Natural Family Planning: Suitability of the CUE™ Method For Defining the Time of Ovulation

Jorge E. Moreno,* Firyal S. Khan-Dawood,† and Joseph W. Goldzieher‡

The purpose of this study was to compare the CUE™ method for family planning with the Ovulation Detection Method for defining the fertile phase of the menstrual cycle. We evaluated 42 cycles from 10 women in Monterrey, Mexico, who were monitored by basal body temperatures, urinary LH, pelvic ultrasound, and the CUE monitor. The fertile phase of the cycle was adequately defined in all cycles using the CUE method, and in 35 cycles (83.3%) by the Ovulation Method. Using our protocol, the period of recommended abstinence with the CUE method is 9 days and with the Ovulation Method 11 days. The CUE method accurately defines the fertile phase of the menstrual cycle, thus improving the predictability of ovulation for women who use natural methods of birth control. CONTRACEPTION 1997;55:233–237 © 1997 Elsevier Science Inc. All rights reserved.

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Introduction

Preliminary studies indicate that the CUE™ method can predict ovulation sufficiently in advance of its occurrence to allow its use for natural family planning. Prediction of ovulation is possible by means of a peak in salivary electrical resistance (SR), and its confirmation by a rise in vaginal resistance (VR) as monitored by a hand-held electronic instrument attached to a specifically designed sensor for each reading.1,2 This method was recently assessed for its possible usefulness in natural family planning.3 It was concluded that the CUE method, due to its simplicity and objectivity, could have significant potential in this regard.

Materials and Methods

Data were obtained from 42 cycles of 10 women. The subjects were housewives with better-than-average education and socioeconomic status, residing in Monterrey, Mexico. All were using the Ovulation Method for family planning and had more than two years experience with this technique. This method was used in this study rather than the Symptothermal Method because it was the primary natural family planning technique being practiced at the test site and not because one method was assumed to be superior to the other. Specific selection criteria other than the above were: a) age, 20-35 years; b) regular menstrual cycles ranging in length from 25 to 35 days; c) no known condition that would interfere with either of the two methods studied.

In a group session, the subjects were informed about the purpose of the study and were given a brief description of the CUE method. A clinical history and a signed consent form were obtained, and instructions on contacting the investigators at the beginning of the menstrual cycle were provided. Cycle day one was defined as the first day of bleeding in any amount. On this day, a personal interview was arranged, and subjects were provided the CUE device, a basal body temperature (BBT) thermometer, and data sheet for recording oral, vaginal, and BBT readings daily. Each subject was instructed to take: a) oral temperature readings from day 1, b) vaginal readings from day 8 of the cycle until 5 days after follicle collapse as observed by pelvic ultrasound, c) twice daily urine collections beginning day 9 and through the day of ovulation, one between 10:00 a.m. and noon, and the other after 7 p.m.; and d) pelvic ultrasound monitoring once daily, from cycle day 9 until follicle collapse. In most subjects, a baseline ultrasound was obtained.
on cycle day 5 or 6. Ultrasonography was performed by one operator who had no knowledge of the subject's cycle history.

Instructions for oral CUE readings were to obtain the reading: a) after swallowing excess saliva and before eating or drinking; b) within 30 min of waking each morning followed by a second reading 30 min later. The CUE vaginal readings were obtained by placing the vaginal sensor in the posterior fornix, two readings were taken within 30 min of each other at the same time daily and at least 10 h from the time of sexual intercourse if it occurred. The BBT was taken after the CUE oral reading in the morning.

The LH surge from each cycle was determined with the OvuStick urine hLH kit (Monoclonal Antibodies, Mt. View, CA). The LH surge was defined as the day on which the color intensity of the test result was equal to or greater than that of the 40 mIU/ml control. Pelvic ultrasound for follicular monitoring was performed using a real-time sector scanner. The criteria for ovulation were either complete disappearance of the follicle or substantial reduction in size, together with one or more of the following signs: a) irregular boundary of the follicle; b) echogenic area within the follicle; or c) free fluid in the cul-de-sac.

The following rules defined the peak in the CUE salivary readings (CUE peak):

1) A rise in salivary electrical resistance with a subsequent drop for at least 2 consecutive days for a cumulative difference of at least 20 units. Thus, the CUE peak is not defined until 2 days after it has occurred. This day was termed the "Oral Signal" for the beginning of fertility.

2) A 1-day decrease with a subsequent rebound could also define the CUE peak, as long as the decrease was substantial, and the rebound did not approach within 10 units of peak value.

A vaginal nadir was defined as a low vaginal resistance value with a subsequent increase for at least 4 consecutive days. Therefore, the vaginal nadir cannot be determined until at least 4 days after it has occurred. The vaginal resistance rise was defined as the first day of increasing vaginal resistance from the vaginal resistance nadir. The signal defining the end of the fertile phase, i.e., the last day of abstinence, was taken to be the day of the vaginal resistance rise plus 2 days (VR signal). In certain cases, the vaginal resistance on some of the days after the nadir may not show a consecutive rise, showing a plateau or a slight decline. The vaginal nadir is still defined adequately, as long as the vaginal resistance on days following the nadir does not fall to within 20 units of it.

For the Ovulation Method, standard definitions were used. The first observation of mucus by the

![Figure 1. Comparison of the CUE oral signal and observations of the first mucus relative to the day of follicle collapse as determined by ultrasound.](image)

Subjects was considered the beginning of fertility. The Peak Symptom (PS) was defined as the last day of "fertile type" mucus. The day of the Peak Symptom plus 3 days was taken as the last day of fertility and, hence, the last day of required abstinence.

In accordance with previous reports, the sonographic period of fertility within the cycle was taken to range from 3 days prior to and 1 day after follicle collapse was observed.

Results

Data from 42 cycles of 10 subjects were collected. The vaginal resistance data from three cycles of three subjects were excluded because the samples were improperly taken. In all cycles, a midcycle LH surge was observed. The day of the LH surge ranged from cycle day 10 to 21, with a mean of 14 ± 2.5 days. Follicle collapse was observed in all but three cycles on the day following the detection of the LH surge. In the three cycles where follicle collapse was not observed, an intact follicle was observed to be present for more than 3 days following the LH surge.

The distribution in the intervals from the CUE salivary peak, which was the oral signal, and first mucus to follicle collapse is shown in Figure 1. CUE peaks were observed from 6 to 12 days prior to ovulation, with an average time interval of 8.0 ± 1.5 days. Seventy-two percent of oral peaks occurred from 6 to 8 days before follicle collapse, with an average time interval between these events of 7.0 ± 2.7 days.

A strong association was found between the day of the CUE salivary peak and the day of the LH surge and also the day of the follicle collapse. The correlation coefficient between day of CUE peak, day of LH surge, and day of follicle collapse was 0.82 (p < 0.001). The within-subject variation in the interval from CUE peak to follicle collapse was ±2 days in 7 of the
10 subjects. In these same subjects, the length of the follicular phase varied by as much as 8 days. A significant intraclass correlation (0.65; p < 0.001) was found for the within-subject effect for the interval between CUE peak and follicle collapse.

The distribution of the vaginal resistance rise and the peak symptoms relative to the day of follicle collapse is shown in Figure 2. The rise in vaginal readings (VR rise) occurred an average of 0.8 ± 0.6 days after follicle collapse, with all increases occurring within one day of follicle collapse. The strong association in the time of the vaginal rise and ovulation is indicated by the correlation coefficient (r) between these two variables of 0.98 (p < 0.001). The peak symptom was observed an average of 0.1 ± 1.5 days before follicle collapse. In 69% of these cases, the peak symptom occurred within 1 day of follicle collapse. A correlation coefficient of 0.85 (p < 0.001) was found between the day of the peak signal and of follicle collapse. A linear association was also seen for the day of the peak signal and vaginal resistance rise (r = 0.87; p < 0.001).

The signal for the beginning of the fertile phase with the CUE method, i.e., the oral signal, is taken to be 2 days post-CUE peak, while the last day of fertility was taken to be the day of the vaginal resistance rise plus 2 days. With the Ovulation Method, the first day of mucus was taken to be the first fertile day, while the last day of fertility was defined as the day of the peak symptom plus 3 days.

Means and ranges for the definition of the fertile phase (first and last days of presumed fertility) by the CUE method and the Ovulation Method are shown in Table 1. The oral signal, with a distribution of 4–10 days before follicle collapse, would have defined the beginning of fertility adequately in all cycles, since in no case did this signal occur within the period of fertility. With first mucus observations as the beginning of fertility by the Ovulation Method, the start of the fertile phase would have been adequately defined in 37 of 39 cycles. In two cycles, first mucus occurred within the fertile phase, and abstinence in these cases would have begun only 3 days prior to follicle collapse. The average intervals for the signals for beginning of abstinence by the CUE method and Ovulation Method are 6.0 and 7.0 days, respectively, a statistically significant difference (p < 0.05).

With the day of the vaginal resistance rise +2 days as the last day of abstinence, the end of the fertile phase would have been adequately defined in all 39 cycles, since in no case would the beginning of the period of post-ovulatory infertility (the safe period, beginning the day after the "VR signal") have been defined within the fertile phase. With this method, the beginning of the post-ovulatory "safe period" would have occurred an average of 3.0 (±0.6) days after follicle collapse, with a range of 2–4 days. With the peak symptom +3 days as the indication of the last day of fertility by the Ovulation Method, the end of the fertile phase would have been adequately defined in 37 of 39 cycles. The beginning of the post-ovulatory "safe-period" by this method was observed from 0 to 7 days after follicle collapse, with an average interval of 4.0 (±1.5) days. In two cycles, the indication for the beginning of the "safe period" occurred within the defined period of fertility.

Use of the CUE method as described defined the fertile period of all cycles adequately. The duration of abstinence by this method would have been an average of 9.0 (±1.5) days, with a range of 6–13 days. In 26 of 39 cycles (66.7%), abstinence required would have been between 6 and 9 days. The average duration of abstinence with the Ovulation Method, in the 37 adequately defined cycles, was an average of 11.0 (±2.9) days, with a range of 6–16 days. Only 30% of these cycles had a period of abstinence of 9 days or less. The difference in the average period of abstinence required for the two methods was significant (p < 0.001). The Ovulation Method requires that, in addition to abstinence during the presumed period of
fertility, abstinence must be observed during menses and following each occurrence of sexual intercourse during the periods assumed to be infertile. Thus, the actual duration of abstinence for the Ovulation Method, in practice, is always greater than that based on the assumed fertile period itself. In these subjects, who were all using the Ovulation Method, the actual duration of abstinence averaged 13.0 (±2.8) days, and ranged from 8 to 20 days.

Discussion

Relationships of salivary and vaginal electrical resistance patterns with the time of ovulation found in this study are consistent with the results in previous reports. The salivary peak predicted ovulation on average of 8.0 days in advance of its occurrence in the present study. It is similar to the 7.0-day interval found in our earlier work. The mean interval from the salivary peak to the LH surge of 6.8 days in this study is consistent with results from several previous studies. The increase in vaginal readings in the periovulatory period was seen within 1 day of follicle collapse in all subjects. A similarly close association between the VR rise and ovulation has been reported in the other studies cited above. As in our earlier study, we again found a significant within-subject correlation in the interval from CUE peak to ovulation. Thus, our findings confirm the results of earlier investigators with regard to the good correlation between salivary electrical resistance patterns and the time of ovulation.

Due to its ability to predict ovulation several days in advance of the event, we evaluated the CUE method's potential for application in natural family planning. This can be defined as the recognition of the fertile phase of the menstrual cycle by one or more parameters and the avoidance of sexual intercourse during this period if pregnancy is not desired. Abstinence from intercourse begins at least 72 h prior to ovulation and should not resume until 1 day after ovulation. The objective of any natural family planning technique is to define this 5-day period of theoretical infertility so that the signals for the beginning and end of the fertile phase do not occur with the actual fertile phase, while keeping the required duration of abstinence to a minimum. The two most commonly used methods of natural family planning are the Symptoermal and the Ovulation Methods. In the Symptoermal Method, a combination of calendar day, mucus discharge, cervical characteristics, and BBT are used to define the fertile period. The Ovulation Method relies on the subject's identification of the characteristic changes in cervical mucus discharge. In addition to the fertile phase thus defined, all menstruating days and the days following each occurrence of sexual intercourse are considered days of abstinence.

In this study, we have compared the Ovulation Method of natural family planning with the CUE method as a potential means of defining the period of fertility, using data from 39 cycles of 10 subjects. We defined ovulation as occurring on the day the ovulatory follicle was first observed to have collapsed, following a documented LH surge. By this criterion, a more precise definition of the beginning and the end of the fertile phase was found with the CUE method than with the Ovulation Method. The time interval from the first indication of fertility until follicle collapse was significantly shorter with the CUE method. These intervals also showed a wider frequency distribution with the Ovulation Method than with the CUE method. In no case did the CUE "oral signal" for the beginning of fertility occur within the fertile phase, while in two Ovulation Method cycles, mucus was first observed only 2 days prior to ovulation, too late to prevent the chance of conception had sexual intercourse occurred. Similarly, in comparing the ability of the two methods to define the end of the fertile phase, better results were obtained with the CUE method than with the Ovulation Method. Not only did the vaginal resistance signal show a narrower distribution than its counterpart for the Ovulation Method, it also adequately defined the end of fertility in all 39 cycles. With the Ovulation Method, in the two cycles, the day of peak symptom +3 days occurred too early to indicate the last day of fertility with safety. Thus, the fertile period of all cycles monitored with the CUE method would have been correctly defined, while in 4 of 39 cycles, incorrect definition of the fertile phase resulted with the use of the Ovulation Method. These four errors occurred in two of the 10 women in the study.

The minimum number of days of abstinence that can be achieved with any method while adequately defining the fertile phase is 5 days, i.e., from 3 days prior to 1 day after ovulation. This theoretical minimum was not achieved by either method in any cycle but the oral and vaginal signals occurring in distributions of 4–10 days before follicle collapse and 2–4 days after ovulation, respectively, represent good parameters for the safe definition of the fertile period in a non-clinical setting. In a large multicenter trial of the Ovulation Method, the average duration of abstinence was 9.6 days. Among centers, this average ranged from 7.2 to 10.8 days. In our study, the average duration of abstinence in cycles adequately defined by the Ovulation Method was 11.0 days. One possible reason for the shorter average abstinence period in the multicenter trial could be that an unknown number
In our study, the duration of abstinence with the CUE method averaged 9.0 days, and is very similar to results of previous studies. Eighty-two cycles monitored by this method would have had a period of abstinence of 10 days or less. With the Ovulation Method, only 15% of cycles showed a duration of abstinence within the same range.

The advantages of the proposed method as applied to natural family planning were that the fertile phase was adequately defined in a greater number of cycles, and with a shorter period of required abstinence than with the Ovulation Method. This difference can be explained by the better definition of the CUE method than by the Ovulation Method of both the beginning of the fertile phase and of the time of ovulation. Another possible advantage of the CUE method as a tool in natural family planning, compared to the Ovulation Method, is that the Ovulation Method's requirement for abstinence during menstrual days and on alternate days following sexual intercourse is not necessary with the CUE method. These factors could be important in terms of better compliance and reduced drop-out rate that are of concern with any natural family planning technique. The simplicity and objectivity of this device in accurately defining the fertile phase of the menstrual cycle indicates that the CUE method is a potentially valuable technique for use in natural family planning.

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References