period (one year) were advised to use another method and were with drawn from the study. The marking card and instructions are shown in Fig. 1.

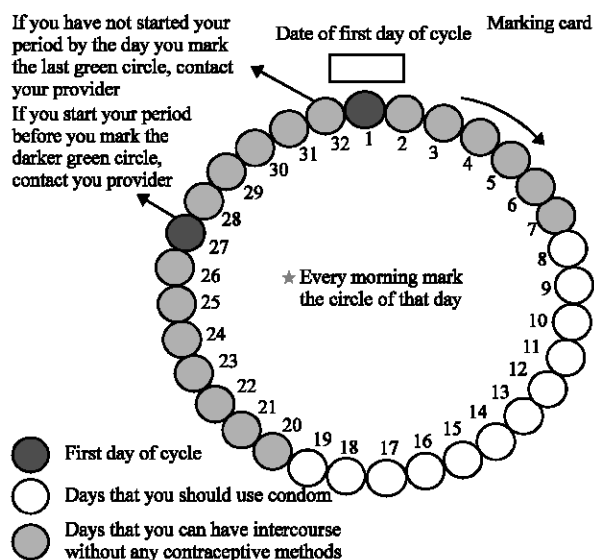


Fig. 1: Marking card and instructions for use

At the beginning of the study providers collected the demographic data of participants. A written consent was obtained from all of them. Women in the study were interviewed bimonthly, until they either completed 12 month or left the study for any reasons. During each interview, the providers gave them 2 marking card, determined whether she continued to use the method (including reason for discontinuation, if applicable) and screened for possible pregnancy. Women who had not had their menses by day 42 of their cycle were tested for pregnancy. If test results were negative, they were followed up until they tested positive or their menses returned. They were then exited from the study because of extremely irregular cycle length.

I use pearl pregnancy rate to determine the first-year pregnancy rate, which is compute as follow:

$$PPR = \frac{\text{Number of unwanted pregnancies}}{\text{Total no. of woman - month exposure} \times 1200} \quad (1)$$

Also independent t-test and chi-square test were used to comparing two groups of subjects, those who completed the study period and those who dropped out.

## RESULTS

A total of 240 women were admitted into the trial, with a mean age of  $30.0 \pm 5.69$  (Rang: 17-40) years. Demographic characteristics of subjects were shown in Table 1. As seen in this table, vast majority of subjects were housewife (93.7%), have lower educational levels and almost all of them (95.8%) had children.

Table 1: Demographic characteristics of participants in the use- effectiveness study of combined contraceptive method (n = 240)

Characteristics	Number	Percent of participants
Age of women ( $\bar{x} \pm SD$ )	30.0 $\pm$ 5.69	(Range: 17-40)
Occupation		
Housewife	225	93.7
Occupied at home	13	5.5
Occupied out of home	2	0.8
Education		
Secondary or lower	165	68.7
High school	68	28.3
University education	7	2.9
Number of children		
0	10	4.2
1	107	44.6
2	99	41.2
$\geq 3$	24	10.0

Table 2: Reason for leaving from use- effectiveness study of combined contraceptive method (n = 240)

Reason	Number	Percent of participants
Completed study period	117	48.8
Had desiring for other family planning methods	39	16.3
Had 2 cycles out the 26-32 day range	15	6.3
Wanted to get pregnant	14	5.8
Husband did not like the method	10	4.2
Emigration	8	3.3
Unwanted pregnancies	8	3.3
Had not intercourse	4	1.7
Did not trust the method	5	2.1
Unknown	20	8.3

Of all women who entered the study, 117 (48.8%) completed 12 months (13 cycles) of method use. Of those who did not complete 12 months, the largest group (16.3% of the total sample) removed from the study because they desire for other family planning methods. Reasons for leaving the study were presented in Table 2.

A total of 1956 women-month were contributed by the 240 study participants. A total of only 8 pregnancies occurred during the study. So the first-year pregnancy rate was 4.91% by computing with pearl pregnancy rate.

Among 8 subjects with pregnancy, 7 subjects were housewife and 1 has occupation at home, 6 subjects have lower and 2 higher educational levels. Of them 1 subject had not child, 4 subject had one child, 1 subject had two child and 2 subjects have three child. Also in each month of 2, 3, 4, 7 and 9, one unwanted pregnancy was occurred and in month 11 of study 3 unwanted pregnancies were occurred.

Comparing the demographics characteristics of two groups of subjects, those who completed the study period and those who dropped out during the study period, was showed no significant differences between 2 groups.

## DISCUSSION

With only 8 of 240 women in our study becoming pregnant, it appears that the combined method is effective in preventing unplanned pregnancies and the first year protection was more than 95%. Recently a multicountry prospective trial of the SDM which was designed to establish its efficacy in diverse settings, showed a one-year failure rate of 4.8 % with correct use (pregnancies that occurred in cycles in which participants reported no intercourse on days 8-19). In which when all cycles and all pregnancies were included in the analysis, the first year pregnancy rate was 12.0%, similar to or better than the rates of several other user-dependent methods such as male and female condoms and the diaphragm (Hatcher *et al.*, 1998).

Actually, the combined method is the same as SDM, but in this method instead of avoiding from unprotected intercourse, the condom is used during days of 8 through 19 of cycle and in cases that the condom is broken or slippaged, ECP is used, as well as instead of CycleBeads the Marking card is being used as a use instruction. The results of present study indicates that first year pregnancy rate in combined method is 4.91%, which suggests that those couples admitted into the study were able to understand the method and were capable of translating the method's recommendation into behavior consistent with their expressed reproductive intention.

Most efficacy studies of fertility awareness-based family planning methods do not actually enroll women into the study until they have completed a learning phase, typically a three month period during which they receive instruction in the method (Gray *et al.*, 1993; World Health Organization, 1981). Pregnancy rates in those studies are artificially reduced if the analysis excludes the early cycles of use. In this study, similar to Arevalo *et al.* (2002) women after being admitted to the study and given instruction of method, began use of combined method with there first cycle.

In this study participants were rural women and although all of them were able to read and write (eligibility requirement to entering to the study), but more than two third of them had lower educational levels. We expect that with increasing the educational level, women will be able to better understand the method; as a result the failure rate of method will be reduced. The result of this study showed that even with these participants, this combined method with instruction, Marking card, was effective. But in the case of urban participant, who have higher educational levels than rural women, we expect this combined method will be more effective.

In Iran more than of 20% of couples are either using natural methods of family planning or none of the family planning methods at all (Shaghaghi *et al.*, 2003; Hajian *et al.*, 2004). Thereby this combined method with its instruction device, Marking card, would integrate in health system services of Iran and others developing countries.

Despite, valuable results of this study, It is important to know the limitations of the study too. First, during some of months, the participants may not have intercourse and during some of months, participants may used another method of family planning on days other than 8 through 19, these months were not excluded in the analysis. Second weakness is that the bimonthly follow-up schedule, while necessary for data collection, may have increased correct use of the method.

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