

Further analysis of the theoretical effectiveness of the TwoDay method of family planning☆

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Abstract

This article validates the theoretical effectiveness of a simple approach to identify the fertile window of the menstrual cycle. The TwoDay method identifies all days in the cycle in which the woman notices cervical secretions, and the days immediately following these days, as the period in which the woman should consider herself fertile. Women who use this method are counseled to avoid unprotected intercourse on these days. The theoretical effectiveness of the TwoDay method was tested previously by applying the method rules to the menstrual cycles of women from a large data set from the World Health Organization (WHO). For the current study, we administered the same analysis to a data set from an Italian Ovulation Method center. These data are better suited for the analysis than were the WHO data because they identify all days with secretions. Results suggest that the method can be highly effective in helping women to identify correctly the days on which they should avoid unprotected intercourse if they do not wish to become pregnant, although some users may identify a few days as fertile that actually are not. © 2001 Elsevier Science Inc. All rights reserved.

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1. Introduction

This article examines the theoretical effectiveness of a simple approach to identify the fertile window of the menstrual cycle: the *TwoDay method*. The method was developed by the Institute for Reproductive Health, Georgetown University, to meet the needs of many women for simple, accurate instructions to help them recognize when they need to avoid unprotected intercourse if they wish to prevent pregnancy [1].

The TwoDay method incorporates a simple approach to interpreting the physical symptoms of fertility. Users of the TwoDay method are instructed to monitor each day the presence or absence of cervical secretions (of any type) by sensation or observation. Some established methods for identifying the fertile window, such as the Ovulation method, require that the user learn to differentiate between

multiple characteristics of their cervical secretions (general appearance, color, and texture) and to interpret their findings [2]. Users of the TwoDay method, on the other hand, do not need to distinguish between different types of secretions, chart their findings, or follow complex rules to interpret their findings. Instead, they follow a simple algorithm to determine whether they should consider themselves fertile and avoid unprotected intercourse on any given day. Each day a user asks herself two simple questions: (a) Did I note secretions today? and (b) Did I note secretions yesterday? If she answers “Yes” to *either* of these questions, she should consider herself fertile that day and avoid unprotected intercourse if she does not want to become pregnant. If she answers “No” to *both* these questions, she is probably not fertile.

The Institute for Reproductive Health at Georgetown University previously analyzed the theoretical effectiveness of the TwoDay method by using a large data set from the World Health Organization (WHO) study of the Ovulation method. Results suggested that the TwoDay method would be very effective in preventing pregnancy for most women [1].

The WHO data set included information on 725 women from five countries, <39 years of age, regularly cycling with proven fertility, who had successfully learned the Ovulation method during the teaching phase of the study [3].

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The women were followed for up to 18 cycles, resulting in almost 7600 cycles with information on various characteristics of the cycle, including days of cervical secretions and signs of ovulation.

One methodological aspect of data collection, however, makes these data less than ideal for the analysis of TwoDay method's theoretical effectiveness. Study participants used a chart to keep track of their cervical secretions each day of the cycle. The data, however, do not include this daily information. Instead, a form that summarized chart information was completed. Only this summary is available in the data set. It includes information on the first day of the cycle in which the woman noticed secretions of any type, then the peak day of fertility (proxy for ovulation) is noted (peak day was defined as the last day on which mucus of fertile type is recognized or the last day on which a wet or lubricative sensation is felt by the woman [3]); information on days with secretions after the peak day is also available, but only if they immediately followed peak day. If there was a day without cervical secretions after the peak day, then following days with secretions were not noted as secretion days, because according to the Ovulation Method rules these days were assumed to be outside of the identified fertile window. It has been noted that some women notice days with secretions in the later part of the cycle that are not consecutive, and thus would not be recorded as days with secretions in the WHO data. Thus, basing the analysis of the theoretical effectiveness of the TwoDay method solely on the WHO data may result in an underestimate of its effectiveness. It also may result in an underestimate of the number of days per cycle when a woman using the TwoDay method would consider herself fertile by identifying days that are outside the actual fertile window as fertile. It is important, then, to perform a similar analysis using a data set that does include all days of secretions. Data provided by the Centro Rezzara in Vicenza, Italy, meet this criterion.

The purpose of this article was to present a further analysis of the theoretical effectiveness of the TwoDay method by using a data set that includes daily information about the presence or absence of cervical secretions. These data allow us to (a) validate previous results of the theoretical effectiveness of the method, and (b) get a better picture of the pattern of days with cervical secretions in the cycle and thus determine how many of those days are actually not likely to be fertile—that is, how many days women would be avoiding unprotected intercourse unnecessarily.

2. Materials and methods

To test the theoretical effectiveness of the TwoDay method, we use data from Ovulation method users collected retrospectively in an Ovulation method center in Vicenza, Italy. Clients of the center regularly chart their cycle characteristics and provide the center with a copy. Charts col-

lected in the period 1978–1989 from 282 women are included in the data (mean age 27 years). Each woman contributed between 1 and 35 cycles to the data (mean 9.6), for a total of 2707 cycles [4,5].

We included in our analysis only 2406 cycles, in which the peak day is uniquely identified, because our method of calculation is dependent on the observation of the peak day. The TwoDay method does not require the identification of the peak day, but it is impossible for us to identify the fertile days of the cycle for the purpose of this analysis in cycles where the peak day is not uniquely identified. The peak day was not uniquely identified in 301 cycles (11.1%) contributed by 113 women (40.1%). These women did notice secretions on some days in the cycles and were covered by the TwoDay method on these days.

The Vicenza data set lends itself well to our analysis in that it offers daily information on cervical secretions. This allows for the identification of nonconsecutive days of secretions. Women recorded when they noticed fertile and nonfertile secretions on every day of the cycle. These data provide insight into the “fit” between the days identified by the TwoDay method as fertile and the actual fertile window.

In our calculations we used two sources of information in addition to the Vicenza data. First, we considered the probability of pregnancy (clinically detected at 6 weeks from last menstrual period) from intercourse on various days relative to ovulation. Wilcox et al. [6] showed that there is a fertile window of several days during each menstrual cycle during which a woman can, with varying degrees of likelihood, conceive if she has unprotected intercourse. Unprotected intercourse on the day of ovulation results in clinically detected pregnancy about 8% of the time. Then, because of the short life span of the ovum, the probability of pregnancy from unprotected intercourse drops sharply, so that the day after ovulation has occurred, unprotected intercourse can rarely result in pregnancy. Before ovulation, because of the life span of the sperm, unprotected intercourse 6 or more days before ovulation can rarely result in pregnancy. The probability of clinically detected pregnancies increases progressively, from about 4% from intercourse 5 days before ovulation to 29% 2 days and 27% 1 day before ovulation, declining to 8% from intercourse occurring on the day of ovulation [7,8]. We use these figures in our calculations. An older study and preliminary results from a multi-center European study show a similar pattern.

Second, our data set does not identify the day of ovulation. Instead, it uses as proxy the peak day of mucus. Hilgers et al. [9] showed that the peak day is a good proxy for ovulation. Most ovulations occur during the period starting 2 days before the peak day and ending 2 days after the peak day, but more before the peak day than after, with 38% occurring on the peak day itself. We used the probability that the peak day occurs on a given day relative to ovulation in our calculations.

2.1. Step 1

We identified the percentage of cycles in which women would have been protected from pregnancy if they had followed the TwoDay method rules to identify their fertile window and avoided unprotected intercourse on the identified days. Women using the TwoDay method would avoid unprotected intercourse on any day on which they noted secretions and on the day after.

2.2. Step 2

We combine the probability that the woman gets pregnant from unprotected intercourse on different days relative to ovulation (as per Wilcox et al. [6], but using the peak day as proxy for ovulation) with the woman using the TwoDay method. For example, a woman would have 0.27 probability of getting pregnant on the day before ovulation [6] but only if she does not have secretions on that day or the day before. If she does have secretions, her probability of pregnancy from intercourse that day would be reduced to zero because the day would be identified as fertile, and the woman would avoid unprotected intercourse.

2.3. Step 3

We weighted the results by the probability that the peak day occurs on a given day relative to ovulation (as per Hilgers et al. [9]). The final result is the theoretical probability of a clinically detected pregnancy from unprotected intercourse on different days relative to the peak day, for the period starting 8 days before the peak day and ending 3 days after, for women using the TwoDay method. Before and after that period, unprotected intercourse only rarely results in pregnancy.

We also calculated the percentage of cycles on each day outside of the fertile period (the period starting 8 days before and ending 3 days after the peak day) in which the women noticed cervical secretions on that day or the day before. These are “false-positive” days that the TwoDay method identifies as fertile, while they probably are not fertile. The results were used to determine the number of days each cycle that the woman would have to avoid unprotected intercourse if she wishes to prevent pregnancy, following the TwoDay method rules.

3. Results

The theoretical effectiveness of the TwoDay method was calculated previously by using data from the WHO study of the Ovulation Method. We compare the results of that analysis with our analysis of the Vicenza data. The method used for calculation is the same.

Table 1 shows the estimated probabilities of pregnancy from unprotected intercourse occurring on various days in

Table 1

Estimated probability of pregnancy from unprotected intercourse on different days relative to the peak day for women observing the rules of the TwoDay method

Day relative to peak day	WHO data	Vicenza data
	n = 7592 cycles	n = 2406 cycles
P-8*	0.001	0.001
P-7	0.006	0.006
P-6	0.017	0.016
P-5	0.021	0.020
P-4	0.025	0.024
P-3	0.016	0.012
P-2	0.005	0.006
P-1	0.001	0.000
Peak day	0	0
P+1	0	0
P+2	0.005	0.005
P+3	0.001	0.001

* P denotes peak day (a proxy for ovulation); WHO = World Health Organization.

the cycle relative to the peak day, for women following the TwoDay method. Results using the two data sets were essentially the same, confirming that the TwoDay method would be an effective family planning method for most women.¹

Our method of analysis did not account for heterogeneity among women and the possibility that the method works better for some women than for others. To determine whether this is a valid concern, we examined cycles in which women were not covered by the method 4 days before the peak day (they had not noticed secretions 4 and 5 days before the peak day). We chose that day because it is the single day with the highest probability of pregnancy for women who follow the method rules (see Table 1). Women were not covered by the method on that day in 427 (10.3%) cycles, contributed by 147 (52.1%) women. This suggests that there is no substantial minority of women for which the method is ineffective.

In almost a quarter of cycles (24.6%), women noticed secretions on the day immediately before getting their menses. These days are usually outside of the fertile window, but the woman would identify them as fertile when following the TwoDay method rules. Table 2 shows the number and percentage of cycles in which the woman noticed cervical secretions outside of the fertile window (defined as the period starting 8 days before the peak day and ending 3 days after the peak day). These are days in which the woman noticed cervical secretions, and thus would have considered

¹ Note that repeating the analysis after discarding from the Vicenza data information not available in the WHO data provides essentially the same results. The estimated probability of pregnancy from intercourse 2 days before the peak day is 0.003, and from intercourse 8 days before the peak day it is 0.0004. All other results are the same.

Table 2
False positives: days outside the fertile window in which the woman noticed secretions

Pre peak phase of the cycle		Post peak phase of the cycle	
Day relative to peak day	Number of cycles (%)	Day relative to peak day	Number of cycles (%)
P-21*	8 (0.3%)	P+4	807 (33.5%)
P-20	10 (0.4%)	P+5	621 (25.8%)
P-19	17 (0.7%)	P+6	575 (23.9%)
P-18	21 (0.9%)	P+7	568 (23.6%)
P-17	20 (0.8%)	P+8	552 (22.9%)
P-16	33 (1.4%)	P+9	551 (22.9%)
P-15	46 (1.9%)	P+10	555 (23.1%)
P-14	74 (3.1%)	P+11	571 (23.7%)
P-13	106 (4.4%)	P+12	554 (23.0%)
P-12	148 (6.2%)	P+13	483 (20.1%)
P-11	210 (8.7%)	P+14	352 (15.6%)
P-10	321 (13.3%)	P+15	195 (8.1%)
P-9	461 (19.2%)	P+16	80 (3.3%)
		P+17	28 (1.2%)
		P+18	8 (0.3%)

* P denotes peak day (a proxy for ovulation).

herself fertile if using the TwoDay method, although she was probably not fertile. On days not shown in the table (22 days before the peak day or earlier; 19 days after the peak day or later), 0.2% of cycles or less had noticeable secretions.

The number of days identified by the TwoDay method as fertile varies depending on the number of days each cycle in which the woman notices cervical secretions. In the WHO data, the identified fertile days would be calculated as the number of consecutive days with secretions plus 1. In the Vicenza data, we calculate the identified fertile days by adding 1 to each group of consecutive days with secretions. Thus, for example, if the woman has 7 consecutive days with secretions, then several days without secretions, then 1 more day with secretions, the WHO data would show that she needs to avoid unprotected intercourse for 8 days if following the TwoDay method rules; the Vicenza data will show that she needs to avoid unprotected intercourse for 10 days.

It is not surprising, therefore, that the number of days in which a woman would need to abstain from unprotected intercourse to prevent unplanned pregnancy is greater based on the Vicenza data than on the WHO data. When calculated using the WHO data, women would consider themselves fertile 9 days on average; using the Vicenza data the mean was 11 days. But if we recode the Vicenza data to correspond with the kind of information that is available in the WHO data (not taking into account nonconsecutive days with secretions), the mean is 10 fertile days. Note that when we applied the rules of the Ovulation method to the cycles (in much the same way as we applied the TwoDay method rules), it appears that women who use the Ovulation method would have to

abstain from unprotected intercourse an average of 10 days using both data sets.

4. Discussion

By definition, the probability of pregnancy for women using the TwoDay method is 0 on the peak day and the following day (P+1) because all women notice secretions on the peak day. They consider themselves fertile on these days and avoid unprotected intercourse if following the method rules. The probabilities of pregnancy on other days vary, depending on when women notice secretions, but the results using the two data sets are virtually the same, and there is no difference in their ability to identify days that are actually fertile (compared to false positives).

A strength of the TwoDay method is that it does not require users to differentiate between different types of mucus, and it does not require the woman to identify the peak day. But this lack of specificity may also be its weakness because women who notice secretions that are not of fertile type will interpret them as fertile and avoid unprotected intercourse even though they are not in their fertile window. As Table 2 shows, some women notice secretions on days outside the fertile window. This translates into more days in which the woman would abstain from unprotected intercourse when following the TwoDay method instructions than if she were following the Ovulation method instructions. However, the difference in the number of fertile days between the TwoDay method and the Ovulation method is, on average, only 1.5 days per cycle and is not likely to change significantly the acceptability of the method to users.

Note, that we included in the analysis only cycles in which the peak day was uniquely identified. The TwoDay method does not require the identification of the peak day, but our method of calculation does. We, therefore, excluded from the analysis 11.1% of cycles where the peak day was not identified at all or where more than one peak day was identified. Women who observed more than one peak day would experience secretions and therefore consider themselves fertile for more days of the cycle. The TwoDay method would, therefore, work well for them. Women who cannot identify a peak day at all also experience secretions, and on those days they are covered by the TwoDay method. Therefore, although we cannot present effectiveness data for cycles with no uniquely identified peak day, we believe that the TwoDay method would reduce the probability of pregnancy in these cycles.

In conclusion, the TwoDay method appears to be a promising approach for identifying the fertile days of the menstrual cycle. Analysis of a second data set confirms its theoretical effectiveness. Even though it identifies some days of the cycle as fertile that probably are not, it does not result in a significant increase in the number of days per cycle a woman would consider herself fertile. A prospective

trial of this method is needed to determine its efficacy (including a cumulative pregnancy rate over 1 year) and its acceptability to users and providers.

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