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Abstract

Problem Statement: The length of periodic abstinence, due to overestimation of the fertile phase of the menstrual cycle is often a reason for dissatisfaction, discontinuation, and user error with natural family planning (NFP) methods. The objective of this research was to compare the length of required abstinence (i.e., estimated fertility) and coital frequency between two NFP methods.

Study Design: Analysis of existing data from a 12 month prospective comparison study in which participants were randomized into either an electronic hormonal fertility monitor (EHFM) group or a cervical mucus monitoring (CMM) group, both of which included a fertility algorithm as a double check for the beginning and end of the estimated FW. The current study involved 197 women (mean age 29.7, SD=5.4) who used the EHFM to estimate the FW and 162 women (mean age 30.4, SD=5.3) who used CMM to estimate the FW. They produced 1,669 menstrual cycles of data. Number of days of estimated fertility and coitus was extracted from each cycle and t-tests were used to compare the means of these two variables between the two NFP methods.

Results: After six months of use, the EHFM group had statistically fewer days of estimated fertility than the CMM group (13.25 days, *SD*=2.79 versus 13.65 days, *SD*=2.99; *t*=2.07, *p* = .04) and significantly more coitus (4.22 coital acts, *SD*=3.16 versus 4.05 acts, *SD*=2.88, *t*=1.17, *p*=.026).

Conclusion: The use of the EHFM seems to provide more objectivity and confidence in self-estimating the FW and use of non-fertile days for intercourse when avoiding pregnancy.

Keywords: fertility awareness based methods; natural family planning; family planning; fertility monitoring

1. Introduction

Although fertility awareness based methods of natural family planning (NFP) are accepted by many cultures and religions and are free of side effects, they are used by only 0.1% of women in the United States of reproductive age.[1,2] Periodic abstinence requirements and anxiety over unintended pregnancy could explain some of lack of use and acceptance of NFP methods [3-6]. Current NFP methods overestimate the actual 6 day fertile window (FW) by 6-11 days, with most methods requiring 12-14 days or more of abstinence to avoid pregnancy [7-9]. Dissatisfaction with length of abstinence often leads to discontinuation, user error (i.e., intercourse on estimated days of fertility), and unintended pregnancy.[10,11]

In an effort to develop a modern method of NFP based on urinary hormonal monitoring, researchers developed and tested a method of NFP that involved both an electronic hormonal fertility monitor (EHFM) and cervical mucus monitoring (CMM) to estimate the fertile time of the menstrual cycle.[12-15] However, although this method was relatively effective in helping couples avoid pregnancy and had good satisfaction with use, it was rather complex to teach and use, furthermore, the combined methods extended the estimated fertile window (FW). Subsequently the same researchers discovered that CMM almost doubled the estimated fertile window of the menstrual cycle compared to the EHFM (i.e., 6 days compared with 12).[9]

These researchers then developed a simplified NFP method based on either (CMM) or an electronic hormonal fertility monitoring (EHFM) (or both) and an ovulation-based calculation as a double check for the beginning and end of the fertile phase.[14] They also developed an online system to teach couples to use this new NFP method which included an online charting system that automatically calculated the fertile window based on the new algorithm and either CMM or EHFM [16]. A pilot efficacy study of this online NFP system was conducted [16] and a subsequent prospective randomized comparison study of EHFM with CMM was completed

{17}. The randomized study showed that EHFM plus fertility algorithm was more effective in helping couples avoid pregnancy with 8 unintended pregnancies per 100 users over 12 months of use compared with 18.5 pregnancies with CMM.[17]

Both the EHFM and CMM methods had women participants rate their fertility as being low, high, or peak, and utilized the following algorithm (i.e., your fertility begins on day 6 of the first 6 menstrual cycles and ends three full days past the last peak day. After 6 cycles of charting, fertility begins on the earliest peak reading of the previous 6 cycles minus 6 days and ends on the latest Peak of the previous 6 cycles plus three days). The purposes of the current study is to determine and compare the length of the estimated fertile window as determined by EHFM plus fertility algorithm with the estimated fertile window by use of CMM plus algorithm (as described above) and second, to determine coital frequency between two NFP methods. We predicted that over time (i.e., with the second 6 cycles of use) that the EHFM plus algorithm would eventually lead to a shorter estimated FW compared with the CMM method and lead to greater coital frequency.

2. Methods

This study was a secondary analysis of data from an existing data set produced through a 12-month (13 cycles) prospective clinical comparison study of the efficacy of the EHFM plus fertility algorithm method of NFP with CMM plus a fertility algorithm. The EHFM used for this study was the Clear Blue Easy Fertility Monitor (CBFM) manufactured and marketed by Swiss Precision Diagnostics GmbH (Geneva, Switzerland). These studies received IRB approval through the university Office of Research Compliance. The study was registered at ClinicalTrials.Gov with the ID number NCT00843336.

The inclusion criteria for female partners of the couple participants were that they needed to be between the age of 18 and 42 years, have a stated menstrual cycle range of 21-42 days, have

no history of hormonal contraceptives for the past 3 months and if post breastfeeding, have experienced at least 3 cycles past weaning.

All EHFM participants used a CBFM, which detects rising levels of urinary estrone-3-gluconuride (E3G) and is 98.8% accurate in detecting the surge in urinary LH. [18,19]. The CBFM is initiated when a user pushes a button on the monitor labeled "M" on the first day of her period. The monitor requests either 10 or 20 daily urine tests per cycle. When the monitor requests a test, the user exposes the strip to her urine stream for 3 seconds and places it in the monitor. The monitor will show a fertility status of "low", "high" or "peak".

The CMM participants were asked to observe for cervical mucus on a daily basis and to chart the highest level observed. They were instructed to observe their cervical/vaginal mucus every day, and to chart the most fertile mucus sign at end of day. They were asked to rate the mucus as to "low," "high", and "peak" based on visual descriptions (pictures) of the three levels of cervical mucus that were provided online to the CMM users. All participants were asked to record on an online fertility chart: their fertility status (low, high or peak), all coital acts and their menstrual bleeding days.

All participants used the online electronic charting system to record their fertility status. The charting system automatically indicated (in light blue, see Figure X) the fertile phase (based on the algorithm). Participants were also instructed to avoid intercourse and genital contact during the fertile window – i.e., from the first day of fertility through the last day of fertility and to refrain from intercourse on all "high" and "peak" days. Initially, the fertile window began on day 6 for the first 6 cycles and ended three days past the last peak day (of either mucus or monitor). After 6 cycles of use, fertility began on the earliest day of peak during the last 6 cycles minus 6 days. Fertility ended on the last peak day of the last 6 cycles plus 3 full days.

Professional nurse graduate student research assistants (who are were seasoned NFP teachers) downloaded into an electronic data set menstrual cycle parameters, length of estimated fertile window and frequency of intercourse for all menstrual cycles charted. Data were analyzed with the Statistical Analysis System (SAS) and the Statistical Package for the Social Sciences (SPSS) software systems.

3. Results

3.1. *Participants*

3.2. Demographics

Mean age, number of years married, number of living children, basal metabolic index, and age of husband/partner of the 197 participants in the EHFM group and the 160 in the CMM group are shown in Table 1. There were no significant statistical differences in the demographics between the two groups of participants. For both groups, the greatest percentages of participants were Caucasian and Catholic. They produced a total of 1,663 menstrual cycles of data, 1,027 for the EHFM group and 636 for the CMM group.

3.2. *Length of Estimated Fertile Window*

There was no difference in mean number of days of estimated abstinence, i.e., estimated fertile phase, between the EHFM or CMM groups (14.34 days, *SD*=4.04 versus 14.19 days, *SD*=3.86; *t*=732, *p* =.464) when all cycles were included in the analysis. However, for the first six cycles of use the CMM group had significantly less estimated days for the fertile phase (See Table 2). After the first six cycles and the algorithm adjusted, the EHFM had significantly less days of abstinence, i.e., shorter estimated fertile window.

3.3 *Frequency of Intercourse/Coitus*

There was significantly more coitus among the EHFM group (4.22 coital acts, *SD*=3.16 versus 4.05 acts, *SD*=2.88, *t*=1.17, *p*=.026) among the CMM group.

4. Discussion

Overall there was no difference in the estimated fertile days between the two online methods of NFP, i.e., the require time for abstinence from acts of intercourse, when all menstrual cycles charted are included in the analysis. It was expected that during the first six cycles of use that there would be no difference in the estimated days of fertility since both the EHFM group and the CMM group used the same algorithm of starting the estimated fertile phase on day six. One reason for the less amount of required abstinence is that the women were asked to ignore the low level rated mucus and only to rate the stretchy mucus as High, and Peak. This method of rating mucus significantly reduced estimated days of fertility using cervical mucus as a marker of fertility. This is evident based on the comparison of mucus versus monitor in an earlier study and earlier method of NFP that included both CMM and EHFM.[9] However, as hypothesized there was less days of abstinence (i.e., days of the estimated fertile phase) with the EHFM after the fertility algorithm adjusted with six cycles of use. The less days of abstinence was most likely due to the greater precision of the EHFM and identifying the LH surge as the marker for ovulation and to the overestimation of fertile days with mucus monitoring. [9, 20-22]

The adjusted six cycle average of 13-14 days of required abstinence (for both monitor and mucus) is less than some reports of an average of 17 days of required abstinence for other cervical mucus only methods.[23] Besides the accuracy and objectivity that the monitor brings to estimating the fertile phase, the use of rating cervical mucus as low, high, and peak offers fewer days of mucus that contributes to a fertile day. It also eliminates mucus that is often not related to estrogen stimulation and fertility. However, the 13-14 days of required abstinence for the NFP analyzed in this study is more than the 12 days of required abstinence with a fixed day calendar method [24] but comparable to combination NFP methods, i.e., mucus and basal body temperature as natural biological markers of fertility.[7]

As hypothesized, there were significantly more acts of intercourse by couples in the EHFM group. The average of four acts of intercourse per menstrual cycle for this study is less than that found with a fixed day calendar method of family planning and less than that among couples, i.e., around six acts per month.[25] An assumption is that as couples get confident in the method through use that there would be more intercourse. This was not the case, in fact there was less intercourse in the second six cycles of use but more with the EHFM method. We suspect that the monitor provides more confident in estimating the fertile window and confident that they will not have an unintended pregnancy. There is a strong possibility that all acts of intercourse are not recorded online.

A limitation of this study was that the participants were screened for having regular cycle lengths. However, this study was more generous than most studies in that our inclusion cycle length was from 21-42 days. This is the cycle lengths that the EHFM is able to cover efficiently. Including longer cycle lengths most likely would increase estimated days of fertility. Furthermore, this study did not include women during the first three cycles post cessation of breastfeeding or post partum nor women older than 42 years of age. Older women in the perimenopause years will have greater variability in cycle lengths and possible more days of estimated fertility based on natural indicators of fertility. Finally, this study excluded women who were less than three cycles post hormonal birth on control, these women often have more mucus days, delays in ovulation, and longer cycles.

Future studies on estimating the days of fertility and subsequently days of abstinence in using methods of NFP need to include these special group, i.e., postpartum (breastfeeding or not), women with long cycle lengths, perimenopause women, and women post hormonal contraception women. Planned further studies also include adjusting and testing the fertility algorithm that might provide shorter estimated days of abstinence, but not lose its effectiveness in helping couples avoid pregnancy with natural methods.

5. Conclusion

The EHFM plus fertility algorithm provides more objective measures of the fertile window of the menstrual cycle than use of CMM and as a result fewer days of abstinence for those couples using these methods of NFP to avoid pregnancy. Fewer days of abstinence also contributed to more frequent intercourse among the EHFM users. The lesser amount of required abstinence and increased frequency of intercourse might be what contributed to greater satisfaction/ease of use for participants in the EHFM group in an earlier study on the efficacy of these natural methods of birth control.

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Table 1. Comparison of demographics between the monitor and mucus group by mean, standard deviation, and range of scores.*

	Monitor group (N=197)	Mucus group (N=160)
Mean age female	29.7 (SD=5.4; 21-42)	30.4 (SD=5.3; 19-42)
Mean age male	31.5 (SD=6.1; 20-44)	32.5 (SD=6.2; 22-47)
Mean years married	5.8 (SD=5.0; 0-18)	6.3 (SD=5.1; 0-20)
Mean # living children	1.8 (SD=1.9; 0-8)	2.1 (SD=1.9; 0-8)
Mean BMI female	24.7 (SD=4.7; 16.5-38.9)	25.3 (SD=5.9; 16.3-49.9)
% Ethnicity female	77%White/7%Hispanic	84%White/5%Hispanic
% Religion female	76%Catholic/18% Protestant	81%Catholic/14%Protestant

** There were no significant differences between the two study groups on demographic variables.*

Table 2 Comparison of Estimated Fertile Window (FW) by Electronic Hormonal Fertility Monitor (EHFM) and by Cervical Mucus Monitoring (CMM)

Total Use:	# of cycles	Mean Days	Std Deviation	T-Test	P level
Monitor	**1027**	**14.34**	**4.04**	**.732**	**.464**
Mucus	**636**	**14.19**	**3.86**		
First 6 cycles of use					
Monitor	**477**	**15.60**	**4.83**	**2.76**	**.006**
Mucus	**322**	**14.67**	**4.47**		
Second 6 cycles of use					
Monitor	**550**	**13.25**	**2.79**	**2.07**	**.039**
Mucus	**304**	**13.68**	**2.99**		

Table 3 Comparison of Coital Frequency per Menstrual cycle by Electronic Hormonal Fertility Monitor (EHFM) and by Cervical Mucus Monitoring (CMM)

Total Use:	# of cycles	Coital	Std Deviation	T-Test	P level
Monitor	**1027**	**4.22**	**3.16**	**1.17**	**.026**
Mucus	**636**	**4.05**	**2.88**		
First 6 cycles of use					
Monitor	**478**	**4.26**	**3.29**	**.019**	**.985**
Mucus	**322**	**4.25**	**3.08**		
Second 6 cycles of use					
Monitor	**550**	**4.19**	**3.04**	**1.87**	**.062**
Mucus	**304**	**3.82**	**2.63**		