

Natural Family Planning

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Natural Family Planning

Women Can Initiate the TwoDay Method during Any Phase of the Menstrual Cycle

The TwoDay method (TDM) is a simplified cervical-vaginal fluid-based method of Natural Family Planning (NFP) that was developed by a research team at Georgetown University Institute for Reproductive Health (IRH). The TDM involves simply asking two questions to determine whether a woman is in the estimated fertile phase or not: whether she senses cervical-vaginal fluids today; and whether she sensed fluid yesterday. If the woman answers “yes” to either question, she is considered to be in the fertile phase of her menstrual cycle. Research among reproductive age couples in Peru, the Philippines, and Guatemala showed that correct use of the method yielded an unintended pregnancy rate of 3.5 and a typical use unintended pregnancy rate of 13.7 (Jennings et al., E-Published Ahead of Print).

Efficacy of the method was based on teaching women the instructions of TDM within the first 7 days of the participants’ menstrual cycle (i.e., before cervical secretion began). This instruction delays the use of the method for women beyond days 1-7 of the menstrual cycle. Delay in the use of TDM could result in unintended pregnancies or non-use of NFP methods. Therefore, the IRH researchers were interested in determining the efficacy and acceptability of the Standard Days Method (SDM) when taught in the mid and late phases of the menstrual cycle. This is referred to as the “quick-start” approach to the TDM.

The IRH researchers were able to obtain 176 participants from family planning clinics in two Peruvian cities. Forty of the participants were taught use of the TDM during the first 17 days of the menstrual cycle, and 121 were in day 8 or more of the menstrual cycle. The participants were assessed by trained interviewers at one, four, and seven months in the home setting. The participants were asked about secretions, unintended pregnancies, and whether they trusted the method or not.

The IRH researchers found that only 1 (2.5%) of the early instructed participants did not trust the method as compared to 8 or 6.6% of the later users. Thirty-two percent of the early instructed participants left the study and 14% of the late users. The pregnancy failure rate of the women who were instructed in the first 7 days of the menstrual cycle was 3.45 per 100 women users and 9.91 for the women who were instructed later in the cycle. There was little difference in the mean number of days of identified cervical-vaginal secretions (12.4 days) between the early cycle users in comparison to the later cycle instructed women (11.2) or the difference in the estimated days of fertility (12.4 versus 11.4 respectively). At the first month of follow-up instruction, 19.4% of the early cycle instructed women had difficulty identifying the cervical secretions as compared to 13.6% of the later cycle instructed women. Although there were identified differences in efficacy, drop out, and vaginal secretions between the two groups, the

researchers did not feel that they were significant. The IRH researchers recommended that the TDM be taught, and used by women, right away, no matter what phase of the menstrual cycle they are in.

Comments

This was a cohort comparison study, and although there were no significant demographic differences in the early and later phase participants, to actually determine if there were differences in efficacy and other variables of interest, a randomized study would be more definitive. The 9-12% of women who had trouble determining the vaginal-cervical secretions is problematic for efficacy and satisfaction in use of the method.

Source

Jennings, V., Sinai, I., Sacieta, L. and Lundgren, L. "TwoDay Method: a Quick-Start Approach." *Contraception*. E-Published ahead of Print.

Current Use of NFP Decreases among Women of Reproductive Age in Spain

Researchers in Spain have been investigating the patterns of contraceptive use and abortion among Spanish women of reproductive age (i.e., 15-49 years) since 1997. A recent study reported on the trends of contraceptive use and abortion from 1997-2007 (Dueñas et al. 2011). The researchers used a randomized stratified sampling technique to obtain a sample of 2,105 Spanish women between the ages of 15-49, i.e., stratified on age, marital status, geographical location, educational level and occupation. These women were administered an in-person interview and a simple survey on their current use of contraceptive methods.

The researchers found that the use of contraceptive methods increased significantly from 49.1% of the participants in 1997 to 79.9% in 2007. The most common methods of contraception in both 1997 and 2007 were (respectively) the condom (21% in 1997 versus 38.9% in 2007) and the pill (14.3% in 1997 versus 20.3% in 2007). The use of Natural Family Planning decreased from 0.9% of reproductive age Spanish women in 1997 to 0.5% in 2007. The surprising finding was the rate of voluntary interruption of pregnancy (abortion) rose from 5.52 per 1000 women in 1997 to 11.49 per 1000 women in 2007 (i.e., from 49,578 in 1987 to 112,138 in 2007). The researchers speculated as to why this happened, i.e., that the abortion rate increased even while the use of contraception increased. Furthermore, there were large government support efforts to promote contraception. The reasons they provided to explain why, even with the increased use and availability of contraception resulted in more abortions, were that there is a younger age of initiating sexual intercourse among Spanish adolescents, there is an inconsistent use of contraception, (in particular the pill and the condom), and the increased

number of immigrants to Spain have a lower education level and have more babies. They suggested, (without good evidence), that the increase use of emergency contraception might help reduce the amount of abortions.

Comments

The researchers pointed out that the birth rate increased by 1.2 per 1000 women from 1997 to 2007 (i.e., from 9.38 per 100 women of reproductive age to 10.5 per 100 women of reproductive age). There were more abortions per 100 Spanish women than live births in 2007, i.e., the abortion rate was 11.49 per 1000 women of reproductive age. They also pointed out that religion is one of the reasons for not using contraception, despite this, there is no difference in the contraceptive use among the Catholic women and non-Catholic women in the patterns of contraceptive use and abortion.

Source

Dueñas, J. L., Lete, I., Bermejo, R., et al. "Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997-2007." *Contraception* 83 (2011): 82-87.

Teaching NFP Via the Internet Is Effective for Women with a Variety of Cycle Lengths and Those Breastfeeding

Reviewed by Thomas Bouchard, MD: Family Medicine Resident, University of Calgary, Calgary, Canada

Natural Family Planning (NFP) users are increasingly looking for new ways of charting. Many organizations are now turning towards online charting and charting on-the-go with smart phones. Researchers at Marquette University have incorporated an online charting tool which not only allows users to electronically document their fertility (based on mucus, data from a urine-based fertility monitor, menstrual patterns and acts of intercourse), but also projects a user's fertile window with a built-in algorithm based on the user's own charts. (R. Fehring et al. 2011). The online charting tool, in turn, provides the researchers with an expanding data set for analysis of pregnancy rates and a way to respond to user-specific questions regarding their charts. The website, (nfp.marquette.edu), provides educational materials that allow users to learn the Marquette Method of NFP independently, consult professionals, (nurses, physicians and an ethicist), and speak to other users through a "virtual community" that is organized by topics.

In this 6-month pilot study, Fehring and colleagues tracked how many users signed up for an account (N=468) and of those, how many actually began charting (N=222, 47%). The only demographic difference they found between those who chose to chart and those who didn't was

that the charting group had significantly more children (2.2 vs 1.7, $p=0.02$). Of interest, nearly half of those who began charting were postpartum breastfeeding (48.6%) and the majority of the others (48%) had regular length menstrual cycles. The correct-use and typical-use pregnancy rates after 6 months of use are shown in Table 1. For those attempting pregnancy, the method also proved to be quite effective, with pregnancy rates of 24% at 1 month, 48% at 3 months and 60% at 6 months. The online users fertility knowledge was tested with a quiz at 0 months and 1 month of use. There was a significant difference in scores, (0 months 8.96/10 and 1 month 9.46/10, $p<0.001$), but it should be noted that scores were fairly high initially. The acceptability of the method was evaluated at 1, 3 and 6 months, but their two statistical measures were conflicting as to whether the acceptability had significantly improved over the course of the 6 months. The authors comment that there was a lack of follow-up in the acceptability surveys (143 responses at 1 month and 40 responses at 6 months) which may lead to bias in acceptability results.

Table 1: Pregnancy rates after 6 months

	Correct-use	Typical-use
Total (N=222)	2%	7%
Non-breastfeeding (N=114)	0%	9%
Breastfeeding (N=108)	3.8%	5%

Comments

Fehring and his colleagues' preliminary data offers promise in several areas. It is the first study that provides efficacy data for an NFP method that is taught online rather than by couples or consultants. This data shows that an online information source can be an effective way to learn NFP. Given that the fertility knowledge quiz scores were quite high initially, it is possible that some users may have already had a background in NFP use, but prior NFP use and knowledge was not mentioned by the authors. The online "learning community" where users interact with others using the method on a variety of health topics is a novel way to network isolated NFP users together, and it also allows users without access to NFP teachers to be able to interact with NFP professionals within a reasonable timeframe (they state a response rate within 24 hours). Unfortunately, because of the poor follow-up of their acceptability surveys, and because acceptability was measured as a single composite score, it is difficult to assess user satisfaction as it relates specifically to online charting, online discussion forums or access to professionals.

Another area of promise is that the Marquette Method has attracted a specific population

of breastfeeding women with more children. It is entirely speculative, but one possibility is that after a second child, especially if the second child were conceived earlier than expected, couples may want more assistance with avoiding pregnancy thereafter. Many women experience an unexpected pregnancy during the breastfeeding period, and this preliminary efficacy data for the Marquette Method suggests that it is an effective way to avoid pregnancy during this period. This pilot study represents the first new data on an NFP breastfeeding protocol in several years. Most NFP research in the breastfeeding period has focused on the Lactational Amenorrhea Method (LAM), but for a minority of couples who have become pregnant while breastfeeding, the Marquette Method breastfeeding protocol provides additional information to help identify the return of fertility.

The main limitation of this study is that the pregnancy rates quoted were based on 6 months of cycles. Most other studies use 12-month survival curves for pregnancy rates. The authors compare their 6-month pregnancy rates to 12 or 13-month pregnancy rates from other studies, which are not directly comparable. Because of the shorter period of this study, their reported rates may underestimate the actual 12-month efficacy of their method. Lastly, the website needs an update to accommodate the differences in charting patterns for breastfeeding women. Since this a primary audience for the Marquette Method, it would be a worthwhile focus for their next upgrade.

Source

Fehring, R., Schneider, M., Raviele, K. "Pilot Evaluation of an Internet-based Natural Family Planning Education and Service Program." *Journal of Obstetrics, Gynecology, and Neonatal Nursing* 40 (2011): 281-91.

Fertility

High Pre-Pubertal Body Mass (BMI) Index Associated with Early Age of Menarche

Although it is known that there is a causal link between body mass index (BMI) and age at menarche (AOM) it is not known whether this link begins in utero. Researchers sought to determine if the pre-natal exposure to excess estrogens produced by fat tissues of overweight mothers affected the age at menarche for their offspring—specifically whether the mother's BMI at the time of pregnancy accounted for some or all of the association between offspring BMI and AOM (Shrestha et al. 2010).

The researchers were able to obtain a data set that was developed in the 1980s from 13,815 pregnant mother participants who resided in two Danish cities. The mothers were interviewed at that time of participation about their lifestyle habits and pregnancy weight and height. The researchers found a total of 3,169 girls from these mothers who were still living in

Denmark and who had reached menarche. Of these girls, 1,634 responded to questions about the month and year they experienced menarche. Applying regression analysis, they found only a weak inverse association between the mother's BMI and age at menarche. However, they found a strong association between the offspring's BMI and AOM. They also found that with every unit increase in offspring BMI there was a corresponding larger acceleration in AOM. They concluded that their findings did not support the influence of maternal BMI on the AOM and BMI of their female offspring. They did suggest that as the BMI and obesity rates climb in countries around the world that the expectation should be of earlier AOMs.

Comments

Health professionals, natural family planning teachers, and school teachers working with adolescents will, most likely, be seeing adolescents in the United States with early dates of menarche due to the obesity epidemic. A risk is early sexual activity and pregnancy.

Source

Shrestha, A., Olsen, J., Ramlau-Hansen, C. H., Nohr, E. A. "Obesity and Age at Menarche." *Fertility and Sterility* E-Published 2.20/2010.

Weight Loss and Exercise Found to Be As Effective As Metformin on Ovulatory Rates among Women with PCOS

Researchers from Penn State College of Medicine hypothesized that the addition of the insulin enhancing medication Metformin to lifestyle changes (i.e., weight loss and exercise), would be superior to lifestyle changes alone in improving ovulation frequency, androgen excess, and insulin insensitivity among women with polycystic ovarian syndrome (PCOS) (Ladson, et al., 2011). In order to test this hypothesis, researchers randomized women who were diagnosed with PCOS (based on National Institute of Medicine criteria) into a lifestyle with placebo group or a lifestyle with Metformin group. The participants and the health providers were blind to which group the women participants were assigned, i.e., the researchers used a randomized double-blind design for this study. The lifestyle modification included weight loss targets (i.e., daily calorie requirements minus 500 calories), and structured exercise of at least 150 minutes per week of aerobic exercise. The Metformin group included a step-up approach of 500 mg of metformin in capsule form from one to four per day. The outcome measures were assessed over a 6 month time-period and included daily urinary measures of ovulation (i.e., pregnanediol-3 alpha-glucuronide), reproductive hormone (FSH, LH, DHEAS, and SHBG) levels at baseline, 3 and 6 months, ultrasound scans, and a quality of life assessment. They enrolled 187 participants, of which 114 were randomized into the two groups, i.e., 55 in the Metformin group and 59 in the

placebo group. Only 22 completed the Metformin group, and 16 in the placebo group. Most of the drop outs were due to lost follow-up.

There were no differences in the age, race, or biometrics between the two groups of women. The researchers found no differences in the number of ovulations over the 6 month time-period. There were significantly lower testosterone levels for the Metformin group at 3 months but not at 6 months. Between the two groups, there were no significant differences in weight loss, however, the Metformin group, had within group, lower changes at all time-periods. There were no significant differences in the quality of life measures at all time-periods between the two groups. The authors concluded that the addition of Metformin to lifestyle modification for the treatment of PCOS had little or no benefit.

Comments

The difficulty with this study was the number of drop outs over time, which demonstrates that implementing life-style changes among patients is difficult, in particular with this low-income group of women. The dropout rate also decreased the statistical power in determining differences.

Source

Ladson, G., Dodson, W. C., Sweet, S. D., Archibong, A. E., et al. "The Effects of Metformin with Lifestyle Therapy in Polycystic Ovary Syndrome: a Randomized Double-Blind Study." *Fertility and Sterility* 95 (3) (2011): 1059-1066.

Return of Fertility for Non-Lactating Postpartum Women

Researchers from the World Health Organization (WHO) recently met to develop guidelines for the use of combined oral hormonal contraceptives (i.e., synthetic estrogen and progestin) for postpartum women. A concern of the WHO researchers was that the risk for venous thromboembolism is high for postpartum women and that it takes about 6 weeks for coagulation factors to return to normal for these women. Use of combined hormonal contraception would aggravate the risk for thromboembolism. WHO researchers decided to do a review of the literature to see when non-lactating women return to fertility, (i.e., first menses and first ovulation), in order to help in the decision-making about postpartum contraceptive guidelines for use of combined hormonal contraception.¹

The researchers searched the literature for studies documenting the first menses and ovulation for postpartum non-lactating women, i.e., resumption of fertility. They accessed 1,623 articles, but found only four studies that met their inclusion criteria. Of these four studies, they rated three of them of poor quality evidence. Table One shows the mean day, (standard

deviation, and range if available), of first menses and ovulation found in the four studies.²⁻⁷ In the first study, (which is actually two but using the same women), researchers found, based on using urinary pregnanediol (Pg; a metabolite of progesterone) and luteinizing hormone (LH) to estimate fertility, that 68% of the first menses were preceded by ovulation, but that 67% of the first ovulations had luteal phases too short to sustain a pregnancy.^{2,3} The second study found, (using urinary Pg measures), that the first menses occurred on day 64 postpartum and the first ovulation day 94.⁴ In the next two studies, (which again used the same participants), 71% of the first menses were preceded by ovulation but 40% of these had effective luteal phases that most likely would not support a pregnancy.^{5,6} In the largest study by Cronin, only 30% of the women had an ovulation before first menses, but of these 70% were likely fertile.⁷

In general from the analysis of the four studies, the WHO researchers found that the average time to first menses in the non-lactating post-partum women ranged from 45 to 64 days and the first ovulation ranged from 45-94 days. The first menses postpartum were found to be anovulatory 29% of the time; however, they also discovered from two studies that the earliest day of ovulation was day 25 and day 27 postpartum. The researchers also noted that the body of evidence on the resumption of fertility for non-lactating post-partum women is limited. This is due to too few studies and few participants. None of the studies indicated any sample size determination. Furthermore, some of the studies used markers of fertility that lack validity during the breastfeeding transition.

Table 1: Mean, standard deviation, and range of estimated day of ovulation and first menstruation and percentage that had ovulation before first menses among non-lactating women.

Study	N	Biomarker	Menses	Ovulation	% Before
Campbell/Gray et al ^{2,3}	22	Urine Pg/LH	45.2/10.1 (30-81)	45/16.9/(25-?)	68%
Glasier ⁴	7	Urine Pg	63.7/13.0 (49-84)	93.8/37.0/(77-84)	60%
McNeilly/Howie ^{5,6}	10	Urine Pg	56.7/7.0	75.6/7.0	71%
Cronin ⁷	93	BBT shift	58.9 (NA)	73.5 (NA)	30%

Comments

Information as to when first ovulation and first menses occur post-partum is of interest for both lactating and non-lactating women who use natural methods of family planning.

Furthermore, knowing how often ovulation occurs before the first menses and whether this is an ovulatory event with resulting luteal phase that would likely support a pregnancy, is also important. Better research is needed to answer these questions.

Source

1. Jackson, E. and Glasier, A. "Return of Ovulation and Menses on Postpartum Non-lactating Women. A Systematic Review." *Obstetrics and Gynecology* 117 (2011): 657-662.
2. Campbell, O. M. and Fray, R. H. "Characteristics and Determinants of Postpartum Ovarian Function in Women in the United States." *American Journal of Obstetrics and Gynecology* 169 (1993): 55-60.
3. Gray, R. H., Campbell, O. M., Zacur, H. A., Labbok, M. H. and MacRae, S. L. "Postpartum Return of Ovarian Activity in Non-breastfeeding Women Monitored by Urinary Assays." *Journal of Clinical Endocrinology and Metabolism* 64 (1987): 645-650.
4. Glasier, A., McNeilly, A. S. and Howie, P.W. "Fertility after Childbirth: Changes in Serum Gonadotrophin Levels in Bottle and Breastfeeding Women." *Clinical Endocrinology* 19 (1983): 493-501.
5. McNeilly, A. S., Howie, P. W., Houston, M. J., Cook, A. and Boyle, H. "Fertility after Childbirth: Adequacy of Postpartum Luteal Phases." *Clinical Endocrinology* 17 (1982): 609-615.
6. Howie, P. W., McNeilly, A. S., Houston, M.J., Cook, A. and Boyle, H. "Fertility after Childbirth: Postpartum Ovulation and Menstruation in Bottle and Breast-feeding Mothers." *Clinical Endocrinology* 17 (1982): 323-332.
7. Cronin, T.J. "Influence of Lactation upon Ovulation." *Lancet* 292 (1968): 422-424.

74% of Couples with Unexplained Infertility Achieved a Spontaneous Ongoing Pregnancy through Expectant Waiting

Fertility researchers from the Netherlands noted that unexplained infertility is one of the most common diagnoses experienced in fertility clinics. They also stated that there is insufficient evidence to indicate treatment for couples with unexplained infertility, i.e., whether medically controlled ovarian stimulation (COS), intrauterine insemination (IUI) and/or in vitro fertilization (IVF) is superior to expectant management. Therefore, they conducted a multicenter longitudinal cohort study to investigate outcomes from evidenced-based fertility management of unexplained infertility (Brandes et al. 2011).

Fertility researchers were able to obtain a cohort of 2,476 couples who were referred by their primary care provider to three outpatient infertility clinics at three major hospitals in the Netherlands. Of these couples, 443 were determined to have unexplained infertility after an infertility workup. These couples were placed into one of three therapeutic strategies according to their predictive prognosis, i.e.: 1) couples with a > 30% outcome probability of conceiving, they were offered expectant waiting for up to two years, followed by 6 cycles of COS + IUI, and then if that did not work, three cycles of IVF, 2) for couples with a < 30% chance of a pregnancy outcome, and the woman was < 38 years of age, three to six cycles of COH/IUI was offered, and 3) for couples with the female > 38 years of age, direct IVF was offered.

The researcher found that overall 73.9% or 263 of 356 women participants conceived spontaneously, whereas, only 12.6% conceived through IVF and 13.5% though COH/IUI. Even 14.7% of the couples who were treated with IUI and 11.7% of the IVF couples, eventually conceived spontaneously, post treatment. Furthermore, 32.2% of couples who discontinued the IUI treatment, and 18.1% of the couples who discontinued IVF, eventually conceived spontaneously. The authors recommended that treatment for unexplained infertility, (for couples with good prognosis, i.e., based on age, follicle stimulating hormone levels, basal metabolic index, and lifestyle), begin attempting pregnancy with expectant waiting.

Comments

A recent randomized control trial of expectant waiting versus with use of clomifene citrate or IUI showed that there was no difference in pregnancy outcomes (Bhattacharya et al. 2008). I would argue that, instead of just random expectant waiting, couples learn how to observe and chart natural indicators of fertility, use focused and frequent intercourse, and reduce any lifestyle factors that interfere with optimal fertility.

Source

Brandes, M., Hamilton, C. J. C. M., van der Steen, J. O. M., de Bruin, J. P., Bots, R. S. G. M., Belen, W. L. D. M. and Kremer, J. A. M. "Unexplained Infertility: Overall Ongoing Pregnancy Rate and Mode of Conception." *Human Reproduction* 36 (2011): 360-368.

Bhattacharya, S., Harrild, K., Mollison, J., et al. "Clomifene citrate or Unstimulated Intrauterine Insemination Compared with Expectant Management for Unexplained Infertility: Pragmatic Randomized Controlled Trial." *British Medical Journal* 337: (2008): a716.

Early Follicular Phase Serum Levels of Antimüllerian Hormone Found to Be Best Predictor of Natural Infertility among “Older” Women

Women are marrying and delaying child birth to a later age. Since fertility declines considerably after the age of 35, being able to predict one’s ability to conceive would be of importance. Furthermore, women who have completed their family size (i.e., peri-menopausal women) would like to know their probabilities of pregnancy as well. Researchers sought to determine the predictability of various endocrine hormones as biomarkers of natural fertility among a sample of women at risk for ovarian aging (Steiner et al. 2011).

The endocrine hormones of interest for the researchers were those that are known to decline or rise due to the decrease in ovarian reserve, i.e., a decline in antimüllerian hormone (AHM) and inhibin B and a rise in early-follicular phase follicle stimulating hormone (FSH) and estradiol.

The researchers were able to enroll 100 women between the age of 30 and 44 who were attempting to achieve pregnancy for 3 months or less and had no known infertility problem. Of these women participants, 98 were able to remain for follow-up assessment, and of these 30% were 35 years or older and 5% were 40 years or older. The participants provided serum and urine samples of early follicular phase FSH, estradiol, AMH, inhibin B, and urine FSH and estrone 3-glucuronide. The participants also kept daily diaries of menstrual cycle length, uterine bleeding, frequency of intercourse, and pregnancy test results. They produced 224 cycles of data for analysis. The estimated day of ovulation was considered to be 14 days before the first day of menses for the next menstrual cycle. They defined the fertile window as the day of ovulation and the five days before. By 6 months of enrollment, 63.6% of the women had conceived.

The researchers found that age was a strong predictor of the day-specific probability of pregnancy. Women who were 35 years or older had a significant reduction in fecundity compared to younger women, i.e., a fecundability ratio of 0.42. They also found that women who had AHM levels of 0.7 ng/mL or less had a significantly lower fecundability compared with those who had higher AHM levels, i.e., a fecundability ratio of 0.36. They also discovered that those women who had early follicular phase FSH levels greater than 10 milli-international units/mL with a ratio of 0.44, had a 40% reduction in fecundability. They did not find statistically significant fecundability ratios with the other endocrine measures. They concluded that early follicular phase AHM serum levels appear to be a good predictor of age-related reductions in fecundability. Urinary FSH was only weakly predictive.

Comments

The results of this study are somewhat limited in that there was a relatively small number of participants and few women participants over 40 years of age. The use of serum biological

marker of AHM might be restrictive and expensive. Use of over-the-counter urinary FSH and age combination might be more useful for women and non-prescribing health practitioners.

Source

Steiner, A. Z., Herring, A. H., Kesner, J. S., Meadows, J. W., Stanczyk, F. Z., Hoberman, S. and Baird, D. D. “Antimüllerian Hormone as a Predictor of Natural Fecundability in Women aged 30-42 years.” *Obstetrics and Gynecology* 117 (2011): 798-804.

Contraception

Characteristics of the Menstrual Cycle Are Found to Be Altered for at Least Two Menstrual Cycles Post Use of Oral Hormonal Contraceptives

Researchers recently sought to determine the influences of oral hormonal contraceptives (OC) on the phases and functions of the menstrual cycle (Nassaralla et al. 2011). Past studies have shown there is a one to three month delay in conceiving for women attempting conception after discontinuing use of OC and that this is caused by a delay in ovulation (i.e., a lengthened follicular phase). What is not known are the effects of discontinuing OC on the intensity of menses and the quality of cervical mucus – information that would be important for women and couples using NFP attempting to conceive. Therefore, the purpose of this study was to compare the phases of the menstrual cycle, the intensity of menses, and quality of cervical mucus among women who recently discontinued OC to attempt conception with women who had not used OC for at least one year.

The researchers were able to obtain menstrual cycle charts (of 70 women between the age of 18 – 42) who discontinued OC within 12 weeks or less) from three NFP sites in the United States (i.e., Atlanta, Milwaukee, and Saint Louis). These 70 women were then matched, (based on age and parity), with 70 women who were using NFP and charting their menstrual cycles but did not use OC in the past 12 months. All 140 women used a standardized form of the cervical mucus method called the Creighton Model System (CrMS). What is unique about the CrMS is that it has a standardized cervical mucus rating system and a method for quantifying both cervical mucus quality and the intensity of menses. There were no differences between the two groups of women (based on mean age, race, education) except recent OC users were more likely to be married. Analysis of the menstrual cycles was based on 6 menstrual cycles of charting with both groups of women.

The data showed that during the first two menstrual cycles the length of menses was shorter and the estimated day of ovulation was significantly later for the menstrual cycles of the post OC group compared to the matched controls. When all six menstrual cycles were included

in the analysis, the post OC cycles were longer, the estimated day of ovulation later, and the cervical mucus and menses scores were significantly lower. The authors speculated that the longer menstrual cycles and the delayed day of ovulation was most likely due to the time needed for the hypothalamus-pituitary-ovarian axis to normalize after suppression of ovulation. They also speculated that this adjustment of the menstrual cycle post OC might help to explain why there is a decreased chance for conception after discontinuing OC.

Comments

NFP teachers and health professionals have been taught that it was best for women to wait three menstrual cycles before trying to conceive. The concern was the effects that the hormones from the OC remaining in the body might have on the developing fetus. The thinking now is that the OC hormones are quickly removed from the body and have little or no effect on human development. A better reason to wait to achieve pregnancy is that it takes 1-3 menstrual cycles for the cycle to adjust to normal and for the ability to target intercourse during the fertile phase. This study was limited in that the number of menstrual cycles of data was diminished from 1-6 cycles of data and thus lacked statistical power as the cycles progressed.

Source

Nassaralla, C. L., Stanford, J. B., Daly, D., Schneider, M., Schliep, K. C., and Fehring, R. J. "Characteristics of the Menstrual Cycle after Discontinuation of Oral Contraceptives." *Journal of Women's Health* 20 (2011): 169-177

Only 2% of US Obstetrician/Gynecologists Would Refuse to Provide Female Sterilization

Sterilization is the second most currently used method of family planning among women in the United States (US) between the ages of 15-44 years. Female sterilization is the number one method among Hispanic women in the US. Female and male sterilization, combined, is the number one method of family planning in the US. Physicians are prime gatekeepers both as providers and referral sources for sterilization. Up until 1971, sterilization for non-medical reasons was largely not available in the US. Although sterilization is one of the most frequent methods of family planning in the US, there still exist some controversy as to when and for whom sterilization is appropriate (e.g., should sterilizations be provided for young women, for women with few children, and when the male partner does not agree with the procedure?). Researchers from the University of Chicago decided to determine how physicians' beliefs in relation to the woman patient's wishes for sterilization affects whether they would provide or refer for sterilization (Lawrence et al. 2011).

To implement this study, researchers devised a scenario-based survey that included items on the age of the woman seeking sterilization, the number of pregnancies and current children, and whether the woman's male partner agreed or disagreed with the sterilization. The researchers also added religiosity questions, i.e., importance of religion, and frequency of church attendance in the survey. The response variables included whether the physicians would provide the surgery themselves, would refer the patient to another physician for the surgery, or would neither provide nor refer for sterilization. The researchers were able to obtain a nationally represented sample of 1,800 obstetrician and gynecologists (65 years of age or younger) from the American Medical Association Physician Master file. Three separate mailings were sent to the physicians. A monetary award was offered for completing the survey. A 66% response rate (i.e., 1,154 surveys of 1,760 eligible respondents) was achieved.

They discovered that 70% of the physicians would discourage sterilization from a Gravida (G) 2, Para (P) 1, 26-year old woman whose husband disagreed with the request for sterilization. Only 9% would discourage sterilization from a G4 P3 36-year old woman whose husband agreed with the request. Religiosity, but not gender, had an influence on the physicians' willingness to discourage sterilization. For example, 33% of physicians who attended religious services, at least twice a month, would dissuade sterilization compared with only 9% of non-attenders. There was no difference in the percentage of religious service attendance and whether physicians would dissuade a 26 year old woman seeking sterilization. Regardless of all of the possible situations, if the patient continued to request sterilization, even after a discussion and recommendation from the physician to not see sterilization, only 2% (N=25) would refuse to provide or refer for sterilization. The researchers concluded physicians' reaction to the request for sterilization was influenced largely by the patient's age and parity. In the end, the autonomy of the patient was paramount.

Comments

The researchers admitted that the scenarios provided in the study were limited in comparison to an actual patient encounter where more depth conversation and assessment can take place. They also pointed out that the responses from 33% of non-responders might have been different. Although religiosity had an influence, as there was a greater reluctance to provide sterilization among the more religious physicians, in the final analysis, even the religious physician would either provide or refer. There was no report as to whether there was any difference in the response from physicians who listed themselves as Catholic. I imagine that there was not, since there were so few physicians in the total group (i.e., 25) who would not refer or provide when the woman persisted in her request.

Source

Lawrence, R. E., Rasinski, K. A., Yoon, J. D. and Curlin, F. A. "Factors influencing physicians' advice about female sterilization in USA: a national survey." *Human Reproduction* 26 (2011): 106-111.

Most (93%) Catholic Obstetrician-Gynecologists in the United States Would Provide Hormonal Contraception to Unmarried 17 Year Old Adolescents without Parental Notification

The provision of health care to female (and male) adolescents can be a challenge to primary care providers, especially when that care involves matters of human sexuality. An especially difficult situation is when a single female adolescent is sexually active and requests hormonal contraception without parental consent. In such a situation, the adolescent minor is then considered an emancipated individual and professional standards recommend that her autonomy be respected and contraception provided. In fact, the provision of adolescent health care through Title X Clinics in the United States (US) requires that contraception be provided. Many states have laws that reinforce the emancipated sexually active adolescent. Despite these laws, the provision of contraception without parental notification and consent is troubling to some health care providers, since the adolescent often does not have the maturity to make responsible family planning decisions and others do not believe that it is moral to do so.

Researchers at The University of Chicago were interested in determining the attitudes of obstetrician-gynecologists (OB/GYNs) in the US in providing contraception to single sexually active adolescents without parental notification (Lawrence et al. 2011). They were also interested in determining the influence of religion and church attendance on the provision of contraception to unmarried adolescents and whether the OB/GYNs would advise sexual abstinence. These researchers obtained a national list of 1,800 board certified OB/GYNs 65 years and younger and submitted, (through the mail), a validated survey on attitudes of providing contraception to a 17 year old college freshman. The survey also measured the OB/GYNs' religion, church attendance, and importance of religion.

The researchers received a usable return rate of 66% (1,154). The survey showed that 54% of the OB/GYNs indicated they would provide abstinence counseling, 47% would advise involving parents, but 95% would very likely, or somewhat likely, provide contraception to the minor without parental consent. Of those physicians who consider religion as very important, 81% would advise abstinence and 54% would advise consulting parents about the decision to provide contraception. There was no difference in the likelihood of actually providing contraception among the more religious physicians compared to the less religious physicians. The same pattern occurred with those physicians who attended church at least twice a month or

more, i.e., 68% would advise abstinence and 53% would like to involve the parents in the decision to provide contraception. Of the Catholic and/or Orthodox physicians, 58% would advise abstinence, 47% would like to involve the parents, but 93% would offer contraception to the minor un-married adolescent. The researchers concluded that most physicians (even those who are religious) would offer contraception to unmarried adolescents without parental consent

Comments

The authors of this study mentioned that the United States Conference of Catholic Bishops contend that providing contraception, to an adolescent, without their parental is an affront to the role of parents. The researchers did not mention that the use of contraception is forbidden by the Catholic Church and is considered an affront to God and the meaning of the conjugal relationship. Furthermore, the Church recommends chastity for single adolescents and young adults, which, from a health standpoint, is the healthy ideal.

Source

Lawrence, R. E., Rasinski, K. A., Yoon, J. D. and Curlin, F. A. “Adolescents, Contraception and Confidentiality: a National Survey of Obstetrician-gynecologists.” *Contraception* (2011): E-published ahead of Print.

Catholic Hospital Staff Study Immediate Post-Partum Use of Injectable Hormonal Contraceptive

Unintended pregnancy among low-income unmarried adolescents is a very common health problem in the United States. One method that has been employed to decrease unintended pregnancy among low-income adolescents, (many of whom are black), is to provide an injection of depot medroxyprogesterone acetate (DMPA) immediately post-partum. In Catholic health care institutions this intervention becomes problematic due to the Church’s stance against the use of contraception. Physicians at Loyola University Medical Center in Chicago were allowed to use DMPA immediately postpartum for medical reasons, i.e., to treat or prevent health problems other than unintended pregnancy. This practice was stopped in 2007, (seemingly because the use was abused) and it was recommended that family planning needs for this population be determined at the first 6 week post-partum visit and not immediately post-partum. Researchers at Loyola therefore wanted to determine the effects of this policy on unintended pregnancy rates within the first year postpartum among women younger than 26 and at risk for unintended pregnancy (Guiahi et al. 2011). The researchers hypothesized that there would be an increased rate of unintended pregnancy the first year post-partum among at-risk young women.

To test this hypothesis, the researchers identified 200 female patients under the age of 26, who, prior to the change of the policy, received DMPA at delivery of their baby. They then

randomly selected a control group of 160 women under the age of 26 who did not receive DMPA immediately postpartum due to the change of policy. After abstracting data from computerized hospital records they were able to use 105 women who were exposed to DMPA postpartum and 153 who were not exposed to the injectable hormonal contraceptive. After analysis they determined that the women in the two retrospective cohorts did not differ in age, marital status, BMI, parity, mode of delivery and postpartum follow-up attendance. The women who received immediate postpartum DMPA were more likely to be of the black race and less likely to be Caucasian, Catholic, and have health insurance.

The researchers found that the women who received DMPA immediately postpartum were significantly less likely to have had a pregnancy within one year (OR 0.34, 95% CI 0.13-0.87). The immediate DMPA postpartum women had a pregnancy rate of 5.7% (i.e., 6 of 105) compared with the other women who had a 15% (i.e., 23 out of 153 women) pregnancy rate within the first year postpartum. Black race and/or Christian religion were also associated with the odds of an increase in the odds of a repeat pregnancy. The authors stated that their results reflected the negative consequences of implementing a restrictive contraceptive policy at Catholic hospitals.

Comments

There are a number of methodological and conceptual problems with this research study besides the obvious fact that the authors were biased towards the immediate use of postpartum contraception.

Methodologically, the number of participants was low and represented only 3.3% of all deliveries at the Loyola University Medical Center during the time-period in which the study took place. Furthermore, since this was not a random assignment study, the different pregnancy rates could be due to differences in the women selected, especially since they were selected by the researchers involved with the study. In addition, the researchers did not determine whether the pregnancies were unintended or not. It could be assumed that since the delayed group had more Christian women, that there might be some intended pregnancies. Finally, it would make sense to only include unintended pregnancies that occurred from the time of birth to the first 6 week postpartum visit, i.e., when the delayed women were offered a family planning method, and when the physician could make a better assessment of the health and family planning needs of the patient. Fertility is naturally and physically low during the first 6 week postpartum and during that time-period health professionals should be encouraging breastfeeding. Full breastfeeding provides a natural anovulation effect.

One of the most disturbing facts from this study was the supposed medical use of DMPA for medical problems. The authors admit that, most of the time, there was no definitive reason for use of DMPA other than stating for medical reasons. They provide a list of potential uses of

DMPA postpartum, such as: endometriosis, dysmenorrhea, iron deficient anemia, ovarian cysts, etc. There is no mention that DMPA is not the best treatment for these types of health problems and actually could lead to other problems, such as bone loss, cardiovascular problems, and future deep infiltrating endometriosis. The quick use of injectable DMPA postpartum is sloppy and dishonest medicine.

Due to the bias in favor of contraception and complete disregard for Catholic teachings at a Catholic institution on the part of the researchers, it could also be argued that this study was undertaken for political motives and not ultimately for the welfare of the patient.

Source

Guiahi, M., NcNulty, M., Garbe, G., Edwards, S. and Kenton, K. “Changing Depot Medroxyprogesterone Acetate Access at a Faith-Based Institution.” *Contraception* 83 (2011): 367-372.

UNDER THE MICROSCOPE

“Perfect, Typical, and Imperfect Use of Natural Family Planning Methods”

The problems of a biased approach to research and the realistic needs for improved studies

James Trussell, a well-known professor in the Office of Population Research at Princeton University and expert on contraceptive efficacy, recently published a “contraceptive failure” review article for the purpose of helping couples make informed decisions when choosing a method of family planning.¹ Trussell indicated that there are four pieces of information about family planning methods in relation to pregnancy rates that are useful to know when choosing a method to avoid pregnancy. They are:

1. *Typical use.* This rate provides information as to how effective a method of family planning is under actual use, and includes both perfect use and inconsistent and incorrect use of a method.
2. *Perfect use.* This rate provides information as to how effective a method of family planning is when couples consistently, and correctly, follow the instructions of the method.
3. *Imperfect use.* This rate indicates how effective a method is when it is used incorrectly and/or inconsistently. A sub-category under this piece of information includes pregnancy rates for various types of imperfect use and as to which behaviors are the most risky for an unintended pregnancy.

and

4. *Perfect use.* Perfect use, and/or the percentage of months of use (or menstrual cycles of use) during which the method is used perfectly, provides information on how difficult the method is to use consistently and correctly.

Trussell indicates that the differences of unintended pregnancy rates between imperfect use and perfect use demonstrates how “forgiving” a method is (i.e., how likely a woman will conceive with imperfect contraceptive behaviors). For example, if a woman forgets to take the hormonal pill for one day, her pregnancy chances are increased, but not by much. However, if a couple using a method of Natural Family Planning (NFP) has intercourse on a fertile day during the fertile window, they most likely will conceive. In Trussell’s perspective, NFP used as a method for avoiding pregnancy, is much more unforgiving than hormonal pills.

The differences between unintended pregnancy rates during typical use and perfect use indicate the level of difficulty to use the method perfectly, and reveals the consequences of imperfect use. Trussell provides a review of the literature for various contraceptive and family planning methods including fertility awareness-based methods (FABM) or NFP methods. This review will take an in depth look at Trussell’s analysis. It will point out its strengths and weaknesses as well as juxtapose classic NFP research with that of Trussell’s analysis. The purpose of this review is to determine any strengths of Trussell’s analysis and to apply it to the design of future NFP research in order to strengthen NFP effectiveness studies.

Perfect use of fertility awareness-based methods

Based on the above definitions, Trussell indicates that there are only four FABM studies that appropriately provide perfect use estimates.²⁻⁵ These studies are that of: the Standard Days method (or SDM), the TwoDay method (or TDM), the Ovulation Method (OM), and the European double check Symptom-Thermal Method (STM). The perfect use estimate for the SDM is 4.8%, the TDM 3.5%, the OM 3.2%, and 0.4% per 100 women over 12 months of use for STM. Trussell insists that published method failure rates for other FABM are incorrect since they do not separate out the imperfect use cycles from perfect use cycles in pregnancy rate calculations. Based on these figures, couples who wish to use FABM can know that the use of these methods, (and in particular the STM double-check method) can be as effective as female sterilization, the intrauterine contraceptive (IUC) and oral hormonal contraceptives.

Before discussing typical use of FABM, it should be pointed out that in order to determine perfect use from imperfect use and typical use, researchers need to have available prospectively-determined menstrual cycle charts that indicate whether the couple plans on using the method to avoid or achieve pregnancy, the days when they have intercourse, and if the days of intercourse are within or outside of the estimated fertile phase as determined by the rules of the method. Only menstrual cycles that have been used and identified as perfect use are used in the calculation of perfect use pregnancy rates.⁶ Typical use pregnancy rates are determined by

using both perfect use and imperfect use menstrual cycles (i.e., when couples have intercourse on identified fertile days) in the analysis. When it is not prospectively known whether the women/couple users of FABM have used the methods perfectly or incorrectly, only typical use rates can be calculated, either by menstrual cycles of use, or months of use over a one year time-period. These criteria are now considered standard for NFP efficacy studies.

Typical use of fertility awareness-based methods

Trussell's estimates of the typical use of FABM are based on the data from the 1995 and 2002 National Survey of Family Growth (NSFG, Cycles 5 and 6). He used weighted averages from each of the national data sets. The NSFG involves a random sample of women in the United States between the ages of 15 and 44.⁷ There are over 7,000 women in each data set and the interviews include current use and ever use of a family planning method, unintended pregnancies, and abortion. It has been determined that there might be an underreporting of abortion and over reporting of using a contraceptive method in these data sets. Trussell reported a typical use rate of 24%, or i.e., 24 unintended pregnancies per 100 women over 12 months of use for all FABM. He does not say why he does not provide separate typical use rates for the SDM, TDM, OM, or European STM even though those studies do report those rates. This is a major flaw in Trussell's analysis in not reporting typical use rates that have been reported in scientifically peer reviewed studies that have been reported in high level journals. For example, the typical use rate in the SDM study was 12%, the TDM typical use rate was 14%, and the European STM was 2%.⁸ A study of the Billings ovulation method in Shanghai, China showed a continuation rate of 80% among 668 couples of child-bearing age.⁹

It is unclear why Trussell trusts the NSFG data despite the fact that it is un-biased. The NSFG is an inadequate source to determine the typical efficacy of modern methods of NFP. The number of women using modern FABM in the NSFG data sets is rather small (around 50 or less). According to Trussell, it does not matter as to whether they were actually taught these methods correctly, just that they indicate that they are using these methods. Other studies like the preliminary reports from the Title X grantees indicate that many women claim to use a "natural method" and that can mean anything from a "made-up" calendar method to the authentic OM or STM.¹⁰

Family planning continuation

Trussell discusses the importance of the continued use rates of a family planning method. A method will be discontinued if it has irritating side effects, is difficult to use, or not acceptable for some reason. Trussell mentions that he does not count "attempting to conceive" or "not having intercourse" as reasons for discontinuation since they do not apply for women or couples wishing to use the method for avoiding pregnancy. The continuation rate that Trussell provides for FABM is 46 per 100 women over 12 months of use. This rate was developed from the data in the 2002 NSFG. The rate of 46 is comparable to rate of 47 attributed to the use of

spermicides, but much lower than the hormonal pill with a rate of 67%. The SDM study had a continuation rate of 46%, the TDM 53%, the European STM 91%, and for the classic OM five-country study 64%.¹¹

Imperfect use of fertility awareness-based methods

In this current analysis, Trussell does not provide an imperfect use rate for FABM or any other family planning method. In the past, he has calculated the imperfect use of the OM utilizing data from the five-country study conducted by the World Health Organization (WHO). Based on this study, and an assumed underreporting of abortions, he calculated the 12 month imperfect use pregnancy rate to be 86% (a higher pregnancy rate than using nothing at all for family planning).¹² The WHO study data indicated that approximately 15% of the unintended imperfect use was due to having intercourse on a day indicated by the method to be fertile.¹³

Forgiveness and difficulty in use of fertility awareness-based methods

Trussell says that forgiveness of a given family planning method is the difference between the imperfect use pregnancy rates and the rates during perfect use. Since there are few FABM studies that provide imperfect use, this would be hard to determine. Trussell and Grummer-Strawn provide a 3% perfect use rate of unintended pregnancies for the OM and an imperfect use rate around 85%.¹⁴ Therefore based on this 82% difference one would assume that the OM is difficult to use. However, we have to trust the re-analysis of the WHO five country study by Trussell and Grummer –Strawn. They are essentially saying that if you have intercourse during the fertile phase as determined by this FABM that you will most likely become pregnant over 12 months of use. That is not too surprising, since focused intercourse during the fertile phase should enhance the pregnancy rate.

A small study of the Marquette FABM with 233 women users of a simplified online charting system that automatically calculates the fertile phase had a perfect use pregnancy rate of 2, a typical use of 12, and an imperfect use of rate of 21.¹⁵ There is a difference of 19 unintended pregnancies per 100 users over 12 months of use from perfect to imperfect use of the Marquette FABM as provided in an online format.

Other factors to take into consideration for FABM/NFP methods

Since, FABM are unique among family planning methods, in that they are designed to work with fertility rather than subvert it, there are other factors that Trussell does not mention and that should be considered when deciding the use of a FABM/NFP method.

One of the factors that affects both satisfaction and ease of use is the length of sexual abstinence required to avoid pregnancy when using an NFP method (i.e., abstaining from intercourse during times of fertility).¹⁶ The longer the days of required sexual abstinence for a

method, the more likely it will have a very low unintended (perfect use) pregnancy rate, but more likely a high typical and imperfect use. The OM and other mucus-based FABM have an average of 11-17 days of required abstinence.¹⁷ Obviously, the SDM has 11 days, and the STM around 11-13.¹⁸ For some couples, this amount of sexual abstinence is difficult to manage. The amount of abstinence might be one of the factors that some FABM have much higher typical use unintended pregnancy rates compared to others.

Other factors include how flexible, usable, and effective the FABM is in helping women avoid an unintended pregnancy. This applies, in particular, to women with special reproductive circumstances such as during the postpartum and breastfeeding transition to regular menstrual cycles, and the variability during the peri-menopause years. NFP researchers are aware that there are no studies on the effectiveness of FABM/NFP during the peri-menopausal years (in particular, for women over 42 years). Only a few studies have documented the effectiveness of FABM, some of which show fairly high pregnancy rates and some indicating that use of the method would actually increase the unintended pregnancy rate compared to not using any method.¹⁹⁻²³ This is an area of major concern for future NFP research.

A final factor with regard to what NFP researchers have to do to strengthen NFP methods in the future is the ease of use in learning and teaching NFP methods.²⁴ Some methods of NFP (especially calendar-based like the SDM) are very easy to use and learn. On the other hand, calendar-based methods also lose some flexibility in use with special reproductive circumstances and when women have menstrual cycles outside of the specifications of the method. The simplified mucus-only methods such as the TDM, and even the OM, have to contend with the variations and confusion of cervical mucus and other vaginal discharges. The STM type FABM are considered more effective, but the woman has to learn how to interpret not only cervical mucus changes but also the variants of basal body temperature and other minor signs of fertility. There are often many rules or instructions that go along with these methods and in-person introductory sessions and follow-up sessions. There have been attempts to simplify these methods and to use technology such as online web sites and menstrual cycle charting applications to enhance the ease of use.

Comparison of FABM with other methods of family planning

Table One (as adapted from Trussell) shows data on FABM in comparison with select and common family planning methods, i.e., nothing at all, the pill, male condom, injectable Depo, withdrawal, IUD, and spermicides. According to this analysis of efficacy by Trussell, FABM are only more effective than using nothing at all or spermicides, even withdrawal is considered more effective in helping women avoid unintended pregnancies. In the past, researchers have compared the efficacy of the male condom with NFP/FABM, but Trussell has maintained that condoms are considerably better. In fact, in this article he has relegated FABM and NFP to the lowest rung of efficacy based on the WHO table of contraceptive efficacy

comparison. He did not indicate why NFP was dropped to the lowest level. This is rather confusing, since some of the FABM/NFP studies that he cites, like the European STM are extremely effective, both with perfect use and typical use. In fact the STM study has a perfect use rate comparable to female sterilization and a typical use comparable to oral hormonal contraception. It is fair to point out that these rates only apply to middle class educated European women. Replication of the European STM needs to take place with other populations of women/couples in multiple settings and with women/couples with diverse backgrounds. Trussell was not forthright in pointing out why he dropped FABM/NFP methods to the lowest rung of family planning efficacy and failed to point out the very low unintended pregnancy rates with some FABM/NFP methods and respectable rates with some very diverse populations.

Conclusion

Sadly, and despite its somewhat biased approach to analyzing NFP effectiveness studies, Trussell's analysis of contraceptive efficacy is significant since his periodic analyses are considered "authoritative" by the medical academy and community.

Trussell's work is used in many venues, notably, in the book *Contraceptive Technology* (the central family planning reference text) and in many articles that appear in medical textbooks and articles.²⁵ There is no indication, by Trussell, why he did not include good NFP studies that provide typical use data, including the articles he used for his analysis of FABM efficacy. He does say, correctly, that the efficacy of the given method of FABM will depend on the population of women utilizing the method. Some populations, like German professional women in the European STM study, will be very compliant to the instructions of the method. Other populations of women might be more *laissez faire* with their desire to achieve or avoid pregnancy.

Other experts on contraceptive efficacy have provided evidence-based reviews of FABM/NFP methods and have concluded that they are not very effective.²⁶ The reviews are based on the few published randomized clinical trials and not on very good prospective cohort studies. The question must be asked: why these studies are being ignored? Furthermore, editors of medical journals are only interested in randomized clinical trials of FAB methods that compare the method with other methods of family planning. FABM/NFP researchers have challenged this notion that RCTs are the only methodologies that provide good evidence of efficacy. FABM researchers continue to work on meeting these challenges. There still is much work in the future, especially work to strategize how to move the authoritative family planning researchers, such as James Trussell, to take seriously the authentic NFP methods and studies. NFP researchers are currently working on criteria and methods to evaluate the effectiveness of FABM/NFP methods. Hopefully, there can be an honest dialogue on these criteria and methods between FABM/NFP researchers and those experts who review family planning studies.

Table One: Efficacy Comparison of Contraceptive Family Planning Methods with Natural Family Planning/Fertility Awareness-Based Methods (FABM)*

Method	Typical Use	Perfect Use	% Women Continuing at 1 year
No method	85	85	
Spermicides	28	18	42
FABM	24		47
- SDM		5	
- TDM		4	
- OM		3	
- STM		0.4	
Withdrawal	22	4	36
Condom Male	18	2	43
Combined Pill	9	0.3	67
Depo-Provera	6	0.2	56
IUD (Mirena/LNG)	0.2	0.2	80
Female Sterilization	0.5	0.5	100

* Adapted from J. Trussell, "Contraceptive Failure in the United States," *Contraception* 83 (2011): 397-404.

End Notes

1. J. Trussell, "Contraceptive Failure in the United States," *Contraception* 83 (2011): 397-404.
2. M. Arévalo, V. Jennings, and I. Sinai, "Efficacy of a New Method of Family Planning: the Standard Days Method," *Contraception* 65 (2002): 333-338.
3. M. Arévalo, V. Jennings, M. Nikula, and I. Sinai, "Efficacy of the new TwoDay Method of Family Planning," *Fertility and Sterility* 82 (2004): 885-892.
4. World Health Organization, "A Prospective Multicentre Trial of the Ovulation Method of Natural Family Planning. II. The Effectiveness Phase," *Fertility and Sterility* 36 (1981): 591-598.

5. P. Frank-Herrmann, J. Heil, C. Gnoth, E. Toledo, S. Baur, C. Pyper, and G. Freundl, "The Effectiveness of a Fertility Awareness Based Method to Avoid Pregnancy in Relation to a Couple's Sexual Behavior during the Fertile Time: A Prospective Longitudinal Study," *Human Reproduction* 22 (2007): 1310-1319.
6. V. Lamprect and J. Trussell, "Natural Family Planning Effectiveness: Evaluating Published Reports." *Advances in Contraception* 13 (1997): 155-165.
7. W. D. Mosher and J. Jones. "Use of contraception in the United States: 1982-2008." *Vital and Health Statistics Series 23, Number 29* (2010): 1-771. See also W. D. Mosher, "Use of contraception and use of family planning services in the United States: 1982-2002," *Advanced Data* 10 (2004):1-36.
8. M. Arévalo, V. Jennings, and I. Sinai (2002); M. Arévalo, V. Jennings, M. Nikula, and I. Sinai (2004); P. Frank-Herrmann, J. Heil, C. Gnoth, E. Toledo, S. Baur, C. Pyper, and G. Freundl (2007).
9. J. X. Xu, J. H. Yan, D. Z. Fan, D. W. Zhang, "Billings natural family planning in Shanghai, China," *Advances in Contraception* 10 (1994): 195-204.
10. See for example, Lina Guzman, Selma Caal, Manica Ramos, and Jennifer Manlove, "FABM Use among young adult low-income minority women." In *Human Fertility: Where Faith and Science Meet, Proceedings*, (Milwaukee: Marquette University Press, 2011).
11. M. Arévalo, V. Jennings, and I. Sinai. (2002); M. Arévalo, V. Jennings, M. Nikula, and I. Sinai (2004); P. Frank-Herrmann, J. Heil, C. Gnoth, E. Toledo, S. Baur, C. Pyper, and G. Freundl (2007); World Health Organization (1981).
12. J. Trussell and L. Grummer-Strawn, "Contraceptive Failure of the Ovulation Method of Periodic Abstinence," *Family Planning Perspectives* 22 (1990): 65-75.
13. World Health Organization (1981).
14. J. Trussell and L. Grummer-Strawn (1990).
15. R. Fehring, M. Schneider, and K. Raviele, "Pilot Evaluation of an Internet-based Natural Family Planning Education and Service Program," *Journal of Obstetrics, Gynecology, and Neonatal Nursing* 40(2011): 281-91.
16. R. Fehring. "Efficacy and efficiency in natural family planning services," *The Linacre Quarterly* 76 (2009): 9-24.
17. B. Colombo, "Evaluation of Fertility Predictors and Comparison of Different Rules," *Genus* 54 (1998): 153-167; F. Bassi, A. Mion, and B. Colombo, "Interobserver Variation in Interpretation of Cervical Mucus as an Indicator of the Fertile Phase in a Menstrual Cycle," *Genus* 53 (2003): 91-102.

18. World Health Organization, "Temperal relationships between indices of the fertile period," *Fertility and Sterility* 39 (1983): 647-655.
19. J. B. Brown, P. Harrisson, and M. A. Smith, "A Study of Returning Fertility after Childbirth and during Lactation by Measurement of Urinary Oestrogen and Pregnanediol Excretion and Cervical Mucus Production," *Journal of Biosocial Science* (Suppl.) 9 (1985): 5-23.
20. L. Hatherley, "Lactation and Postpartum Infertility: The Use-Effectiveness of Natural Family Planning (NFP) after Term Pregnancy," *Clinical Reproduction and Fertility* 3 (1985): 319-334.
21. M. H. Labbok, R.Y. Stallings, and F. Shah et al., "Ovulation Method Use during Breastfeeding: Is there Increased Risk of Unplanned Pregnancy?" *American Journal of Obstetrics and Gynecology* 165(Suppl) (1991): 2031-2036.
22. M. P. Howard and J. B. Stanford, "Pregnancy Probabilities during Use of the Creighton Model Fertility Care System," *Archives of Family Medicine* 8 (1999): 391-402.
23. A. Perez, M. Labbok, D. Baker, and R. Gray. "Use-effectiveness of the ovulation method initiated during postpartum breastfeeding," *Contraception* 38 (1988): 499-508.
24. R. Fehring (2009).
25. J. Trussell. Contraceptive Efficacy. In, R. A. Hatcher, J. Trussell, A. L. Nelson, W. Cates, and D. Kowal, (eds.) *Contraceptive Technology*, Twentieth revised edition (New York: Ardent Media; 2011): 777-861.
26. D. A. Grimes et al., "Fertility Awareness-Based Methods for Contraception: Systematic Review of Randomized Controlled Trials," *Contraception* 72 (2005): 85-90.