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Efficacy of the new TwoDay Method of family planning

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Objective: To test the efficacy of the TwoDay Method, a new fertility awareness–based method of family planning that provides women with simple instructions to identify the days each cycle when they are most likely to become pregnant. Users avoid unprotected intercourse on days when cervical secretions are present on that day or on the day before, to prevent pregnancy.

Design: Prospective, nonrandomized, multicenter study.

Setting: Five culturally diverse sites in Guatemala, Peru, and the Philippines.

Patient(s): Four hundred fifty women, aged 18–39 years, wishing to use a fertility awareness–based method to prevent or delay pregnancy.

Intervention(s): Study participants were followed for up to 13 cycles of method use.

Main Outcome Measure(s): Life table pregnancy rate.

Result(s): The first-year pregnancy rate was 3.5 (pregnancies per 100 women/years) with correct use of the method (pregnancies and cycles with no intercourse on identified fertile days), 6.3 with use of a backup method on the fertile days, and 13.7 including all cycles and all pregnancies in the analysis.

Conclusion(s): The TwoDay Method offers a valuable addition to the services that reproductive health and other programs can offer. Its efficacy compares well with that of other coitus-dependent family-planning methods; it is easy to teach, learn, and use; and it can address the need of women for simple, accurate instructions for identifying their fertile days. (Fertil Steril® 2004;82:885–92. ©2004 by American Society for Reproductive Medicine.)

Key Words: TwoDay Method, contraceptive efficacy, fertility awareness

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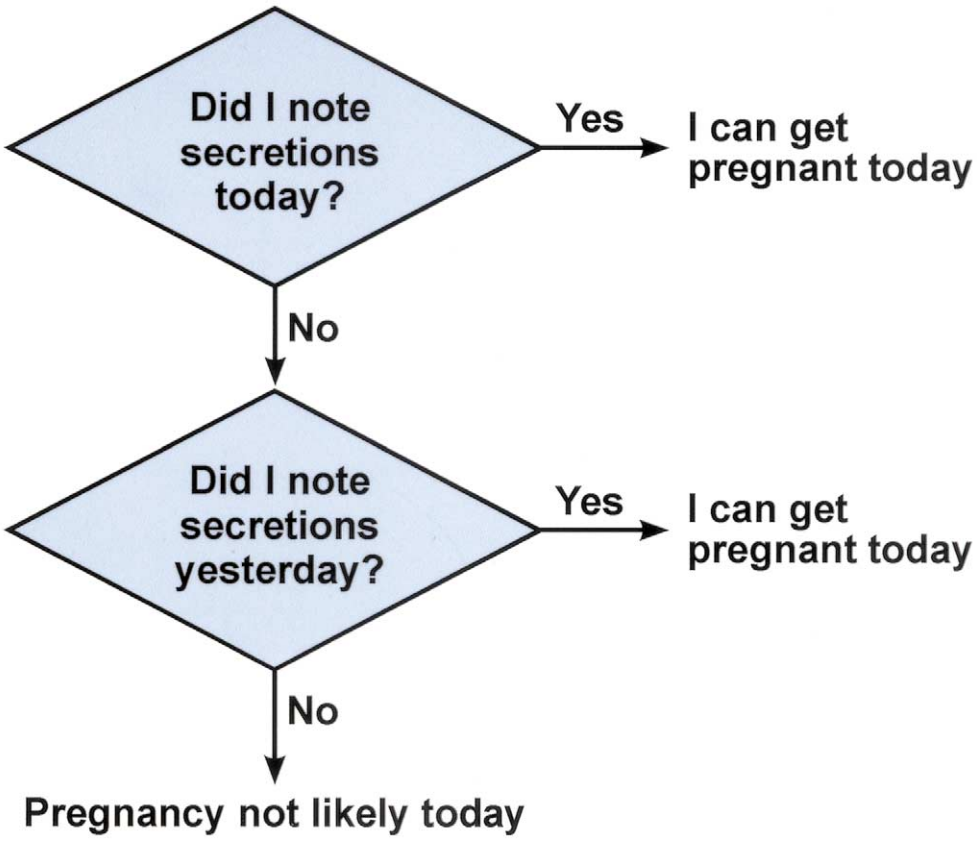
Fertility awareness–based methods of family planning help women identify the days of their menstrual cycle on which they are most likely to become pregnant if they have unprotected intercourse. Couples who wish to prevent or delay pregnancy might use a barrier method or avoid intercourse on these days. For the average woman in an average cycle, the fertile window 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). Fertility awareness–based methods of family planning take into account the variability in timing of ovulation both among women and across cycles of the same woman (3).

The TwoDay Method is a new fertility awareness–based method of family planning, developed by the Institute for Reproductive Health, Georgetown University, to respond to the need for simple, accurate ways for women to recognize when they should avoid unprotected intercourse to prevent pregnancy. This article describes the results from an efficacy trial of the method.

Women using the TwoDay Method rely on the presence or absence of cervical secretions to determine whether or not they are fertile each day. The woman asks herself two simple questions: [1] "Did I note secretions today?" and [2] "Did I note secretions yesterday?" She should consider herself fertile today if she notices cervical secretions of any type today or she noticed them yesterday. She avoids unprotected intercourse on these days to prevent pregnancy. If she noticed no cervical secretions of any type today or yesterday, her probability of getting pregnant from intercourse today is very low. Figure 1 shows this algorithm.

FIGURE 1

The TwoDay algorithm.



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The TwoDay Method is simpler than other tested fertility awareness–based methods that rely on the identification of cervical secretions, such as the Billings Ovulation Method (4), the Symptothermal Method (5), and the Modified Mucus Method (6). Unlike these methods, following the rules of the TwoDay Method does not require distinguishing among different types of cervical secretions. Rather, the presence of secretions of any type is considered an indicator of fertility. Secretions are considered any substance that the woman perceives as coming from her vagina, except for menstrual bleeding or semen.

Before conducting the efficacy study of the TwoDay Method, we determined the theoretical efficacy of the method by applying the algorithm to appropriate data sets from the World Health Organization (WHO) and from an Ovulation Method center in Vicenza, Italy. These studies, reported elsewhere (7, 8), showed that for women using the TwoDay Method, the highest theoretical probability of pregnancy from intercourse on any day relative to ovulation was 0.025. We also calculated the theoretical failure rate of the method on the basis of day-specific intercourse information, using data from a multicenter European study. Results indicated that the theoretical first-year pregnancy rate compared favorably with reported rates of other widely used family-planning methods (9). On the basis of these findings, we conducted a clinical trial of the TwoDay Method to determine the real efficacy of the method in actual use. Here, we report the results of the trial.

MATERIALS AND METHODS

A prospective, nonrandomized, multicenter study to test the efficacy of the TwoDay Method was conducted in culturally diverse populations in five sites in Guatemala, Peru, and the Philippines. Totonicapán is a rural indigenous site in western Guatemala. Iquitos is the largest city in the Peruvian Amazon. The Piura site, also in Peru, included urban and semirural communities. In the Philippines, the Alfonso site consisted mostly of semirural communities, and the Valenzuela site included several poor urban communities that are part of Metro Manila.

The study design, data collection instruments, study procedures, participant enrollment, pregnancy definitions, and data analysis followed the guidelines recommended by Trussell and Kost (10). Thus, our sample included only women who were likely to be fecund and exposed to the risk of pregnancy: they were aged 18–39 years, were living in union, and had a previous pregnancy. Breast-feeding women were admitted only if they had at least three cycles (four menses) postpartum, to ensure normal fertility. Women who had previously used hormonal contraceptives were only admitted if their last injection was 6 or more months earlier, or their last oral contraceptive pill was taken 3 or more months before admission.

Women also were screened for risk of sexually transmitted infections (STIs) (the TwoDay Method does not reduce the risk of STIs) and contraindications of pregnancy (because the efficacy of the TwoDay Method was unknown). Women who responded positively to questions about STI risk (i.e., they perceived themselves to be at risk, or they had a pattern of secretions that suggested existing STIs) or pregnancy contraindications (i.e., had been told by a health care provider that another pregnancy would endanger her life or her health) were not eligible to participate in the study. In addition, all participants and their partners were willing to avoid intercourse on days the TwoDay Method identified as fertile.

A total of 450 women were admitted to the study. They were interviewed every cycle to assess their use of the method and their pregnancy status. Pregnancies were determined by hormonal tests at 42 days after the last menstrual period; women who tested negative for pregnancy but remained amenorrheic were followed until they either menstruated or tested positive for pregnancy. We used single-decrement, multicensoring life tables to calculate failure rates of the method. The protocol, data collection instruments, and consent form were approved by the Georgetown University Medical Center institutional review board. All participants provided written, informed consent.

The method was offered through existing programs. The Institute for Reproductive Health trained 5–10 health service providers in each site to offer the TwoDay Method. These providers screened potential participants for study eligibility, counseled participants in TwoDay Method use, and collected the data.

After the initial screening, participants were counseled in the use of the TwoDay Method. If the woman's partner was available, he was invited to participate in the counseling session. Participants were first taught how to monitor their secretions. Providers explained that secretions might look or feel different on different days of the cycle and that amounts of secretions vary, but that the woman should consider herself fertile if she noticed secretions of any type, regardless of characteristics or amount. Participants were also told to expect that once secretions started, they would be continuous for several days of their cycle. Secretions could be detected in a variety of ways (i.e., by observing or touching them in underwear or toilet paper, by touching the genitals, or by the sensation of wetness in the genital area or on underwear), and each woman was advised to monitor her secretions in a way that worked best for her. To avoid confusing cervical secretions with semen, we recommended that women pay attention to their secretions in the afternoon and evening (previous focus group research in the study sites confirmed that in these sites intercourse occurs very rarely other than at night or early in the morning).

Participants were then taught to use the two-question algorithm (see Fig. 1) to determine each day whether they were fertile that day and to register their findings on a diary card that helped women track their fertile days and also served as the first level of data collection. Participants marked on the card the presence or absence of secretions each day. The diary card was also a coital log. Participants indicated the days they had intercourse and whether they used another method (i.e., condom or withdrawal) as backup. Users of the TwoDay Method might use a barrier method or abstain during the days the method identifies as fertile. However, to study the efficacy of the TwoDay Method, participants were instructed to avoid intercourse altogether on these days but to report it (in their diary card) if they did have intercourse and to report the use of a backup method if they used one.

Providers visited women up to three more times during the first cycle, to determine (by reviewing the woman's diary card and techniques for checking secretions) whether women were correctly identifying their secretions. We took this step to help develop guidelines for an appropriate number of counseling sessions when the method is offered outside of a study setting in the future. Women were then interviewed once each cycle until they either completed 13 cycles of method use or left the study for another reason.

During each follow-up interview, the provider checked the woman's completed diary card and her willingness to continue using the method and to participate in the study (including reason for discontinuation, when applicable). Women who had not had their menses by day 42 of their cycle were tested for pregnancy. If results were negative, they were visited weekly until they tested positive or their menses returned. If their menses returned after day 42 of the cycle they were removed from the study. Although the method would still have been effective for them, following women with very long cycles for 13 cycles would have significantly extended the length of the study period. The long cycles that caused these participants to be removed from the study were included in the analysis.

The study protocol specified that participants with <5 days with secretions would be removed from the study, with the assumption that they were either unable to learn how to detect secretions or they were not ovulating. Only two par-

ticipants left the study for this reason. Similarly, we removed women from the study who had >14 consecutive days of secretions, assuming that this might indicate infection or some hormonal disorders. Twenty-seven women left the study for this reason and were referred for further assessment.

Using single-decrement, multicensoring life tables to calculate failure rates of the TwoDay Method allowed us to exclude some cycles from the analysis without censoring the woman contributing the cycles from the rest of the study (11). Multicensoring life tables are similar to conventional life tables. However, on the basis of the Trussell and Kost (10) recommendations, we excluded cycles in which the woman reported no intercourse (2.1%) because there was no exposure to the risk of pregnancy. We also excluded cycles during which the participant used a barrier method or withdrawal on days that were not identified as fertile by the method (0.9%). These cycles were excluded because it is not possible to determine whether the woman was protected from pregnancy by the TwoDay Method or by the other method. Each cycle we used these criteria to decide which cycles would be excluded from the analysis in that cycle, but women were not censored from the study until they permanently left the study.

RESULTS

Client Profile

A total of 450 women were admitted to the trial, with a mean age of 29.2 years. They contributed 3,928 cycles to the study. Table 1 shows the participant profile.

There was considerable variability between sites, partly because the Guatemala site was more rural than the other study sites. All study participants had children (mean 2.5), and approximately 63% had a child 2 years old or younger. The youngest child in the Peru sites (mean 4.6 and 4.1) was older than in the Guatemala site (mean 1.6) and Philippines sites (mean 3.2 and 2.6). Some 40.5% of participants were still breast-feeding at admission, but all had at least four menstrual periods since the birth of their child.

The educational level of participants in Guatemala was significantly lower than that of participants in the other sites. Some 76% of Guatemala participants did not complete primary education, compared with 2.3% in the other sites. More than half of participants in Guatemala could not read or could only read with difficulty, and only 4.7% completed secondary education or higher. In comparison, only 2% of participants in the other sites could not read or could only read with difficulty, and 70.5% had completed secondary education or higher.

Participants in Guatemala were also poorer than participants in the other sites. We calculated an index of living conditions, including access to water, electricity, fuel used for cooking, and the materials of which the walls of the dwelling were made. To calculate the index, we coded all included variables using the same scale. We then added their values and divided the result by the number of variables for which information was available. The index ranges 3–9. Participants in Guatemala scored on average 3.8, compared with 4.7–4.8 in the other sites.

There was considerable variability in previous use of a family-planning method. More than half of participants in Guatemala had never used a family-planning method, and only 15% had ever used a hormonal method. Iquitos, Peru was the other extreme. All participants in Iquitos had used a family-planning method in the past; 70.8% of them had used a hormonal method.

TABLE 1

Profile of participants in the TwoDay Method efficacy study (n = 450).

Characteristic	Percent of participants
Study site	
Totonicapán, Guatemala	32.9
Iquitos, Peru	21.3
Piura, Peru	22.2
Alfonso, Philippines	12.4
Valenzuela, Philippines	11.1
Age at admission (y)	
18–24	23.3
25–29	28.7
30–34	26.4
35–39	21.6
Parity	
No children	0
1–2 children	60.9
3–4 children	28.2
≥5 children	10.9
Education	
No education or some primary education	26.7
Completed primary education	20.2
Completed secondary education	19.6
Some technical or university	33.4
Occupation	
No income-earning occupation	47.8
Agriculture	0.9
Sales (including also street vendors)	15.3
Blue collar job	25.5
White collar job	10.5
Ever-use of family planning methods[a]	
None	20.7
Rhythm	42.2
Withdrawal	31.8
Lactational amenorrhea method	6.4
Other traditional method	0.7
Barrier method	28.9
Intrauterine device	10.7
Hormonal method	41.8

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

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Cycle Characteristics and Days With Secretions

Mean cycle length was 29.9 days. The mean first day in which women noted secretions was day 8. Women who were breast-feeding at admission showed similar patterns.

Wilcox et al. (1, 2) used hormonal data to determine the length of the fertile window and concluded that it usually lasts 6 days—the 5 days before ovulation and the day of ovulation. Their findings show that the probability of pregnancy from intercourse earlier or later in the cycle is negligible (with 95% confidence interval). However, studies that relied on the symptoms of ovulation (cervical secretions, basal body temperature) show a slight probability of pregnancy as early as 8 or more days before and as late as 2 or more days after peak day, which they used as proxy for ovulation (12, 13).

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). The efficacy of the TwoDay Method suggests few false negatives. However, the identified fertile period is longer than 6 days for most women, suggesting some false positives or the possibility of fertile periods longer than 6 days.

The mean number of days with secretions was 12.1 days (median 12 days, minimum 3 days, maximum 31 days). Most cycles had between 10 and 14 identified days with secretions. Women identified <10 days with secretions in only 4.5% of cycles (women who identified <5 days were removed from the study). Women identified >14 days in only 4% of cycles. There were >16 days with secretions in only 1% of cycles (women who had >14 consecutive days with secretions were removed from the study).

Continuation

Of the 450 participants who entered the study, 52.7% completed 13 cycles of method use. Some 99% of these women were planning to continue using the TwoDay Method. Table 2 shows the reasons for leaving the study before completing 13 cycles.

Of those who did not complete 13 cycles, the largest group (15.7% of the total study) was asked to leave the study for a method- or study-related reason. Method-related reasons for leaving the study included cycles with <5 days or >14 consecutive days with secretions (2 women and 27 women, respectively); study-related reasons for leaving the study included not complying with the study requirements of checking secretions and marking on the diary card for two cycles (12 women) and having cycles of 42 days or longer (30 women). Approximately half of the women who were asked to leave the study were nevertheless planning to continue using the TwoDay Method.

TABLE 2

Reason for exit from TwoDay Method efficacy study (n = 450).

Reason for exit	Percent of participants
Completed 13 cycles	52.7
Was asked to leave the study for study reason	9.3
Was asked to leave the study for method reason	6.4
Client did not like or trust the method	1.8
Partner did not like or trust the method	2.0
Wanted to get pregnant	2.2
Exited for another voluntary reason	10.4
Unknown reason	0.2
Lost to follow-up	4.4
Pregnant	10.4

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Very few women (3.8%) left the study early because they or their partners did not like or trust the method. One woman left because other relatives were opposed to her using the method, and one left because a local religious leader suggested to her husband that he should not use the TwoDay Method. Other women left the study before completing 13 cycles because of changed fertility intention (2.2%). Some 17 women (3.8%) left because of marital dissolution or no need of a family-planning method because their partner migrated or died. Only 20 women were lost to follow-up, and 47 became pregnant during the study period.

Correct Use

The 450 study participants contributed 3,928 cycles. At the end of the first cycle of method use, 96.4% of participants reported that they had no problem detecting the presence or absence of secretions. Only 2% of respondents still reported trouble detecting secretions by the third cycle. In comparison, some 93.1% of participants in a WHO study of the Ovulation Method charted an interpretable ovulatory pattern at the end of their first cycle of use (97.1% at the end of the third cycle) (14).

To facilitate the calculation of method failure, study participants were asked to avoid sexual intercourse on their fertile days, but they also were asked to report if they did have intercourse and if they used another method. In 93.6% of cycles, women reported no intercourse during the days the method identified as fertile; in 2.9% of cycles, they had intercourse in the fertile days but used a backup method. Women had unprotected intercourse during their fertile days in only 3.9% of cycles (the figures add up to 100.4% because in a few cycles women had intercourse with backup protection and unprotected intercourse at least once during the fertile days).

None of the couples who had intercourse during the days the method identified as fertile did so habitually. The 3.9%

of cycles with unprotected intercourse during fertile days were contributed by 25.8% of participants. Of women who contributed at least six cycles to the study, some 70.5% reported no intercourse on the fertile days in any of their cycles in the study, and only four (1.4%) had unprotected intercourse during fertile days in a quarter or more of cycles.

Most incidents of incorrect method use occurred during the first cycles in the study (some 9.4% of women had unprotected intercourse in cycle one, compared with only 0.8% in cycle 13). Mean coital frequency was 5.6 days with intercourse per cycle, regardless of whether the woman did or did not have intercourse (protected or unprotected) on her fertile days.

Efficacy

A total of only 47 pregnancies occurred during the study. As expected, most (53.2%) were in cycles in which women reported unprotected intercourse during the fertile days. Additional pregnancies happened when the couple was using withdrawal (12.8%) or condoms (8.5%) as backup during the fertile days. Only 12 pregnancies (25.5% of pregnancies) occurred in cycles for which couples reported no intercourse during the fertile days.

The 40.5% of participants who were breast-feeding at admission contributed 44.4% of pregnancies. Breast-feeding women whose child was younger than 1 year at admission (11.3% of participants) contributed 13.3% of pregnancies.

Almost half of pregnancies occurred during the first three cycles of method use; only four pregnancies occurred during the last three cycles. This phenomenon, which is common in contraceptive trials, might be explained by three factors. First, women for whom the method is biologically not effective (i.e., their secretions are not adequate markers or are not sufficiently detectable to serve as markers of their fertility) get pregnant early in the study. Second, learning to correctly identify the presence or absence of secretions might take some practice. Finally, in the first few cycles of method use, couples learn to modify their sexual behavior during the cycle (as evidenced by the reduced frequency of unprotected intercourse on the identified fertile days in later cycles).

The first-year pregnancy rate was 3.5 (95% confidence interval [CI] 1.44–5.52) with correct use of the method (pregnancies occurring in cycles for which participants reported no intercourse on the days the method identified as fertile). This was the definition of correct use during the study. When we included in the analysis cycles for which participants reported intercourse with use of condoms or withdrawal during their fertile days (and pregnancies occurring in such cycles), the first-year pregnancy rate was 6.3 (95% CI 3.61–8.81). Possible use of a barrier method during the fertile days is how correct use would be defined when the method is offered through regular service delivery, outside of an efficacy study setting. When we included all cycles and pregnancies in the analysis, the pregnancy rate was 13.7 (95% CI 9.93–17.34). The single-decrement, multicensoring life table for correct use (including only cycles and pregnancies with no reported intercourse on the fertile days) is presented as Table 3. The life table including all cycles and all pregnancies is presented as Table 4.

TABLE 3

Life table pregnancy rates for correct use of the TwoDay Method.

Cycle	No. of women exposed[a]	No. of pregnancies	Pregnancy rate	95% confidence interval
1	319	2	0.63	0.24–1.49
2	335	3	1.52	0.19–2.83
3	317	2	2.14	0.56–3.69
4	307	1	2.46	0.76–4.12
5	293	1	2.79	0.97–4.57
6	282	1	3.14	1.20–5.03
7	264	0	3.14	1.20–5.03
8	262	1	3.50	1.44–5.52
9	249	0	3.50	1.44–5.52
10	239	0	3.50	1.44–5.52
11	237	0	3.50	1.44–5.52
12	237	0	3.50	1.44–5.52
13	233	0	3.50	1.44–5.52

[a] Excluding censored cycles.

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The efficacy of the TwoDay Method compares very well with the efficacy of other (more complex) fertility awareness–based methods of family planning (15). For example, a well-known multicenter efficacy study of the Ovulation Method, conducted by WHO, showed a pregnancy rate of 19.6 when all cycles (correct and incorrect use) were in-

TABLE 4

Life table pregnancy rates for correct and incorrect use of the TwoDay Method.

Cycle	No. of women exposed[a]	No. of pregnancies	Pregnancy rate	95% confidence interval
1	411	11	2.68	1.10–4.22
2	380	7	4.47	2.43–6.47
3	347	5	5.85	3.49–8.14
4	319	4	7.03	4.42–9.56
5	305	4	8.25	5.41–11.00
6	289	4	9.52	6.44–12.49
7	272	1	9.85	6.71–12.88
8	269	3	10.85	7.54–14.04
9	257	2	11.55	8.12–14.85
10	246	2	12.27	8.72–15.68
11	243	2	12.99	9.32–16.51
12	240	2	13.71	9.93–17.34
13	234	0	13.71	9.93–17.34

[a] Excluding censored cycles.

Arévalo. Efficacy of the TwoDay Method. Fertil Steril 2004.

cluded in the analysis (16). We can speculate that efficacy is influenced by ease of use. This was the rationale of the effort to develop methods that are simple: that making them easy to use can increase method use (by making them more acceptable to potential clients), improve continuation (by making them more acceptable to actual users), and increase effectiveness (if a method is easy to use, clients are more likely to use it correctly).

Acceptability

Most participants liked using the TwoDay method. When asked in the exit interview what they thought of the method, 96.1% gave positive comments, including comments about ease of use, the fact that the method is natural and causes no side effects, effectiveness, and affordability. All of the 237 women who completed 13 cycles of method use were satisfied with the method. Most women (87.7%) who were asked to leave the study commented positively, as did 92.2% of women who left for personal reasons. The 20 participants who gave negative comments said that the identified fertile period was too long or that the method was difficult to use. Some 93.7% of participants thought that their partner liked the method.

DISCUSSION

This efficacy trial demonstrated that the TwoDay Method is an effective and acceptable method of family planning. The correct-use pregnancy rate of 3.5 is comparable to other coitus-dependent methods, such as condoms (17). We also have shown that clients can learn to recognize the presence and absence of cervical secretions and to correctly use the TwoDay Method to avoid pregnancy.

In the past, many efficacy studies of fertility awareness–based family-planning methods have not enrolled women into the study until they have completed a learning period, usually 3 months of method use, during which they received continued instruction (16, 18). Excluding early cycles of use artificially reduces pregnancy rates. In this study, we included women beginning with their first cycle of use. Because most pregnancies occurred in the early cycles, our results are very conservative compared with some efficacy studies of other fertility awareness–based methods of family planning. This is demonstrated when we compare pregnancy rates for the first 10 cycles and the last 10 cycles in the study. The pregnancy rate for correct use (with abstinence) for the first 10 cycles was 3.5 (the same as for 13 cycles, because there were no pregnancies in the last three cycles); for the last 10 cycles it was 2.4. Similarly, when we included cycles with correct and incorrect use in the analysis, the pregnancy rate was 12.3 for the first 10 cycles but only 8.4 for the last 10 cycles. Clearly, the failure rate was lower in the last 10 cycles than in the first 10 cycles in the study. If we had excluded the first three cycles from the analysis as a "learning phase" and followed participants for three more cycles, the pregnancy rate would have been significantly lower.

Our results also are somewhat conservative compared with results of many other contraceptive efficacy studies because we excluded from the analysis cycles with no intercourse and conducted repeated pregnancy tests beyond 42 days from last menstrual period.

A weakness of the study is our reliance on women's self-reported intercourse and use of backup methods. We expect that women might have under-reported intercourse, especially on the days identified by the method as fertile. Although there is no way to confirm the extent of this under-reporting, it is reassuring that the mean reported coital frequency in our study is 5.6 days with intercourse per cycle, similar to the 64 yearly (5.3 monthly) days with intercourse reported for users of coitus-dependent methods in 32 countries (19). However, if participants did under-report days with intercourse in the fertile days, then the results we present here are conservative.

Another weakness of the study is the monthly follow-up schedule and the requirement to complete a coital log, which were necessary for data collection but which might have increased correct use of the method and continuation rates. In addition, the study requirement of abstaining from intercourse during the fertile days might have implications for efficacy. The failure rate for those who had intercourse with a barrier method or withdrawal during the fertile days (6.3) might not reflect efficacy of the method when it is offered with the option of barrier method use in the fertile days. On the one hand, we expect that study participants had less intercourse during the fertile days than they might have when regular service delivery protocols and counseling include the option of intercourse with a barrier method during the fertile days; on the other hand, those who have intercourse on those days might be more likely to have condoms available on hand when the method is provided in a regular service delivery context. Also, removing women from the study for study reasons, particularly for not marking the diary card, might have artificially reduced our failure rate.

The TwoDay Method increases contraceptive choice and offers a valuable addition to the services that reproductive health and other programs can offer. It is effective and easy to teach, learn, and use, as evidenced by the high proportion of women who, from the very first cycle of method use, had no trouble identifying and monitoring the presence and absence of secretions and deciding each day whether they should consider themselves fertile.

The Institute for Reproductive Health, Georgetown University, has recently developed another fertility awareness–based method—the Standard Days Method. The Standard Days Method identifies days 8–19 of the cycle (inclusive) as the fertile days for every user in every cycle. An efficacy study resulted in a pregnancy rate of 4.8 with correct use (20). The Standard Days Method can be successfully used after just one counseling session, compared with the TwoDay Method, which might require more than one counseling

session. However, the TwoDay Method has one advantage over the Standard Days Method. Whereas the Standard Days Method is most appropriate for women with cycles that usually range between 26 and 32 days, the TwoDay Method can be used successfully and effectively by women with cycles of any length. Our study participants were not screened for cycle regularity. Whereas 72.8% of cycles contributed to the TwoDay Method study were within the 26–32-day range, 8.1% were shorter (minimum 13 days), and 19.1% were longer, including 80 cycles that were 40 days or longer (the latter include the very long cycles—>42 days long—that were a reason for women to be removed from the study; maximum 54 days).

The TwoDay Method can address the need of women for simple accurate instructions for identifying their fertile days. Additional research is planned to test the viability of offering the TwoDay Method and the Standard Days Method in the same programs; to study method delivery issues when offering the method through regular service delivery, with the option of barrier method use on the fertile days and without keeping a coital log; and to examine efficacy and acceptability of the method to couples in specific subgroups.

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