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Natural Family Planning

The Frank-Dunlap Temperature Method of Determining the Infertile Phase

One of the challenges of using Basal Body Temperature (BBT) for Natural Family Planning is the determination of the post-temperature shift phase (and presumably post-ovulation phase) of the cycle. Body temperature can be altered by numerous factors including illness, stress, lack of sleep, food, alcohol, and medications. This variability often makes interpretation of the temperature shift difficult. Over the past 50 years, a number of formulas have been developed to help determine the post-ovulatory infertile phase of the menstrual cycle based on the BBT shift, including the "three high over the previous 6 lows," averaging the first 10 temperatures in the cycle and waiting until there are at least 3 readings a tenth of a degree above that average, or averaging the temperature of the previous cycle and waiting until there are three temps over that average. Interpreting the BBT shift in individual charts is often difficult because of the patterns of the rise - including slow rises, step rises, and fall back rises. All of the current methods of interpreting the BBT shift are retrospective in that the "rules" call for at least three temperatures after the suspected shift. A more objective and prospective means of determining the post shift (luteal) phase of BBT might help those who use BBT as a natural biological marker of infertility.

One way of determining if the post shift luteal phase of a woman's menstrual cycle has taken place is by comparing her basal body temperature with a comparable basal body temperature reading that does not undergo a shift in temperature, i.e., the male partner's BBT. Two researchers from Emory University demonstrated in a case study that exogenous factors that affect temperature can be controlled by comparing the BBT of a woman's male partner with her BBT recordings.(1) They hypothesized that most exogenous factors that happen to body temperature with the woman would also happen to the man - except of course the shift due to ovulation. Their case study showed that the temperature readings of the male and female partner were similar in the pre-ovulatory phase but after ovulation an obvious gap appeared in the recordings.

To determine if this pattern of pre-ovulatory similarities and post-ovulatorty gaps appear in a larger cohort of paired couples monitoring their basal body temperatures, three researchers from the Department of Family and Preventive Medicine from Emory University recruited a sample of 12 couples and had them monitor their BBT for 2-3 cycles.(2) The investigators wanted to determine if the male partner could serve as a control for the exogenous changes (other than ovulation) in the female's BBT. The females of the 12 (co-habitating) couples were between the ages of 21 to 43, had not been pregnant for at least 6 months and were not using any hormonal form of birth control for the past 6 months. The women had to be in a stable relationship with the male partner, sleep together, sleep at approximately the same time, follow similar work patterns, and not be apart for more than two days a month. The female participants also monitored their urinary LH with an ovulation predictor kit. The researchers estimated the day after the LH surge to be the day of ovulation.

A total of 41 cycles of data were collected of which 5 were non-ovulatory. The data showed that the temperatures of the pre-ovulatory phase had a highly significant co-variance and the postovulatory temperatures had a significant difference. The size of the mean temperature gap in the post-ovulatory phase between the men and women (pairs) was at least 0.3 degrees Fahrenheit higher than the pre-ovulatory mean temperature difference.

The researchers concluded that the recording of the male's BBT may improve the objectivity, interpretation and accuracy of the female's BBT. They also concluded that the size of the couple's temperature gap could be used to determine the transition from the pre to post-ovulatory phase. The researchers then proposed the Frank-Dunlap BBT method of determining if the women's cycle has begun its infertile luteal phase. The Frank-Dunlap method requires that the couple record their temperatures for a few cycles. They then calculate the magnitude of their unique temperature gap that indicates when the luteal phase has begun. In subsequent cycles when this gap is reached they would consider themselves in the infertile phase.

Comment

Although the Frank-Dunlap method of determining the infertile phase with the use of BBT monitoring might be more objective than the traditional retrospective methods (e.g., 3 high over the previous 6 lows) there needs to be a much larger study to determine the accuracy and effectiveness of this method to avoid pregnancy. However, the Frank-Dunlap method does represent fresh and innovative thinking about the use of BBT and determining the phase shift in a more objective prospective manner.

There are a number of possible problems with the Frank-Dunlap method of determining the BBT luteal phase that is inherent with BBT. First of all, taking the temperature by both the male and female doubles the error in temperature taking and it complicates the use of the method. Although having the male partner take his temperature might help the couple feel that he is more involved, it requires the motivation of both--how long this motivation is sustained is doubtful. Another problem is that the variability in temperatures is now doubled, i.e., the stress, alcohol use, illness, etc. that alters temperature readings for the female is now doubled by including the male. Although, the assumption of this study was that the exogenous changes in temperature between the man and woman partner will be similar, they did discard 4 cycles from the analysis, 2 for febrile illness and two for work related travel. The investigators also determined that the 12 women subjects had 5 anovulatory cycles. How they determined that the cycles were anovulatory was not mentioned. However, if it was due to no urinary LH surge, the cycles might not have been anovulatory but rather the test kits might have failed to pick up the LH surge. Past studies have shown that home urinary ovulation detection kits miss the urinary LH surge in about one out of ten cycles.

- 1. Frank, E. and White, R. An updated basal body temperature method. *Contraception* (1996): 319-21.
- 2. Dunlop, A. L., Allen, A. D. and Frank, E. **Involving the male partner for interpreting the basal body temperature graph.** *Obstetrics and Gynecology* 98 (2001): 133-138.

Evidence Shows that Cervical Secretions are Associated with Higher Fecundability

Researchers at Georgetown University recently developed a "two day" algorithm as a simple means to determine the fertile days in a woman's menstrual cycle.(1) The TwoDay Algorithm states that there needs to be two consecutive dry days before a woman is to consider herself infertile, or vice versa. A day is fertile if the current day or the day before had mucus present. The motivation behind developing this two day Algorithm is to have a simple to use and easy to teach method of NFP.

Researchers from the University of Padua, Italy and the National Institute of Environmental Health Statistics collaborated on a project with the original Georgetown University researchers to test the theoretical effectiveness of the TwoDay Algorithm and to determine the relationship between cervical-vaginal secretions and fecundability.(2) The hypothesis tested was "that the presence of secretions is predictive of not only impending ovulation, but also of the day-specific pregnancy probabilities within the fertile interval defined relative to ovulation." (p.2278) The researchers utilized existing NFP charts that had recordings of cervical mucus, basal body temperature and the incidence of coitus. These NFP data charts were obtained from 782 women from 7 European centers that were part of a prospective daily fecundability study from 1992-1996.

The estimated day of ovulation for the study was based on the BBT shift - i.e., the first day of the BBT rise was considered the day of ovulation. The fertile window was eleven days - defined as the eight days before and two days after the estimated day of ovulation. Out of 7,288 cycles, approximately 80% (5,860) had interpretable BBT shifts and of these cycles, 2,832 cycles had coitus charted in the estimated 11-day fertile window. The researchers used Bayesian statistics and fertility modeling to analyze the results.

The results showed that the TwoDay Algorithm was very effective in identifying the fertile days of the cycle, i.e., the coverage probabilities were high across all 11-days of the fertile window. The researchers also determined the probabilities for pregnancy during the fertile window and found that the highest days of fecundity were the 5 days before the estimated day of ovulation and the day of ovulation. The two days before the estimated day of ovulation had the highest probability of fertility. Furthermore, in the 5 days before the estimated day of ovulation the probability of pregnancy decreased nearly 50% when there were no cervical-vaginal secretions on those days. The researchers estimated that the first year pregnancy rate (based on a 13 menstrual cycle year) would be approximately 8.2%.

The investigators concluded that the TwoDay Algorithm is effective in both identifying the fertile days of the menstrual cycle and predicting within the fertile window those days that have a high pregnancy rate. They also concluded that this was the first study to provide evidence that cervical-vaginal secretions are associated with higher fecundity within the fertile window.

Comment

Although this is the first study to provide evidence for the association of the presence of cervical-vaginal secretions with a higher fecundity within the fertile window, it also is the first study to show evidence that there is a degree of fecundity when there is no cervical-vaginal secretions (i.e., a dry day) in the fertile window. The results seem to indicate that the degree of fecundity is about half of what it would be when secretions are present. Whether this is a high enough level of fecundity to be a problem for single indexed (mucus only) NFP methods needs to be determined.

This study utilized what some would consider an imprecise measure of estimating the day of ovulation - i.e., the last day of hypothermia. About 20% of the BBT and mucus secretion data charts did not have enough information to provide an interpretable BBT shift. The authors also point out that the majority of the 782 couples contributed multiple cycles of data. Having an uneven number of cycles from each couple could skew the results. Furthermore, how many of the cycles had more than one day of intercourse in the 11 day fertile window and how and who determined which act of intercourse resulted in a pregnancy is not indicated in the article. A statistical model to account for cycles that had multiple acts of intercourse in the 11-day fertile window was utilized.

The authors of this study estimated the theoretical pregnancy rate of the TwoDay method to be about 8.2% over the first year of use (i.e., 13 menstrual months). This effectiveness rate, however, is "very" theoretical since it has not been tested prospectively with a "real" population of women/couples. The investigators only looked at the TwoDay Algorithm within the 11-day window of fertility (determined by the last day of hypothermia). The question is how many days of secretions were outside of the 11 day window? The TwoDay Algorithm is easy to teach and

understand - but I wonder if it will be confusing to women/couples with continuous mucus cycles, vaginal irritations, vaginal and cervical infections, cervical erosions and the presence of seminal fluid. The authors of the original study on the TwoDay Algorithm state that women could be taught to only look for mucus in the afternoon and evening when the seminal fluid would have exited the reproductive tract.

I look forward to reading future studies on the probability of pregnancy within the fertile window on dry and non-dry days. I congratulate the authors of this study for looking at the probability of pregnancy with cervical-vaginal secretions and for "thinking out of the box" on new ways of simply determining "fertility or not" during the menstrual cycle.

- 1. Sinai, I., Jennings, V. and Arevalo, M. **The TwoDay Algorithm: A new algorithm to** identify the fertile time of the menstrual cycle. *Contraception* 60 (1999): 65-70.
- 2. Dunson, D. B., Sinai, I. and Colombo, B. The relationship between cervical secretions and the daily probabilities of pregnancy: effectiveness of the TwoDay Algorithm. *Human Reproduction* 16 (2001): 2278-2282.

Comment on the Dunson, Sinai and Colombo study from Joseph Stanford, MD- University of Utah:

This study used data from the European sympto-thermal group involving multiple countries and multiple centers, a database of 782 couples, 2,832 cycles with intercourse in the fertile window, and 434 conceptions. The fertile window was defined with reference to the BBT shift. Day 0, estimated day of ovulation, was defined as the last day of hypothermia (last day before temperature rise begins). They did not use OM Algorithm for fertility by mucus observations, but rather tested the applicability of the simplified TwoDay Algorithm developed at Georgetown. That Algorithm is: if there is mucus observed on a given day or the day before (regardless of its quality, lubrication etc), then a woman is fertile. Otherwise, she is infertile. They found that the peak probability of achieving a pregnancy occurred on day -2. If mucus was present that day or the day before, the probability of pregnancy from intercourse on this day was about 0.33. However, if mucus was not present on that day or the day before (an uncommon event), then the probability of pregnancy from intercourse on this day was about 0.17, about half, but NOT zero. While this means that intercourse on a dry day in the fertile window may result in pregnancy, it does NOT necessarily apply to the BOM or CrM systems. The main reason for this is that they are using the simplified TwoDay Algorithm, not the "1,2,3, wait and see" algorithm of BOM (and essentially same version in CrM). The latter are overall more conservative, calling more days fertile than the TwoDay Algorithm does- though the relationship is not simple because there are also cases where the TwoDay Algorithm would call a day fertile and the BOM or CrM systems would not (namely a dry day following a single day of nonlubricative (BOM),

non"peaktype" (CrM) mucus. (There is also certainly the question of how comparable the S-T mucus observations are to observations according to BOM or CrM instructions, but I think that is a secondary issue.)

An analysis of the same dataset will hopefully be forthcoming at some point that uses the 3-day count rather than the 1-day count, and calculates probabilities of pregnancy relative to the BBT marker of ovulation by whether the days are considered fertile or not. That will be very illuminating. But in my opinion, it is almost certain that the day specific probabilities of conception on "infertile" dry days (dry and also not within a count of 3) that are a few days before ovulation will NOT be zero. It will be low, but not zero.As noted, a dry "infertile" day within a couple of days before ovulation is a relatively rare event. This same paper calculated the probability that a day near ovulation (again defined by last day of BBT hypothermia) would be considered infertile by the TwoDay Algorithm AND that intercourse on that day would result in pregnancy. The probability was highest on day -4 and was 0.005, or 0.5%. Low, but not zero. I think the same will be true when the 3-day rule is used for the same analysis. Probably even lower, but still not zero.

Theoretical Effectiveness of the TwoDay Algorithm

In 1999, researchers from the Georgetown University Institute for Reproductive Health (IRH) utilized data from the 5 Country World Health Organization (WHO) study of the Ovulation Method (OM) to determine the theoretical effectiveness of what they call the TwoDay Algorithm.(1) As mentioned in the above review, this algorithm was developed as a simple means to determine the fertile and infertile days of the woman's menstrual cycle utilizing external cervical mucus observations. The Algorithm essentially states that two days of no cervical-vaginal secretions i.e., "yesterday and today" are needed in order to be in an infertile state. (See *Current Medical Research* Winter/Spring 2000 on the NFP website for a short report of this study.) A replication of this study by the Georgetown University researchers was recently conducted with a different data set of OM charts than from the WHO study.(2)

The WHO study data set included only the first day that women noticed cervical-vaginal secretions and the Peak Day. Although the 725 women in the WHO study charted daily observation of cervical mucus this data was not available to the Georgetown researchers and thus they were unable to determine how many "false positives" occurred outside of the fertile phase of the cycle. The Georgetown University researchers, however, were able to obtain OM data charts from Italy in which 282 women (average age of 27 years) contributed 2,707 cycles of data that included daily observations of vaginal-cervical secretions.

In order to determine the theoretical effectiveness of the TwoDay Algorithm the IRH researchers calculated the fertile phase to be a generous 8 days before the Peak Day of cervical mucus and the three days after the Peak Day. They based their days of fertility on the relative

accuracy of the Peak Day in determining the day of ovulation (i.e., the Peak Day of cervical mucus falls plus or minus two days of the day of ovulation 95% of the time) and on the probabilities of pregnancy during the 6 day fertile window as determined by Wilcox et al in a 1995 study.(3)

The study showed that with retrospective application of the TwoDay Algorithm on the Italian OM charts, the probability of pregnancy on the Peak Day of cervical mucus and the two days before and after were zero or near zero (i.e., a probabilities in the range of 0 -0.006). The two highest days of probability of pregnancy were days 4 (0.024) and 5 (0.020) before the Peak Day. The probabilities of pregnancy within the period of 8 days before and 3 days after the Peak Day of cervical mucus were very similar to the probabilities that they found with the WHO study data. However, with the Italian OM data charts they were able to determine that, from Peak Day plus 4 days through Peak Day plus 14 days, 15-30% of the days studied had false positives (i.e., the TwoDay Algorithm would indicate days as fertile when in truth they were not fertile). The pre-Peak Days from day 9-12 had 6-19% false positives.

Based on the researcher's calculations of the Italian OM charts the average number of fertile days using the TwoDay Algorithm is 11 days versus 10 days if they followed the OM rules. However, the researchers concluded that this one-day difference is not significant. The investigators found the TwoDay Algorithm to be theoretically effective and a promising (and simple to use and teach) method of family planning.

Comments

The Georgetown researchers mention in their article that one of the deficits of the TwoDay Algorithm is that it does not teach women how to differentiate vaginal-cervical secretions as the OM and other mucus only methods do. Because of this the TwoDay method has a significant amount of false positives, i.e., secretions that are interpreted as fertile that are in actuality not fertile. With the OM method these days might be interpreted as a basic infertile pattern of unchanging mucus.

Although the Georgetown researchers theoretically calculated the false positives of the 2day algorithm to be only one day more than the OM rules, they based this on a data set that eliminated 11% (or 301 cycles) that did not have a Peak Day identified. Furthermore, the data set had a lot of homogeneity (each women contributed from 1-35 cycles of data) that could have inflated or deflated the results.

Of interest is that in 427 cycles (i.e., 10.3%) the Algorithm failed to identify days 4 and 5 before the Peak Day (the two days of highest probability of pregnancy) as fertile days. The question this raises is - what is the probability of pregnancy on those dry days in the fertile window? The researchers also found that 24.6% of the cycles were identified to have secretions on the day before menses - which adds to the number of false positives for fertility.

- 1. Sinai, I., Jennings, V. and Arevalo, M. **The TwoDay Algorithm: A new algorithm to** identify the fertile time of the menstrual cycle. *Contraception* 60 (1999): 65-70.
- 2. Jennings, V. and Sinai, I. Further analysis of the theoretical effectiveness of the TwoDay method of family planning. *Contraception* 64 (2001): 149-153.
- 3. Wilcox, A. J., Weinberg, C. R. and Baird, D. **Timing of sexual intercourse in relation** to ovulation: effects on the probability of conception, survival of the pregnancy and sex of the baby. *New England Journal of Medicine* 333 (1995): 517-521.

Acceptability: The Ultimate Measure of NFP Success

Besides effectiveness and safety of a method of family planning, another important outcome measure is whether the method is acceptable to the woman or couple user. Long-term use is (in a sense) the ultimate measure of success of a method of family planning and of NFP. A method of NFP might be extremely effective in helping couples achieve or avoid pregnancy but if few couples use it then a question to be asked is whether the given method is acceptable. Besides long-term use other measures of acceptability include ease of use and whether the method can involve both partners.

Larry Severy, PhD, (Department of Psychology, University of Florida, Gainesville) recently assessed the acceptability of two hand held fertility devices among couple users in England and the United States.(1) The fertility devices are the PERSONA and the ClearPlan Easy Fertility Monitor that have been developed and manufactured by Unipath (a division of Unilever). Both of these fertility monitors measure urinary metabolites of estrogen and LH. The PERSONA monitor was developed as a device to help couples avoid pregnancy and the ClearPlan Easy Fertility Monitor was developed to help couples achieve pregnancy. (Both of these devices have been described in previous issues of *CMR*.) PERSONA is currently not available in the US.

The acceptability of the PERSONA was assessed through in-depth interviews and questionnaires provided to 721 PERSONA users in the UK. The qualitative data showed that the women users readily accepted the device, it had a positive effect on their relationship with their partner, and it provided important information about their cycles and reproductive health. The UK users also recorded their evaluation on the ease of use of the PERSONA monitor on 5 functional tasks (i.e., pressing the start button; remembering to view the monitor on a daily basis, using the test strips; understanding the results and understanding the test booklets) on a 10 point scale with 1 being the most difficult and 10 being the easiest. All of the 5 functions were rated at least 7 or above.

Another 220 US women users of the PERSONA recorded their acceptability and ease of use of the fertility device on a 7 point scale with 1 being the least acceptable (and most difficult to use) and 7 the most acceptable (and the easiest to use). The 220 women users were between the ages of 18 and 35, were in monogamous relationships, sexually active, were not intending to have a child in the next year and used the device for at least 6 months. The mean ratings of the ease of use was above 6 and the mean acceptability score was close to 6.

The investigator concluded that the PERSONA fertility monitor is highly acceptable to volunteer couples and that the data suggests that the monitor has a positive effect on the woman's reproductive functioning, her health and the couples' relationship.

Comment

Dr. Severy suggested that the dimensions of acceptability evaluated in his study could become standards on which to evaluate other methods of family planning. This idea has merit. Developers of NFP methods and NFP teachers need to assess the acceptability of NFP methods on ease of use, adaptability by both partners, and whether it helps inform the couple about reproductive functioning and health. I believe that most NFP methods could demonstrate that they inform about reproductive functioning and health but ease of use and adaptability by both partners might be more challenging.

1. Severy, L. J. Acceptability of home monitoring as an aid to conception. *The Journal of International Medical Research* 29 (2001,Suppl 1): 28A-34A.

Infertility

Intercessory Prayer Increases Pregnancy Rate Among Infertile Women

Distant intercessory prayer for the needs of others (especially the sick) has been used from time immemorial among many societies and religious groups. Medical scientists and clinicians have recently tested the effectiveness of distant prayer on behalf of others (i.e., intercessory prayer) in a number of settings. A classic study published by Byrd in 1988 tested the effects of intercessory prayer for acutely ill patients in an intensive care unit (ICU) in San Francisco.(1) His study was a randomized control study that showed those patients who were prayed for did significantly better on a number of outcome measures (e.g., readmission) than those who were not prayed for. A more recent study was published in a 1999 issue of the *Archive of Internal Medicine* that also showed a significantly better improvement in patients in a coronary care unit who were not prayed for (28 days) by Christian people unknown to the patients compared to those patients who were not prayed for by these same Christians.(2) The study was not only a randomized control study as the Byrd study but also a double blind study in that

neither the patients nor the patients care givers knew that the patients were being prayed for. The authors concluded that intercessory prayer may be used as an adjunct to standard medical care.

In order to test the effects of intercessory prayer on the success of in-vitro fertilization treatments for women with infertility problems, a group of researchers from Columbia University College of Physicians and Surgeons (New York City) conducted a prospective double blind randomized clinical study in which the patients and the providers were not informed about the intervention.(3) The subjects were 219 women aged 26-46 (mean 33.9) who were treated for infertility with IVF - embryo transfer over a four-month period at a hospital site in Seoul, Korea. The 219 subjects were randomized into either an intercessory prayer (IP) treatment or no intercessory prayer (NIP) treatment group. The women in the IP group were prayed for by groups of Christians in the United States, Canada and Australia. The intercessory prayer groups in turn were prayed for by other Christians so that they would have more effective prayers, i.e., sort of a double dose prayer network.

The results showed that the IP women had statistically higher pregnancy rates (50%) compared to the non IP group (26%) (p = 0.0013). The IP group also showed a statistically higher implantation rate (16.3% vs. 8%) compared with the NIP group (p = 0.0005). Although this was a double blind randomized control study, the researchers were more cautious in their conclusions compared with the coronary care IP study. They concluded that although there was a statistically better outcome for the IP-IVF women, they only viewed the results as preliminary.

Comments

The above cited prayer studies are intriguing, in that by utilizing a recognized scientific process that included randomization and control, the researchers were able to demonstrate that prayer works. However, I would be more cautious in my evaluation of the prayer treatments as are the authors of the IVF study. First of all, the results might be due to what is called type I error, i.e., the effects are not really due to the intercessory prayer but rather to chance. The only way to scientifically validate that IP works is by replicating these studies in multiple sites with different populations. I wonder how many studies on IP have been conducted that had no significant results and were not published.

A confounding factor in these studies might be the use of the private prayer that the patients in the ICU and the infertile women were using and the prayers by family and friends on their behalf. The authors in the coronary care unit study recognized this and stated that what was really tested was the effects of supplementary prayer. Both studies also lacked a theological underpinning of why Christian intercessory prayer might work. My final concern was that I question would God intervene to help make an immoral treatment (i.e., IVF-ET) work? I would imagine that God might want to help the new vulnerable human being (the human embryos) find

a receptive womb so that they might live - but not necessarily help the treatment. But that is a question for theology not science.

- 1. Byrd, R. C. Positive therapeutic effects of intercessory prayer in a coronary care unit population. *Southern Medical Journal* 81 (1988): 826-829.
- 2. Harris, W. S., Gowda, M. and Kolb, J. W. et al. A randomized, controlled trial of the effects of remote, intercessory prayer on outcomes in patients admitted to the coronary care unit. *Archives of Internal Medicine* 159 (1999): 2273-2278.
- Cha, K.Y., Wirth, D. P. and Lobo, R. A. Does prayer influence the success of in vitro fertilization-embryo transfer? *The Journal of Reproductive Medicine* 46 (2001): 781-787.

Research Briefs

Satisfaction With Natural Family Planning Methods

Knowing what factors influence "satisfaction of use" with methods of birth control and NFP is important. Satisfaction influences both compliance and continuation of use. European researchers recently surveyed 1,466 German female users (20-49 years of age) of oral contraception, condoms, IUDs, sterilization and NFP, to determine the factors that influence satisfaction.(1) Of the 1,466 women surveyed, 428 had used NFP sometime in the past. Of these women, 181 were satisfied with use of NFP and 139 were not. Of the dissatisfied users 70% had concerns about becoming pregnant, 76% felt that NFP was not easy to use, 64% experienced negative moods from use of NFP, and 50% felt that NFP had a negative effect on their sexual life. The factors that contributed the most to dissatisfaction of use among all users of NFP were concerns about pregnancy (i.e., becoming pregnant and not intending to), and ease of use (i.e., NFP was not easy to use). The authors recommended that providers of NFP should address pregnancy concerns and ease of use among women users of NFP.

Comment

Most modern NFP couple service programs already include information about pregnancy rates and ease of use. In this study it is not clear which methods of NFP were used by the 428 German women. Since they were randomly selected from a large population it is reasonable to ask if many were "self-taught" or using a type of "self - devised" calendar method.

1. den Tonkelaar, I. and Oddens, B. J. Factors influencing women's satisfaction with birth control methods. *The European Journal of Contraception and Reproductive Health Care* 6 (2001): 153-158.

Oral Contraceptive Use and Risk for Myocardial Infarction

A large population based case control study was carried out by researchers in the Netherlands to determine the risk of myocardial infarction (MI) in association with use of oral contraception.(1) The aim of the research was to determine the relative risk of an MI with the use of second versus third generation oral contraception. The differences between second and third generation consist of different formulations of progestogen compounds used in the pill. Second generation formulations of the pill contain levnorgestrel and third generation formulations contain desogestrel or gestodene. A previous study provided evidence that the risk for an MI is higher with third generation oral contraceptives. (2)

The participants were 248 women between the ages of 18 through 49 with first time myocardial infarctions selected from 16 participating centers in the Netherlands. These women were matched on age, year of MI, and area of residence with 925 control women who did not have an MI. Other risk factors for MI, including obesity, smoking, hypercholesterolemia, and genetic links were also assessed.

The results showed that the overall risk for MI among users of any type of oral contraceptive was twice that of non-users. The odds ratio for MI for users of first generation oral contraceptives was 2.8, 2.4 for second generation oral contraceptive users, and 1.3 for women who used third generation oral contraceptives. Among users of any type of oral contraception, the highest risk for MI was among those who had hypercholesterolemia (odds ratio, 24.7), diabetes (odds ratio, 17.4) and those who smoked (odds ratio, 13.6). The authors concluded that the risk for MI was increased for those women who used second generation oral contraceptives but that the increased risk of MI for users of third generation oral contraceptives.

Comments

Study results also showed that when the researchers compared women who had no risk factors for MI (i.e., smoking, diabetes, and hypercholesterolemia) the risk for MI was three times higher for user of oral contraception than for non-users. The authors recommended that the most important advice to give to women who use oral contraceptives is to not smoke. I wonder why no thought was given to advising women who had risks for MI not to use oral contraceptives.

- Tanis, B. S., van den Bosch, M. A. and Kemmeren, J. M. et al. Oral contraceptives and the risk of myocardial infarction. *The New England Journal of Medicine* 345 (2001): 1787-1793.
- Dunn, N, Thorogood, M. and Faragher, B. et al. Oral contraceptives and myocardial infarction: results of the MICA case-control study. *British Medical Journal* 318 (1999): 1579-83.

Contraceptive Use Among Navy Enlisted Women and Men

Although US Naval policy dictates that pregnancy is compatible with a naval career, being pregnant while aboard ship can be difficult. The US Navy recommends that pregnancy be planned to coincide with non-operational tours of duty. How to avoid or plan a pregnancy while being on active duty and especially on sea duty is important to naval personnel. Naval and civilian researchers conducted a study to determine the contraceptive behaviors and beliefs of Navy personnel.(1) Contraceptive attitudes and use were assessed by a survey administered to 714 enlisted women and 665 enlisted men aboard 15 ships. Although 28.5% of the women and 48.6% of the men were married, only 14.5% of the women and 6.1% of the men were not sexually active. Birth control pills and condoms were the most commonly cited methods of contraception. However, 14% of the sexually active women and 15.6% of the sexually active men reported no use of a birth control method. Only one woman and one man listed "rhythm" as their method of birth control. The researchers also found that contraceptive use was related to more favorable attitudes about contraception and that the Naval women had more positive responses to contraception than men. The investigators concluded that there is a need to identify strategies to increase the use of more effective means of birth control among Naval women who do not want to become pregnant.

Comment

It is bewildering that there was no mention of the need to help non-married Naval personnel to be chaste. A logical question is "Why doesn't the Navy create a standard policy and programs to encourage chastity among the non-married Naval personnel as a health measure to prevent pregnancy, sexually transmitted diseases and appropriate male-female relationships?" Of interest is that the incidence and frequency of sexual intercourse aboard Naval vessels is a behavior subject to disciplinary action. Also of interest is that the use of "rhythm" was classified as not using a method of birth control.

1. Thomas, M. D., Thomas, P. J. and Garland, F. C. **Contraceptive use and attitudes toward family planning in Navy enlisted women and men.** *Military Medicine* 166 (June, 2001): 550-556.

Oral Contraceptive Use and Ovarian Cancer Risk

It is known that both pregnancy and use of oral contraceptives reduce the risk of ovarian cancer among women. The mechanism of action is thought to be a result of suppressed ovulation and incessant ovulation is thought to be a cause. However, recent evidence suggests that another mechanism might be due to the chemical formulations found in oral contraceptives (OC). Researchers speculate that progestins in OC somehow activate some type of chemo-preventive pathways in the ovarian epithelium, i.e., they somehow help eliminate the DNA damaged cells caused by incessant ovulation. To test the hypothesis of the preventive protective mechanism that OC (and in particular progestins) might play in preventing ovarian cancers, researchers at Duke University re-analyzed data from the Cancer and Steroid Hormone Study (CASH) that was conducted in the early 1980s.(1.) They compared 390 women (from eight geographic locations between the ages of 20-54) who were diagnosed with ovarian cancer between December 1, 1980 and December 1, 1981 with 2,865 randomly selected women from the same locations and same age range. The participants in the CASH study were interviewed for the type or types of oral contraceptives used. The results showed that there was a reduced risk of ovarian cancer among users of all different formulations and potency of oral contraceptives. They also found that women who used OC with formulations that had higher levels of progestins had a greater reduction of risk for ovarian cancer than those that did not - even among women who used the higher levels of progestins for a short time period. The authors concluded that the protective mechanism of progestin formulated OC include not only the suppression of ovulation but also some type of biologically activated pathways.

Comment

The results of this study contradict an earlier study (2) that showed there was not a difference in the protective effect among different formulations of OC. The authors also point out that the memory recall of the different OC formulations used by the women participants could be in error and that OC formulations have changed considerably from the early 1980s. They did not look at the relative protective effect of pregnancy and breastfeeding in comparison with OC use. The incidence of ovarian cancers are less frequent than breast cancer and the coronary artery and vascular problems that might or might be linked to OC use.

- Schildkraut, J. M., Calingaert, B., Marchbanks, P. A., Moorman, P. G. and Rodriguez, G. C. Impact of progestin and estrogen potency in oral contraceptives on ovarian cancer risk. *Journal of the National Cancer Institute* 94 (2002): 3238.
- 2. Ness, R. B., Grisso, J. A., Klapper, J., Schlesselman, J. J. et al. **Risk of ovarian cancer in** relation to estrogen and porgestin dose and use characteristics of oral

contraceptives. SHARE study group. Steroid Hormones and Reproduction.

American Journal of Epidemiology 152 (2000): 233-241.

Moderate Alcohol Consumption Not Associated With Longer Waiting Times to Pregnancy

Recent research has indicated that even moderate consumption of alcohol by women trying to become pregnant have longer waiting periods. However, this research was based on relatively few subjects. In order to determine the relationship between alcohol consumption and waiting time to pregnancy Danish researchers surveyed 39,612 women on alcohol consumption and waiting time who were within their first 24 weeks of pregnancy.(1) What they discovered was that moderate and high consumption of alcohol was not associated with longer waiting times to pregnancy. The only group of women alcohol drinkers that had a significant longer waiting time to pregnancy were those who drank on average more than 14 alcoholic drinks per week and had previous pregnancies. In fact women who had a low consistent alcohol intake of 1-2 drinks per week had a shorter waiting time period than those who were non-drinkers. The authors speculated that moderate amounts of alcohol may have a positive effect on the female reproductive system, especially by the way of stress reduction.

Comments

Although the authors did not find a prolonged waiting time to pregnancy among moderate alcohol drinkers, they did find a longer waiting time among smokers, overweight women and older women. These results apply only to Danish women.

1. Juhl, M., Anderson, A. M., Gronbaek, M. and Olsen, J. Moderate alcohol consumption and waiting time to pregnancy. *Human Reproduction* 16 (2002): 2705-2709.

Long and Irregular Menstrual Cycles Found to be Risks for Type II Diabetes

Since 1976 Harvard researchers have been monitoring the health behaviors of a large cohort of female professional nurses. The original purpose of the 1976 study was to determine the long-range health effects of using oral hormonal contraception. In 1989 another cohort of 116,671 nurses were recruited for a longitudinal study (called the Nurse Health Study II) in order to prospectively study a wide array of health outcomes. On a biannual basis these nurses complete a detailed health questionnaire that include questions about the length and regularity of their menstrual cycles. In order to determine if menstrual cycle length and regularity is predictive of future type 2 diabetes researchers from Boston's Brigham and Women's Hospital and Harvard University analyzed 507 documented cases of diabetes that were diagnosed among the original

Nurse Health Study II participants. (1) The investigators found that women with a usual cycle length of 40 days or more (or who had cycles that were too irregular to estimate) had a significantly increased risk for type 2 diabetes compared with women who had normal menstrual cycle lengths (of 26-31 days). They also found that the risk for diabetes was further increased among women who were overweight. The authors suggested that women with long and irregular menstrual cycles consider lifestyle approaches to decrease the risk of ovarian cancer through weight control and exercise.

Comment

A limitation of this study was that cycle characteristics were retrospectively self-reported. Some women might have classified their cycles as normal length while being treated with oral contraceptives. Over classification as normal, however, would bias the results towards not finding long cycles being a risk. Women who monitor their cycles through NFP will have an accurate record of their cycle length. If they have consistently long menstrual cycles they might want to be aware of the potential risk for diabetes and to monitor their blood glucose levels and weight. About 7.6% of the 116,671 nurse participants had menstrual cycles of 40 days or more or cycles that were too irregular to estimate.

1. Solomon, C. G., Hu, F. B., Dunaif, A. et al. Long or highly irregular menstrual cycles as a marker for risk of type 2 diabetes mellitus. *Journal of the American Medical Association* 286 (2001): 2421-2426.

Less Depression Found Among Women With Unintended Pregnancy Who Do Not Abort Their Child

Researchers at the Elliot Institute recently reanalyzed a sub-set of 4,463 women from the *National Longitudinal Survey of Youth* to determine if prior psychological state among women with unintended pregnancy was predictive of depression whether they abort or carry to term their unborn child.(1) The survey took place in 1992 and included questions on depression, pregnancy intention, and pregnancy outcome. Out of the original subset of women, 421 had either a first unintended delivery or first abortion. Controlling for previous psychological states, the researchers found that among the 239 married women in this group those who aborted their child were significantly (138%) at more risk for clinical depression than those that did not abort. However, they did not find the same risk differential among the 182 unmarried women in the same subset. The investigators attributed the no difference in depression risk between the unmarried women who did or did not abort their first unintended pregnancy due to the under reporting of abortion. Compared with national averages, the unmarried group reported only about 30% of the expected abortions, whereas the married group reported about 74% of the expected

abortions.

Comment

In an earlier study of this same group of women, a feminist psychological investigator did not find any differences in self-esteem among those who aborted or did not abort their first pregnancy.(2) This earlier study has been used to show that abortion has no risk of psychological damage. Dr. David Reardon from the Elliot Institute believes a fault of this earlier study was the failure to look at the under reporting of abortion among the unmarried group. He also believes that the use of "self-esteem" is not a very sensitive measure of mental health risk after an abortion.

- Reardon D. C., Cougle, J. R. Depression and unintended pregnancy in the National Longitudinal Survey of Youth: a cohort study. *British Medical Journal* 324 (2002): 151-152.
- 2. Russo, N. F., Zierk, K. Abortion, childbearing, and women's well-being. *Professional Psychology: Research and Practice* 23 (1992): 269-280.

Under the Microscope

NFP and Marital Dynamics - "Help or Hinder?"

The issue of how the use of Natural Family Planning (NFP) affects the marital relationship is of great concern to NFP couple users, teachers and advocates. Although this legitimate concern has been addressed somewhat in the Catholic press (see end notes 1-4), the critics of NFP raise important issues. NFP teachers can speak to these concerns based on their own anecdotal client stories. But although anecdotes can provide insight into the dynamics of human behavior, they are, in the end, often misleading. Scientific studies are needed to reveal the effects of NFP use on the marital relationship. Indeed, some studies have been done and they are reviewed below. But more is needed in order to help NFP educators identify and correct the weaknesses of NFP as well as continue to validate its benefits.

One of the first studies on how NFP affects marital relationships was conducted by John Marshal and Beverley Rowe and reported in a 1970 issue of *Fertility and Sterility*.(5) Marshall was one of the original members of the Papal Birth Control Commission. He and Rowe were concerned that the practice of NFP (i.e., in the form of BBT) and the amount of abstinence required might have a negative effect on marriage. Their study showed that of the 502 couples who responded to their detailed psychological questionnaire, 75% of the wives and 66% of the husbands felt their overall use of BBT was satisfactory and 75% of the wives and 74% of the

husbands felt that the use of BBT was helpful to their marriage. However, 48% of the husbands and wives felt that the practice of periodic abstinence was somehow harmful to their marriage.

Since the 1970 Marshall and Rowe study, a number of modern methods of NFP have been developed and utilized for family planning throughout the world. Specifically the Billings Ovulation Method (BOM) which is based on the changing characteristics of cervical secretions as a marker of fertility (6) and the multiple indexed methods (i.e., Sympto-Thermal Method) that combine changes in cervical mucus and the cervix with BBT.(7) These newer methods are thought to be less restrictive in the length of time required for abstinence from sexual intercourse than BBT and are effective when used to avoid or achieve a pregnancy. The Marshall and Rowe study was never repeated with newer methods of NFP, but there have been similar quantitative studies that have measured various psychological and spiritual dynamics among users of NFP.

Satisfaction with NFP

Satisfaction with the use of NFP probably has been one of the most consistent "psychological" measures of NFP dynamics. Besides the 1970 Marshall Rowe study, the World Health Organization 5 country study of the Ovulation Method (OM) included an investigation in satisfaction of use.(8) Satisfaction was ranked as either "poor," "good" or "excellent" in the WHO study. The combined good and excellent satisfaction among the 725 women participants was (good 71.9% + excellent 26.3%) 98%. The male partners rating of satisfaction was slightly lower at 97%. Grace Boys reported a study in which 424 women users of NFP (either OM or STM) reported a combined (Very true = 27.6% or True = 44.6%) 72% satisfaction with "my usage to avoid pregnancy." (9) The 424 women participants were from five NFP teaching centers in Oregon in the early 1980s. Not all were current users of NFP (and some would question if some were ever users in that to be a respondent all they had to do is attend one NFP class). Attending a NFP class does not mean that the women respondent ever used NFP.

In a more recent study, 72% of 81 current German female users of NFP indicated that they were satisfied with use of their NFP method.(10) However, the researcher in this study does not indicate what method of NFP was currently used. The subjects were randomly selected by phone survey. Many of the respondents might have been using a self-taught calendar method of NFP. Of interest is that only 43% of the 413-424 ever users of NFP in this study indicated that they were satisfied when they used NFP. Obviously many of them stopped using NFP due to some dissatisfaction. Finally, this author recently completed a satisfaction survey of OM and Creighton Model (CrM) system users (unpublished study). Seventy five percent of the 345 respondents were current users of OM or CrM and 25% were past users. Eighty -seven percent of the male users and 91% of the female users were satisfied with their use of NFP. A visual summary of the satisfaction ratings of the above mentioned studies can be found in Table One.

Study	No. of participants	% Satisfied Men	% Satisfied Women
Marshall (5)	510	66	75
WHO (8)	725	97	98
Boys (9)	424	NA	72
Oddens (10)	81	NA	72
Fehring*	345	87	91

Table One: Satisfaction of Current and Ever Users of NFP

*Unpublished study.

The differences of satisfaction in use of NFP by the female (and some male) users of NFP in the above five studies vary from a low of 66% among the men in the Marshall and Rowe BBT study and a high of 98% in the WHO five country OM study. The variation in satisfaction is probably a reflection of the different populations, time periods, methods of NFP used, sampling methods, NFP teaching methods, and response formats for the questions on satisfaction. However, it would be safe to say from the results of these studies that the vast majority of men and women are satisfied with their use of NFP.

Sexuality and NFP

Trying to measure the sexual dynamics among couple users of NFP is much more complex than satisfaction of use. There are no consistent measures of sexuality in use of NFP in published studies. Sexuality is measured by "difficulty with abstinence," "sexual spontaneity," "intercourse frequency" and "sexual pleasure."

Difficulty with Abstinence

Marshall and Rowe reported that 93% of the husbands and 78% of the wives had difficulty with abstinence either often or sometimes with the use of BBT. Another study of English and Welsh couple/users of NFP (chiefly STM) found 55% of the husbands and 63% of the wives responded "yes" or "sometimes" to having difficulty with abstinence.(11) This author found that 79% of the 334 husbands and 72% of the 334 wives in the use of OM or CrM had difficulty with abstinence either sometimes or often (unpublished study). However, 82% of the women and 53% of the men (partners) in the five- country WHO study reported no difficulty with abstinence.(8) When the "no difficulty" responses are combined with the "occasional

difficulty" responses the percent among the women OM users was 98% and the men (partners) was 96%. Combining the never to occasional or sometimes difficulty with abstinence with use of NFP in all of the reported studies can be found in Table Two. As can be seen the majority of men and women users of NFP experience only "sometimes" or "occasional" difficulty with abstinence and many never have experienced difficulty with abstinence with use of NFP. Again, the variation of results can be explained by the different populations studied, the time frame of the studies, the different NFP methods used and the type of question asked to generate a response. The overall impression from the studies cited is that most people who use NFP most of the time do not have difficulty coping with abstinence. Occasionally couples do have difficulty with abstinence, but if they are having a lot of difficulty then they are not normative of the whole and in essence are most likely experiencing other problems.

Study	No. of Participants	% Men Users	% Women Users
Fragstein (11)	464	57	76
Marshall (5)	510	60	78
Fehring*	345	81	89
WHO (8)	725	96	98

Table Two: Never to Occasional or Sometimes Difficulty With Abstinence in Using NFP

*Unpublished study.

Intercourse Frequency

The mean number of acts of intercourse recorded in the 5-country WHO study was 4.8 (with a standard deviation of 2.4).(8) The WHO study also reported that 84% of the women participants and 67% of their male partners were satisfied with the frequency of intercourse. The frequency of intercourse among the English and Welsh couples was 7.4 acts on average per menstrual cycle.(11) This average however was a perception rather than an actual count. Of the 81 German current users of NFP, 32% felt that the frequency of intercourse was less and 8% felt that it was more.(10) I would assume that the remaining 60% felt that there was no change or had no response. The data on intercourse frequency is too limited to make much of a conclusion, other than it seems that perception is a key factor.

Appreciation of Intercourse

NFP advocates often say that the use of NFP increases intimacy and keeps the sexual act fresh. This is often called the "honeymoon" effect. Marshall and Rowe found that 69% of the husbands and 61% of the wives had a greater appreciation for intercourse.(5) This author's study of OM and CrM users found that 79% of the husbands and 80% of the wives found a greater appreciation for intercourse (unpublished study). Oddens found among 81 current German users of NFP that 22% felt that their sex drive had increased.(10) This percent increase in sexual libido was greater than the percent found among the IUD, Pill, condom or sterilized German women. Furthermore, the sexual pleasure found among the female German NFP users on a percent basis was found to be more pleasurable than all of the other methods of contraception reported with the exception of sterilization. The data from these studies seems to support the notion that periodic abstinence does stimulate the sexual drive and helps maintain an appreciation for intercourse. Further research on this sexual dynamic needs to take place.

NFP and Spirituality

There is very little published research on how NFP affects spirituality among couple users of NFP. Previous qualitative studies have indicated that NFP couples feel that NFP somehow enhances their spirituality.(12-16) Couples using NFP have reported that they "feel in step" with Church teaching, that they are "doing God's will," they are "allowing God's will" to take place in their lives, they "appreciate God's gift of fertility more," and that they allow themselves "to be co-creators with God." There are only two quantitative studies on spirituality among users of NFP that this author is aware of.(14,15) Both of these studies showed that NFP couples had statistically higher levels of spiritual well-being than couples using contraceptives. The results of these two studies, however, could be explained by selection bias and or that the NFP couples had higher levels of spiritual well-being before they used NFP. Many couples who seek to use NFP do so for moral, ethical and religious reasons.(11,16)

A recent survey conducted by this author among 334 couple users of NFP found that 70% of the husbands and 88% of the wives felt that NFP had a good effect on their spiritual wellbeing (unpublished study). In the same survey 71% of the husbands and 85% of the wives felt that NFP had a good effect on their relationship with God. If these high rates of positive effects on spirituality and relationship with God can be found in other large populations of NFP users it would be significant from a religious and spiritual perspective. Comparison of NFP users with users of other forms of family planning on spiritual variables would be of interest. From all indications in the qualitative and quantitative research, it seems that NFP enhances spiritual and religious well-being among NFP couples users.

Conclusions

In summary, the research findings on marital, sexual and spiritual dynamics of NFP seem to indicate that NFP is helpful to marital life. Marshall and Rowe reported that 74% of husbands and 75% of the wives found the use of BBT to be helpful to marriage.(5) These results are similar to the English and Welsh couple users of NFP in which 75% of the wives felt NFP (STM) was helpful to marriage.(11) This author found that 80% of the husbands and 85% of the wives felt that using (OM or CrM) was helpful to their marriage.(Unpublished study.)

Research also indicates that most users of NFP are satisfied with their use of NFP, that most find periodic abstinence is not a problem and that NFP enhances their sexual drive. Most NFP couples also feel that the use of NFP enhances their spiritual well-being and relationship with God. However, all of these results need to be qualified in that there are not a lot of good published studies on the affects of NFP on marital dynamics. More research needs to take place.

One of the areas of research that would be of importance is to design good measurement tools on marital dynamics that can be used, repeated and compared with multiple studies. Most family planning studies seem to be approached from a "one person" perspective, i.e., personal satisfaction, sexual pleasure, etc. Although these variable are important, other aspects of marital dynamics need to be addressed. These dynamics include mutual understanding, trust, self-mastery, communication, non-genital expressions of intimacy and spiritual well-being. These dynamics are important in marriage and are the dynamics that NFP use tends to favor. Future studies on NFP and other methods of family planning need to include these issues. Use of NFP can be a challenge to couples especially in coping with abstinence, charting, and making decisions on their fertility and infertility. These challenges however are worth the effort if they prove to be marriage builders.

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For Your Information:

Web Resources:

The January 2002 issue of *Contraceptive Technology Update* listed the following as web resources for current information on contraceptive research.

Reproductive Health Outlook. www.rho.org

Published by the Seattle-based Program for Appropriate Technology in Health (PATH) and designed for reproductive health program managers working in "low-resource settings." Provides up-to-date summaries of research findings, program experience, and clinical guidelines related to key reproductive health topics as well as analyses of policy and program implications. It offers in-depth information on reproductive health topics.

Media/Materials Clearinghouse. www.jhuccp.org/mmc/index.stm

Published by Johns Hopkins Population Information Program and funded by U.S. Agency for International Development (USAID). This is an international resource for health professionals who seek samples of pamphlets, posters, videos, and other media materials designed to promote public health.

ReproLine. www.reproline.jhu.edu/index.htm

Affiliated with Johns Hopkins University, JHPIEGO is a nonprofit organization aimed at improving the health of women and families. Provides extensive tools for trainers, and its "Reading Room" offers on-line documents on contraceptive methods.

The following information is reproduced from Abstinence Clearing House e-mail communications:

Abstinence grant available under Title XX

The Department of Health and Human Services (HHS) had announced \$6.5 million for 35 prevention (abstinence) projects, under Title XX Adolescent Family Life, with an application deadline of March 11. (This is not the Title V welfare money or SPRANS program that has more funding.) Proposed projects had to focus on preventing teenage pregnancy. The A-H components of Title V are also followed under this grant. The Web site for the Office of Population Affairs at http://opa.osophs.dhhs.gov has a step-by-step application process for Title XX abstinence grants, including a question and answer sheet that appears to be friendly toward faith-based providers.

FDA Approves New Saliva-Based Home Ovulation Test

The FDA recently approved the country's first saliva-based ovulation prediction test, giving women an alternative to urine testing that can be used at home. The salt content of a woman's saliva increases as she nears ovulation and the TCI Ovulation Tester allows women to gauge the amount of potassium chloride in their saliva. Saliva is placed on a slide and looked at through a handheld microscope. Small dots of salt indicate that ovulation is not close at hand, while a larger ferning pattern suggests that ovulation is "imminent." FDA reviewer Veronica Calvin said that the saliva test has proven more than 90% reliable in predicting ovulation. The test does not require a doctor's prescription and will cost approximately \$60.00.