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In this issue

Natural Family Planning	2
Menstrual Cycle	4
Contraception	6
Fertility/Infertility	8
Under the Microscope	11
Trends in the Use of Contraception and Natural Family Planning in United States: New Data	ı
from the National Survey of Family Growth (2002-2013)	



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Natural Family Planning

Low Income Women Express Confidence and Comfort in Use of Kit to Monitor Ovulation

Low income women are more vulnerable to unintended pregnancy and lack of preconception health for better pregnancy outcomes. Knowledge of fertility and the menstrual cycle would empower women, especially women with low resources, to be more attuned to their reproductive health and proactive in their family planning needs. One way to empower women, and in particular vulnerable women with low incomes and resources, is through teaching them about their fertility, their menstrual cycles, and providing them with tools to monitor their fertility. A "knowing your body" (KB) kit was developed that included fertility monitoring charts, instructions in the TwoDay method of Natural Family Planning, an electronic body temperature monitor, and luteinizing hormone (LH) test strips. The KB kit was designed to help women know when they ovulated, when they menstruated, to help them keep track of their menstrual cycles, and to inform them of the signs and symptoms of early pregnancy. The KB costs less than \$10 to assemble. Researchers were interested in determining the confidence and comfort in using this kit among vulnerable women of reproductive age, not pregnant and not trying to get pregnant (Ayoola, Slager, Feenstra, and Zandee 2015).

Researchers developed a cross sectional study that included 22 women aged 18 to 39 years (mean 28.5 years) who were purposely selected from 3 community health clinics in medically underserved neighborhoods in a large Midwestern city. The women participants were instructed in a home setting on how to use the KB kits and were asked to use them for at least until the next home visit. After 6-8 weeks the participants were again visited at home and asked to provide them with their menstrual cycle charts and then interviewed to confirm their experiences. They were asked how confident they were in using the content of the kits and how comfortable in using the different methods of monitoring fertility with the kits. They found that 17 (77.3%) of the women were confident in using the LH test kits, 7 (32%) in using the body temperature and temperature graph, and 5 (22.7%) in the use of the TwoDay mucus monitoring method. They also found that 16 (73%) were comfortable in using the LH test kits, 18 (81.8%) in using the thermometer and 7 (31.8%) in using the TwoDay cervical mucus method for identifying or estimating ovulation. In addition, they discovered that 91% used the Ovulation LH test kits, 77.3% the thermometer, 45.5% used the Two Day method, and 45.5% the menstrual cycle calendar. The authors concluded that use of the ovulation LH test strips and other content of the KB helped provide the underserved women of reproductive age knowledge of their body, their fertility and menstrual cycle changes and potential pregnancy planning.

Comments

The strength of this study is that the researchers purposely sought out vulnerable low income and medically underserved women. The study's weakness is that it had a small sample of women and they only used the KB kit for one menstrual cycle. Of interest is that the most accurate and most used measure to estimate ovulation were the LH test strips. The test strips cost only \$1.00 per cycle (i.e., for 6 test strips) and thus could be used as a simple means to monitor fertility for the purpose of achieving or avoiding pregnancy or for health monitoring.

Ayoola, A. B., D. Slager, C. Feenstra, and G. L. Zandee. **A feasibility study of women's confidence and comfort in use of a kit to monitor ovulation.** *Journal of Midwifery and Women's Health* 60 (2015): 604-609.

BBT Shift and Cervical Mucus Peak Correlate with Estimate End of Fertile Phase in only 7-17% of Menstrual Cycles

The basal body temperature (BBT) shift and the cervical mucus peak are traditional markers for the peak in fertility and a prediction for the end of the fertile phase. The peak day of cervical mucus is the last day of a slippery, watery, clear and stretchy consistency. After the peak day of cervical mucus, the characteristics return to a sticky tacky type or dry as it appears in the pre-ovulatory phase of the menstrual cycle. This change is thought to be due to the influence of rising levels of progesterone. So too, the rise in body temperature is a reflection of the rising and threshold levels of the hormone progesterone. In other words, both natural markers used in Natural Family Planning (NFP) methods (i.e., BBT and the cervical mucus peak) are based on progesterone levels.

The Ovarian Monitor was designed to measure urinary levels and excretion rates of estrogen (i.e., estrone glucuronide (E1G)) and progesterone (i.e., pregnanediol glucuronide (PdG)). Past research on the Ovarian monitor has shown that its results compare well to laboratory measures of urinary and serum reproductive hormones and has demonstrated that the end of the fertile phase of the menstrual cycle coincides with a PdG threshold excretion rate of 7.0 μ mol/24 hours. Researchers set out to compare the threshold excretion rate of PdG as measured by the Ovarian Monitor with the natural indicators of fertility that estimate the end of the fertile phase (i.e., BBT shift and cervical mucus peak day) of the menstrual cycle.

The participants in this study were 62 normally cycling women selected from three centers located in Chile, Australia, and New Zealand who collected daily urine and measured their levels of E1G and PdG. All participants observed and recorded their daily cervical mucus observations. Forty-four of the 62 observed daily BBT as an additional fertility marker. The estimated end of the fertile phase was considered the day of the BBT shift day plus two days, the peak day of cervical mucus plus three full days, and when BBT was combined with cervical mucus either the BBT shift day or the cervical mucus peak day, whichever comes last, plus three full days. The researchers also correlated the ovarian monitor PdG threshold with serial ultrasound determination of the day of ovulation with 15 of the participants who contributed 26 cycles of data and found that there was no PdG threshold on or before the estimated day of ovulation. The PdG threshold based on the ultrasound day of ovulation was ovulation +1 (zero cycles), +2 (two cycles), +3 (eight cycles), +4 (six cycles) and +7 (two cycles). The participants were able to produce 91 fertile menstrual cycles for the main analysis.

The researchers discovered that the BBT shift day plus 2 days occurred later than the PdG threshold in 43 of 59 cycles (72.9%), on the day of the PdG threshold in 10 of 59 cycles (16.9%), and earlier than the PdG threshold in 6 of 59 menstrual cycles (10.2%). They also discovered that the mucus peak plus four days occurred later than the PdG threshold in 73 of 90 cycles (81.1%), on the day of the PdG threshold in 8 of 90 59 cycles (8.9%), and earlier than the PdG threshold in 9 of 90 menstrual cycles (10.0%). Finally, they found that the combination of the mucus peak and BBT shift plus three days occurred later than the PdG threshold in 51 of 59 cycles (86.4%), on the day of the PdG threshold in 4 of 59 cycles (6.8%) and earlier than the PdG threshold in 4 of 59 cycles (6.8%). Although the natural indicators of fertility predicted the end of the fertile phase in 90% of the menstrual cycles tested, the 10% in which the end of the fertile phase was too early is troublesome and can result in an unintended pregnancy.

Comments

The fact that in 73-86% of the menstrual cycles included in the study the natural indicators estimated the end of the fertile phase later than the actual PdG determined end of the fertile phase could also be troublesome in that the overestimation of the fertile phase will result in more abstinence than is necessary. A limitation of this study is that only regular menstrual cycles were used in the analysis. Further research on how well the natural markers of fertility do with estimating the end and beginning of the fertile phase of the menstrual cycle needs to be determined with irregular menstrual cycles and in particular during the postpartum breastfeeding transition to fertility. The authors do mention that at this time the current Ovarian Monitor, while efficient and specific for identifying the actual biological fertile window, is too time consuming for practical use. Newer models, however, might make them more user friendly and a reality for use in NFP.

Blackwell, L. F., P. Vigil, M. E. Alliende, S. Brown, M. Festin, and D. G. Cooke. **Monitoring of Ovarian Activity by Measurement of Urinary Excretion Rates Using the Ovarian Monitor, Part IV:**The Relationship of the Pregnanediol Glucuronide Threshold to Basal Body Temperature and Cervical Mucus as Markers for the Beginning of the Postovulatory Infertile Period. *Human Reproduction*, Advance Access (December 17, 2015).

Menstrual Cycle

Only 2.1% of Reproductive Age Women Able to Identify the Fertile Phase of the Menstrual Cycle

Primary care physicians recently conducted a study among women seeking pregnancy with artificial reproductive technologies. They found that after 12 months of treatments only 12.7% had fertility awareness knowledge, up from 2.1% at the beginning of treatment (Hampton, Mazza, and Newton 2012). These same authors now were interested in the fertility awareness and fertility knowledge among women that were of reproductive age, attending a general medical practice and not seeking infertility services (Hampton and Mazza 2015).

The researchers obtained participants (i.e., women aged 18-44 years) consecutively presenting at three general practice clinics in Australia. They also intentionally selected women from all socioeconomic classes by using an index measure of relative socioeconomic disadvantage. They approached 510 women through the receptionist at the three practices and asked them to complete a fertility knowledge questionnaire. The questionnaire was the same one used in the previous study with some grammatical changes. The questionnaire included demographic information, pregnancy intention, use of contraception, attitudes to fertility awareness, and fertility-awareness-knowledge and practice. Of the 510 women approached, 328 returned completed questionnaires for a response rate of 64.3%. The researchers found that only 4.3% of the respondents were using fertility-awareness based methods for family planning, 9.8% were seeking pregnancy, 37.1% actively sought to improve their knowledge of fertility, and 76.6% strongly agreed or agreed that having intercourse during the fertile time of the menstrual cycle would aid couples in achieving a pregnancy. Only 2.1% of the participants however, were able to correctly identify the fertile phase of the menstrual cycle. Most indicated that they received their information about fertility from books (67.7%) or the internet (39.8%). They concluded that most women who attend general medical clinics express interest in fertility awareness education. They also mentioned

that those women who indicate that they use fertility-awareness based methods be assessed as to their actual knowledge of these methods.

Comments

The authors also mentioned that there is a need for further research as to how best to provide information to women on fertility-awareness methods and fertility knowledge. The authors did not express familiarity with newer methods of Natural Family Planning that used hormonal monitoring or the use of fertility monitoring apps.

Hampton, K., D. Mazza, and J. M. Newton. **Fertility-Awareness Knowledge, Attitudes and Practices of Women Seeking Fertility Assistance.** *Journal of Advanced Nursing* 69 (2012): 1076-1084.

Hampton, K. and D. Mazza. Fertility-Awareness Knowledge, Attitudes and Practices of Women Attending General Practice. *Australian Journal of Family Medicine* H44 (2015): 840-845.

Vigorous Exercise Found to Be More Effective than Moderate Exercising in Managing PCOS

Lifestyle modification with weight loss, exercise, and diet are considered the first line treatment for managing and controlling polycystic ovarian syndrome (PCOS). There has been no evidence on the right intensity of exercise that might best treat PCOS. Researchers therefore, set out to determine whether high intensity exercise is better than moderate exercise on metabolic outcomes of women with PCOS.

Participants for this study were recruited from one academic based multidisciplinary PCOS specialty clinic over a 7 year period. Patients from the clinic were enrolled if they met the Rotterdam criteria for the diagnosis of PCOS, i.e., 2 out of the following 3 features, oligomenorrhea, hyperandrogenism, and/or ultrasound visualized polycystic ovaries. Three hundred twenty-six women met the inclusion guidelines and were classified by Department of Health and Human Services (DHHS) exercise guidelines as to whether they met vigorous, moderate or inactive activity levels through an exercise self-report measurement tool. Vigorous exercise was defined as difficult effort and much harder breathing for at least 75 minutes per week and moderate exercise as moderate effort and breathing somewhat harder than normal for at least 150 minutes per week. The inactive category meant that the participant did not meet these guidelines.

Based on the DHHS activity levels, 151 of the 326 participants (56%) met the vigorous level and 31 (17%) met the category of moderate exercise. The remaining 145 did not meet exercise requirements. The participants were measured for multiple metabolic outcomes including blood pressure, weight, body mass index (BMI), waist circumference, fasting lipids, fasting glucose and insulin, 2-hour glucose tolerance test, and homeostatic model assessment of insulin resistance (HOMA-IR) to determine those participants who had metabolic syndrome. The researchers discovered that the women in the vigorous group had significantly lower, BMI, HOMA-IR, higher levels of high-density lipoprotein cholesterol and reduced prevalence of metabolic syndrome. A multivariate logistic regression analysis determined that controlling for age and BMI, every hour of vigorous exercise reduced the odds of metabolic syndrome by 22% (odds ratio 0.78; 95% confident interval, 0.62-0.99). The authors concluded that those women with PCOS who met DHHS criteria for vigorous exercise had superior metabolic health parameters compared to women with only moderate exercise levels. They proposed that women with PCOS should be

encouraged to meet vigorous levels of exercise. They also recommended that randomized comparison studies between levels of exercise be conducted on metabolic parameters among women with PCOS.

Comments

A limitation of this study is that the levels of individual exercise was through self-report and recall. Furthermore, there were far fewer participants in the moderate exercise category. Although the patients were systematically evaluated over two weekly sessions by a multidisciplinary team that included a reproductive endocrinologist, dermatologist, genetic counselor, registered dietician and psychologist, there was no analysis of fertility, ovulation, or menstrual cyclicity – 175 of the participants were on hormonal contraception. NFP healthcare providers who identify women with oligomenorrhea might recommend lifestyle changes and increased levels of vigorous exercise as a first line treatment.

E. A. Greenwood, M. W. Noel, and D. N. Kao, et al. **Vigorous Exercise Is Associated with Superior Metabolic Profiles in Polycystic Ovary Syndrome Independent of Total Exercise Expenditure.** *Fertility and Sterility* (Nov. 6, 2015) pii: S0015-0282(15)02031-2. doi: 10.1016/j.fertnstert.2015.10.020. [Epub ahead of print.]

Contraception

Comparison of Family Planning Providers Use of Contraceptive Methods with Use of Contraception by U.S. Population

Over the past ten years newer methods of family planning have been developed with an emphasis placed on long acting reversible contraceptives (LARCs). In addition, advanced practice health professionals (i.e., nurse practitioners, certified nurse midwives, and physician assistants) have been promoted as providers of family planning services in the United States especially for the poor through Title X funded programs. Due to these changes, researchers wished to determine the prescribing patterns of family planning (FP) providers and to see how these patterns match the actual use of FP among United States (U.S.) women of reproductive age (i.e., 25-44 years of age).

Researchers obtained e-mail addresses from major national medical and advanced practice health provider organizations as the main pool of FP providers. The comparison group of reproductive age women and their current contraceptive use was obtained from the latest (2011-2013) National Survey of Family Growth (NSFG). The survey questions they used to determine FP use were the same questions used in the NSFG, i.e., "What is your current FP method and what methods of FP have you ever used?" The researchers determined that they needed a sample of 500 FP provider participants to make statistically valid comparisons. They used an online survey system and obtained 2,300 responses. Of the responses, they selected the first 500 that met their criteria of a FP provider who is currently in practice and providing FP services.

The surprising differences (with probabilities of less than .01) in use of FP methods was with regard to the use of the interuterine contraceptive (IUC) by 39.9% of the FP providers compared with 11.3% of the FP users and the overall LARC use of 41.7% by the providers and only 12% by the users. Another disparity was in the use of female sterilization with only 5.1% of the providers indicating use of sterilization but 33 percent by the users. There was also less condom use by the providers (8.8%) versus

13.2% among the users (p < .02). There was no significant difference in hormonal pill use by the providers (16.3%) versus by the users (18.7%), nor use of NFP by the providers (2.7%) and by the users (1.5%). The authors concluded that the use of FP methods differed significantly between the providers and users. They felt that these findings have implications for clinical practice, FP education, and health policy.

Comments

The use of LARCs has been promoted in the FP literature for a number of years and this is reflected in the wide use among FP providers but not the general population of US women. The authors thought this might be reflected in the cost and access of LARCs. This study was conducted before the Affordable Care Act was implemented that provides subsidized FP methods. The fact that a large percentage of U.S. women use sterilization as compared to the FP providers is of concern (by this author) that there might be subtle coercion by providers to offer sterilization especially among the minorities and poor. It is discouraging (but also a challenge) that there is little use of NFP methods among providers and users.

Stern, L. F., H. R. Simmons, J. F. Kohn, E. J. Devevee, J. M. Morfesis, and A. A. Patel. **Differences in Contraceptive Use Between Family Planning Providers and the U.S. Population: Results of a Nationwide Survey.** *Contraception* 91 (2015): 464-469.

Pregnancy Risk Exposure Best Predictor for Type of Current Contraceptive Method Among Privately Insured Women

The Patient Protection and Affordable Care Act (ACA) requires most private health insurance to cover Food and Drug Administration (FDA) approved contraceptives without cost-sharing. Eliminating co-pays and deductibles helps to make prescription based contraceptive methods more accessible to women. This is important to advocates of contraception, since the most effective methods of family planning are the prescription based long-acting reversible contraceptives (LARCs) which include intrauterine devices and hormonal implants. Requiring contraceptive coverage in health insurance plans is the reason why some religious based systems of healthcare, education and business object to this regulation of the ACA, especially Catholic healthcare systems. Researchers were interested in finding out the contraceptive patterns of women with private health insurance that do not require cost-sharing for contraception. In particular they were interested in whether the use of prescription based contraception and especially LARCs were a function of pregnancy intention. Pregnancy intention was categorized as the time frame for the intention to avoid pregnancy and the strength of intention to avoid pregnancy. The contraceptives were categorized as LARCs (the most effective), other prescription methods as second level effectiveness, non-prescription methods (e.g., condoms, Natural Family Planning, and withdrawal) as third level effectiveness, and no use of contraception. Other factors of interest in contraceptive use were having prior live births, prior unintended pregnancy, current partner status and frequency of intercourse.

The participants for this study were 987 women with private health insurance that did not require cost-sharing for contraception and who intended to avoid pregnancy for at least the next 12 months. These women were part of a larger study that is testing an intervention to empower women to make contraceptive choices in the context of contraceptive coverage without cost-sharing. They were randomly

selected from a database of the Highmark Health plans in Pennsylvania excluding employer groups that have a religious objection to contraceptive coverage.

The researchers found out with use of logistic regression analysis that pregnancy intentions were significantly associated with using LARCs and other prescription methods versus no method but not with those women who are using other non-prescription methods or no method. The intention to never have a baby and feeling it is important to never have a baby was associated with increased use of LARCs. They also found that pregnancy risk exposure (i.e., having a sexual partner and frequency of intercourse greater than once a month or more) were more strongly associated with use of LARCs and other prescription methods. Likewise pregnancy risk exposure was also associated with increased odds of using non-prescription methods compared to no method. Ever having an unintended pregnancy was associated with a more than threefold odds of using LARCs compared to no method. The authors concluded that among women with non-cost sharing contraceptive coverage healthcare insurance that women's choice of contraceptive method was largely a function of pregnancy risk exposure rather than pregnancy intention.

Comments

Obviously the vast majority of subjects had no issue separating the unitive and procreative aspects of intercourse in their family planning method decision making. Of interest was that partner status also influenced contraceptive decision making, in that being in a new non-marital or premarital relationship was associated with greater use of LARCs and prescription contraceptive methods. Married couples who did not intend to get pregnant were more willing to risk unintended pregnancy and to use nonprescription contraceptive methods. Thirty-three (or 3.3%) of the participants were currently using Natural Family Planning. This percentage is greater than the percentage (i.e., 0.1%) of reproductive age women in the United States using Natural Family Planning as reported in the National Survey of Family Growth (See this issue of *Current Medical Research*, *Under the Microscope* review).

Weismann, C. S., E. B. Lehman, R. S. Legro, D. L. Velott, and C. H. Chuang. **How Do Pregnancy Intentions Affect Contraceptive Choices When Cost Is Not a Factor? A Study of Privately Insured Women.** *Contraception* 92 (2015): 501-507.

Fertility/Infertility

Poor Lifestyle Choices Are Made by Women with Infertility

New Zealand researchers were interested in whether women about to undergo infertility treatment (i.e., use of artificial reproductive technologies) were able to modify their health behaviors in order to enhance their chance of success. The health behaviors of interest were evidenced based and known to enhance fertility and included not smoking, moderation in alcohol and caffeine, normal weight, good diet, dietary supplements, and regular exercise.

The researchers were able to obtain 250 volunteer women between the ages of 20-43 years of age about to undergo infertility treatment from two large infertility centers in the area of Auckland, New Zealand from March 2010 through August 2011. At their first medical assessment and before treatment the participants were all provided lifestyle behavior instructions that enhance fertility, i.e., 1) not to smoke, 2) to reduce caffeine intake, 3) no alcohol intake at the time of embryo transfer, 4) that being

overweight can reduce a response to ovulation stimulus medication, and 5) that weight loss and some exercise can be beneficial. The participants were interviewed at their initial clinic visit. Thirty-five days before initiation of infertility treatment, the participants were administered a 13 item lifestyle questionnaire that assessed their lifestyle changes prior to their first treatment. The participants were asked to respond to the questionnaire based on the previous three months in anticipation of their infertility treatments.

The New Zealand researchers found that most women undergoing infertility treatment fail to make lifestyle behaviors that will enhance their fertility. Specifically, about half (50.8%) of the participants reported that they drank alcohol regularly before their treatment, a large majority (86.8%) reported drinking caffeinated beverages, a majority (83.6%) did not reduce their weight and (64.4%) reported no change in their exercise levels. Regression analysis showed that those women who consumed caffeine had half the odds of becoming pregnant than those women who did not use caffeine. Those women who did not drink alcohol or reduced their intake of alcohol had twice the odds of becoming pregnant than those who did not stop drinking alcohol or reduce their intake. The researchers concluded, due to the lack of positive lifestyle changes by women undergoing infertility treatment that staff at fertility clinics should provide education on appropriate lifestyle modification to enhance fertility. They also stated that there was a need to determine what will motivate women seeking pregnancy to make positive fertility enhancing lifestyle changes.

Comments

A comparative study of lifestyle changes among women with subfertility, who use Natural Family Planning, and are provided a moral approach to treating infertility, would be of interest.

Gormack, A. A., J. C. Peek, J. G. B. Derralk, P. D. Gluckman, N. L. Young, and W. S. Cutfield. Many Women Undergoing Fertility Treatment Make Poor Lifestyle Choices that May Affect Treatment Outcome. *Human Reproduction* 30 (2015): 1617-1624.

Supplemental Progesterone Found Not to Be Effective as Treatment for Repeat Miscarriage

A recent systematic review of four small studies on the use of progesterone supplementation to treat repeat miscarriage showed a significantly lower likelihood of miscarriage among women receiving progesterone compared to women who received a placebo or no treatment (Haas and Ramsey 2013). Reviewers concluded however, that the quality of the four trials of progesterone supplementation was poor. Researchers conducted a large multisite randomized placebo-control study to determine if use of progesterone supplementation would increase the rates of live birth and pregnancy outcomes among women with unexplained repeat miscarriages (Coomarasamy, Williams, and Truchanowicz 2015).

The participants for this study were recruited from 45 hospitals across the United Kingdom and Netherlands. The criteria for selection was that participants be between the ages of 18 to 39, are actively trying to conceive, and have experienced three or more first trimester pregnancy losses. After being screened for multiple medical conditions that could be a cause of miscarriage, participants were randomly assigned to either twice daily use of a vaginal suppository of 400 mg of progesterone or a placebo soon after receiving a positive pregnancy test and not later than six weeks of gestation. The main outcome of

interest for the study was live birth. Secondary outcomes included clinical pregnancy and complications of pregnancy and birth.

The researchers assessed 1,568 women for eligibility, and of these, 836 conceived naturally within 1 year. These women then were randomly assigned to either the progesterone group (N = 404) or the placebo group (432). They found no significant difference in their personal characteristics. They did discover that the progesterone group had a live birth rate of 24 weeks of gestation or later of 65.8% while the placebo group had a rate of 63.3% with a relative rate of 1.04; 95% CI, 0.94 to 1.15. They also found no significant differences in the rates of clinical pregnancy, ectopic pregnancy, miscarriage, still birth and neonatal outcomes. The researchers concluded that this large multicenter, randomized, placebo-controlled trial showed that use of progesterone supplementation in the first trimester of pregnancy did not result in a significant increase in the rate of live births among women with a history of unexplained repeat miscarriages. They recognized that the progesterone supplement was not administered during the luteal phase, that they did not use the muscular injection method of providing progesterone, nor did they test for various levels of supplemental progesterone.

Comments

A comforting secondary finding was that they found no significant increase in congenital anomalies with the progesterone group, since progesterone supplements are commonly prescribed for assisted conception management. The study, however, was not statistically powered to test if there were differences in congenital anomalies between the two groups. The Cochrane systematic review did not find any differences between the route of administration of progestogen (oral, intramuscular, vaginal) versus placebo or no treatment (Haas and Ramsey 2013). Haas and Ramsey did not recommend the use of supplemental progesterone in early to midterm pregnancy. They did recommend further research for use of supplemental progesterone for those women with repeat (i.e., two to three) miscarriages.

Coomarasamy, A., H. Williams, E. Truchanowicz, et al. **A Randomized Trial of Progesterone in Women with Recurrent Miscarriages.** *The New England Journal of Medicine* 373 (2015): 2141-2148.

Haas, D. M. and P. S. Ramsey. **Progestogen for Preventing Miscarriage.** Cochrane Database Syst Rev. (2013 Oct 31);10:CD003511. doi: 10.1002/14651858.CD003511.pub3.

Low Dose Aspirin Found to Be Effective in Increasing Fecundability Among Women with One Previous Miscarriage

Theoretical pathophysiological mechanisms that contribute to recurrent pregnancy loss are a decrease in uterine blood flow and inflammation in the reproductive organs. Low dose aspirin (LDA, 81mg/day) is known to decrease inflammation and to increase blood flow. Whether LDA use preconception will increase fecundability and live birth rates is of concern to health professionals who manage women with recurrent pregnancy loss. These researchers recently hypothesized that use of preconception LDA among women with recurrent miscarriage would improve fecundity. o test this hypothesis they conducted a randomized double-blind placebo control trial that compared use of LDA preconception versus placebo in time to pregnancy and cumulative pregnancy rates across six cycles of attempting pregnancy among women with recurrent pregnancy loss.

The participants were 1,128 women between the age of 18 to 40 years, with menstrual cycle lengths between 21 to 42 days and who had 1 to 2 confirmed pregnancy losses. They were recruited from medical centers across the United States. These women participants were randomized into either a group receiving LDA plus folic acid daily (N=615) or a group that received a placebo plus folic acid daily (N=615)613). The outcome measures were cumulative pregnancy rates over six months determined by either an hCG confirmed pregnancy or a clinically confirmed pregnancy (i.e., by ultrasound or fetal heart tones). The researchers found no differences between the two groups on individual characteristics. They also found no significant differences in 6 month pregnancy rates by hCG detected pregnancies between the LDA and placebo group with a fecundity ratio (LDA/Placebo) of 1.14 (95% CI: 0.97 to 1.33) nor in the clinically determined pregnancy rate between the two groups. They did find a significant increase of fecundity of 28% among the LDA group who had only one miscarriage of less than 20 weeks pregnancy in the past year compared to the placebo group who also had only one miscarriage of 20 weeks or less. Overall, the researchers concluded that the findings indicated daily use of LDA preconception does not significantly shorten time to pregnancy with any history of pregnancy loss. They did suggest that since LDA is inexpensive and relatively well-tolerated that its use might be recommended among women with specific types of pregnancy loss but that generalized use is not recommended until further studies are conducted.

Comments

Of interest was that electronic hormonal fertility monitors (i.e., the Clear Blue Brand – Swiss Precision Diagnostics) were used by all participants to time intercourse to achieve pregnancy. Adherence to the use of the LDA or placebo was by periodically weighing the medication bottles.

This research group also reported on a previous study with the same participants and groups but the major outcome was live birth rates (Schisterman, Silbver, and Lesher et al. 2014). Like the current study they found no significant difference in live birth rates between the LDA and the placebo groups, but did find that LDA significantly aided the birth rate of the subset of women with one miscarriage of less than 20 weeks in the past year.

Schisterman, E. F., S. L. Mumford, and K. C. Schliep et al. **Preconception Low Dose Aspirin and Time to Pregnancy: Findings from the EAGeR (Effects of Aspirin in Gestation and Reproduction) Randomized Trial.** *The Journal of Clinical Endocrinology and Metabolism.* Early Release Online (2015) ISSN online 1945-7197 Doii: 10.1210/jc.2014-4179.

Schisterman, E. F., R. M. Silbver, and L. L. Lesher, et al. **Preconception Low-Dose Aspirin and Pregnancy Outcomes: Results from the EAGER Randomised Trial.** *Lancet* 384 (9937): 29-36.

Under the Microscope

Trends in the Use of Contraception and Natural Family Planning in United States: New Data from the National Survey of Family Growth (2002-2013)

Every 3 to 7 years, researchers at the National Center for Health Statistics administer a nationwide survey on issues that affect family life, including marriage, divorce, co-habitation, and the use of contraception. This survey is called the National Survey of Family Growth (NSFG). It was conducted in 1973, 1976, 1982, 1988, 1995, 2002, 2006-2010, and the most recent in 2011-2013.

The 2002 survey involved, for the first time, both men and women (N = 12,571) between the ages of 15 and 44. These surveys entail a national random selection of 5,000 to 12,000 women between the ages of 15 and 44 and have a response rate consistently over 70%. The participants are interviewed inperson by trained interviewers. The in-person laptop computer-assisted survey interview takes approximately 85 minutes. The data generated from the surveys are accessible to researchers to download from an internet site into data sets from the National Center for Health Statistics. Many published studies by researchers and scholars around the United States result from the NSFG data. The survey data are also used to calculate contraceptive effectiveness, and, as such, have influence in the health care community, especially for women's health and contraceptive decision making.

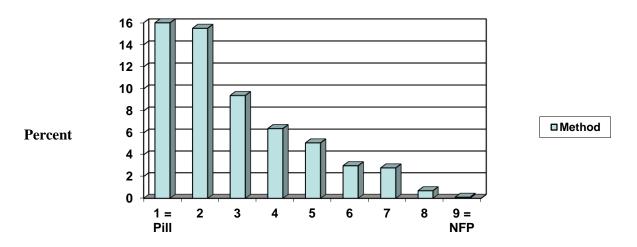
On November 15, 2015 the Centers for Disease Control and Prevention (CDC) submitted a report on the use of contraceptives and family planning services in the United States between 2011 and 2013 that was generated from the NSFG data (Daniels, Daugherty, Jones, and Mosher 2015). There were 5,601 women between the age of 15 and 44 interviewed for this report, with a response rate of 73.4%. The report also includes a trend comparison of contraceptive use from the 2006-2010 NSFG and earlier surveys. In interpreting the findings it is good to know that some reports include percentages of all women in the survey, some with women who are only sexually active, and others only include women who are using a method of contraception. The report also includes women who are "currently" using a method of contraception and women who "ever" used a method of contraception. The following are some highlights of interest from the 2011-2013 NSFG in regards to contraceptive and Natural Family Planning (NFP) use and some trend comparisons from earlier surveys.

Current Contraceptive Status

- In 2011-2013 approximately 37.6 million women in the United States between the ages of 15-44 were currently using some method of contraception, that is about 62% of women of reproductive age (Daniels, Daugherty, and Jones 2014).
- The most common methods of contraception currently being used among all reproductive age women in the NSFG are the oral contraceptive pill (16.0%), female sterilization (15.5%), condoms (9.4%), and long acting reversible contraceptives (7.2%) see Table 1.
- About 5% of women in the reproductive age are pregnant or postpartum and about 4% were seeking pregnancy. But 19% were not using any method of family planning because they either were not sexually active in the three months before the interview or they never had sexual intercourse.
- The use of long acting reversible contraceptives (i.e., the use of IUDs or hormonal implants) has steadily increased in use since 2002, with 2.4% in 2002, 6.0% in 2006-2010, and 11.6% in the 2011-2013 survey.
- With regard to marital status in the 2011-2013 survey, 43.5% of never married women were currently using the hormonal pill, 26.1% of cohabitating women were using the pill, 17.9% of married women, and 11.5% of formerly married women were currently using the pill.
- Although the oral hormonal pill was the most frequent method of contraception used by women in 2011-2013, if the sterilized male partner is added to the equation, sterilization is by far the leading method, involving 20.6% of either the woman participant or the partner of the woman participant. Furthermore, sterilization was the leading method among all women 35 years and older. About 44.2% of women between the ages of 35-44 were using female sterilization and 17.9% were using the sterilization of their male partner, thus 62.1% use some form of sterilization.

• Furthermore, women who were using Medicaid or State sponsored health insurance were more likely to be using sterilization (40.9%) compared with those women using private insurance (22.3%).

Table 1: Percent distribution of *current* family planning methods among United States Women 15-44 years of age.

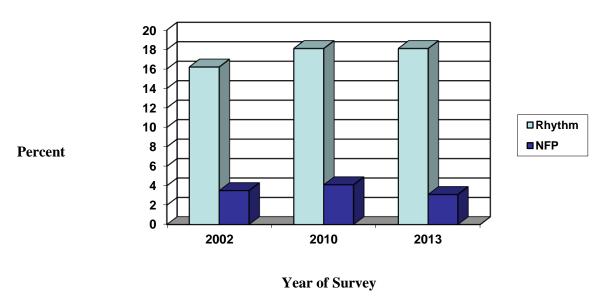


- 1 = Pill (Oral Hormonal)
- 2 = Female Sterilization
- 3 = Condom (Male)
- 4 = IUD
- **5** = Male Sterilization
- 6 = Withdrawal
- 7 = Hormonal Injection (Depo-Provera)
- 8 = Rhythm
- 9 = NFP (Mucus and/or Temp)

Some of the findings specific to Natural Family Planning (NFP) use are as follows:

- As seen in Table 1, approximately 0.1% of women of reproductive age in the 2011-2013 NSFG were currently using NFP. The 0.1% translates to about 60,887 women using NFP in the US.
- The trend in the use of NFP has not changed much since 1982 when NFP was separated from the variable "Rhythm Method." In 1982 the percentage of current use of NFP was (0.3%), in 1988 (0.4%), in 1995 (0.2%), in 2002 (0.2%), 2010 (0.1%) and now in 2011-2013 (0.1%).
- If only women using some form of contraception are included, then the current use of NFP was 0.3% in 2002, 0.2% in 2006-2010, and 0.2% in 2011-2013. The *ever use* rate is around 3.3% among women who find religion important or very important.
- The *ever use* of NFP among sexually active women in 2011-2013 is lower than in 2010 (i.e., 3.1 to 4.1%). *Ever use* and *current use* of Rhythm exceeds use of NFP. The Rhythm Method that is reported in the data is not a specific method or formula, but rather just a "feeling" of when a woman thinks her fertility begins and ends in the menstrual cycle (See Table 2).

Table 2: Percent ever use of rhythm and NFP among sexually active women 15-44 in the United States by year.



Comments

Echoing the comments from the 2002 and 2008-2010 surveys, it is apparent from the data presented in the NSFG 2011-2013 survey that few women in the United States use NFP as a means of family planning. Only approximately 60,887 women of reproductive age report current use of modern methods of NFP. Interestingly, the persons most likely to be using NFP are married couples. This could reflect the belief that it takes commitment and mutual support to use NFP successfully. That said, around 426,209 women report current use of Calendar Rhythm as a method of family planning, perhaps because calendar methods are more accessible, easier to use, and are self-devised. Often Calendar Rhythm methods are self-devised and "blanket type," i.e., starting abstinence on a certain day in the beginning half of the menstrual cycle and ending abstinence sometime after the middle of the menstrual cycle (Lamprecht and Grummer-Strawn 1996).

According to the CDC, most women seek family planning and women's health services from a medical or health systems service provider. For example, about 44.7 million received medical or family planning services in 2002, and of these, 34.4 million received family planning services from a private physician or HMO, 13.5 million from a health clinic, and 1.2 million from other sources (e.g., military health facilities). Of the 13.5 million who obtained family planning services from a private clinic, 5.4 million received care from a Department of Health and Human Services Title X family planning program. In other words, most family planning services are provided by some type of health professional (e.g., Title X clinics primarily use nurse practitioners). Health professionals are the usual gatekeepers of family planning services. One way to increase use of NFP services is to convince health professionals that NFP services are viable, desirable, and, ideally, simple enough to be prescribed in a short office visit.

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