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*To determine the effectiveness of the Marquette Method (MM) of natural family planning (NFP) as a method of avoiding pregnancy. **Study Design and Methods:** This was a 12-month retrospective evaluation of the MM system of NFP. Two hundred and four women (mean age, 28.6 years) and their male partners (mean age, 30.3 years) who sought to learn a method for avoiding pregnancy with the MM from four clinical sites were taught to track their fertility by self-observation of cervical mucus, by use of an electronic monitor that measures urinary levels of estrone-3-glucuronide and luteinizing hormone, and by use of basal body temperature. All unintended pregnancies were evaluated by professional nurses as to whether they were intended or not. Pregnancy rates over 12 months of use were determined by survival analysis. **Results:** There were a total of 12 unintended pregnancies, only 1 with correct use. The 12-month “correct use” pregnancy rate was 0.6 (i.e., 99.4% effective) and the “typical use” (total pregnancy rate) was 10.6 (i.e., 89.4% effective) per 100 users. **Clinical Implications:** When used correctly, the MM system of NFP is an effective means of avoiding pregnancy. The efficacy of the MM system includes proper preparation of the professional nurse NFP teachers.*

There have been few new developments in natural methods of fertility regulation in the past 50 years (Fehring, 2005). The purpose of this study was to determine the effectiveness of a new system of natural family planning (NFP) called the Marquette Method (MM) that incorporates the use of an electronic hormonal fertility monitor (EHFM) to estimate the fertile phase of the menstrual cycle in combination with other traditional natural markers of fertility such as cervical mucus changes and the postovulatory shift in basal body temperature (BBT).

The ability for women to self-test urinary levels of reproductive hormones to estimate fertility is a significant new development in fertility monitoring. A hand-held home use EHFM was recently developed to help women estimate the fertile days of their menstrual cycle by measuring two key fertility hormones (estrogen and luteinizing hormone) in the urine (May, 2001). The fertility monitor (marketed in the United States as ClearBlue or ClearPlan Easy Fertility Monitor by Inverness Medical Innovations) is intended as an aid for achieving pregnancy. However, the information it provides is also useful for women and couples who wish to avoid pregnancy.

Background

The EHFM used for this study was designed to track the changing levels of a urinary

metabolite of estrogen (estrone3-glucuronide or E3G) and a urinary metabolite of luteinizing hormone (LH) (May, 2001). The monitor targets the optimal days to achieve a pregnancy by indicating three levels of fertility: low, high, and peak. The high-fertility reading is indicated when a threshold level of E3G is detected, and the peak reading occurs when a threshold level of LH is detected. The EHFM has a small LCD window screen that tells the user about her daily fertility status, the day of her cycle, and whether a urine test is needed or not. Accuracy studies have shown that the markers of fertility (E3G and LH) from the EHFM correlate well with the gold standard of ovulation detection through serial ultrasound of the developing follicle and with serum levels of LH (Behre et al., 2000). Recent studies have demonstrated a significantly higher pregnancy rate (over 3 months) with use of the EHFM compared with chance (Robinson, Wakelin, & Ellis, 2007) and a high acceptability when used to achieve pregnancy (Severy, Robinson, Findley-Klein, & McNulty, 2006). The EHFM is sold and marketed in the United States, Canada, and Europe. According to the U.S. Food and Drug Administration, the EHFM cannot be sold as a contraceptive device but may be used as an aid for monitoring fertility. Essentially, the information provided by the monitor could be used inversely as an aid for avoiding pregnancy, along with another check for the beginning and end of the fertile window.

Physiologically, there are only 6 days in the menstrual cycle that have a probability of achieving a pregnancy with an act of intercourse (Wilcox, Weinberg, & Baird, 1995). These days are the day of ovulation and the 5 preceding days. Practically, there are a number of natural self-monitored biological indicators of fertility that can be utilized with NFP systems to estimate the beginning, peak, and end of the 6-day fertile phase. These biological markers are (a) changes in cervical-vaginal mucus (CVM) that is stimulated by rising levels of estrogen secreted by the developing follicle, (b) changes in BBT stimulated by rising levels of progesterone secreted by the corpus luteum postovulation, (c) threshold levels of E3G detected by the EHFM, and (d) threshold levels of LH detected by the EHFM or other urine assay self-test kits.

In 1999, we developed a system of NFP that incorporated the use of the EHFM along with other natural biological markers to estimate the 6-day fertile window. These other markers include the use of self-observed CVM or BBT. Users of this system of NFP, called the MM, have the option of using one or more of these biological markers. A recent prospective efficacy study with 195 couples who used CVM monitoring and the EHFM to estimate the fertile window and to avoid pregnancy yielded a 2.1% correct use unintended pregnancy rate and a 14.2% total unintended pregnancy rate over a 12-month study period (Fehring, Schneider, Raviele, & Barron, 2007). The participants in this study were prospectively selected and agreed through signed consent to participate for 12 months.

From January 2000 to June 2007, we conducted the current study at four clinical sites in the United States to evaluate the efficacy of the MM in avoiding pregnancy among couples who have used the MM system and who were not participants in the prospective study. Because these participants were not in a study protocol, they better reflected the typical unintended pregnancy rate, that is, what you would expect with the general public with similar backgrounds. Furthermore, unlike the participants in the prospective efficacy study, the participants in the current study had a choice as to which natural biological indicators of fertility to use to estimate the fertile phase of the menstrual cycle.

The specific questions answered in this study were as follows:

1. What is the 12-month “perfect use” unintended pregnancy rate of the MM system of NFP?
2. What is the 12-month “typical use” unintended pregnancy rate of the MM system of NFP?
3. Is there a significant increase in the satisfaction with the MM system of NFP from 1 to 6 months of use?

Research on contraception traditionally uses the term “correct use” to signify those pregnancies that occur when the method is used consistently and according to instructions; some literature uses the term “perfect use” instead of “correct use.” Another term used is “typical use,” which includes the combination of unintended pregnancies when the methods are followed correctly and the unintended pregnancies that occur when users of the method do not always follow the instructions for the method. The typical pregnancy rate will better reflect the efficacy of the method when used by the general population.

Study Design and Methods

Design

Although the current study is a retrospective chart review of MM users of NFP since 2000, all of the participants received a standardized introductory session on the method by a professional nurse and had follow-up sessions to evaluate their compliance with assessing and charting their biological indicators of fertility for the first 3 months, and then at 6 and 12 months at a minimum. Every pregnancy, whether intended or not, was evaluated by the professional nurse teacher with a structured in-person pregnancy evaluation. Therefore, although this was a retrospective study, all participants were followed prospectively as clients in a clinical setting.

Participants

All the 204 participants in this study were women and their partners who sought training

in the use of the MM at four clinical sites in four cities (St. Augustine, FL; Atlanta, GA; Milwaukee, WI; Fargo, ND; and St. Louis, MO) from 2000 to 2007 and who were not participants in the 2007 prospective efficacy study (Fehring et al., 2007). The women and their partners were taught the MM system of NFP by a professional nurse or physician trained in the MM. All participants indicated the initial intention to use the MM for avoiding pregnancy. Women users of the MM system of NFP who were breastfeeding, being treated for infertility, or were past the age of 42 years were not included in the study. The mean age of the female participants was 28.59 years ($SD = 5.91$) and that of the male partners was 30.33 years ($SD = 6.14$). The mean years of marriage was 5.68 ($SD = 6.79$), the mean number of pregnancies 1.06 ($SD = 1.41$; range = 0-5), and the mean parity was 1.04 ($SD = 1.04$; range 0-4). Economically, 77.7% had combined household incomes greater than or equal to \$70,000 or more, 25% had incomes of \$40,000 or more, and only 2.3% had combined incomes of less than \$40,000. Most of the participants (72.5%) were married and the others (27.5%) were in steady relationships. Details of race, religion, and educational level were not recorded in this data set; however, approximately 88% of the couples from the clinical sites listed Catholicism as their religion, and more than 80% were Caucasian and had at least a high school education.

Outcomes

The records and data charts from the 204 users of the MM system of NFP were reviewed for the following (nonidentification) information: age of the women and men, marital status, number of children, reproductive status, months of use of the MM system of NFP, biological markers used to estimate fertility, and unintended pregnancies in the first 12 months of use—if unintended, whether the pregnancy was due to the correct or incorrect use of the method.

Satisfaction with the use of the MM was evaluated with 97 (47.5%) of the 204 female participants at the 1-month in-person follow-up session. Of these 97 participants, 54 were also assessed of their satisfaction at the 6-month in-person follow-up session. The remaining 107 participants were not included because the authors did not ask for that information from two of the clinical sites (Florida and North Dakota). Satisfaction was assessed by the MM NFP teacher by asking the woman user to self-rate her satisfaction with use of the MM system of NFP on an ordinal scale of 1 to 4, where 1 = *not satisfied*, 2 = *unsure*, 3 = *satisfied*, and 4 = *very satisfied*.

Pregnancies were included if they were verified by an in-person pregnancy evaluation by the health professional NFP teacher with use of the Marquette pregnancy evaluation form. Pregnancy evaluations included information from the MM NFP charting system with verification of intent, menstrual cycle data, charting results from the pregnancy cycle, and acts of intercourse. The pregnancy evaluation also included the date of the last menstrual period and how the

pregnancy was confirmed, that is, by lab test, home urine test, physical exam, or other means. It is important to note that the MM charting system included having the couple verify their intent for using the fertility monitoring data either to achieve or to avoid a pregnancy. The months of use for this study included only months while avoiding pregnancy and only those that have been verified through in-person follow-up.

Procedure

Permission from each of the proposed clinical sites was obtained from the professional nurse MM NFP teacher. All the teachers learned how to provide the MM system of NFP either through a university-based continuing education program or through the university for credit courses. The MM NFP teacher collected the above information from the NFP charts and records. The information was extracted from the charts and records by the professional NFP provider at the given clinical site and submitted (without any identifying information) to the authors of this study. Permission to utilize this data for reporting and publication was obtained through the University Office of Research Compliance.

Statistical Analysis

All data outcomes were entered into an SPSS data file (SPSS version 15). To answer Questions 1 and 2 (i.e., unintended pregnancy rates by correct and incorrect use) survival analysis (Kaplan-Meier) to test the effectiveness was utilized based on months of use—up to and including 12 months of use. A power analysis based on a maximum unintended pregnancy rate of 25 per 100 over 12 months of use projected a sample size of 132 to 220 participants. Question 3 was answered by use of descriptive statistics (i.e., means and standard deviations of the satisfactions levels) and paired t tests to determine differences from 1 to 6 months of use of the MM system of NFP.

Results

Of the 204 participants, 76 (37.3%) utilized BBT along with CVM as a method of avoiding pregnancy; 69 (33.8%) utilized the EHFM and CVM to estimate the fertile window; 29 (14.2%) used CVM as the sole indicator of the fertile window; 25 (12.2%) used a combination of EHFM, BBT, and CVM; and 5 participants (2.4%) used EHFM as the sole indicator of fertility. Among the 204 women participants there were a total of 12 unintended pregnancies and 1,034 documented months of use.

Correct Use Pregnancy Rate

There was only one correct use unintended pregnancy. This yielded a 12-month correct use pregnancy rate of 0.6% (i.e., 99.4% effective in avoiding pregnancy), with a 95% confidence

interval (CI) of 0.9 to 1.00.

Total Pregnancy Rate

The total unintended pregnancy rate over 12 months of use was 10.6% (i.e., 89.4% effective) with a 95% CI of 0.84-0.94. The total number of unintended pregnancies for the (N = 76) women who used BBT and CVM was five, with a cumulative effectiveness rate of 0.871 (see Table 1). In contrast, the 69 women who used a combination of EHF and CVM to estimate fertility experienced four unintended pregnancies with an effectiveness rate of 0.922. The number of months of use and number of women users for CVM alone; BBT, CVM, and EHF; and EHF alone did not reach a level of significance (see Table 1).

However, the total number of unintended pregnancies for the 99 women who used the EHF alone or in any combination with BBT or CVM was six, and the unintended pregnancy rate was 9.20% (i.e., 90.8% effective at 12 months of use; 95% CI = 0.83-0.98). There were six unintended pregnancies among the 105 women who used the MM without the EHF. The 12-month unintended pregnancy rate was 12.2% (i.e., 87.8% effective; 95% CI = 0.78-0.96).

Satisfaction

The mean satisfaction of the 97 female participants who used the MM system of NFP and were assessed at the 1-month follow-up was 3.10 (*SD* = 0.70). Of the 97 female participants, 54 were assessed on their satisfaction at the first and sixth month follow-up session. Their mean satisfaction was 3.00 (*SD* = 0.75) at the first month follow-up and 3.57 (*SD* = 0.54) at the sixth month follow-up session (1 = *not satisfied* to 4 = *very satisfied*). There was a significant change in satisfaction with use of the MM for these 54 female participants ($t = -5.50, p < .001$).

Clinical Implications

The study showed that the “perfect use” of MM could result in an unintended pregnancy rate of 0.6%, and a “typical use” pregnancy rate of 10.6%. Trussell (2004) estimated the perfect use unintended pregnancy rate for modern NFP methods (the ovulation method and symptothermal method) to be from 2% to 3%, and the typical use unintended pregnancy rate to be approximately 25%. The 25% typical rate that Trussell provided is largely based on a five-country World Health Organization (WHO) study of a CVM-only method (WHO, 1981). The perfect and typical use unintended pregnancy rates of the MM as presented in this article fall between the unintended pregnancy rates of the condom (0.6 for perfect use and 15.0 for typical) and the oral hormonal pill (0.3 perfect use and 8.0 typical). However, the results of this study need to be viewed with caution, because the participants were mostly White, middle class, with at least a high school education or higher. The lower typical unintended pregnancy rate in the

current study, therefore, could be due to better educated and more homogeneous participants. A recent study among typically middle class German women who used a combination BBT plus CVM method yielded a very similar 13 cycles of perfect use pregnancy rate of 0.6% (Frank-Herrmann et al., 2007).

An earlier study of a CVM-only method at Marquette University yielded a prospective perfect use unintended pregnancy rate of 2% and a typical use rate of 12% among a similar population of women users to the current study (Fehring, Lawrence, & Philpot, 1994). So too the 2007 prospective efficacy study of the MM yielded a perfect use rate of 3% and typical rate of 12%. The total or typical unintended pregnancy rates, in these studies, are not too dissimilar to the 10.6% found in the current study and, in particular, the 12.2% rate among the BBT plus CVM users. The lower perfect use rate of unintended pregnancy in these studies (compared with the current retrospective study) might be due to the prospective nature of the studies or to the differences in the participants. However, the participants in the current study were followed prospectively by the NFP teachers and the participants came from similar backgrounds. The only way of truly knowing the differences in efficacy between methods of NFP would be by conducting a randomized comparison study.

The German efficacy study with the combination of BBT and CVM yielded a typical use pregnancy rate of only 1.8 per 100 users over 13 cycles of use (Frank-Herrmann et al., 2007). This much lower typical use rate could be due to a number of reasons. First, they had many more participants (900 vs. 204), and second, they calculated the rates based on cycles of use rather than months of use. Another more plausible reason for the differences is that they only used women who had cycle lengths between 22 and 35 days (20% of the cycles could be outside of this range for each participant). About 11% of the participants in the current study had menstrual cycles longer than 35 days in length. Furthermore, the German study included a calendar formula as another marker for the beginning of the fertile phase.

The satisfaction with the use of the MM method of NFP among the 97 participants that assessed their satisfaction in the current study is fairly high, averaging above 3 on a 1-4 scale. The participants in the prospective study of the MM received a 10-item tool to measure satisfaction utilizing a modification of a tool developed by Severy (Severy, 2001; Severy & Robinson, 2004). All of the items were rated around a mean of 6 with a 1-7 rating scale (Fehring, 2007). Although there seems to be high satisfaction with use of the MM system of NFP, in general, other studies have shown that women utilizing NFP report lower satisfaction scores than women who utilize oral hormonal contraception or sterilization (Oddens, 1999). Whether the MM is an improvement in satisfaction over other NFP methods or other methods of family planning is

unknown. The satisfaction in the current study increased over time among the female participants over a 6-month time period. This increase most likely reflected experience and confidence in the use of the method.

Of interest is that almost half of the 204 participants chose to purchase and use the EHF as an adjunctive device to monitor their fertility. A new monitor costs around \$200 and, on average, about \$20 per month for the test strips. Less costly EHFMs can be found on the Internet for about half the price. The number of unintended pregnancies with use of the EHF along with CVM monitoring was 6 per 99 users compared with 6 per 105 without the use of the fertility monitor. The survival rate with the use of the monitor was somewhat higher (90.8% vs. 87.8%), but to determine which combination is more efficacious would require a randomized comparison study.

Although this is a retrospective study, this type of research design might be advantageous in determining the efficacy of the NFP method as it is presented in a real-life setting rather than in a controlled research format. Furthermore, the MM system does have built-in evaluation mechanisms and individual follow-up sessions that might increase compliance with the method and offer better efficacy rates. However, the retrospective nature also decreases control over extraneous variables, such as the type of participant, age, reproductive category, and obtaining all of the data that would exist in a prospective study, such as a more complete satisfaction rating score or more refined measure of satisfaction.

The real disadvantage of this design, however, is that it is not a randomized comparison study. A comparison of the MM system with other methods of NFP would provide more insurance of comparative efficacy. However, even within the MM system, it would be worthwhile to compare the efficacy of avoiding an unintended pregnancy when monitoring the various types of natural fertility indicators, for example, a comparison of the electronic fertility monitor as a method with monitoring cervical mucus changes alone as another method to avoid pregnancy or monitoring cervical mucus changes and the electronic fertility monitor versus monitoring cervical mucus changes along with body temperature monitoring. A recent review of randomized comparison studies of the NFP methods indicated the need for such studies (Grimes, Gallo, Grigorieva, Nanda, & Schulz, 2004).

Another concern with the MM system of NFP and with other systems of NFP is that they can be time consuming for the professional nurse to teach and for the women and couples to learn how to use with confidence (Stanford, White, & Hataska, 2002; Fehring, 2005). The MM system includes a minimum of three group sessions and three to four individual follow-up sessions within a year. Simplification of the system and process is warranted. We currently have

developed two simplified versions of the MM system, one of which can be taught in a 20-minute office session. Verification of the efficacy of these systems through research is also needed. Finally, efforts are underway to offer a user friendly MM system of NFP through the Internet with access to professional consultation. This system of delivery needs verification of efficacy as well.

The MM system of NFP is a viable form of family planning for those whose value system coincides with noncontraceptive methods. In particular, when the MM system includes the new technology of hormonal fertility monitoring, it provides a new alternative system of NFP. Efforts are underway to improve the ease of use and access to this system of NFP and use with special reproductive categories, such as breastfeeding (Fehring, Schneider, & Barron, 2005). Professional nurses who are interested in learning how to provide the MM system of NFP can access online continuing education and degree credit programs through Saint Louis and Marquette University.

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Appendix

Table 1
Twelve-Month Typical Effectiveness Rates In Avoiding An Unintended Pregnancy By
Combination of Biological Markers of Fertility

Biological Marker	Number	Number of Pregnancies	Effectiveness Rate
BBT + CVM	76	5	.871
EHFM + CVM	69	4	.922
CVM only	29	1	NS
BBT + EHFM + CVM	25	2	NS
EHFM only	5	0	NS
Total	204	12	.896

Note. BBT = basal body temperature; CVM = cervical-vaginal mucous; EHFM = electronic hormonal fertility monitor; NS = not significant.