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Efficacy of a new method of family planning: the Standard Days Method☆

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Abstract

The Standard Days Method is a fertility awareness-based method of family planning in which users avoid unprotected intercourse during cycle Days 8 through 19. A prospective multi-center efficacy trial was conducted to test, in a heterogeneous population, the contraceptive efficacy of the Standard Days Method. A total of 478 women, age 18–39 years, in Bolivia, Peru, and the Philippines, with self-reported cycles of 26–32 days, desiring to delay pregnancy at least one year were admitted to the study. A single decrement multi-censoring life table analysis of the data indicate a cumulative probability of pregnancy of 4.75% over 13 cycles of correct use of the method, and a 11.96% probability of pregnancy under typical use. This article describes the study and the results. Results suggest that despite its requirement that couples modify their sexual behavior when the woman is fertile, the Standard Days Method provides significant protection from unplanned pregnancy and is acceptable to couples in a wide range of settings.

Keywords: Standard Days Method; Contraceptive efficacy; Fertility awareness

1. Introduction

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 [1,2]. However, the timing of ovulation is variable both among women and across cycles of the same woman, with some women experiencing much greater variability than others [3]. A fertility awareness-based method that takes into account this variability could be a 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 [4].

Ideally, a woman using a fertility awareness-based method should be able to identify the 6 days of her fertile window, with neither "false positives" (i.e., days identified as fertile that actually are infertile), nor "false negatives" (i.e., days identified as infertile that actually are fertile) [5]. The technology necessary for this degree of accuracy, however, is not widely available or affordable, especially in developing countries. Balancing the need to provide effective protection from unplanned pregnancy while restricting the identified fertile period to as few days as possible, we developed the 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.

To develop the SDM, we applied various formulae (i.e., various numbers of days and various sets of days) to over 7500 menstrual cycles in an existing data set from the World Health Organization (WHO) [6]. The goal was to determine which formula provided the best balance between

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length of the identified fertile period and efficacy in avoiding unplanned pregnancy. To accomplish this, we developed a computer simulation that took into account the variable probability of pregnancy on different cycle days before and including the probable day of ovulation as well as the variable probability of ovulation occurring on different cycle days.[1] The 8 through 19 formula provided maximum protection while minimizing the number of days of avoiding unprotected intercourse. We estimated that if women with cycles ranging 26 to 32 days had used the 8 through 19 formula and avoided unprotected intercourse on those days, the highest probability of pregnancy on any given day was only 0.007.

We then estimated that the method would be almost as effective for women who typically have cycles within the 26 through 32 day range but occasionally (no more than twice in a 12-month period) have a shorter or longer cycle. However, the 8 through 19 formula would be less effective for women who consistently have cycles shorter than 26 days or longer than 32 days. Nonetheless, even when all women and all cycles regardless of length were included in the computer simulation, the highest probability of pregnancy/intercourse on any given day was still only 0.011.

In designing this efficacy study, we followed the guidelines recommended by Trussell and Kost [7]. Data collection instruments, participant enrollment, and pregnancy definition were all influenced by those recommendations. Their guidelines also affected the way we analyzed the data and, thus the results presented in this article.

2. Materials and methods

A prospective, non-randomized, multi-center study to test the efficacy of the SDM was conducted among culturally diverse populations. Participants were enrolled from five sites in Bolivia (Trinidad), Peru (Juliaca and Lima), and the Philippines (La Trinidad and Tuba).

2.1. Study participants

A total of 478 women (married or living with a stable partner) were admitted to the study. All participants were between 18 and 39 years old (to minimize cycle variability and subfertility), had regular menstrual cycles (defined as recent history of most cycles between 26 and 32 days long, as determined by a screening protocol), were willing to avoid intercourse 12 consecutive days every cycle, and had partners willing to collaborate. Potential participants were screened for subfecundity, risk of sexually transmitted diseases, and contraindications of pregnancy.

2.2. Procedures

In all sites, the Institute for Reproductive Health trained 5 to 10 health workers (service providers) in the SDM and in study procedures. Method provision involved a counseling session in which the woman (or the couple, if her partner was available) was instructed in the SDM, and counseled on the importance of following the method recommendations to avoid pregnancy. She was invited to contact the provider with questions and to include her partner in any subsequent contact, as appropriate. To assist women in monitoring their cycles, the provider gave them a mnemonic device, a string of 32 beads in which each bead represents a day of the menstrual cycle. The first bead is red, representing the first day of menses; the next 6 beads are brown, representing the additional non-fertile days preceding the fertile window; the next 12 beads are white, representing days that should be considered fertile (8–19); and the remaining 13 beads are brown, again representing non-fertile days. The bead assembly also has a moveable, tight-fitting rubber ring that is used to mark the current day of the cycle. Women were instructed to place the ring on the red bead on the day their menses began and to move the ring one bead per day until their menses returned. They also were told that to avoid pregnancy, they should not have unprotected intercourse on the days the ring was on a white bead. If they had menstrual bleeding before Day 27 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 beads (i.e., a cycle longer than 32 days), they were instructed to contact their provider for further assessment and advice. Women who had two cycles outside the 26 through 32 day range during the study period were advised to use another method and were withdrawn from the study.[2] The mnemonic device, called CycleBeads, and its instructions are shown in Fig. 1.

Providers also were trained to collect the data needed for the study. The protocol, data collection instruments and consent form were approved by the Georgetown University Medical Center Institutional Review Board. Written, informed consent was obtained from all study participants.

In addition to using the CycleBeads to monitor their cycle days, for study purposes participants also marked the first day of their menses on a calendar and kept a coital log in which they also indicated the days they used another method (i.e., condom or withdrawal). Women in the study were interviewed each cycle, until they either completed 13 cycles or left the study for other reasons. During each interview, the interviewer reviewed the woman's completed coital log, checked the cycle day indicated on the calendar with the position of the ring on the CycleBeads, 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 results were negative, they were followed until they tested positive or their menses returned. They were then exited from the study because of extremely irregular cycle length. Loss to follow-up was minimized by interviewing study participants in their homes and actively seeking out each participant, with a minimum of three attempts per cycle.

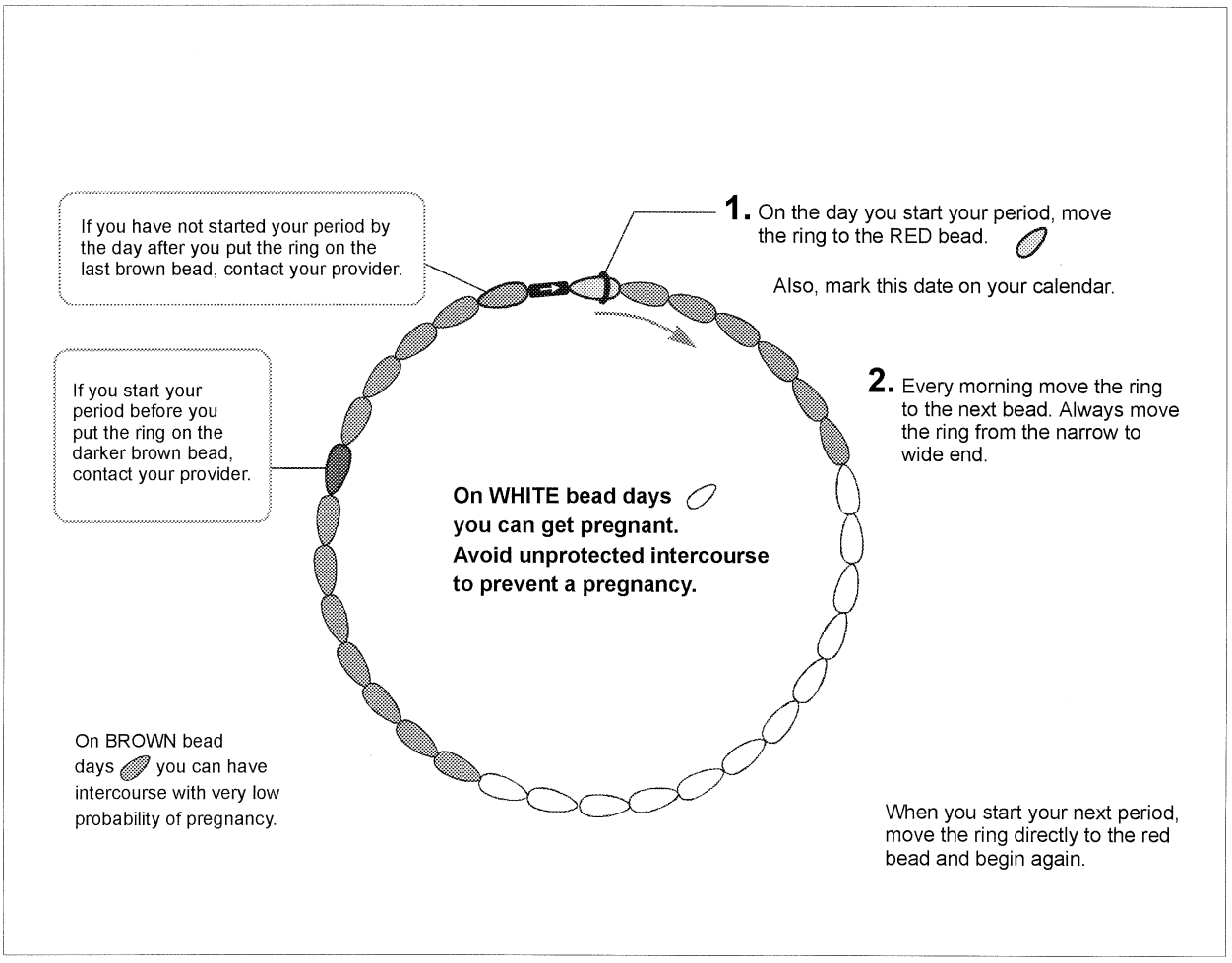

Fig. 1. CycleBeads and instructions for use.

2.3. Analysis

We used single-decrement multi-censoring life tables. Multi-censoring life tables allowed us to exclude some cycles from the analysis without censoring the woman contributing the cycles from the rest of the study [8]. We excluded cycles during which the participant did not have intercourse (0.35%) because there was no exposure to the risk of pregnancy. We also excluded cycles during which another method of family planning was used on days other than 8 through 19, which are identified as non-fertile by the SDM. These cycles were excluded because it is not possible to determine whether the woman was protected from pregnancy by the SDM only or by the other method.

3. Results

A total of 478 women were admitted into the trial, with a mean age of 29.4 years. Women in the study were drawn from urban, mixed urban/rural and rural sites. Lima was the largest city; study participants from La Trinidad (the Philippines), Trinidad (Bolivia), and Juliaca (Peru) lived in a variety of mixed urban/rural settings in these smaller cities; Tuba (the Philippines) was a rural site.

Participants' educational levels were relatively high: more than 90% of women had completed primary education. When asked to read simple instructions related to the method, only 9% of women either could not read them or had difficulty completing the task.

Almost all (98.9%) study participants had children, with a mean of 2.5 children per woman. Most participants had at least one child 2 years old or younger. As would be expected given the communities where they lived, almost 80% of study participants stated they were Catholic, although only one woman mentioned her religious beliefs as a factor in her choice of method.

There was significant variability among the sites with regard to previous use of family planning. Women living in more urban areas had more experience with hormonal contraceptives and intrauterine devices, while traditional methods were more common in rural areas. Although one-third of women were breastfeeding at admission, they met all study criteria, including having experienced at least three

Table 1
Profile of participants in the Standard Days Method efficacy study (n = 478)

Characteristic	Percent of participants
Study site	
Trinidad, Bolivia	11.5
Juliaca, Peru	21.3
Lima, Peru	21.1
La Trinidad, Philippines	21.3
Tuba, Philippines	24.7
Age at admission	
18–24	23.5
25–29	25.6
30–34	29.4
35–39	21.4
Parity	
No children	1.1
1–2 children	58.3
3–4 children	32.1
5 children or more	8.5
Education	
Completed primary education or lower	14.9
Some secondary education or higher	85.1
Occupation	
No income earning occupation	51.9
Agriculture	5.5
Sales	18.3
Blue collar job	15.3
White collar job	8.9
Ever use of family planning methods[a]	
None	9.6
Calendar	55.9
Withdrawal	37.0
Lactational Amenorreah (LAM)	1.3
Other natural methods	2.7
Barrier method	30.8
Intra Uterine Device	12.8
Hormonal method	30.0

[a] Figures add to more than 100% because many respondents specified more than one method.

regular cycles since the last birth. Almost half of study participants received an income from work outside the home. The client profile is shown in Table 1.

Of all women who entered the study, 46% completed 13 cycles of method use. Of those who did not complete 13 cycles, the largest group (28% of the total sample) corresponds to those who, following the study protocol, were removed from the study after they had two cycles outside the 26 through 32 day range (including 13 women erroneously exited after a single such cycle) or experienced a single cycle longer than 42 days. Throughout 13 cycles of method use, very few women (4%) left the study because they or their partner did not like or trust the method. Reasons for leaving the study are presented in Table 2.

A total of 4035 cycles were contributed by the 478 study participants. Correct method use (no intercourse on Days 8–19) was reported in 92% of cycles. In an additional 5% of cycles, intercourse did occur, but with use of another method (condom or withdrawal). Unprotected intercourse

Table 2
Reason for exiting from Standard Days Method efficacy study (n = 478)

Reason for exit	Percent of participants
Completed 13 cycles	45.6
Had 2 cycles out of the 26–32-day range[a]	28.0
Was told that a pregnancy would be high risk	0.2
Client did not like the method	0.2
Client did not trust the method	1.7
Partner did not like the method	2.1
Wanted to get pregnant	2.1
Exited for another voluntary reason	4.0
Lost to follow-up	7.1
Pregnant	9.0

[a] Includes also 25 clients who exited after just one cycle out of range. Of these, 12 clients had a cycle 42 days or longer, and 13 clients exited early because of an error.

occurred in only 3% of cycles. A total of only 43 pregnancies occurred during the study. Predictably, most (65%) of the pregnancies occurred during cycles in which the woman reported unprotected intercourse during Days 8 through 19 (days identified as fertile by the method). Only 15 study participants became pregnant in cycles in which no intercourse was reported during Days 8–19. Most pregnancies occurred during the first cycles of method use (42% of all pregnancies occurred in the first three cycles) and very few in the latter cycles (only three pregnancies in the last five cycles).

The first-year pregnancy rate was 4.8 (95%; CI 2.33–7.11) with correct use of the method (pregnancies occurring in cycles in which participants reported no intercourse on Days 8–19). When we include cycles in which women reported intercourse with use of condom or withdrawal during their fertile days, the first-year pregnancy rate is slightly higher (5.7%; CI 3.11–8.16). A 1-year pregnancy rate of 12 (CI 8.47–15.33) was calculated when taking into account all cycles and all pregnancies.

The single-decrement multi-censoring life table for correct use (including only cycles and only pregnancies with no intercourse on Days 8–19) is presented in Table 3. The life table for all cycles is presented in Table 4.

4. Discussion

With only 43 women of 478 in our study becoming pregnant, it appears that the SDM is effective in preventing unplanned pregnancies. As shown in Table 5, efficacy of the SDM is comparable to that of male condoms and is significantly better than that of other barrier methods (female condom, diaphragm, cervical cap, or spermicides) [9].

The finding that the method was used correctly in most cycles (i.e. that couples avoided unprotected intercourse during the entire fertile period as identified by the method)

Table 3
Life table pregnancy rates for correct use of the standard days method

Cycle	Women exposed[a]	Pregnancies	Pregnancy rate	95% confidence interval
1	373	1	0.27	0.00 to 0.79
2	384	2	0.79	0.00 to 1.67
3	361	3	1.61	0.32 to 2.89
4	342	2	2.19	0.68 to 3.68
5	317	0	2.19	0.68 to 3.68
6	297	4	3.51	1.53 to 5.45
7	264	0	3.51	1.53 to 5.45
8	244	2	4.30	2.04 to 6.50
9	242	0	4.30	2.04 to 6.50
10	223	0	4.30	2.04 to 6.50
11	225	0	4.30	2.04 to 6.50
12	215	0	4.30	2.04 to 6.50
13	215	1	4.75	2.33 to 7.11

[a]Excluding censored cycles.

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. Couples participating in the study seemed no more or no less sexually active than the general population. They reported an average of 5.5 acts of intercourse per cycle. This figure is similar to the 64 yearly (5.3 monthly) acts of intercourse reported for users of coitus-dependent methods in 32 countries throughout the world [10].

Almost all study participants were literate (91% were able to read simple method instructions). No reliable figures are available about schooling in study localities; however, study participants had more years of formal education than their respective national averages.

Participants in the SDM trial are very different from the population of a recent study by Wilcox et al., which reported ovulation as early as cycle Day 8 or as late as cycle Day 60. Unlike SDM trial participants, participants in the Wilcox study were neither screened for cycle length before admission to the study nor withdrawn because of cycle length variations (they reported usual cycle lengths from 19 to 60 days) [3]. Many of them clearly would not be eligible to use the SDM.

Table 4
Life table pregnancy rates including correct and incorrect use of the standard days method

Cycle	Women exposed[a]	Pregnancies	Pregnancy rate	95% confidence interval
1	452	5	1.11	0.14 to 2.07
2	436	5	2.24	0.86 to 3.60
3	395	8	4.22	2.29 to 6.11
4	363	5	5.54	3.31 to 7.72
5	340	5	6.93	4.41 to 9.38
6	308	6	8.74	5.87 to 11.53
7	280	2	9.39	6.39 to 12.30
8	262	4	10.78	7.52 to 13.92
9	252	0	10.78	7.52 to 13.92
10	236	1	11.16	7.82 to 14.37
11	230	0	11.16	7.82 to 14.37
12	220	1	11.56	8.14 to 14.85
13	218	1	11.96	8.47 to 15.33

[a] Excluding censored cycles.

Table 5
Rates of unintended pregnancy during the first year of typical use and the first year of perfect use of user-dependent family planning methods[a] and the standard days method

Method[b]	Pregnancy rate	
	Typical use	Correct use
Chance	85	85
Spermicides	26	6
Cap		
Parous women	40	26
Nulliparous women	20	9
Diaphragm	20	6
Condom		
Male	14	3
Female	21	5
Standard Days Method	**12**	**5**

[a] Source: Hatcher et al. [9].
[b] These figures are drawn from studies using different methodologies, and, therefore, may not be directly comparable.

In designing this study, we were careful to adhere to the criteria for contraceptive efficacy studies defined by Trussell and Kost [7]. Thus, our sample included only women who were likely to be fecund and exposed to the risk of pregnancy. Defining the reason(s) for discontinuation and identifying and reporting early pregnancies detected by laboratory tests also are important. Pregnancies were identified at 42 days post LMP; women who tested negative for pregnancy but who were still amenorrheic were followed until they either menstruated or tested positive for pregnancy.

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 [11,12]. Pregnancy rates in those studies are artificially reduced if the analysis excludes the early cycles of use. In this study, we included women beginning with their first cycle of use. As previously noted, most pregnancies occurred in earlier cycles.

A weakness of the study was reliance on women's self-reported intercourse and other method use. We expect that women may have under-reported intercourse, especially on Days 8 through 19, and that they may have used other methods (barrier or withdrawal) more frequently than reported. Because the collection of information on intercourse relied on self-reporting, we have no way of confirming the extent of this under-reporting. Another weakness is that the monthly follow-up schedule, while necessary for data collection, may have increased correct use of the method.

Additional questions about the SDM will be addressed in

forthcoming articles, drawing on both additional analysis of the efficacy trial data and from other ongoing research.

5. Conclusion

This efficacy trial demonstrated that the SDM is an effective method of family planning. With a first year pregnancy rate of less than 5% with correct use, it is comparable to other user-controlled methods currently available through reproductive health and other programs. The study also has shown that clients are able to learn the method and to use it successfully to avoid unplanned pregnancy. The SDM offers a valuable addition to the services that reproductive health and other programs can offer. Because it is simple to teach, learn and use, the SDM also has the potential to be provided outside the context of traditional family planning programs, through community development, non-governmental, and social marketing organizations. Operations research studies are ongoing to address some of these issues and explore how best to provide the SDM in these and other settings.

Notes

1. We used Peak day as a proxy for ovulation. Peak day is defined in the Ovulation Method as the last day in a given menstrual cycle on which fertile-type mucus is recognized, or the last day on which the wet or lubricative sensation is felt at the vulva.
2. For ethical reasons, we referred these women for another method because the theoretical protection conferred by Standard Days Method is slightly less for women who consistently have cycles outside the 26 through 32 days range [4]. Although it was explained to them that they were more likely to become pregnant if they continued using the SDM, many of them continued to do so. A further study of these women is ongoing.

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