Cohort Efficacy Study of Natural Family Planning among Perimenopause Age Women

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Abstract

Objective: The purpose of this study was to determine the efficacy of using natural family planning (NFP) methods to avoid unintended pregnancy among women of perimenopause age (i.e., 40 – 55 years old).

Design: A secondary analysis of subset data from two prospective observational cohort studies.

Setting: A university based in-person and online NFP service program.

Participants: One hundred and sixty couples who utilized either a website or an in-person NFP service to learn how to avoid pregnancy from January 2001 to November 2012.

Methods: A prospective 12-month effectiveness study among 160 women (between the ages of 40 and 55) who used NFP to avoid pregnancy. The women utilized either a hormonal fertility monitor, or cervical mucus monitoring or both to estimate the fertile phase of their menstrual cycle. Survival analysis was used to determine the pregnancy rate over 12 months of use.

Results: There were a total of 5 unintended pregnancies among the participants. The typical use pregnancy rate was 6 per 100 women over 12 months. The monitor alone participants (n=35) had a 12-month pregnancy rate of 3, the (n=73) who used mucus alone had a pregnancy rate of 4, and the participants (n=42) who used the fertility monitor plus mucus had a pregnancy rate of 6.

Conclusion: NFP methods can be effective for older women to avoid an unintended pregnancy with correct use and adequate instructions. The pregnancy rate most likely was affected by diminished fertility and motivation to limit family size.

Key words: natural family planning; fertility monitoring; peri-menopause
Little is known about the efficacy of natural family planning methods among perimenopause age women.

There was a typical use unintended pregnancy rate of 4 per 100 women over 12 months of use among perimenopausal age women using the Marquette Model of NFP.

Effectiveness of NFP methods among perimenopause age women is most likely confounded by reduced fertility and a high motivation to avoid pregnancy.

Use of natural family planning (NFP) by *perimenopausal* women (i.e., those who are 40 years age and above) can be a challenge. NFP during the perimenopause is difficult because the menstrual cycle becomes more variable and the natural signs of fertility are difficult to track (Brodin, Bergh, Berglund, Hadziosmanovic & Holte, 2008; Fehring & Schneider, 2006; Treloar, Boyton, Behn, & Brown, 1967). Furthermore, the peri-menopause is a time of a woman’s and couples’ life when they have completed their family size. There is also the greater chance of having a child with congenital abnormalities such as downs syndrome during the later
Although fertility of women decreases with age, there still is a concern with unintended pregnancies especially among women with apparent ovulatory menstrual cycles. Little is known about use of NFP during the peri-menopause transition to infertility. Conceptually, NFP is knowledge of and the ability to track the fertile phase of the menstrual cycle with natural indicators of fertility (Fehring, Kitchen, & Shivanandan, 2009). With knowledge of the fertile phase a couple can modify their behaviors to either avoid or achieve pregnancy. The common natural indicators of fertility used in methods of NFP are changes basal body temperature (BBT), cervical mucus changes, and urinary reproductive hormones. A significant elevation from baseline of BBT occurs due to the rise in progesterone after ovulation, cervical mucus becomes more profuse, stretchy, clear, and slippery due to the rise in estrogen from the dominant follicle/egg complex, and hand held electronic fertility monitors are available to track rising levels of estrogen from a dominant follicle and threshold levels of luteinizing hormone (LH) that occurs about 24-36 hours before ovulation in urine samples. These natural signs of fertility can be used alone or in combination to track the beginning, peak and end of the fertile window and the variability from menstrual cycle to menstrual cycle (Fehring, Kitchen, & Shivanandan, 2009).

Brown (2010) mentioned that the perimenopause transition to infertility is almost like the reverse of the experience of menstrual cycle initiation and variability with adolescents. Physiologically fertility decreases and the menstrual cycle becomes more variable due to a significant decrease in egg/follicles in the ovaries, aging of the male and female gametes, anovulatory menstrual cycles, large increases in follicle stimulating hormone (FSH), and
decreases in antimullerian hormones (AMH) (Brodin, Bergh, Berglund, Hadziosmanovic, & Holte, 2008; Hale, Hughes, Burger, Robertson, & Fraser, 2009; Speroff & Fritz, 2005; Van Zonneveld et al., 2003). Studies based on the Natural Survey of Family Growth (NSFG) have shown that the prevalence of infertility after 12 months of attempting to achieve a pregnancy is only 6.7% among those 20-24 years of age, but increases to 16.1% among women 30-34 years and 22.9% among women 35-39 years (Chandra, Martinez, Mosher, Abma, & Jones, 2005).

The World Health Organization (WHO) (1990) published a report on the peri-menstrual transition, diminishing fertility, and the use of family planning. The report indicated that 50% of women over forty are potentially fertile but the risk of pregnancy for women 40-44 is about 10%, around 2% for women 45-49, and not zero for women over the age of 50 (Metcalf, 1979; Gray, 1997). The severe decrease in fertility after the age of 45 was demonstrated by researchers that observed records of all Israeli women who delivered naturally after the age of 45 and found only 209 women out of 104,659 who delivered a baby were 45 years or older or i.e., 0.2% of the total (Laufer, Simon, Samueloff, Yaffe, Milwidsky, and Gielchinsky, 2009). The WHO report recommended contraception until menopause is established and mentioned that due to the irregular menses and amenorrhea that use of NFP would be impractical during the perimenopause (1990). However, the report also mentioned that among women who have been amenorrheic for one year, approximately 2% of them would experience a subsequent ovulation. Hence there is still a concern for potential pregnancy and a recommendation for contraception for one-year post menopause.

In reviewing the literature there are no studies that specify the efficacy of NFP among perimenopausal women. A study was conducted with 36 users of the symptom-thermal method of NFP (i.e., a combination of self-monitoring of mucus changes and BBT) who were between
the ages of 45 and 53 (Flynn, James, Collins, & Royston, 1991) and found that 33% of the
women were potentially fertile and that 61% of the 177 menstrual cycles charted were potentially
fertile. They did not determine efficacy of the method to avoid pregnancy.

Professional nurses at Marquette University have developed a method of NFP that
includes an electronic hormonal fertility monitor (EHFM) that measures metabolites of estrogen
and luteinizing hormone (LH) in the urine and provides an estimate of the fertile window
(Fehring, Schneider, & Raviele, 2007). Subsequent efficacy and effectiveness studies on this
new method called the Marquette Model (MM) of NFP for couples wishing to avoid pregnancy
ranged from 0-3 unintended pregnancies per 100 users over 12 months of use with correct use
and 8-13 with typical use (Fehring, Schneider, & Barron, 2008; Fehring, Schneider, Barron, &
Raviele, 2009; Fehring, Schneider, & Raviele, 2011; Bouchard, Schneider, & Fehring, 2013;
Fehring, Schneider, Raviele, Rodriguez, & Pruszynski, 2013). The purpose of this report is to
provide evidence for efficacy in the use of the MM of NFP for avoiding pregnancy among
women 40 to 55 years of age. The specific research objectives were to determine the correct use
and the typical use unintended pregnancy rate among women age 40 to 55 years of age using the
MM of NFP. A secondary objective was to determine typical use pregnancy rates among
subpopulations of women 40 to 55 years of age using different forms of the MM, i.e., cervical
mucus monitoring (CMM) plus fertility algorithm, EHFM with fertility algorithm, and a
combination of CMM and EHFM plus fertility algorithm.

Methods

Research Design

This study was a secondary analysis of data collected from two 12 month prospective
efficacy studies of the new MM of NFP (Fehring, Schneider, & Raviele, 2007; Fehring,
Schneider, & Raviele, 2011) and of new data collected prospectively since completion of the 2011 study. Data from each study was generated from two university based NFP programs i.e., an in-person NFP service program and an online NFP program. Both programs taught women and couples how to use either a cervical mucus based method of NFP, a hormonal fertility monitoring method of NFP, or both to avoid or achieve pregnancy. The in-person program was initiated in 2001 and the online program in 2008. There is an ongoing research effort with the online program to determine the efficacy of the MM NFP (to help couples either achieve or avoid pregnancy) and use by sub-populations, e.g., postpartum breastfeeding women (Bouchard, Schneider, & Fehring, 2013), women wishing to achieve pregnancy (Mu & Fehring, 2014) and now efficacy to avoid pregnancy among women between the age of 40 and 55.

Setting and Subjects

We were able to obtain 160 women who were between the age of 40 and 55 and who sought to learn the MM of NFP from either an in-person nurse managed NFP service program (n = 80) or an online nurse managed NFP service program (n = 80) from January 2001 to November 2012. The participants learned about the online program or in person program through word of mouth, online blogs, and/or NFP e-mail list services. The participants in the in person program sought and received education and counseling in the MM of NFP from professional nurse NFP teachers in private offices in the College of Nursing. The online participants (n=115) received self-knowledge of the MM NFP method by reading the online materials and charting their menstrual cycles in the online automatic charting system.

The age range of 40-55 was chosen as an inclusion criteria since fertility decreases significantly by the age of 40, many couples have completed their family size, and because 40 is the traditional age that NFP systems start to classify women as in the perimenopausal
reproductive category (Howard & Stanford, 1999). Pregnancy after the age of 55 is extremely rare, in fact, the national survey of family growth (NSFG) only calculates pregnancy rates up to the age of 44 (Trussell, 2011). The participants were at least three months past cessation of breastfeeding or discontinuation of hormonal contraception. We sought to have a minimum of 100 participants in order to apply and obtain an adequate survival analysis based on 100 women users over 12 months of use with a standard error of approximately of .05 or less.

Both the in person and online versions of the NFP efficacy studies were approved by the university office of research compliance. All participants completed demographic registrations forms and signed consent for this study either in person during a teaching session or to access the online program. The 160 participants that met the age inclusion criteria were all women that have registered and used either the in-person or online system, i.e., they were not selected from a group of participants. Participants in these two programs came from over 47 states and Canada.

**Procedures**

All participants charted their menstrual cycles, their estimate days of fertility, and days of intercourse on either a paper chart (first study) or an online charting system (second study). Participants, who used the cervical mucus method, observed their cervical mucus on a daily basis and rated their observations as Low, High or Peak type mucus based on a provided pictorial (online or in-person) diagram. The women who used the hormonal fertility monitor also rated their fertility as Low, High, and Peak based on the information provided by the electronic hormonal fertility monitor. The fertility monitor (the Clearblue Easy Fertility Monitor) provides a Low fertility reading until it detects a significant rise in urinary estrogen from base line to provide a High reading, and the Luteinizing hormone (LH) threshold to provide a Peak reading
When using both cervical mucus and the fertility monitor they were instructed to wait for both the monitor and mucus to establish their daily fertility. All women used a fertility algorithm along with their fertility indicators, i.e., fertility begins on day 6 of the menstrual cycle and lasts three full days past the last peak reading of either the mucus or monitor. After 6 cycles of charting, fertility begins with the earliest Peak recording from the previous 6 cycles minus 6 days. All participants indicated their intention to avoid or achieve pregnancy on each menstrual cycle chart before beginning the charting for that menstrual cycle. One page protocols on the MM method and use with special reproductive categories (i.e., postpartum breastfeeding) can be found at http://nfp.marquette.edu. This web site also has one page Quickstart instructions that could be used for replication and visual pictures of the three levels of cervical mucus observations.

**Measurement of Outcomes**

All pregnancies were reviewed by two professional nurse NFP teachers with use of a pregnancy evaluation form that included feedback by the user and by assessing the menstrual cycle chart in which the pregnancy occurred. The pregnancy evaluation form was developed by Gray and Kambic (1984) for NFP service programs as an aid for assessing and determining pregnancy rates. Two professional nurses, trained and certified in NFP, reviewed all pregnancies and all pregnancy menstrual cycles, and classified the pregnancy as either a correct use unintended pregnancy or an inconsistent or incorrect use pregnancy – with 100% agreement. To determine the correct use pregnancy rates only menstrual cycle charts with correct use (i.e., no intercourse during the estimated fertile phase) were included in the analysis. Typical use pregnancy rates included menstrual cycles with correct use and incorrect or inconsistent use. Of
the 160 women, we were able to determine correct use pregnancy rates among the 80 women who used the online NFP program.

Data from the demographic forms and the paper and online menstrual cycle charts were entered into a data set by a professional nurse NFP provider and was validated by two advanced practice graduate student NFP trained nurses. The data set included age of the woman participant, numbers of menstrual cycles charted using the NFP method, the number of correct use and incorrect use cycles, unintended pregnancies, and whether the pregnancy was due to correct use or not.

Analysis of Data

Analysis of pregnancy rates followed the recommended instructions by Lamprecht and Trussell (1997). Survival analysis (Kaplan Meier) was used to determine both correct use and typical use pregnancies rates with the statistical package for social sciences (SPSS Version 9) software. Analysis by research objectives were as follows: 1) to determine the correct use pregnancy rates only menstrual cycles with correct were used in the analysis, 2) to determine total or typical pregnancy rates the total of correct use, inconsistent use, and incorrect use menstrual cycles were used in the analysis, and 3) pregnancy rates with the subpopulation of CMM users, EHFM users, and combination of CMM plus EHFM use (plus a fertility algorithm) was based on correct use and incorrect use menstrual cycles. Cumulative pregnancy rates were calculated with two different censoring variables: correct use (also referred to as perfect use) and total cycles.

Results

Demographics
The mean age of the 160 female participants was 41.2 (SD = 2.4) with an age range of 40–54 years. Fifteen of the participants were 45 years of age or older. The participants were married a mean of 13.3 years (SD = 7.3) and a range of 1-32 years. They had a mean of 5.2 (SD = 2.6; range 0-13) pregnancies and a mean 4.2 live children (SD = 2.2; range 0-9). All participants were married, 94% were of the Catholic faith, and 79% were Euro-Americans; 9% were Hispanic American. Thirty-five of the participants used only the fertility monitor, 73 used only cervical mucus, and 52 used both mucus and monitor to estimate the fertile phase of the menstrual cycle. They produced 1,221 menstrual cycles of data, 452 of which were with correct use and 289 with incorrect or inconsistent use.

Unintended pregnancy rates

Research Objective One -- correct use pregnancy rate: We were able to determine the correct use pregnancy for those (n = 79) participants who used the online system to learn and chart the Marquette Model of NFP. There was only 1 correct use unintended pregnancy which yielded a survival pregnancy rate of 1.5 pregnancies per 100 users over 12 months of use.

Research Objective Two -- total or typical pregnancy rate: There were a total of 5 unintended pregnancies for all participants (n = 160) that produced a typical unintended pregnancy rate of 6 per 100 users (i.e., 94% survival) over 12 months of use (See Table 1 for pregnancy rates by cycles of use).

Objective Three -- subgroup pregnancy rates: There was one unintended pregnancy among the participants (n = 35) using only the EHFM plus fertility algorithm (with a survival pregnancy rate of 3 per 100 women over 12 months of use), 2 pregnancies with the (n = 73) CMM only participants (with a survival analysis of 4 pregnancies per 100 users over 12 months of use), and 2 unintended pregnancies among the (n = 52) participants who used both monitor
and mucus as fertility indicators (with a survival pregnancy rate of 6 per 100 users over 12 months of use) (See Table 2).

**Discussion**

*The results of this report indicate that use of the MM of NFP among older women (i.e., age 40-55) can be an effective means of avoiding unintended pregnancy especially with correct use and consistently following the instructions to avoid intercourse during the estimated fertile phase of the menstrual cycle. Our report provided a pregnancy rate of 6 among the older women users (between the ages of 40-54 years) of either cervical mucus only method, mucus plus fertility monitor method, or a combination of mucus plus fertility monitor method of NFP and a correct use rate of only 1.5. This rate compares with unintended pregnancy rates of our previous NFP efficacy studies of 7-16 typical use unintended pregnancies per 100 women over 12 months of use and 0-3 correct use pregnancies among younger women between the ages of 18-42 years (Fehring, Schneider, Raviele, & Barron, 2007; Fehring, Schneider, & Barron, 2008; Fehring, Schneider, Barron, & Raviele, 2009; Fehring et al., 2011; Fehring, et al., 2013) and among women using our special postpartum protocol to avoid pregnancy (Bouchard, Fehring, & Schneider, 2013). These unintended pregnancy rates also are within the range of efficacy of other methods of NFP, for example, a simplified mucus only method and a standard day calendar method, and in particular the ovulation method (World Health Organization, 1981; Arévalo, Jennings, & Sinai, 2002; Arévalo, Jennings, Nikula, & Sinai, 2004; Frank-Herrmann, Et al., 2007; ). Furthermore, the unintended pregnancy rate is comparable to the 8-9 per 100 women who use hormonal birth control (Trussell, 2011).

However, the perimenopausal women in this data set were rather young. We had only 15 participants that were 45 years of age or older and no pregnancies were from women older than
44 years. Three of the unintended pregnancies were within the first menstrual cycle post-partum among the younger women in the data set. There is an obvious bias in this study towards younger women in the 40-55 age group, however, this bias is toward more fertile women participants. Furthermore, all of the participants had what appeared to be ovulatory menstrual cycles based on the estimated day of ovulation and normal looking phases of the menstrual cycle, i.e., follicular and luteal phase lengths. How fertile these 15 post 45-year-old women are remains to be determined, as indicated by the Israeli study of older women, the pregnancy rate is only .2% (Laufer et al., 2009). An obvious limitation of this study is the rather homogenous nature of the participants, being mostly white, educated and middle class. So too, this study had a relatively small number of participants. Finally, it is not known how much the reduction in fertility among these women contributed to the results.

A recent study comparing the efficacy of using the EHFM versus CMM showed that the EHFM method was more effective in helping women avoid unintended pregnancy (Fehring, et al., 2013). In the current study, we also found that there was a lower pregnancy rate among our study participants that were only using the EHFM with a fertility algorithm to estimate the fertile phase. The lower rate might be due to the more objective and accurate nature of hormonal monitoring with the electronic fertility monitor than the more subjective method of CMM. Furthermore, the highest unintended pregnancy rate in this study was among the women who used a combination of EHFM and CMM. The higher pregnancy rate with the combination methods might be because the NFP method is too complex, is difficult to use with consistency, and the multiple indicators lengthens the required abstinence. Length of required abstinence with NFP methods correlates with taking chances during the long fertile phase and as a result, higher unintended pregnancy rates (Fehring, 2009). These results should be taken with caution
as they are not a result of a randomized comparison study and there needs to be many more participants with each method (i.e., approximately 500 participants for each method) in order to have enough statistical power to analyze statistical differences in unintended pregnancy rates.

The implication from a practice standpoint is that older women who are still ovulating and wish to use natural methods of family planning (and in particular the MM) can do so with confidence of its efficacy when used with correct use. So too, health professionals could recommend these methods for older women, especially those who might have health considerations for use of hormonal methods of family planning or who wish to use natural methods of family planning to avoid health risks or for religious reasons. However, there is the question as to how much the effectiveness of these NFP methods are due to reduced fertility among older women. A clinical implication is that women over 45 could be informed that their fertility is reduced to a level of about 2% or less, about the same as correct use of the male condom and better than typical use of hormonal contraception (i.e., 7-9 unintended pregnancies with use of the hormonal pill). They can also be informed that there are ways of monitoring their fertile phase with guidance from competent professional nurse NFP teachers until menstrual cycle variability indicates infertility. We recommend that women (especially those with serious reasons to avoid pregnancy) utilize professional nurses who have completed NFP teacher training programs that meet established standards (Fehring, 2004).

Another factor that might have influenced low unintended pregnancy rates in this study is motivation. Motivation in avoiding pregnancy is important for NFP efficacy as was recently determine with the Marquette Model of NFP (Fehring, Schneider, Barron, & Pruszynski, 2013). Assessing motivation to avoid (whether using NFP or any other behavioral methods of family planning) is important. Most couples and women who are older and who have completed their
family size usually have high motivation. Rice, Lanctôt, and Garcia-Devesa (1981) discovered that couples who had limited their family size had a pregnancy rate of 4.5% with use of NFP compared with a pregnancy rate of 15% among couples who were still spacing their children. Although couples who are limiters are generally older than delayers, the Rice, et al., (19981) study did not determine efficacy of NFP among women in the perimenopause transition.

Future research is recommended with a larger and more diverse sample of women and couples. Comparison of the MM of NFP with other forms of NFP and various combinations of self-indicators of fertility could also be conducted. A high priority would be to determine what indicators would determine when a woman is no longer fertile or that her fertility is so low that there is no concern. There might be some simple algorithms of cycle length and hormonal variability (such as FSH and/or AMH blood levels) that indicate infertility. Significant decreases in AMH, high levels of FSH, and running differences in the length of the menstrual cycle have been found to be somewhat predictive of pending menopause (Ferrell et al., 2007; Freeman, Sammel, Lin & Gracia, 2012; Santoro, Brockwell, & Johnston, et al., 2007; Taffe & Dennerstein, 2002). Some of these algorithms are currently being tested (Taffe & Dennerstein, 2002; Brodin et al., 2008; Hale et al., 2007; Santoro et al., 2007).

We concluded that use of the MM of NFP among older women can be very effective for those who have serious reasons to avoid pregnancy. However, the high efficacy to avoid pregnancy might in large part be a reflection of diminished fertility among older women and their motivation to do so. More research needs to be conducted as to when women can be confident that they are no longer fertile during the perimenopausal transition.
EFFECTIVENESS OF NATURAL FAMILY PLANNING

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Table 1

Total pregnancy rates of NFP use (n = 160) per 100 women over 12 menstrual cycles of use

<table>
<thead>
<tr>
<th>Cycles</th>
<th>Preg.</th>
<th>Estimate</th>
<th>Std. Error</th>
<th>Pregnancy rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 cycles:</td>
<td>3</td>
<td>0.97</td>
<td>.01</td>
<td>3</td>
</tr>
<tr>
<td>6 cycles:</td>
<td>0</td>
<td>0.97</td>
<td>.01</td>
<td>3</td>
</tr>
<tr>
<td>9 cycles:</td>
<td>1</td>
<td>0.96</td>
<td>.02</td>
<td>4</td>
</tr>
<tr>
<td>12 cycles:</td>
<td>1</td>
<td>0.94</td>
<td>.03</td>
<td>6</td>
</tr>
<tr>
<td>Total pregnancies</td>
<td>5</td>
<td></td>
<td></td>
<td>6</td>
</tr>
</tbody>
</table>
Table 2. Twelve cycle typical (total) survival rates in avoiding an unintended pregnancy by NFP method; 1) electronic hormonal fertility monitor (EHFM), 2) cervical mucus monitoring (CMM), and 3) combination of EHFM and CMM.

<table>
<thead>
<tr>
<th>NFP Method</th>
<th>Number</th>
<th># Preg.</th>
<th>Estimate</th>
<th>Std. Error</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHFM</td>
<td>35</td>
<td>1</td>
<td>0.97</td>
<td>0.03</td>
<td>3</td>
</tr>
<tr>
<td>CMM</td>
<td>73</td>
<td>2</td>
<td>0.92</td>
<td>0.06</td>
<td>4</td>
</tr>
<tr>
<td>EHFM+CMM</td>
<td>52</td>
<td>2</td>
<td>0.94</td>
<td>0.04</td>
<td>6</td>
</tr>
</tbody>
</table>