Original research article

TwoDay Method: a quick-start approach
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Abstract

Background: Requiring that women wait until the onset of menses to initiate a family planning method is a medical barrier that can result in unintended pregnancies. In the efficacy study of the TwoDay Method, a new fertility awareness-based method of family planning, women were taught the method in the first seven days of their cycles. This study tested a quick-start approach (providing the method at any time in the cycle) to TwoDay Method delivery.

Study Design: In Peru, 167 women were counseled in TwoDay Method use (regardless of cycle day) and followed for up to 7 months. They were interviewed periodically to assess their use of and satisfaction with the method. Simulated clients gauged providers’ ability to correctly counsel in method use at different times of the cycle.

Results: No significant differences were observed in correct use, continuation rates, and acceptability of the method among women who were counseled at different points in the cycle; quality of counseling was not undermined by the quick-start approach.

Conclusions: There is no need to limit delivery of the TwoDay Method to the first seven days of the menstrual cycle.

Keywords: TwoDay method; Quick start; Fertility Awareness based methods (FAM)

1. Introduction

Women seeking a family planning method expect to get the method when they request it. Asking them to return for the method days or weeks later, when they menstruate, is a medical barrier that can result in more unintended pregnancies. We present a study that tested a quick-start approach — offering a method at any time during the cycle without waiting for the woman to menstruate — to providing TwoDay Method®, a new fertility awareness-based method of family planning.

The TwoDay Method relies on the presence or absence of cervical secretions to determine when in the cycle the woman should avoid unprotected intercourse to prevent pregnancy. We define cervical secretions as anything coming out of her vagina other than menstrual bleeding or semen. Each day the woman asks herself two simple questions: (1) “Did I note any secretions today?” and (2) “Did I note any secretions yesterday?” If the answer is “yes” to either of these questions (she noted secretions today, or she noted secretions yesterday), she considers herself fertile today. If the answer is ‘no’ to both of these questions (she noted no secretions today, and she noted no secretions yesterday), it is very unlikely that she would become pregnant if she had unprotected sexual intercourse today [1].

The Institute for Reproductive Health, Georgetown University, conducted a prospective, non-randomized, multicenter study to test the efficacy of the TwoDay Method in culturally diverse sites in Guatemala, Peru, and the Philippines. The first year failure rate was 3.5 (per 100 women-years) with abstinence on the fertile days and 13.7 with typical use [2]. These rates are within the range of a number of other user-dependent family planning methods [3].

Hormonal methods and intrauterine devices (IUDs) conventionally used to be offered only in the first week of the cycle, to avoid possible harm to an undetected pregnancy. Stanback et al. [4] posited that this approach created a medical barrier that had no scientific justification and that denied clients their right to obtain contraceptive services. They argued that when non-menstruating women are told to return at the onset of menses, they may be discouraged and abandon their plans to use the method. Others become pregnant while waiting to menstruate. In addition, travel to and from service-delivery points can...
represent significant time and monetary costs to clients, especially those living in remote locations, and make the methods less accessible.

Current guidelines of the World Health Organization recommend a quick-start approach to offering contraception, and the literature on offering hormonal methods and IUDs clearly demonstrates that offering these methods to women at any time during their cycle is acceptable to providers and clients, is feasible and does not negatively impact effectiveness and continuation rates (see, for example, [5–10]). Lopez et al. [11] recently conducted a Cochrane review of randomized controlled trials of a quick-start approach to contraceptive provision. They found that method discontinuation was similar between groups in all trials, as were bleeding patterns. The quick-start approach to providing DMPA resulted also in fewer unintended pregnancies, compared to women who were using a ‘bridge’ method until they could start using DMPA.

Clearly, then, offering the TwoDay Method to women on any cycle day in which they seek the method may be advantageous. Moreover, initiating use of the TwoDay Method cannot cause any possible harm to an undetected pregnancy. However, the characteristics of the method may hinder correct use of the method if taught at certain times of the cycle. The method requires the identification of the presence or absence of cervical secretions. Secretions typically start several days after the end of menstruation and end a week or more before the onset of the next menses. When the initial efficacy study was conducted, participants were offered the method if they were on the first week of the cycle, before the onset of cervical secretions. Before a quick-start approach can be recommended in service delivery settings, we needed to ascertain that women can learn to use it correctly if taught after the onset of secretions or after secretions had already ended for the cycle, and if a quick-start approach to offering the method would be feasible and acceptable to providers. This is the purpose of the current study.

2. Materials and methods

The TwoDay Method was offered to Peruvian women in clinics run by the Ministry of Health and Instituto Peruano de Paternidad Responsable (a nongovernmental organization that provides family planning services). A peri-urban site in Lima and a more rural site in Piura were chosen for the study. These sites were selected because of the interest partner organizations expressed in the TwoDay Method and the study. The Instituto para la Salud Reproductiva (ISR), Peru, a local research and technical assistance organization, supported implementation of study activities. The study was approved by the Georgetown University Institutional Review Board.

Providers from both service delivery institutions received training and offered the method through their respective health facilities to interested clients, regardless of cycle day. The method was offered along with other available family planning methods.

2.1. Client perspective

We followed TwoDay Method users for up to seven cycles of method use. We did not use power calculations to determine sample size. Rather, all women were admitted to the study who chose the TwoDay Method during the recruitment period, and who were willing to participate in the study and signed the informed consent form.

A total of 176 women were admitted to the study. They were counseled in TwoDay Method use regardless of their cycle day. Participants were interviewed in their homes one, four, and seven months after they initiated method use. The questionnaire included questions on correct use (self-reported, as no coital logs were collected), continuation, and acceptability of the method to clients and their partners.

In the analysis, we compare women who were counseled in TwoDay Method use during the first 7 days of their cycle, to women who were counseled later in the cycle. To determine significance levels of differences between the two groups, we used t-tests and $\chi^2$ to compare means and response categories respectively. The users were counseled by 28 different providers, each counseling between one and 15 participants. We therefore did not attempt to compare the outcomes of the women counseled by different providers.

We calculated pregnancy rates using multi-censoring lifetables, which allowed us to censor women who left the study for any reason other than pregnancy [12].

2.2. Provider behaviors

We used the Service Test methodology [13] to assess provider attitudes and practices while offering the TwoDay Method. The Service Test methodology involves visits by simulated clients. In the weeks after provider training, simulated clients visited the trained providers in both Lima and Piura. Providers believed they were attending real clients. After each visit, the simulated clients completed a checklist about their experience. This methodology had been validated in a number of studies, and research has shown that it results in unbiased observations in several related fields [13].

The simulated clients were trained by ISR-Peru. They were dressed to look like local women and used specially designed scripts that included contraceptive history and method preference. Three client profiles were created based on whether the woman was in the beginning, middle or end of her cycle. The first profile placed the woman on Day 4 of her cycle, clearly before the onset of secretions; the second profile placed her on Day 13, so that she was very likely to be experiencing secretions during the consultations; the last profile placed the woman on Day 25 of her cycle, after secretions for the cycle are usually finished. We used three profiles rather than two (before and after Day 7 of the cycle) because instructions for the providers were somewhat
different on how to counsel women, depending on whether they were in the beginning, middle or end of their cycle. Since programmatically there is no difference between the two profiles for women who are on Day 13 and 25 of their cycle (either the woman is in the first week of her cycle or she is not), we combined them in the analysis.

After each clinic visit, the simulated clients completed a checklist about their experience. The checklist listed the provider behaviors expected in an interaction with a client with the attributes of the given profile. Each item on the list was coded 1 (for the desirable outcome) or 0. This coding system allowed us to calculate scores for the entire checklist or for sub-sets of items, and compare means between profiles. The check list we used included 63 items in eight categories: (1) interpersonal relations (items on how responsive the provider was), (2) need diagnosis within the context of informed choice, (3) method options presented to the clients, (4) information provided about secretions, (5) contraindications (information provided about the risk of using this and other methods), (6) action mechanisms (how the methods works) including advantages and disadvantages of the method compared to others, (7) instructions on how to correctly use the method and (8) instructions for follow-up. The goal was to compare the scores of providers who were counseled on Days 1–7 to those who were counseled on Day 8 or later of the cycle.

3. Results

3.1. The client perspective

Service statistics from participating clinics show that some 1.3% of new family planning users in participating clinics in Lima and 2.9% in Piura chose to use the TwoDay Method during the study recruitment period. A total of 176 women were admitted to the study, 113 in Piura and 63 in Lima. Their mean age was 32.6 years. Demographic differences between participants in Piura and Lima reflect known differences between these populations [14]. Women in Piura had, on average, two children, compared to 1.4 in Lima. Education levels were somewhat higher in Lima. Most participants from both sites had used a modern contraceptive method previously, reflecting the high contraceptive prevalence in Peru [14]. Some 43 clients (24.4%) received counseling on Days 1–7 of their cycle, the rest received counseling on Days 8 or later (90 women on Days 8–20, or the “middle” of the cycle, and 43 women on Day 21 or later). There is no statistically significant difference in the profile of participants who were counseled on Days 1–7 and those counseled later in the cycle.

3.2. Continuation

About two thirds of participants successfully completed seven cycles of method use. Table 1 shows the reason for leaving the study according to when in her cycle the woman was counseled in method use. A higher proportion of women who were counseled on Days 8+ completed seven cycles of method use, while the proportion of women who left the study for reasons that were not related to the method or the study was higher in the group counseled on Days 1–7. These differences are statistically significant.

A few participants reported abnormal secretions — too few or too many days with secretions (9 women in the first cycle), or secretions that suggested pathology (3 women in the first follow-up interview). This finding measures the woman’s perception of abnormal secretions, and could reflect either physiological problems or incorrect identification of secretions. While it appears to have happened more to women who were counseled early in the cycle, the numbers are small, such that even one more or one less women in either group would change the proportion (four women who were counseled in Days 1–7; three women who were counseled later in the cycle), and the difference is only approaching statistical significance (p=.072). Similarly, only 6.6% of women who were counseled later in the cycle left the study because they or their partner did not like or trust the TwoDay Method, compared to only one woman (2.4%) who was counseled in Days 1–7. This difference is also not statistically significant (p=.276).

Only 12 participants became pregnant during the study period. Only one unintended pregnancy was a woman who was counseled on Days 1–7, the remaining nine unintended pregnancies occurred in women who were counseled on Days 8+. We calculated the seven-cycle failure rate of the method for the two groups (including the two intended pregnancies). The life-table failure rate was 3.45 (for 100 women using the method for seven cycles) for women who were counseled on Days 1–7, and 9.91 for women who were counseled later in the cycle. Both figures compare well with an earlier efficacy study where the seven-cycle life-table typical use failure rate for 100 women using the method for seven cycles was 9.85 [2].

About three quarters (n=73) of respondents who completed seven cycles of method use said they would continue

Table 1

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Reasons for leaving the study</th>
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<tbody>
<tr>
<td></td>
<td>Counseled on Days 1–7</td>
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<tr>
<td></td>
<td>n=40</td>
</tr>
<tr>
<td>Completed 7 cycles of method use</td>
<td>21 (52.5%)</td>
</tr>
<tr>
<td>Unintended pregnancy</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Planned pregnancy</td>
<td>0</td>
</tr>
<tr>
<td>Abnormal secretions</td>
<td>4 (10.0%)</td>
</tr>
<tr>
<td>She or her husband did not like or trust the method</td>
<td>1 (2.5%)</td>
</tr>
<tr>
<td>Other^</td>
<td>13 (32.5%)</td>
</tr>
</tbody>
</table>

^ Other reasons for leaving the study included continuing to use the method but no longer willing to be interviewed, changed fertility intentions, marital dissolution, no longer needing protection from pregnancy (i.e., menopause, hysterectomy) and several unspecified.
to use the TwoDay Method after the study. Participants who decided to discontinue after seven cycles did so for a variety of reasons, similar to those for early discontinuation. These figures are similar for both groups.

3.3. Correct use

To use the method correctly, the woman needs to (1) correctly identify the presence or absence of secretions; (2) determine whether she noted secretions today or yesterday—make the connection between secretions and fertility; and (3) avoid unprotected intercourse on the days she identifies as fertile.

3.3.1. Identification of secretions

Since no biological specimens were collected, we could record only the women’s perception of her secretions. We therefore define correct identification of secretions as: (1) at least 5 days with secretions in the cycle, and (2) the days with identified secretions are consecutive. Table 2 shows the percent of participants who correctly identified secretions in the first and fourth cycles of method use. Most participants correctly identified their sections in Cycle 1 and Cycle 4. Differences between the two groups were small and not statistically significant.

We also examined the reported first day of secretions, the number of days in which respondents noted secretions, and the number of identified fertile days, in the first cycle for which we have complete record of secretions (Table 2). For women who were counseled in method use before the onset of secretions, this is their first cycle in the study. For women who were counseled after the onset of secretions, or after secretions have ended for the cycle, this is the following cycle. For pregnancy cycles and cycles longer than 45 days, these figures include information on the first 45 days of the cycle. Participants who were counseled early in the cycle identified, on average, one more day of secretions than other participants, but these differences were not statistically significant.

3.3.2. Management of the fertile days

In this study the TwoDay Method was introduced into regular service delivery, so participants were not asked to complete coital logs. We therefore rely on reported behavior and the accuracy of participants’ recollections when asked if they had always had only protected (or no) intercourse during the identified fertile window of the previous cycle. This information is shown in Table 2. Almost all (97.2% and 98.2% in Cycle 1 and Cycle 4 respectively for those counseled on Days 1–7; 100% and 98% for those counseled on days 8+) participants reported that they followed instructions well and avoided unprotected intercourse on their fertile days. The differences between participants who received instructions early and later in the cycle were minimal and not statistically significant.

3.4. Experience with secretions

To avoid confusion between secretions and semen, it is recommended that women check for secretions in the afternoon and evening. This way if they have sexual intercourse at night or early in the morning, the semen will no longer be present by the time they check for secretions. Clients are told that they should check at least twice in the afternoon and evening. Table 3 shows when during the day study participants had checked for secretions during the first cycle of method use.

Participants appeared to have followed instructions well. Some 82.5% of women counseled in Days 1–7 and 91.9% of women counseled later in the cycle checked for secretions in the afternoon, evening, or before bed. Differences are not statistically significant.

TwoDay Method clients are counseled that they can check for the presence or absence of secretions in several ways — they can look on their underwear or panty liner,
wipe themselves, touch themselves or feel (or sense) the secretions. Table 3 also shows how respondents chose to check for secretions during the first cycle. Some participants reported sometimes having trouble identifying their secretions, or being sure whether they had secretions or not. This is also shown in Table 3. Differences between the groups were not statistically significant.

### 3.5. Acceptability

Most participants were very satisfied with the method. Some 94.7% of participants who were counseled on Days 1–7, and 92.7% of those counseled later, said in their exit interview that they would recommend the method to other women. Table 4 shows what participants thought about various aspects of learning and using the method. Differences between the groups were not statistically significant.

### 3.6. Provider behavior

To determine if the quality of counseling was affected by whether the client was in the first seven days of her cycle or later, we examined the simulated client checklists. We first review the mean percent of providers who correctly responded to the items on the list. Each category on the checklists comprises of several items, and the same provider could correctly respond to some but not others. Thus, the percent of providers who correctly responded to one item on the list would be different from another. For each category, we averaged the percent of providers who correctly responded for each item in the category, and present these means (% of correct responses in each category) in Table 5. We see that providers did better when counseling women who were later in the cycle in six of the eight sections, suggesting that they had no difficulty in counseling these women. This is confirmed when we look at the mean duration of counseling sessions. The mean counseling time for clients on Day 4 of their cycle was 32 min, compared to only 27 min for clients who were on Days 13 or 25 of their menstrual cycle, suggesting that it was easier for the provider to go through the counseling session at this time.

We can see also that when counseling women who were early in their cycles, providers paid more attention to discussing secretions (including items on secretions that suggest pathology and the client’s willingness to check for secretions daily, but excluding instructions on how to use secretions to determine if the woman is fertile, which were included in the section on action mechanism); when counseling clients who were later in their cycle, they gave more information about follow-up. We conclude that a quick-start approach does not undermine the quality of counseling.

### 4. Discussion

Earlier experience with the TwoDay Method showed that it is a promising new fertility awareness-based method of family planning [2]. It is easy to teach, learn and use and is effective when used correctly. It is a good option for women who do not wish to (or cannot) use hormonal contraceptives, and for couples who prefer a fertility awareness-based approach to family planning. This study was designed to test a quick-start approach to offering the method — providing it to women at any time during their menstrual cycle.

We found few differences between the groups. One difference was in pregnancy rates. The 7-month pregnancy rate for women who were counseled in on Days 1–7 was 3.45, compared to 9.91 for those counseled on Days 8+. This may be a function of the small numbers — only one woman counseled on Days 1–7 had an unintended pregnancy. If even one more woman had become pregnant, that pregnancy rate could have been as high as 8.81 (depending on which cycle she had become pregnant in). Also, three women counseled on Days 8+ became pregnant during the first cycle of method use. It is possible that some were already pregnant but may have been uncertain of their fertility at that time.
when they were admitted to the study, as they were not using another family planning method at the time. Another possible explanation for the higher pregnancy rate among women counseled later in the cycle is the number of women who left the study for reasons such as marital dissolution and travel — 9 women (of 40) among those counseled on Days 1–7 of the cycle, compared to only 6 women (of 121) women counseled later in the cycle. Therefore, there were fewer women left in the study who could become pregnant among those counseled early in the cycle. In any case, the higher figure reported for women counseled later in the cycle is almost identical to the typical use failure rate reported during the efficacy trial of the TwoDay Method, which compares well with other user-directed methods [2].

The study has some limitations. On the one hand, the more frequent follow-up of a study setting may result in more correct use of the method; on the other hand, since participants were interviewed quarterly, recall may have created a bias, though if there is such bias, there is no reason to expect the amount of bias to be different for the two groups. In addition, we can only estimate correct use based on participant report, as we did not physically check for the presence or absence of secretions, and participant report may be biased. Also, the small sample size may mask differences between the groups.

Despite these limitations, our data present a fairly consistent picture, providing the basis for programmatic recommendations. Providers offer the method equally well to clients who are in the first seven days of their cycle, before the onset of secretions; to clients who are in the middle of their cycle, after secretions started and to clients who are at the end of their cycle, after secretions ended. Similarly, clients use the method correctly, regardless of when they learned to use it. Continuation rates and satisfaction also were not affected by recommendations. Providers offer the method equally well to participants were interviewed quarterly, recall may have created a bias, though if there is such bias, there is no reason to expect the amount of bias to be different for the two groups. In addition, we can only estimate correct use based on participant report, as we did not physically check for the presence or absence of secretions, and participant report may be biased. Also, the small sample size may mask differences between the groups.

Given these positive results, and the clear advantages of reducing medical barriers, family planning programs can consider including the TwoDay Method among the family planning options they offer, and can provide it to women during any phase of their menstrual cycle. The study contributes to the evidence that providing a woman with the family planning method of her choice when she requests it is appropriate and that delaying method initiation until she is menstruating is unnecessary.

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