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Efficacy of a New Postpartum Transition Protocol for Avoiding Pregnancy

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Introduction: The postpartum period is a challenging time for family planning, especially for women who breastfeed. Breastfeeding delays the return of menses (lactational amenorrhea), but ovulation often occurs before first menses. For this reason, a protocol was developed to assist women in identifying their return of fertility postpartum to avoid pregnancy.

Methods: In this prospective, 12-month, longitudinal cohort study, 198 postpartum women aged 20 to 45 years (mean age, 30.2 years) were taught a protocol for avoiding pregnancy with either online or in-person instruction. A hand-held fertility monitor was used to identify the fertile period by testing for urinary changes in estrogen and luteinizing hormone, and the results were tracked on a web site. During lactational amenorrhea, urine testing was done in 20-day intervals. When menses returned, the monitor was reset at the onset of each new menstrual cycle. Participants were instructed to avoid intercourse during the identified fertile period. Kaplan-Meier survival analysis was used to calculate unintentional pregnancy rates through the first 12 months postpartum.

Results: There were 8 unintended pregnancies per 100 women at 12 months postpartum. With correct use, there were 2 unintended pregnancies per 100 women at 12 months.

Conclusion: The online postpartum protocol may effectively assist a select group of women in avoiding pregnancy during the transition to regular menstrual cycles. (J Am Board Fam Med 2012;26: 35–44.)

Keywords: Breast Feeding, Lactation, Natural Family Planning Methods, Ovulation Detection, Postpartum Period

The breastfeeding transition (from amenorrhea to regular menstrual cycles) is one of the most challenging situations for women wishing to use natural family planning (NFP) to avoid pregnancy. This is because of the variability in the length of postpartum lactational amenorrhea, the uncertainty of whether ovulation will occur before the first menses, and the irregularities in the first menstrual

cycles postpartum.¹ In nonlactating women, ovulation can occur as early as 25 days postpartum but usually occurs between 45 to 94 days postpartum, and ovulation leading to sustained pregnancy usually occurs at 42 days or later.² However, in lactating women, ovulation is significantly delayed: only 20% will have ovulated by 6 months and only 64% ovulate by 12 months, with a mean of 322 days of anovulation.³ There is reduced fertility while not in cycles even when ovulation returns, and although two thirds of women ovulate before their first menses, only half of these (one third of breastfeeding women) have adequate pregnanediol excretion and luteal phase lengths to theoretically sustain a pregnancy.⁴ Because it is difficult to predict which subset of women will ovulate before their first menses, it is important to give women tools to detect their return to fertility should they choose to use NFP to avoid pregnancy.

NFP methods use natural signs of fertility, which include observations of cervical mucus and

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basal body temperature, to identify the fertile period (the alternative term *fertility awareness-based methods* has been used to denote those methods that identify the fertile phase and teach users to avoid unprotected intercourse during the fertile phase but allow for use of barrier methods during this time).⁵ During the breastfeeding transition, cervical mucus changes often do not coincide with hormonal variations⁶ or with ovulation as confirmed by ultrasound.⁷ Temperature measurements may not be accurate in the first cycles after the return of menses,⁸ and integrated rules of an NFP method that used mucus and temperature signs showed low specificity and positive predictive value but good sensitivity in predicting the return of fertility.⁴ One study has suggested that breastfeeding women who adhered to the rules of the ovulation method (based on identifying when mucus becomes fertile) after menses returns may have a higher unintended pregnancy rate than those who were not lactating.⁹ In addition, there is confusion among users about the interpretation of the natural signs of fertility during the breastfeeding transition,¹⁰ especially if these women have had irregular cycles previously.¹¹

In studies that have investigated the efficacy of NFP during the breastfeeding transition,^{4,6,11-18} the pregnancy rates at 12 months have ranged from 11.1^{13,15} to 24 per 100 women.¹⁶ A more recent study of a new calendar-based NFP method (the Bridge Method), to be used once a woman has had her first menses, determined a pregnancy rate of 11.2 per 100 women over a typical 6-month period

of use,¹⁸ but it assumes that women use the lactational amenorrhea method (LAM) before this.

A recent Cochrane systematic review of the literature about LAM suggested that there was no difference in unintended pregnancy rates between fully breastfeeding amenorrheic women and those who followed the LAM rules. Pregnancy rates ranged from 0.45 to 2.45 at 6 months of use in the 2 controlled studies and from 0 to 7.5 at 6 months of use in the uncontrolled studies.¹⁹ Although the unintended pregnancy rate found by some studies of the LAM that have been extended to 12 months is reasonable (ie, the highest being 7.4 per 100 women), these results are applicable only to those women who continue to have postpartum amenorrhea.²⁰

Researchers from Marquette University have developed a new postpartum protocol (Table 1)²¹ that uses an electronic hormonal fertility monitor (EHFM; ClearBlue Easy Fertility Monitor, Swiss Precision Diagnostics, Geneva, Switzerland; Figure 1) to identify the fertile period. The EHFM measures changes in urinary estrone-3-glucuronide from baseline and urinary luteinizing hormone (LH) above a specific threshold.²² Product testing has shown the ClearBlue monitor to be 98% accurate in detecting the LH surge.²³ Although the EHFM was originally marketed to help women identify their fertile period to assist with conception, the Marquette postpartum protocol customizes the use of the monitor to identify the fertile period to avoid pregnancy. During postpartum amenorrhea,

Table 1. Revised Postpartum Protocol With Additional Rules

Original Protocol* for Artificial Cycles During Amenorrhea	Additional Rules for First 6 Cycles After the Return of Menses
<ol style="list-style-type: none"> 1. Trigger a cycle by pushing the "M" button on the monitor. 2. Fast-forward the monitor to day 5. 3. The monitor will ask for a test for the next 20 days. 4. Test your first morning urine every other day. 5. When a high is recorded, test the urine every day. 6. Retrigger the monitor and fast-forward every 20 days. 7. Continue steps 1-6 until you detect a peak reading and resume menses. 8. To avoid pregnancy, avoid intercourse on high and peak days and 3 full days after the last peak day. 	<ol style="list-style-type: none"> 9. When menses returns, reset the monitor and erase the memory (erase the memory for all 6 cycles postpartum). Day 1 is the first day of menses. Begin testing when the monitor asks for a test on day 6. 10. Fertility begins on day 10 of the first cycle after the return of menses, day 9 in the second cycle, day 8 in the third cycle, day 7 in the fourth cycle, and day 6 in the fifth cycle onward. However, if the monitor records a high reading before these days, then fertility starts on the day of the first high reading. 11. (Optional) Beginning on day 6 of the first menstrual cycle postpartum, women may do a second test for the LH surge in the evening with a separate LH test kit.

This study used the rules of the original protocol, which are listed in the left column. The revised rules are in the right column.

*The original protocol is taken from Ref. 21.

LH, luteinizing hormone.

Figure 1. ClearBlue Easy Fertility Monitor with a test stick inserted. Three bars indicate low (1 bar), high (2 bars, based on detection of E3G rise), or peak fertility (3 bars and an egg symbol, based on detection of luteinizing hormone threshold).



women use the monitor to test urinary estrone-3-glucuronide and LH levels from days 6 to 26, creating 20-day “artificial cycles.” If, during a 20-day interval, no LH surge has been detected, the monitor is retriggered to start a new 20-day interval. When an LH surge is finally detected, ovulation will occur within the next few days²² and menses will ensue within the next few weeks (Figure 2).

In addition to using the EHF_M, the Marquette protocol incorporates a website (<http://nfp.marquette.edu>) that integrates education, charting, and a health care professional support system. The website has instructions for achieving or avoiding pregnancy, including specific protocols for special circumstances (eg, the postpartum protocol described here). Women who register on the website are able to access an online electronic charting system and discussion forums and can obtain private consultation from professional nurses and an obstetrician gynecologist. The charting system has designated sections for recording the results of the EHF_M or self-observed cervical/vaginal mucus or both (Figure 2); however, this study analyzed the use of the rules for using the EHF_M without mucus observations. In addition to these observations, the charting system also has a place to record menses on a scale of 1 to 3 (1 = light; 2 = moderate; 3 = heavy) and a row for recording acts of intercourse (I). Before charting each menstrual cycle, the user clicks on a section of the chart that indicates their intention of use (ie, to achieve or avoid pregnancy; Figure 2).

Pilot use of the postpartum protocol among 10 women who also monitored their cervical mucus

demonstrated that the monitor would cut the estimated time of abstinence approximately in half.²¹ In a separate study including postpartum women and women with regular cycles, the same researchers identified a typical-use pregnancy rate of 5 per 100 women over 6 months in the subset of 108 breastfeeding women.²⁴ The purpose of this study was to evaluate the efficacy and acceptability of this protocol for avoiding pregnancy among a larger group of postpartum breastfeeding and nonbreastfeeding women over a 12-month period.

Materials and Methods

Design

Efficacy and acceptability of the Marquette postpartum protocol were analyzed longitudinally over a 12-month period. Participants were asked to evaluate the website over a 6-month time period and have their acceptability measured at 1, 3, and 6 months of use. All pregnancies were evaluated prospectively as being either intended or unintended. This study analyzed the efficacy for avoiding pregnancy and, as such, evaluated specifically the unintentional pregnancies.

Participants

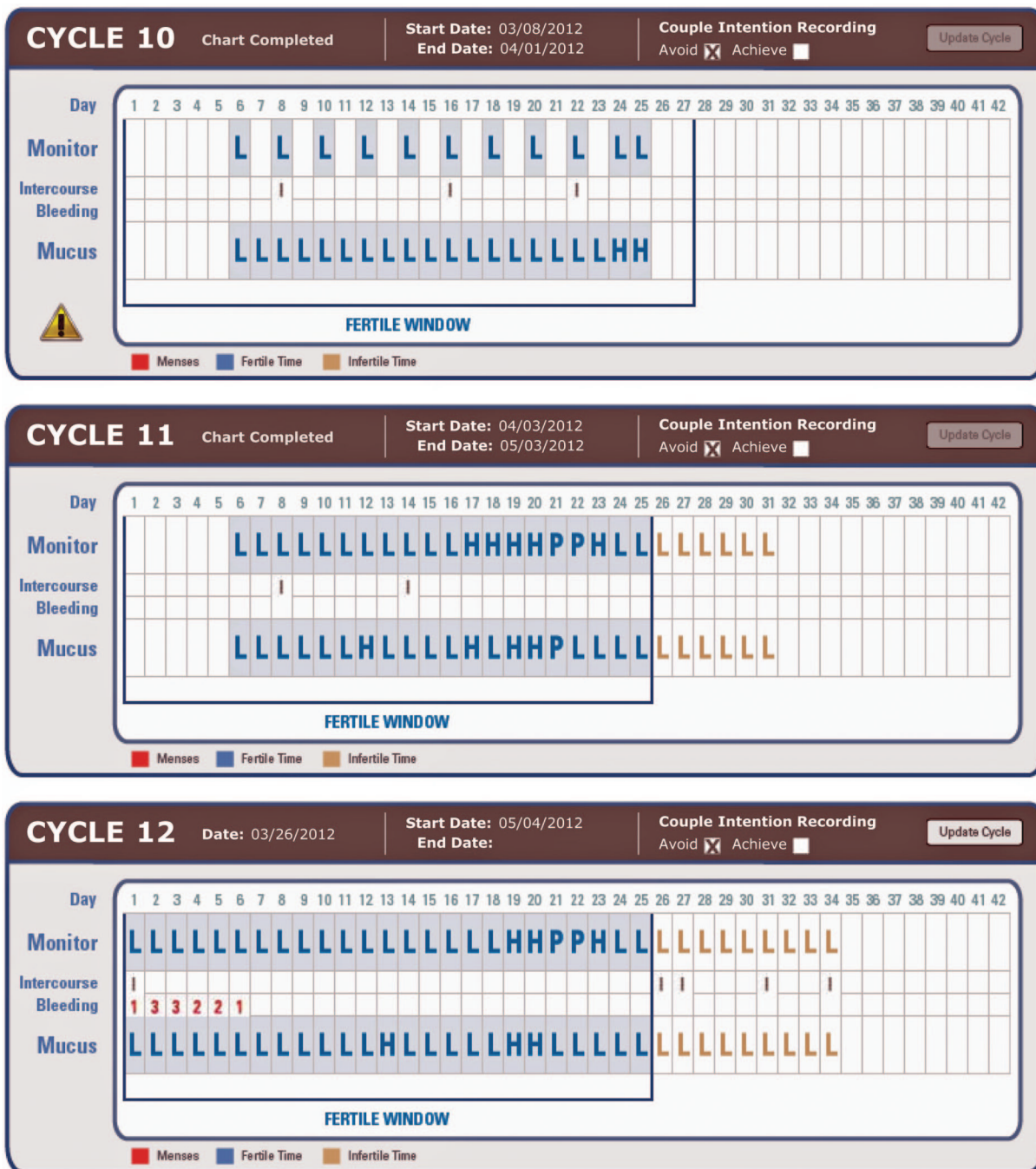
Postpartum (lactating and nonlactating) women in North America were recruited via online advertisements on breastfeeding blogs and social networking sites and by word of mouth. When participants registered on the NFP website, they were asked to read and agree to an electronic consent form. Those who consented were allowed access to the online charting system and discussion forums. The study received human subject approval through the Marquette University Office of Research compliance (HR-1597). Participants' personal information and their fertility charts can be accessed with a protected password only by the participants and the professional nurses and physicians managing the website.

Outcomes

Pregnancy Outcomes

The online charting system automatically notifies the user of the possibility of a pregnancy when the luteal phase of the charted menstrual cycle goes beyond 19 days. The charting system prompts the user to take a pregnancy test to confirm or rule out

Figure 2. These 3 cycles are illustrative of the online charting system that records monitor readings, intercourse, bleeding, and mucus observations. L refers to low fertility per the monitor or mucus, H refers to high fertility, and P refers to peak fertility and impending ovulation. Cycle 10 illustrates the artificial 20-day cycle and testing every second day on the monitor. Cycle 11 illustrates the first ovulation as picked up by the electronic hormonal fertility monitor (EHFM) and reflected in mucus observations. Cycle 12 illustrates the first menses (menses score ! 12) occurring soon after the first ovulation and shows the later ovulation and longer length of the first menstrual cycle postpartum. Note that the “fertile window” shown on the website applies to only women with regular cycles and not to the first 2 cycles during amenorrhea.



pregnancy and to complete an online pregnancy evaluation form. Two professional nurse NFP teachers evaluated all pregnancies and reviewed the

pregnancy evaluation forms. The evaluation includes assessing the charts for the estimated days of fertility, days of recorded intercourse, and informa-

tion on the pregnancy evaluation form. A determination is made if intercourse occurred during the fertile time, as designated by the postpartum protocol. Each pregnancy was classified (with agreement of the couple) as either intended (when a couple reports before the pregnancy cycle an intention to become pregnant) or unintended (when a couple reports before the pregnancy cycle an intention not to become pregnant). Unintended pregnancies occurring during cycles in which the postpartum protocol rules were followed correctly were used in the analysis of correct use pregnancy rates. All unintended pregnancies were used in the analysis of pregnancy during typical use regardless of whether the couple used the postpartum protocol correctly.

Acceptability

All participants were sent an electronic 10-item questionnaire about acceptability and ease of use of the website as well as the postpartum protocol. The 10-item questionnaire is a shorter form of an acceptability questionnaire developed by Severy et al.^{25,26} The 10 items are ranked on a scale from 1 to 7, so the possible total scores range from 10 to 70, with a higher score indicating higher acceptability. Internal consistency α values of this survey ranged from 0.85 to 0.89 in the most recent study of the method.²⁴ For this study, the internal consistency α values ranged from 0.78 to 0.86. We also evaluated the frequency of intercourse as another component of acceptability. Participants were asked to record days of intercourse in the online charting system when they began charting. Frequency of intercourse was calculated monthly (over 30 days) during postpartum amenorrhea and through the first 6 menstrual cycles.

Analysis

Information from online demographic registration forms, the menstrual cycle charts, the acceptability survey, and the pregnancy evaluations were coded so that no identifying information was included in the datasets (using SPSS version 20.0, IBM, Chicago, IL). Group comparisons were done using one-way analysis of variance (ANOVA) (age, years married, living children, body mass index) and χ^2 tests (religion and ethnicity). Kaplan-Meier survival analysis was used to determine both rates of unintended pregnancy with correct use and typical use, based on months of use

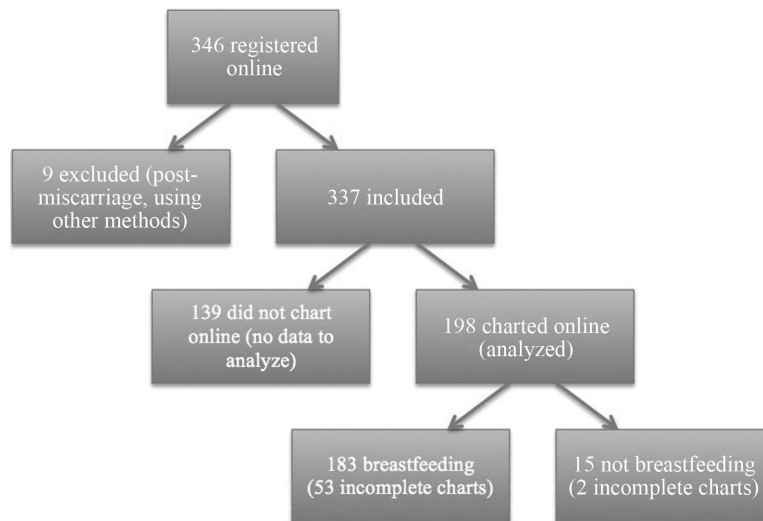
from the infant's date of birth, when provided, or from the onset of charting if no date of birth was provided. Menses was defined objectively as a bleeding score of ≥ 5 ; bleeding was coded as described earlier (1 = light, 2 = moderate, 3 = heavy) and was summed for all the consecutive days of bleeding (eg, in Figure 2, cycle 12, the menses score would be 12). The objective definition of menses coincided with each participant's subjective impression that menses had returned (as demonstrated by her identification of the onset of a new cycle) for all but one participant, who had a menses score of 4. Descriptive statistics, repeated measure ANOVA, and paired *t* tests were used to determine differences in acceptability between the 3 time periods when acceptability surveys were sent out, with a significance level of $P < 0.05$. Differences between the frequency of intercourse from cycle 0 (postpartum amenorrhea) through cycle 6 were calculated using a repeated measures ANOVA.

Results

Participants

Of the women who registered on the website from April 2008 through November 2011, 346 indicated they were postpartum and specified whether they were breastfeeding. Five were excluded because they had had a miscarriage, and 4 were excluded because after registration they stated they were using another method (one was taking the pill, 2 were using barrier methods, and one was using no method). Of the remaining 337 postpartum women who registered on the website since it was launched in April 2008, 198 (59%; 183 breastfeeding and 15 not breastfeeding) used the online charting system and the postpartum protocol. However, 55 (16%) had incomplete charting. The other 139 women (41%) chose not to chart online despite registering to use the website. This is summarized in the inclusion flowchart shown in Figure 3. The 337 postpartum women were between the ages of 18 and 45 years (mean age, 30.5 years) and had an average of 3.0 children (range, 0–9 children). Most were white (70%), married (97%), and Catholic (79%). The 198 participants who used the online charting system had demographic characteristics similar to the group of 337 women as a whole (Table 2). The charting participants were between the ages of 20 and 45 years (mean age, 30.2 years) and had an average of 2.9 children (range, 1–9 children); 73% were white, 99% were married, and 79% were Catholic.

Figure 3. Inclusion flow diagram.



Pregnancy Outcomes Per Cycle and Months of Use

Among the 198 postpartum participants who used the online charting system to avoid pregnancy, there were 2 unintended pregnancies per 100 women with correct use during the first 12 months postpartum. The method-related pregnancies occurred during (1) the amenorrheic period (in the ninth month postpartum) and (2) the third cycle after the return of menses (in the 12th month postpartum). The total unintended pregnancy rate was 0 per 100 women at 6 months of use and 8 per 100 women at 12 months of use (Table 3). The first unintended pregnancy with incorrect use occurred in the seventh month postpartum.

Acceptability

Mean acceptability scores were 55.4 (standard deviation [SD], 8.8) at 1 month (among 143 par-

ticipants who responded); 57.7 (SD, 8.3) at 3 months (among 93 participants who responded), and 58.3 (SD, 7.7) at 6 months of use (among 57 participants who responded). The one-way repeated measure ANOVA of the 3 time periods showed no significant effect ($F_{(2,21)} = 0.40$; $P = .67$). The individual item scores ranged from a low of 4.8 (of a total of 7) for item 1 (“Including website in your daily routine”) to a high of 6.2 (of a total of 7) for item 4 (“Your overall opinion of this website”) and 6.2 (of a total of 7) for item 7 (“Ease of use of the website”) at 6 months of use (Table 4).

Frequency of Intercourse

Frequency of monthly intercourse increased from 2.9 times per 30 days in cycle 0 (postpartum amenorrhea) to 4.5 times per 30 days in cycle 6 (cycle 0: 2.9 ± 2.2 ; cycle 1: 2.8 ± 2.0 ; cycle 2: 3.4 ± 2.2 ; cycle 3: 3.7 ± 2.1 ; cycle 4: 3.8 ± 2.6 ; cycle 5: 4.0 ± 2.5 ; cycle 6: 4.5 ± 2.3 times). There was a significant difference in the fre-

Table 2. Demographics of Total Participants (N = 337) and Online Charting Participants (n = 198)*

Demographics	Total (N = 337)	Charting (n = 198)
Age, years (mean [SD])	30.5 ± 5.1	30.2 ± 4.9
Years married (mean [SD])	5.7 ± 4.6	5.3 ± 4.3
Living children (mean [SD])	3.0 ± 1.7	2.9 ± 1.7
White ethnicity (%)	70	73
Catholic religion (%)	79	79

*There were no significant differences in demographics between the total online participants and the online charting participants.

Table 3. Rate of Unintended Pregnancies With Use Over 12 Months

Months	Women Exposed (n)	Cumulative Pregnancy Rate (n)
1	198	0
3	138	0
6	117	0
12	74	8

Table 4. Acceptability and Ease of Use Surveys at 1, 3, and 6 Months

	Month 1	Month 2	Month 6
Ease of including into daily routine	4.9 ± 1.9	4.8 ± 1.8	4.8 ± 2.0
Ease of using electronic chart	5.6 ± 1.7	5.7 ± 1.5	5.9 ± 1.3
Understanding information available on the website	5.7 ± 1.4	6.0 ± 1.0	5.8 ± 1.3
Overall opinion of website	6.0 ± 1.1	6.0 ± 1.3	6.2 ± 1.0
Increased ability to avoid pregnancy with website	5.2 ± 1.5	5.7 ± 1.4	5.8 ± 1.3
Decreased anxiety about becoming pregnant with website	4.8 ± 1.7	5.4 ± 1.6	5.5 ± 1.6
Ease of using website	5.9 ± 1.2	6.1 ± 0.9	6.2 ± 1.0
Do you like the website?	5.5 ± 1.3	5.7 ± 1.1	5.8 ± 1.0
Compared with other methods to avoid pregnancy, how much of an improvement is the website?	5.7 ± 1.3	6.0 ± 1.1	6.0 ± 1.2
Chances of avoiding pregnancy this month	5.7 ± 1.1	6.1 ± 1.1	6.0 ± 1.2
<i>Totals</i>	55.4 ± 8.8	57.7 ± 8.3	58.3 ± 7.7

Values are means ± standard deviations. Items are scored on a scale of 1 to 7, with 1 being the most negative response and 7 being the most positive response.

quency of monthly intercourse from cycle 0 through cycle 6 ($P = .01$).

Discussion

Efficacy of Protocol to Avoid Pregnancy

The typical (or total) pregnancy rate of 8 per 100 women over 12 months is lower than previous studies of the Marquette Method in women with regular cycles (11–14 per 100 woman-years)^{27,28} and lower than other NFP methods during the breastfeeding transition (11–24 per 100 woman-years).^{13,15,16} However, given that this was not a randomized controlled trial, we cannot be sure whether the lower pregnancy rates are an improvement on previous studies or whether they reflect a difference in participant characteristics.

Acceptability/Ease of Use

Although the increase in the overall acceptability score, from 55.4 to 58.3 from 1 to 6 months, was not significant, the scores nevertheless show a high acceptance of the protocol and website charting system. The scores are comparable to those found for women with regular cycles in an earlier pilot study of the NFP website and charting system.²⁴ The mean values for the individual items indicate that the website was well liked and easy to use (ie, items 4 and 7), but it seems that including online charting of the menstrual cycle in a daily routine was the most difficult to do (ie, item 1). Most participants indicated that the website and protocol was an improvement over other methods of naturally regulating fertility (item 9).

Ease of use would increase with smart phone applications that would make it easier to incorporate charting in a daily routine. We are developing online examples of charts of the breastfeeding transition and the return to fertility so that women see the variety of transition patterns that are possible. We are also updating the charting system (originally designed for women with regular cycles) for the postpartum protocol, which should help women better understand the transition. In addition, we are analyzing characteristics of the breastfeeding transition cycle, which will be helpful for instructing women about the average extent of amenorrhea and the time from first ovulation to first menses.

The online forums on the website offer a significant advantage for users of this postpartum protocol. These forums allowed almost daily instruction for some women who were transitioning through postpartum amenorrhea to fertile menstrual cycles. It also allowed for participants who recently went through the protocol to share their experiences and give encouragement to novice users of the protocol.

Frequency of Intercourse

Participants had more intercourse during later cycles (4.5 times per month during cycle 6 vs 2.9 times per month during cycle 0). The rates reported here are less than those reported by Tomaselli et al⁷ (2 per week) and similar to those reported by Gross¹⁴ (3.9 times during cycle 1 and 3.8 times during cycle 2), but higher than the rates reported in a more comprehensive study of inter-

course during breastfeeding (2.5–3.5 times per month at 12 months postpartum).²⁹ The intercourse rate of 4 to 5 times during cycle 6 is comparable to other NFP studies³⁰ but is less than the amount of intercourse on a monthly basis worldwide.³¹ The increasing frequency of intercourse during later cycles may be related to women feeling more confident with the method once menses have returned but may also be related to women's increased levels of energy and comfort during the later postpartum period.

Limitations of the Study

The major limitation of this study was the lack of a control group. Future studies comparing this postpartum protocol with other NFP-based methods in a randomized fashion would be warranted. Moreover, this study represents a relatively highly educated sample of white women who were attracted to the website and method, which limits the study's generalizability. A more diverse population of breastfeeding women, especially poor women from Hispanic and African-American populations, would be of interest. However, the cost of the fertility monitor might be prohibitive for some women (approximate cost, US\$150–\$200; test strips, \$1–\$2 each, with about 15 test strips per month required), and online access may be a barrier.

Attrition

The attrition rate of this study (41% chose not to chart after they registered and 16% had incomplete charting) is inflated because many likely signed up to see the charting tool and experiment with it without actually pursuing use of the method. The reasons why these women chose not to pursue the method are not known, given that contact information was not always available, and when it was, efforts to contact participants for feedback did not yield any responses. It is possible that some discontinued use because they disliked the method, which may bias the acceptability results. It also is possible that some who discontinued the method became pregnant and did not report it, which would lead to an underestimate of pregnancy rates. Of the charting participants who had fewer than 12 months of survival data, at the time of data analysis 20% had active charts within the past 1 to 2 months, which likely represents women who are using the method but have not yet completed the survival period.

Practice Implications and Protocol Modifications

Given the relative infertility of breastfeeding women during the first 6 months postpartum (only 20% of breastfeeding women will ovulate before their first menses in the first 6 months,³ and those who do often have short luteal phases that most likely would not support implantation of an embryo^{4,32}), using a LAM approach before starting an NFP method would require fewer days of abstinence during the early postpartum period.^{18,33} Such an approach could be used to simplify this postpartum protocol and keep costs down during the first 6 months. For this reason, this protocol may be more helpful for lactating women in the period beyond the first 6 months.

The initial protocol²¹ and new modifications are shown in Table 1. Most of the unintended pregnancies occurred during the first few cycles postpartum and in the first menstrual cycle in particular. One of the most likely reasons for this is that ovulation and the fertile phase are delayed and the cycles are longer than usual. Couples get frustrated with the long period of abstinence required when there is a delay in detecting the day of ovulation. Two modifications shown in Table 1 are recommended to address these concerns: (1) the use of a second LH test to minimize the chance of a missed LH surge on the monitor, and (2) adjusting the calculation for the beginning of the fertile phase based on the cycle length.

Future Directions

The new postpartum charting system could be used to compare other postpartum protocols of other NFP methods in a randomized study. In addition, it will be useful to prospectively collect information about the exclusivity and intensity of breastfeeding as well as the introduction of solid foods on a month-to-month basis to clarify further the effect of breastfeeding on postpartum amenorrhea. Further studies should also focus on whether in-person teaching of the protocol is more effective and acceptable than online teaching of the protocol.

Conclusions

The use of an online teaching and charting protocol for the postpartum transition, along with online professional support, enabled women to avoid pregnancy during this challenging period. There were only 2 unintended pregnancies per 100 women among participants who used the protocol correctly within the

first 12 months and 8 pregnancies per 100 women when including those who used the protocol incorrectly. Acceptability and ease of use of the online system was encouraging, but enhancements to the website and protocol modifications should further improve acceptability of the method.

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