Natural Family Planning

CMR

CURRENT MEDICAL RESEARCH

A SUPPLEMENT OF *NFP FORUM* Vol. 15, Nos. 1 & 2, Winter/Spring 2004

NATURAL FAMILY PLANNING

MAJORITY OF COUPLES EXPERIENCE IMPROVED RELATIONSHIPS WITH USE OF NFP

Over 35 years ago Patrick and Patty Crowley, the founders of the Christian Family Movement (CFM), conducted a study to determine how the practice of Calendar-Rhythm affected marital life.[1] The Crowleys were members of the Papal Birth Control Commission that was studying whether the Catholic Church should change its teachings on birth control. The Crowleys distributed a questionnaire to members of CFM throughout the United States and Canada asking them how the Rhythm method helped or harmed their marriage. The responses from the couples were mostly negative, that is, the majority felt Rhythm somehow harmed their marriage. The results of this study were never published but were submitted as a written report to the Papal Birth Control Commission. According to McClury, a religious historian from Northwestern University, this CRM report influenced members of the Papal Commission to recommend that the Catholic Church change its teachings on the use of contraception.[2] Since the time of the Crowley study (1964), new methods of NFP, such as the Billings Ovulation Method (BOM), the Creighton Model Fertility*Care*™ (CrMS), and the Sympto-Thermal Method (STM), have been developed. These modern methods of Natural Family Planning (NFP) are thought to be more scientific and more effective than the old Rhythm/Calendar or BBT methods when used to either avoid or to achieve a pregnancy. Furthermore very little is known on how methods of family planning affect marital dynamics.

Researchers from Marquette University College of Nursing recently replicated the Crowley study among couples who have or were using a modern method of NFP.[3] The purpose of this study was to identify the effects of these methods on marital dynamics by asking couples the same open-ended questions the Crowleys posed in their study of CFM members. The open-ended question asked of husbands and wives was whether the use of NFP had been helpful or harmful to their marriages. This open-ended question was part of a longer questionnaire mailed to 1,400 randomly selected couples known to use NFP (either BOM or CrMS) and reside in the United States. Three hundred thirty four couples (23.9%) or 668 individuals responded. Of these, 523 (78.3%) responded to the open-ended question, including 292 (87.4%)

RESEARCH ON. . .

EDITOR: RICHARD J. FEHRING, DNSC, R.N.

MANAGING EDITOR: THERESA NOTARE

Send all inquires to: DDP/NFP, USCCB, 3211 4th St., N.E. Washington DC 20017.
Questions: 202-541-3240;
Orders: 202-541-3070; FAX 202-541-3054.

wives and 231 (69.2%) husbands. Graduate student coders, in conjunction with faculty researchers, used content analysis to identify meanings and themes in all the responses. A response was not coded under a given theme until 100% agreement was reached. Numeric analyses were used to determine frequency and percent of responses.

The researchers found that 74% of the total responses were positive and only 26% were negative. There were four positive themes identified (enhanced relationships, improved knowledge, enriched spirituality and method successes) and three negative themes (strained sexual interactions, worsened relationships, and method problems). Sub-categories for each of these main themes can be found in Tables One and Two.

Some example responses under the positive theme of "improved relationships" not reported in the published paper are as follows:

IMPROVED COMMUNICATION

"It [NFP] has helped us to be closer and we communicate on a different level than just the ordinary ways. We seem to be very comfortable with each other."

"Since we speak about our fertility on a daily basis (my husband charts and asks my observations daily) NFP has helped our level of communication remain very deep and intimate and always above-board, open and honest."

APPRECIATED SEXUALITY

"Our sexual relationship is incredible. I have no complaints and truly believe the periodic abstinence of NFP causes us never to get in a rut sexually."

UNDERSTAND CYCLES AND BODIES

"[NFP was] helpful to understand PMS symptoms for myself and my husband because of our awareness of my cycle. Thus, helped keep our moods/reactions/issues in balance/in perspective."

SELF CONTROL

"About the time when you are ovulating is when you're most susceptible to having sex, because it is a natural time to be having sex, but on the other hand it teaches us self-discipline and… priorities."

ENRICHED SPIRITUALITY

"It has helped my relationship with God which has positively affected my relationship with my spouse….I've come to know and love God all the more for learning His beautiful truth about the real…meaning of human sexuality."

Some example negative responses that did not make the cut for the published paper are as follows:

DIFFICULTY WITH ABSTINENCE

"Abstinence is often difficult and can be prolonged. The 'honeymoon' phase often starts out great, but the full benefit is not obtained because she becomes less receptive and PMS kicks in."

DECREASED SPONTANEITY

"Our sex life has disintegrated quite a bit. All sense of spontaneity is gone. Therefore from a woman's perspective, it takes twice as long to achieve orgasm. The passion is dead, or at least is most often suppressed."

UNBALANCED SEX DRIVES

"My sex drive is very low on infertile days when intercourse is okay. This causes trouble because my husband complains that I never want to have intercourse. I feel that my sex drive is about normal on fertile days, but then we can't have intercourse."

OTHER PROBLEMS

"I wish the medical community were better educated, open-minded, and supportive of NFP. It is an integral part of my experience as a woman, and I would like to feel free to share more about it when I do have doctor visits."

The researchers concluded that compared to the Crowley study the respondents were dramatically more positive about the use of NFP. Although about one-fourth of the comments indicated that NFP presented challenges, the majority expressed that using NFP improved relationship dynamics, most often resulting in stronger bonds, better communication, and improved knowledge. The limitations of the study were that the response rate was low and respondents were a self-selected group of couples that were fairly homogeneous in regard to race, religion and education.

TABLE ONE

FREQUENCY OF POSITIVE RESPONSES ACCORDING TO MAJOR THEMES

Theme & Category	Number % Percent	Theme subtotals
Enhanced Relationship		31%
Deepened relationship	185 (8)	
Improved communication	209 (9)	
Shared responsibility	86 (3)	
Respected partner	92 (4)	
Appreciated sexuality	145 (7)	
Improved Knowledge		13%
Understand body & cycles	204 (9)	
Learn other lovemaking	100 (4)	
Enriched Spirituality		15%
Connected closer to God	153 (7)	
Supported Church teachings	88 (4)	
Open to new life	94 (4)	
Method Successes		15%
Spaced pregnancies	96 (5)	
Learned self-control	89 (3)	
Remained healthy	100 (5)	
Other successes	49 (2)	
TOTAL POSITIVE		**74%**

TABLE TWO

FREQUENCY OF NEGATIVE RESPONSES ACCORDING TO MAJOR THEMES

Theme & Category	Number % Percent	Theme subtotals
Strained Sexual Interactions		**13%**
Difficulties with abstinence	138 (5)	
Decrease frequency/spontaneity	106 (5)	
Unbalanced sex drives	63 (3)	
Worsened Relationships		**6%**
Anger and frustration	80 (3)	
Misunderstandings resulted	51 (3)	
Method Problems		
Fear of pregnancy	67 (3)	
Method failed	42 (2)	
Other problems	50 (2)	
TOTAL NEGATIVE		**26%**

Comment

Drs. VandeVusse and Hanson and two graduate nursing students (not involved with NFP) did the coding and content analysis for this study. I was not active in the qualitative analysis process, thus the NFP couples responses were analyzed and categorized with a fresh and open mind. Further qualitative research needs to take place that provides a more in-depth understanding of the marital dynamics involved with NFP. For example, how is couple communication increased with NFP? What coping mechanisms are available for helping couples with abstinence and other difficulties with NFP methods? Quantitative research is needed for tracking psychological and marital responses across time and in comparison with other methods of family planning.(RJF)

1. Crowley, P., & Crowley, P. *Report to the Papal Birth Control Commission*. Notre Dame, IN: University of Notre Dame, Archives, 1966.
2. McClury, R. *Turning Point*. New York: Cross Roads, 1995.
3. VandeVusse, L., Hanson, L., & Fehring, R.J., et al. **Couples' views of the effects of natural family planning on marital dynamics.** *Journal of Nursing Scholarship.* 2003;35:171-176.

RELIGIOSITY AND DESIRE FOR FUTURE PREGNANCY STIMULATES CHOICE FOR NFP

Past studies have shown that when women (in the United States and Germany) are presented with information on NFP in a positive light, about 20%– 40% will indicate that they have interest in using NFP for family planning purposes. However, there are only about 2.3% of US women and about 7% of German women who choose to actually use NFP. Researchers recently conduced a study to determine why there is such a disparity in the interest and use of NFP among women in developed countries.[1] A detailed 14-page questionnaire was administered to 456 women from Berlin and 404 women from Cracow during their post-partum hospital stay. Of these 860 women, 223 or 49% of the Berlin women and 233 or 58% of the Cracow women returned a sufficient questionnaire. Of these women 60% indicated they would consider using NFP, and of these women, 54% actually chose to use NFP with or without condoms. Therefore, 14% of all the women in the study chose to use NFP. The mean age of the Berlin women was 28.4 years and about 89% had completed at least secondary education; the Cracow women had a mean age of 27.1 years and close to 95% had at least a secondary education.

The results showed that those who would consider using NFP (as opposed to those who would not) were more likely to have used NFP in the past, have good knowledge of NFP, have a desire for a future child, perceived that NFP methods were accurate, felt that periodic abstinence was good for their relationship and gave high importance to religious beliefs. Those who actually chose to use NFP (as opposed to those who did not) had the additional factors of "being married and having only one child." The researchers then conducted a regression analysis on the outcome items of "interest to use" and the "choice to use" NFP and found that knowledge of NFP, past use of NFP and expected effects of abstinence were associated with interest of NFP. However, desire for future pregnancy, location in Cracow, and the importance of religion were associated with the choice to use NFP. The researchers cautioned that the results of the study are limited by the fact the participants were post-partum and fairly well educated women. They concluded that the results suggest that increased access and cultural support would likely lead to a higher use of NFP in developed countries.

Comment

Almost 99% of the Cracow women were Catholic as opposed to only 7.8% of the Berlin women. I suspect that the location factor in choice of use of NFP was influenced by the fact

that Cracow is a very Catholic and religious city. The authors speculated that the use of NFP is not necessarily associated with a denomination but rather with the belief that fertility is a divine gift. (RJF)

1. Mikolajczyk, R.T., Stanford, J.B., & Rauchfuss, M. **Factors influencing the choice to use modern natural family planning.** *Contraception.* 2003;67:253-258.

STUDY SUGGESTS THAT PEAK MUCUS DAY HAS HIGHEST PROBABILITY FOR CONCEPTION

Researchers at the University of Utah and the National Institute of Environmental Health Sciences recently conducted a study to determine the day-specific probabilities of pregnancy in relation to the timing of intercourse and the quality of self-observed vulvar mucus among a group of normal and sub-fertile couples.[1] The couples came from six different Creighton Model Fertility*Care*™ System centers in four different cities in Missouri, Nebraska, Kansas, and California. The Creighton Model (CrMS) is a cervical mucus system of natural family planning that utilizes a standardized vulvar discharge recording system. The researchers retrospectively obtained two groups of CrMS system users; one group was comprised of couples with normal fertility who had the initial intention of avoiding pregnancy and the other group were couples defined as sub-fertile based on having previous difficulty in achieving pregnancy. There were 309 couples in the normal fertility group that generated 1,681 usable data charts and 117 couples in the sub-fertile group that yielded 373 cycles of usable data. Two research assistants and one researcher identified the peak day for each cycle and the day or days of intercourse 6 days before and 4 days after the peak day of cervical mucus. A numerical score for the peak day and the 5 days before was calculated based on a mucus scoring system developed by Dr. Thomas Hilgers from the Pope Paul VI Reproductive Institute (Omaha). A statistical model was used to determine the day-specific probabilities of pregnancy and to accommodate multiple acts of intercourse during the potential fertile phase.

The researchers found 81 pregnancies among the 1,681 cycles from the couples of normal fertility and 30 pregnancies among the 373 cycles of data from the couples with sub-fertility. All pregnancy cycles had acts of intercourse 6 days before to 3 days after the peak day of cervical mucus. The researchers calculated that the highest probability of conception was on the peak day of cervical mucus with a probability of 0.38 for couples of normal fertility and 0.14 for sub-fertile couples. The probability of pregnancy was higher than 0.05 from 3 days before to 2 days after the peak day of cervical mucus for couples of normal fertility and from 1 day before to 1 day after for couples of sub-fertility. They also found a linear positive relationship between the mucus cycle scores and the probability for pregnancy among the normal fertile couples but not the sub-fertile couples. However, there was no significant difference between the mucus cycle scores of the normal and sub-fertile groups. The researchers concluded that a standardized system of rating vaginal mucus discharges can help couples of normal fertility and of sub-fertility identify the days of the menstrual cycle that have the greatest likelihood of conception. They also speculated that the highest probability of pregnancy occurred on the peak mucus day – their estimated day of ovulation.

Comment

I agree with the analysis, that the peak day of cervical mucus coincides with the day of the highest probability of pregnancy. However, I would also say that the highest probability of pregnancy is on the two days before the day of ovulation and that the highest quality of cervical vaginal mucus is usually on those two days. I base this statement on the research by Dunson and others that indicated the highest probability of pregnancy is on the day before

PLEASE LET US KNOW WHAT YOU THINK OF THE CONTENT OF THIS SUPPLEMENT. IS THE RESEARCH PRESENTED OF INTEREST TO YOU? WHAT OTHER RESEARCH WOULD YOU LIKE TO SEE FEATURED? DO YOU HAVE QUESTIONS WHICH YOU WOULD LIKE TO SEE ANSWERED IN EDITORIALS?

Call us at (202) 541-3240

We look forward to hearing from you!

ovulation and on my research that showed the highest average of quality mucus on the two days before the estimated day of ovulation (based on the day after the urinary LH surge).[2,3]

The authors do indicate a limitation of this study: no reference marker was given for the day of ovulation, e.g., follicular ultrasound. Another limitation of the study is that the sub-fertile couples were on average older then normal fertile couples. For example the average age of the normal fertile women was 27 years and the sub-fertile 30.3 years.

This affected the difference in probability of pregnancy between the normal fertile and the sub-fertile groups of couples. (RJF)

1. Stanford, J.B., Smith, K.R., & Dunson, D.B. **Vulvar mucus observations and the probability of pregnancy.** *Obstetrics & Gynecology.* 2003;101:1285-1292.
2. Dunson, D.B., Baird, D.D., & Wilcox, A.J., et al. **Day-specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation.** *Human Reproduction* 14 (July, 1999):1835-1839.
3. Fehring, R. **Accuracy of the peak day of cervical mucus as a biological marker of fertility.** *Contraception.* (2002): 836-47.

TURKISH WOMEN ABLE TO USE BILLINGS OVULATION METHOD TO DETERMINE PATTERNS OF FERTILITY

Turkish researchers from Istanbul Medical School at Istanbul, Turkey recently conducted a small study to determine the accurate usage of cervical mucus to estimate the time of ovulation.[1] The participants were 15 women who applied to the Education and Research Unit of Istanbul University to learn the Billings Ovulation Method (BOM). The 15 women were between the ages of 25 and 43 years (mean age 32) and had no known fertility problems or vaginal discharges. They were taught the BOM and how to use the Clearplan LH detection kit to measure the urinary LH surge as an estimate of ovulation. The women were able to generate 30 cycles of data.

The results showed that the average length of the cervical mucus symptoms were 10 days. The peak in cervical mucus was on average day 13.65 ± 2.62 of the cycle and the day of the LH surge in the urine was on average day 13.40 ± 2.58. The correlation between the mucus peak and the LH surge was 0.956 $p \leq 0.001$. The researchers concluded that Turkish women could self-detect changes in cervical mucus and that the peak in cervical mucus correlated closely with the urinary LH surge.

Comment

The researchers also mentioned that the present study might play a role in promoting urinary LH kits as adjunctive devices in the education and use of NFP. The study findings are very similar to the numerous studies since 1977 in which the self-observed peak in cervical mucus is correlated with a serum or urinary hormonal marker of fertility. The study is old in that the "gold standard" for estimating the day of ovulation is the use of serial ultrasound to monitor the developing follicle and resulting collapse at ovulation. (RJF)

1. Attar, E., Gokdemirel, S., Seraroglu, H., & Coskun, A. **Natural contraception using the Billings ovulation method.** *The European Journal of Contraception and Reproductive Health Care.* 2002;7:96-99.

SIMPLE NATURAL FAMILY PLANNING METHODS FOR BREASTFEEDING WOMEN

Regardless of whether a woman's menstrual cycle has returned afrer giving birth or not, use of NFP methods during breastfeeding can be difficult. Breastfeeding not only affects the regularity of cycles (both the length and phases of the cycle) but also the common natural indicators of fertility such as cervical mucus and basal body temperature patterns. The time in which breastfeeding women often achieve pregnancy is during the transition from breastfeeding/no cycles to breastfeeding/cycles. Current NFP methods (both temperature and mucus based methods) manage breastfeeding while not in cycles by having women users determine a consistent pattern of cervical mucus characteristics or of dryness. Any change from the consistent pattern and three full days after is considered fertile. However, the use of either the Sympto-Thermal methods (STM) or the Ovulation Method (OM) during breastfeeding can be difficult at times. Use of current methods of NFP (during breastfeeding) results in over estimating the actual days of fertility, prolonged periods of mucus requiring long periods of abstinence, confusing mucus patterns and an increased pregnancy rate.[1-3]

Researchers at the Georgetown University Institute for Reproductive Health (IRH) have developed two simple methods of NFP, the Standard Day Method (SDM) and the TwoDay Method (TDM). Both of these methods have been reported in the literature and in past issues of *Current Medical Research*.[4-6] The SDM is a fixed day system in which days 8-19 of the menstrual cycle are considered fertile. The method is intended for women who have cycles between 26 and 32 days in length. When used correctly the SDM has a one-year effectiveness rate (to avoid pregnancy) close to 95%. The TDM requires the user to determine if she has observed mucus symptoms that day or the day before, if "yes" to either of those days, she then considers herself fertile. Georgetown University IRH researchers recently determined the potential (i.e., theoretical) effectiveness of both of these simple NFP methods by applying their algorithms to data charts from a past study on the effectiveness of STM with breastfeeding women.[1,7]

The pre-existing data charts were from 73 breastfeeding women in Australia, Britain and Canada who were followed from postpartum day 42 through two potentially fertile cycles in 1986 through 1990.[1] Daily urine samples were collected and assayed for metabolites of estrogen and pregnanediol glucuronide in order to estimate the potential fertile days and the day of ovulation. The women participants also recorded the frequency of breastfeeding episodes. The Georgetown researchers utilized 274 of the potential 359 cycles in which the woman participant was fully or partially breastfeeding. Cycle zero was defined as the time before the first postpartum menses. The fertile phase was defined as the estimated day of ovulation (EDO) and the five days before. The mean number of days before the first menses (i.e., for cycle zero) was 215.9 (range 65-469). The mean length of the first cycle postpartum was 34.6 days (range 15-115). By the 5th cycle the mean length was 28.6 days and the range 22-35 days.

The SDM algorithm could not be utilized for cycle zero (i.e., the time before the first menses) since it is based on counting from the first day of menses. However, when applied to the first cycle postpartum the day specific probability of pregnancy ranged from 0.0092 on ovulation day minus five to a high of 0.0753 the day before the EDO. The highest average probability of all 204 cycles was 0.0529 on the day before the EDO. The researchers concluded that SDM was not as effective for breastfeeding women as for non-breastfeeding women. The highest probability of pregnancy for non-breastfeeding women on any given day was 0.0108 in past studies. However, when they applied the algorithm to just those cycles that fell within the 26-32 day cycle length range, the highest probability was 0.0170 (N = 111 cycles) on the day before the EDO. They also found that by waiting 4 or more cycles after menses resumes,

the highest probability was 0.0338 the day before the EDO. The researchers calculated that up to 75% of breastfeeding women would not be able to use the SDM in the early postpartum period.

Unlike the SDM, the TDM could theoretically be used during cycle zero when the women participants were not in cycles. This is so since the TDM is based upon the presence or absence of cervical mucus and not the first day of menses. However, the Georgetown researcher found that during cycle zero, there was a mean of 77 days with detected secretions and during the later part of cycle zero (i.e., as the women participants approached their first ovulation) 80% or more of the days had cervical secretions. They concluded that based on the extensive number of days of secretions and the extensive time required for avoiding intercourse, the TDM may not be acceptable for breastfeeding women not in cycles.

However, when the TDM was applied to breastfeeding women who were in cycles it was theoretically very effective. The highest day specific probability of pregnancy for all cycles (N = 204) was 0.009 on ovulation day minus 4. The probabilities of pregnancy ranged from a high of 0.0142 two days before the EDO in the first cycle after the return of menses to 0.0026 on the EDO and the EDO minus day 3 and day 5. The researchers also found that the probability of pregnancy was very low regardless of the daily number of breastfeeding episodes. However, they did notice that those women who breastfeed 6 or more times a day experienced less cervical secretions.

A final issue that the researchers addressed when using the SDM and the TDM during breastfeeding was the length of abstinence required. Obviously the SDM requires only 12 days on a consistent basis when used by breastfeeding women who are in cycles. The TDM required a mean of 18.7 days (median 19) and a range of 3-84 days. The number of days as a proportion of the cycle calculated out to be a mean of 52.9% - which is about half of the length of the menstrual cycles included in the study. In comparison, the study in which the pre-existing data was obtained determined that a mean of 79% of the days would be required for abstinence with the Sympto-Thermal method (STM).[1]

Comment

Another interesting finding from the Georgetown research was that 67% of the women participants ovulated before their menses. However, the researchers calculated that only 49% of these cycles could sustain a pregnancy based on the estimated day of ovulation and the length of the luteal phase. Women who breastfeed less than 5 times a day were more likely to have an ovulatory cycle zero that could sustain a pregnancy.

Although the SDM and the TDM theoretically have an effective application for specific sub-groups of women during breastfeeding (e.g., the SDM once regularity is assumed and the TDM for the early breastfeeding in cycles time period) the researchers concluded that there remains a need for simple fertility awareness based methods during breastfeeding. The Georgetown researchers suggested further research and "tweaking" of these simple natural methods, such as extending the SDM from 12 days to a longer time period during the first cycles after the first menses (i.e., until cycle regularity is established) and possibly combining the SDM and TDM.

Teachers and advocates of the STM and OM methods might argue that their methods are already simple and effective during breastfeeding. However, the length of abstinence required and the actual effectiveness to avoid pregnancy (e.g., around 78%) invites us to find better ways. I am pleased that the Georgetown IRH research group has ongoing research to help get a better understanding of natural methods during breastfeeding and their effectiveness.(RJF)

1. Labbok, M.H., Stallings, R.Y., Shah, F., Perez, A., Klaus, H., Jacobson, M., and Muruth, T. **Ovulation method use during breastfeeding: Is there increased risk of unplanned pregnancy?** *American Journal of Obstetrics and Gynecology*. 1991;165:2031-2036.
2. Zinaman, M. and Stevenson, W. **Efficacy of the sympto-thermal method of natural family**

planning in lactating women after the return of menses. *American Journal of Obstetrics and Gynecology*. 1991;165:2037-2039.
3. Kennedy, K.I., Gross, B.A., Parnteau-Carreau, S., Flynn, A.M., Brown, J.B. and Visness, C.M. **Breastfeeding and the sympto-thermal method.** *Studies in Family Planning*. 1995;26:107-115.
4. Arevalo, M., Jennings, V. and Sinai, I. **Efficacy of a new method of family planning: the Standard Day Method.** *Contraception.* 2002;65: 333-338.
5. Sinai, I., Jennings, V. and Arevalo, M. **The TwoDay Algorithm: A new algorithm to identify the fertile time of the menstrual cycle**. *Contraception*. 1999;60:65-70.
6. Jennings, V. and Sinai, I. **Further analysis of the theoretical effectiveness of the TwoDay method of family planning**. *Contraception*. 2001;64:149-153.
7. Arevalo, M., Jennings, V. and Sinai, I. **Application of simple fertility awareness-based methods of family planning to breastfeeding women**. *Fertility and Sterility.* 2003;80:1241-1248.

CLOSE TO 90% OF FERTILE COUPLES ACHIEVE PREGNANCY WITHIN 6 MONTHS USING STM AND FERTILITY FOCUSED INTERCOURSE

There are relatively few published prospective studies that estimate cumulative pregnancy rates among couples trying to achieve pregnancy with the use of natural markers of fertility. Previous studies are mostly retrospective or exclude infertile couples. Researchers from the University of Dusseldorf and Heidelberg recently reported the largest prospective study among volunteer couples using the sympto-thermal method (STM) of natural family planning (i.e., mucus symptoms and temperature shift) to achieve pregnancy.[1] The purpose of the study was to estimate the cumulative probabilities of conception (CPC) among a cohort of couples using natural family planning from their first cycle onwards.

The German researchers recruited 346 couples that indicated a desire to achieve a pregnancy from 1,357 couples that were taught the STM by experienced NFP teachers. The 346 couples were observed from the first cycle they attempted to achieve a pregnancy. Pregnancies were confirmed by ultrasound, a positive pregnancy test, or a luteal phase greater than 18 days. Prior to each cycle the volunteer couple indicated their intention to achieve a pregnancy and during that cycle recorded all acts of intercourse. Cycles that did not have at least one act of intercourse during the fertile phase were excluded. This turned out to be about 3% of the cycles in the study. The mean age of the women volunteers was 29.0 $\pm$ 3.6 (range 20-44) and the mean age of their male partners was 31.6 $\pm$ 5.5. There were a total of 310 pregnancies among the 346 couples during a maximum of 29 cycles of observation. The researchers labeled the couples that achieved a pregnancy as "truly fertile (TF)."

The cumulative pregnancy rates for cycles 1, 3, 6 and 12 for all couples (N = 340) were 0.38, 0.68, 0.81, and 0.92 respectively. For the TF couples (N = 304) the pregnancy rates at cycles 1, 3, 6, and 12 were 0.42, 0.75, 0.88, and 0.98. Therefore, close to 90% of the TF couples and close to 80% of all couples in the study achieved a pregnancy within the first 6 cycles of fertility-focused intercourse. A total of 8% of all the volunteer couples failed to conceive with the first 12 cycles of trying and were considered sub-fertile. For approximately 30% of these couples this was a secondary infertility (i.e., couples who had conceived at least once in the past). The researchers also found a significant age-related decrease in CPC for all the couples (i.e., the combination of the truly fertile and sub-fertile couples). However, among the TF couples there was no significant age-related decrease in CPC.

Based on the findings from this prospective CPC study, the researchers made some clinical recommendations.[1,2] They concluded that since almost 20% of couples do not achieve pregnancy within 6 cycles of fertility-focused intercourse (and approximately 10% of truly fertile couples) that almost every second couple is either sub-fertile or infertile after 6 cycles of trying to achieve a pregnancy. Therefore, they proposed a new threshold of referring for or initiating a basic infertility work-up by a primary care provider; i.e., they recommended

referring couples that have 6 cycles of fertility-focused intercourse utilizing STM without achieving a pregnancy for a primary infertility workup. However, if the couple in question has a good prognosis (i.e., no unexplained infertility, no tubal defects, low sperm counts, no oligoamenorhoea, and no signs of reduced ovarian reserve) and the woman's age is less than 35 years, they recommended only fertility-focused intercourse during the next 36 months – i.e., these couples have a fairly good chance (greater than 60%) of achieving within that time period. Finally they also recommended an advanced infertility work-up for couples with a poor prognosis and 12 unsuccessful cycles with fertility-focused intercourse.

Comment

The results and recommendations from this study are similar to those of a smaller study conducted by Hilgers and others with the Creighton Model Fertility*Care*™ (CrMS) ovulation method.[3] Hilgers also has recommended infertility work-up referral for couples that practice fertility focused intercourse with the CrMS and do not achieve within 6 months of trying. The normal practice is for a couple to have at least 12 months of random unprotected intercourse before an infertility workup would be recommended. The recommendation that couples who have a primary infertility work up and have no tubal defects, anovulation, and oligospermia just use NFP for the next three years could save a lot of money and avoid expensive advanced reproductive techniques. However, besides utilizing NFP to determine the fertile window for fertility focused intercourse, I would also recommend lifestyle changes that would help increase the chances of pregnancy, i.e., proper diet, exercise, stress management, no smoking, and rest.(RJF)

1. Gnoth, C., Godehardt, D., Godehardt, E., et al. **Time to pregnancy: results of the German prospective study and impact on the management of infertility.** *Human Reproduction*. 2003;18:1959-1966.
2. Gnoth, C., Frank-Hermann, P.m. and Freundl, G. **Opinion: Natural family planning and the management of infertility.** *Archives of Gynecology and Obstetrics*. 2002;267:67-71.
3. Hilgers, T.W., Daly, K.D., Prebil, A.M. and Hilgers, S.K. **Cumulative pregnancy rates in patients with apparently normal fertility and fertility-focused intercourse.** *Journal of Reproductive Medicine*. 1992:37:864-866.

USERS OF PERIODIC ABSTINENCE IN DEVELOPING COUNTRIES HAVE FEWER ABORTIONS THAN CONTRACEPTIVE USERS

According to studies conducted through the auspices of the United Nations, at the turn of the (21st) century approximately 27 million (2.6%) couples of reproductive age world-wide were using some form of periodic abstinence (PA) as a means of child spacing. Of these 27 million couples, 21 million came from developing countries. Researchers recently reported a survey study among users of PA in 15 developing countries: 1) to determine if correct knowledge of the fertile period leads to better use-effectiveness; 2) to determine if unwanted pregnancies from PA users are more or less likely to be aborted than unwanted pregnancies from women using other forms of contraception; and 3) to identify the characteristics of couples who choose to use PA rather than other methods.[1]

The data for this study came from 4 Asian, 2 sub-Sahara African, 2 Arab and 7 Latin American countries that participated in a nationally representative survey conducted under the Demographic Health Survey (DHS) UN project. The respondents were women between the ages of 15 and 49 years. Based on the number of reported pregnancies while using PA the researchers determined gross pregnancy rates with life-table procedures. With 8,387 documented PA-use episodes they calculated a median 12-month probability of pregnancy of 23.6 per 100 episodes. The highest pregnancy rate was 38 per 100 in Jordan, and the lowest

12 per 100 in Nicaragua. However, when the researchers factored in a "correct knowledge of the fertile period" the overall pregnancy rate decreased by 12%. The researchers also found that women who used PA and experienced "unwanted" pregnancies were less likely to report an abortion (or miscarriage) than those who experienced an unintended pregnancy with modern methods of contraception (15% vs. 23%) or with another so called traditional method (15% vs. 35%). PA use was more likely to be used by older women and single women, by more educated women, and by women who have exceeded their family size. However, those women who had less than the desired amount of children were more likely to choose PA than women who achieved their desired family size.

Comment

A limitation of this study is that the survey questionnaire did not make a distinction between abortions and miscarriages. However, the researchers did indicate that it was reasonable to assume that the majority were induced abortions rather than miscarriages. They indicated that abortion is severely restricted in all study countries except Armenia and Kazakhstan, and that "under reporting is to be expected and abortion/miscarriage probabilities should be regarded as lower-bound estimates." (p.20) Another confounding variable is what they include as PA – i.e., self devised calendar methods to modern NFP methods! PA was defined in the questionnaire as "Every month that a woman is sexually active she can avoid having sexual intercourse on the days of the month she is most likely to get pregnant." Current users are then asked how they determined the days of sexual abstinence with the following pre-coded responses, calendar, body temperature, cervical mucus/Billings method, both or no specific system. It would be nice to find out how the abortion/miscarriage rates compared with women who used modern NFP systems.

Another interesting finding is the level of knowledge of the fertile period among PA users. Only 62% of PA users were able to identify "in the middle of the cycle," as the correct answer to knowledge of the fertile period. The other choices in the survey were – "during her period," "right after her period," and "just before her period." The correct knowledge among current users of PA ranged from a low of 8.2% in Zimbabwe to a high of 90.6% in Kazakhstan. Users of PA in the Philippines had a surprising low percentage of correct answers (25.7%). The researchers concluded that up to half of the 21 million PA users in developing countries are probably practicing an entirely erroneous version of the calendar method.(RJF)

1. Che, Y., Cleland, J.G. and Mohamed, M.A. **Periodic abstinence in developing countries: an assessment of failure rates and consequences**. *Contraception*. 2004;69:15-21.

FERTILITY MONITORS

OVARIAN MONITOR RESULTS FOUND TO BE COMPARABLE TO LABORATORY STANDARDS

The Home Ovarian Monitor has been in development for over 10 years primarily under the influence of James Brown from Australia. The Ovarian Monitor is designed to measure urinary assays of estrone glucuronide (E1G) and pregnanediol glucuronide (PdG) as measures of ovarian activity during a woman's menstrual cycle. Researchers from New Zealand, Australia, and Chile, undertook a study to determine the accuracy and reliability of the Ovarian monitor in comparison to those found in a laboratory.[1] Approximately 60 women volunteers with a mean age of 34 years, regular ovulatory cycles, who were current users of a method of NFP and who charted their fertile signs were asked to use the Ovarian Monitor for 6 cycles. These volunteers generated close to 360 cycles of data. The researchers

then randomly selected 18-19 of these cycles to compare the results with Ovarian Monitor results at the three centers by experts and with the results from a World Health Organization reference laboratory in London.

The researchers essentially compared the initial E1G rise (which indicated the beginning of fertility), the peak levels of E1G (which indicated the peak in fertility and the approximate time of ovulation), and the PdG threshold level (which indicated or confirmed that ovulation occurred). The overall correlation between the Ovarian Monitor E1G results and the laboratory results utilizing radioimmunoassay methods (RIA) was 0.653 (range 0.581-0.949) and the overall correlation between the Ovarian Monitor and the laboratory PdG results was 0.842 (range 0.712 to 0.968). The Ovarian Monitor agreed with the laboratory in determining the day of the E1G rise in 50% of the cycles, but was delayed by up to 3 days in the other 50%. In contrast the day of the peak in E1G and the PdG threshold by the monitor agreed very closely to the laboratory results. Overall, the correlation between the results from the monitor and the laboratory results were better than 0.84 in 80% of the cycles. The researchers concluded that the results of the monitor produced by women in the home setting were comparable to those produced by laboratory procedures. However, the researchers also indicated that the women volunteers needed close supervision to maintain quality control.

Comment

When the researchers asked the women volunteers if they would use the Ovarian Monitor as a means of natural family planning they answered that they would prefer to monitor their own symptoms. The average time to conduct the P1G test with the monitor is around 40 minutes and the PdG test about 15 minutes. The monitor also requires timed urines (over a minimum of three hours) and diluting the urine in a large jug. Furthermore, close supervision is required to maintain quality. Therefore, at this time the Ovarian Monitor is viewed as a research tool to improve current methods of NFP and as a possible alternative to more costly laboratory testing. The monitor costs about $220 and each assay tube about 40 cents. (RJF)

1. Blackwell, L.F., Brown, J.B., & Vigil, P., et al. **Hormonal monitoring of ovarian activity using the Ovarian Monitor, Part I. Validation of home and laboratory results obtained during ovulatory cycles by comparison with radioimmunoassay.** *Steriods.* 2003;68:465-476.

DETERMINING THE FERTILE PHASE: A COMPARISON OF THE CLEARPLAN EASY FERTILITY MONITOR™ WITH SELF-ASSESSMENT OF CERVICAL MUCUS

The accurate determination of the 6 days of fertility during the menstrual cycle (i.e., the fertile phase) and the peak of fertility is critical for women and couples who wish to use natural biological markers to achieve or avoid pregnancy. Self-monitoring of cervical-vaginal mucus is one of the most common biological markers used in the self-assessment of the fertile window. However, cervical mucus can at times be a confusing and subjective biological marker.[1-4] The Clearplan Easy Fertility Monitor (CPEFM) (Unipath Diagnostics Company, Princeton, New Jersey) is a relatively new electronic device that has been developed to help women determine their fertile window.[5] The CPEFM measures urinary metabolites of estrogen and LH and provides the user with a daily indication of "low", "high" and "peak" fertility. Evidence from the manufacturer shows that, on average, the monitor will provide the user with 3-5 days of high to peak fertility. Research also shows a strong correlation of the CPEFM "peak" with the actual day of

ovulation as determined by serial transvaginal ultrasound and serum measures of LH and the rise of circulating estrogen.[6]

Researchers from Marquette University and Atlanta, Georgia recently conducted a study to compare the beginning, peak, and length of fertility in a woman's menstrual cycle as determined by the CPEFM with the beginning, peak, and length of the fertile period as determined by self-monitoring of cervical mucus.[7] The comparison was made with a 6-day fertile phase as the standard for comparison (i.e., the day of ovulation and the 5 days preceding ovulation). The estimated day of ovulation was defined as the day after the LH surge or, i.e., the second "peak" day on the CPEFM. One hundred volunteer women participants (mean age 29.4) were recruited for this study. They observed their cervical mucus and monitored their urine for estrogen and LH metabolites with the CPEFM on a daily basis for 2-6 cycles and generated 378 cycles of data; of these, 347 (92%) had a CPEFM peak. The beginning of the fertile window was, on average, day 11.8 (SD = 3.4) by the monitor and day 9.9 (SD = 3.0) by cervical mucus ($r = 0.43$, $p < 0.001$). The average first day of peak fertility by the monitor was 16.5 (SD = 3.6) and by cervical mucus 16.3 (SD = 3.7) ($r = 0.85$, $p < 0.001$). The mean length of the fertile phase by the monitor was 7.7 days (SD = 3.1) and by cervical mucus 10.9 days (SD = 3.7) ($t = 12.7$, $p < 0.001$).

Therefore, the beginning of the fertile phase as determined by the CPEFM was, on average, almost 2 days later than the beginning of fertile phase as determined by the self-observation of cervical mucus. These results make sense in that the monitor is based on an elevated threshold level of urinary estrogen and is designed to target the high and peak days of fertility, i.e., narrow the fertile window. The first externally observed signs of cervical mucus probably reflect a lower level of circulating estrogen.

The average day for the peak of fertility by the CPEFM and the self-observation of cervical mucus were very similar (i.e., day 16). The fact that the average length of the fertile phase as determined by cervical mucus was statistically longer by almost 4 days as compared to the CPEFM fertile phase was not surprising. The fertility monitor was designed to narrow the fertile window and past studies have shown that cervical mucus observations overestimate the fertile window by almost 200%. Cervical mucus monitoring also underestimated the beginning of the estimated 6-day fertile phase in about 26% of the cycles in this study. However, as expected, the CPEFM misses the beginning of the fertile window about 40% of the time.

Comment

Use of the monitor as a sole source of avoiding pregnancy would be easier and more accurate if the monitor provided a longer pre-ovulatory warning of fertility, i.e., detected a lower threshold of estrogen. On average, the monitor provides a long enough warning time in about 60% of the cycles. Therefore, to use the monitor as a method to avoid pregnancy would require the use of another marker, unless the woman user is comfortable with a 60% accuracy for the beginning of the fertile phase or uses the monitor as a post-ovulatory device only. Studies are underway to determine the effectiveness of these 2 approaches in using the CPEFM monitor as an aid to estimating the fertile window and avoiding pregnancy.(RJF)

REFERENCES

1. Guida, M., Tommaselli, G.A., Palomba, S., et al. **Efficacy of methods for determining ovulation in a natural family planning program.** *Fertility & Sterility.* 1999;72:900-4.
2. Fehring, R. **Accuracy of the peak day of cervical mucus as a biological marker of fertility**. *Contraception.* 2002;66:231-5.
3. Moghissi, K.S. **Prediction and detection of ovulation**. *Fertility & Sterility.* 1980;34:89-98.
4. Moghissi, K.S. **Cervical mucus changes and ovulation prediction and detection.** *Journal of Reproductive Medicine.* 1986;31(Suppl): 748-53.
5. May, K. **Home monitoring with the ClearPlan Easy Fertility Monitor for fertility awareness.** *Journal of International Medical Research.* 2001;29 (Suppl 1):14A-20A.

6. Behre, H.M., Kuhlage, J., Gassner, C., et al. **Prediction of ovulation by urinary homone measurements with the home use Clearplan Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements.** *Human Reproduction.* 2000;15:2478-82.
7. Fehring, R., Raviele, K. and Schneider, M. **A comparison of the fertile phase as determined by the Clearplan Easy Fertility Monitor and self-assessment of cervical mucus.** *Contraception.* 2004;69:9-14.

QUALITY OF FERTILITY MONITORS ASSESSED BY GERMAN RESEARCHERS

Over the past ten to fifteen years a number of fertility monitors have been developed to help women users determine the fertile phase of their menstrual cycles. These monitors include several varieties of miniature microscopes designed to visualize dried saliva and salivary ferning patterns that indicate fertility (i.e., PG 53, Maybe Baby, PC 2000), three computerized basal body temperature (BBT) monitors that include built in temperature and calendar algorithms (i.e., the Bioself, Cyclotest 2 Plus, Babycomp / Ladycomp) and a hormonal monitor that measures urinary metabolites of E3G and LH (i.e., the Persona). German researchers from Dusseldorf and Heidelberg recently evaluated these monitors in comparison with the Symto-Thermal method (STM) of Natural Family Planning in order to make recommendations on their quality and effectiveness in helping women and couples avoid pregnancy.[1]

Each of the three types of salivary ferning monitors (listed above) was paired with one of the computerized BBT monitors and evaluated by 5 women volunteers. This resulted in each of the monitors being utilized by 15 women. Another 15 women who used the STM to determine their fertile phase were paired with the Persona hormonal fertility monitor. The women participants were between the ages of 21 and 42 with previous cycle lengths between 17 and 40 days. The first 6 cycles of use of each of the computerized BBT monitors and the personal hormonal monitor and 3 cycles of use of the salivary ferning monitors were considered "learning cycles"and the next cycle (i.e., the 7th or 4th) was considered the "test cycle." During the test cycle the women participants underwent daily pelvic ultrasound scanning of their ovaries and the dominant follicle and utilized a Clearplan urinary test kit to determine their surge in LH. The estimated day of ovulation (EDO) was considered to be 12 hours past the maximum follicular diameter and 24 hours past the urinary LH surge. The researchers recruited 65 women volunteers, of which 62 (mean age 31) contributed 122 test cycles.

The fertile phase as determined by each of the monitors and the STM was compared with an 8-day theoretical fertile phase based on the EDO. The eight-day theoretical fertile phase included the EDO, and the 5 days before and the 2 days after the EDO. The researchers also evaluated the monitors and the STM on the day specific probabilities of pregnancy during the 8-day theoretical phase of fertility. The day specific probabilities were taken from a previous study that utilized the BBT shift as the reference point. From this data the German researchers were able to calculate the correct identification of the days of fertility, and the false negative and false positive days for each monitor and the STM. They then gave an overall quality score for each of the monitors and the STM. The quality scores were between 0 and 1, with the smaller the score (i.e., the score closest to 0) indicating a good method for preventing pregnancy. A score near 1 would indicate that the method was not much better than using no method.

The salivary fertility monitors had the highest false negative rates (i.e., a theoretically fertile day that was indicated as infertile by the monitor) from 51.6% to 73.4% of the cycle days

monitored, followed by the Persona hormonal monitor (20.8%) and then the computerized BBT monitors (1.7% to 4.7%). The STM had "0" false negatives. The highest false positive readings (i.e., a theoretically infertile day which was predicted as fertile by the monitor) ranged from a low (6.6%) by the PG 53 salivary ferning monitor and a high (53.9%) with the computerized Bioself BBT monitor. The Persona fertility monitor had a 23% false positive rate and the STM a 25.3% false positive rate. The STM had the highest correct rate of predicting the fertile days (82%) and the Bioself BBT monitor had the lowest (58.4%). The Persona had a 77.6% correct fertility rate.

The German researchers calculated that the STM obtained the best quality score (0.000) and lowest average day specific probability of pregnancy (0.000). The computerized BBT monitors obtained the next best quality scores (range 0.0483 to 0.1213) and lowest average day specific probability of pregnancy (range 0.0134 to 0.0336). The Persona hormonal monitor had a quality score of 0.4169 and an average day specific probability of pregnancy of 0.1155. The salivary ferning microscopes received the lowest quality scores (range 0.8349 to 0.8552) and the highest day specific probability of pregnancy (range 0.2313 to 0.2369).

The German researchers concluded that only those monitors that received quality index scores of less than 5 should warrant further study and be utilized in large prospective population based effectiveness studies. Based on their findings they only recommended that the STM, the computerized BBT monitors and the Persona monitor be further studied in large prospective clinical trials. The salivary ferning monitors were not recommended for client use or for population based efficacy studies.

Comment

There is a need to evaluate fertility monitors that can be purchased by the consumer and are readily available. The German researchers from the University of Dusseldorf and Heidelberg conducted an objective study of fertility monitors that are available in Europe. The study utilized gold standards (i.e., follicular ultrasound and urinary LH) to estimate the day of ovulation and to evaluate the fertile phases as determined by 7 fertility monitors and the STM. For the most part I agree with their methodology and results, however, I have some observations and concerns.

First of all, I found it interesting that they utilized an 8-day window of fertility rather than a 6-day window that has become somewhat standard in fertility assessment. The 6-day window is based on several research studies at the National Institute of Environmental Health Sciences and that have been reviewed in the *CMR*.[2,3] With an 8-day window you will find less false positive days on fertility monitors that are less precise, i.e., like the BBT monitors and the STM, and more false negatives with more accurate devices like the Persona. For example, if you would base the accuracy of a given fertility monitor on a 6 day window of fertility – with day 6 the EDO, then, a monitor that indicated "fertility" on EDO minus 6 or 7 days or EDO plus one day would be considered a false positive, but with the 8-day window they would not. The results of this study were also biased towards the STM and electronic BBT monitors since the estimated day specific probability of pregnancy are based on a BBT shift model -- a model that utilized a less precise indicator of fertility and the EDO.

It is not astonishing that the STM had zero false negatives, since the average estimated days of fertility are double the 6-day window of fertility. However, that it only had a 25% false positive rate is. When almost double the actual days of fertility are common with the STM method, one would expect a close to 50% false positive rate.

I also found it rather fascinating that one of the markers of the EDO was the urinary LH surge detected with the Clearplan fertility test kit. The Clearplan LH test kit and the Persona monitor are made by the same company (i.e.,Unipath). The Persona monitor uses a similar assay of urinary LH to determine the beginning of the end of fertility. Although Persona has an estimated correct use failure rate of 6.4%, the Persona with a new algorithm needs to be prospectively tested in a population of users to determine its actual population effectiveness. A recent Italian study at the University of Naples evaluated the accuracy of the Persona

monitor.[4] The Italian researchers utilized 20 volunteer women participants who generated 200 cycles of data. The women participants were also monitored with follicular ultrasound and serum LH to estimate the theoretical fertile window and the EDO. The Persona monitor provides the user with a green light to indicate infertility and a red light to indicate fertility. The beginning of the fertile window by ultrasound was in agreement with the beginning of fertility by the Persona (i.e., the first Red day) 94% of the time, the ultrasound EDO agreed with the Persona EDO 95.8% of the time, and the ultrasound first day of infertility (after ovulation) agreed with the Persona first green day after the red fertile days 97.5% of the time. The Italian researchers concluded that the Persona was effective in recognition of the fertile phase and stated that it was a welcome alternative for couples that want to use NFP. (RJF)

1. Freundl, G., Godehardt, E., Kern, P.A., Frank-Hermann, P., Koubenec H.J. and Gnoth, Ch. **Estimated maximum failure rates of cycle monitors using daily conception probabilities in the menstrual cycle**. *Human Reproduction*. 2003:18(2):2628-2633.
2. Wilcox A.J., Weinberg C.R. and Baird, D.D. **Timing of sexual intercourse in relation to ovulation; effects of the probability of conception, survival of the pregnancy, and sex of the baby**. *New England Journal of Medicine.* 1995;333:1517-21.
3. Dunson, D.B., Baird, D.D., Wilson, A.J. and Weinberg, C. **Day-specific probabilities of clinical pregnancy based on two studies with imperfect measures of ovulation.** *Human Reproduction.* 1999;14:1835-9.
4. Guida, M., Bramante, S., Acunzo, G., et al. **Diagnosis of fertility with a personal hormonal evaluation test**. *Minerva Ginecol*, 2003:55(2):167-73.

MENSTRUAL CYCLES

MENSTRUAL CYCLE DISTURBANCES OBSERVED FOR UP TO NINE MONTHS FOLLOWING DISCONTINUATION OF ORAL CONTRACEPTIVE

Very few studies have been published on the effects of oral contraception on menstrual cycle parameters. Researchers from the University of Dusseldorf have been collecting charts of Sympto-Thermal users for over 15 years.[1] As of July 1, 1998, 22% of the 1,426 women in their data set had previously used oral contraceptives (OCs). From this data set, 175 post-pill women were compared to a similar (according to age and socioeconomic characteristics) group of 284 women who never used OCs. The post-pill women generated 3,048 cycles of data and the control group of women 6,251 cycles. The mean age of the post-pill women was 26.25 years and for the control group 25.29 years.

The results showed that the post-pill group had significantly longer (length) cycles than the control group for up to 9 cycles. Further, with regard to frequency, the post-pill group had significantly longer cycles greater than 35 days for up to 6 cycles.

The follicular phase length (based on the day of the temperature shift minus one day) was significantly longer for up to 8 cycles in the post-pill group. The differences might be as long as 15 cycles, but the number of cycles produced by the post-pill group decreased due to anovulatory cycles or "difficult to interpret" temperature graphs. The biggest difference in the follicular length occurred in the first cycle – with an average prolonged difference of 4 days. There was a significant difference in the first two cycles in the length of the luteal phase, with the post-pill group being shorter, due mostly to insufficient luteal phase lengths (< 10 days). The onset of cervical mucus did not differ between the two groups, but the peak in cervical mucus differed for up to 9 cycles. In the first cycle the average day of peak was 23.19 for the post-pill group and 18.09 for the control group.

The researchers considered major "cycle disturbances" to be those cycles with either a

monophasic BBT, a cycle length over 35 days, or a luteal phase of less than 10 days. Although none of these disturbances were found in 51.4% in the first cycle of the post-pill group, there were significantly more of these disturbances among the post-pill group than the control group for up to cycle 7 due primarily to cycles longer than 35 days. The researchers defined the beginning of regular cycling to be the first of 3 subsequent cycles with a luteal phase of at least 10 days. Based on this definition, over 70% of the post-pill group returned to a regular, ovulatory cycle pattern by the 7th cycle.

Comment

The researchers concluded that although cycle disturbances after discontinuation of OCs are reversible, the time of regeneration takes up to 9 months or longer. They theorized that the delayed regeneration is due to the time it takes for the hypothalamic-pituitary-ovarian axis to normalize and not be influenced by the circulating hormones from the OCs. Although the cycle disturbances, as described by the German researchers, are certainly similar to those observed by NFP teachers, I would urge some caution in interpreting the results. First of all, although the control group was matched by age and socio-economics, it is not a true randomized control and hence the differences could be a result of other factors, e.g., the post-pill group might have had a propensity to cycle disturbances before taking the pill. Secondly, the biological indicators of ovulation used in the study (BBT and cervical mucus) are somewhat imprecise indicators of ovulation, they vary considerably around the actual day of ovulation and just because there is no BBT shift does not mean that the women did not ovulate. Of interest is that 14% of the subjects in the post-pill group and about 9% of the control group were unable to interpret a cervical mucus pattern. (RJF)

1. Gnoth, C., Frank-Hermann, P., & Schmoll, A., et al. **Cycle characteristics after discontinuation of oral contraceptives.** *Gynecological Endocrinology*. 2002;16:307-317.

EARLY START OF FOLLICULAR GROWTH AND LIMITED OOCYTE POOL HELPS EXPLAIN AGE RELATED FERTILITY

Researchers from the Netherlands recently conducted a study to help explain age-related loss of fertility by comparing menstrual cycle parameters from a group of healthy "relatively" young women with cycle parameters from a group of older women.[1] The researchers recruited 26 "relatively" older women (mean age 42; range 41-46) matched them with 35 healthy younger women (mean age 31; range 22-34) and measured their follicular development (by serial transvaginal ultrasound), endometrial growth, and hormonal patterns (i.e., blood levels of LH, FSH, estradiol, and Inhibin A and B). The younger women generated 33 cycles of data and the older women 24 cycles of data.

The researchers found that on average the cycle lengths of the older women were almost 3 days shorter than the younger women's (26.5 days versus 29.0 days) and the shorter cycles were due to the average shorter length of the follicular phase (12.4 days versus 16.2 days). There were no statistical differences between the lengths of the luteal phase between the two groups. Other parameters that reached statistical differences were the cycle day that the dominant follicle was first observed (on average day 7.7 for the older women and day 10.5 for the younger women), the diameter of the follicle just before ovulation was smaller for the older women (19.8 mm versus 21.5 mm), FSH levels for the older women were significantly higher during the late luteal and early follicular phase than the younger women, LH and Inhibin B levels were lower for the older women and the early antral (i.e., immature follicles) follicular count was significantly higher in the younger women (13.6 versus 4.9). Progesterone levels in the luteal phase, endometrial thickness, and the peak of estradiol did not

significantly differ between the two groups. The researchers stated that in contrast to the theory that older women had accelerated follicular development, their data suggest that older women have an earlier start to follicular development that begins in the luteal phase of the previous cycle.

The authors concluded that in spite of a dramatically decreased number of immature follicles, they found that follicular development, hormonal events and endometrial growth are remarkably undisturbed in older women, until the age of 45-46 years. They speculated that an earlier start in follicle growth in a less favorable hormonal environment coupled with a diminished oocyte pool could lead to decreased follicle and oocyte quality and thus result in diminished fertility among older women.

Comment

The authors of this study were careful to describe the differences in the smoking habits between the two groups of women but not the post-hormonal contraception use. They only said that the women needed to be off oral contraception for at least 2 cycles. I would think that the hormonal events of the cycle would be affected more by the post-pill hormones than smoking – especially in light of the German study of post-pill cycles reviewed earlier in this issue of CMR.[2] Readers should also be aware that the groups were selected by convenience and that the differences in cycle parameters could be due to other factors. (RJF)

1. Van Zonneveld, P., Scheffer, G.J., & Broekmans, F.J.M, et al. **Do cycle disturbances explain the age-related decline of female fertility? Cycle characteristics of women aged over 40 years compared with a reference population of young women.** *Human Reproduction.* 2003;18:495-501.
2. Gnoth, C., Frank-Hermann, P., & Schmoll, A., et al. **Cycle characteristics after discontinuation of oral contraceptives.** *Gynecological Endocrinology.* 2002;16:307-317.

WAVES OF FOLLICULAR DEVELOPMENT FOUND IN HUMAN MENSTRUAL CYCLES

Animal models (in particular the bovine estrous cycle) have been used to help understand the human menstrual cycle. During a cow's estrous cycle 2-3 waves of follicular development emerge throughout the cycle at regular intervals and are preceded by an increase of FSH. However, it is only the final wave of development that is ovulatory. Opposed to the wave theory of development is the theory that a single follicle grows by chance during a hormonally optimal period of the menstrual cycle. Based on the observation of ovarian follicular development during the luteal phase among women undergoing high-resolution transvaginal ultrasound, researchers from the University of Saskatchewan, Canada speculated that there might also be waves of follicular development in women as in animal models.[1] To test the hypothesis that wave-like follicular development (i.e., changes in the number and diameter of follicles) occurs in women, the Canadian researchers observed and described the daily growth and regression of ovarian follicles in women during an interovulatory interval (IOI). The IOI was defined as the interval from one ovulation to the next ovulation.

In order to test the follicular wave development theory, the researchers recruited 63 healthy women of reproductive age (average age 28 years and an age range of 19-43 years) to undergo daily "high resolution" transvaginal ultrasound. One ultrasonographer observed 90% of the cycles. Data from 13 of the 63 women participants were excluded due to what they called ovarian irregularities, e.g., 7 of the women developed an ovarian follicular cyst. They used two methods to characterize changes in follicular diameter; 1) the Identity Method in which they observed individual follicles of $\geq$8 mm throughout the IOI, and 2) the Non-Identity Method in which they sorted and counted the follicles of $\geq$4 mm in descending

order of diameter. They identified the waves by defining the peaks and troughs of the graphed follicles. For example, "an increase and subsequent decrease in the number of follicles ≥ 5 mm, occurring in association with the growth of at least two follicles to ≥ 6 mm, was considered a "wave" of follicular development."

What the researchers observed was that 34 of the 50 women (68%) had two waves of follicular development and 16 (32%) had three waves of development. They also observed that the final wave of the cycle was ovulatory and the preceding waves were anovulatory in all 50 women. However, the diameter of ovulatory follicles grew smaller in 3-wave cycles as opposed to the 2-wave cycles. None of the 50 cycles observed had a single wave of follicular development.

The researchers indicated that their hypothesis that follicular development in women occurs in a wave-like fashion during the menstrual cycle was supported. They also stated that this challenges the previously held notion that a single cohort of antral follicles grows only during the follicular phase of the menstrual cycle. They postulated "the development of anovulatory follicles in the luteal phase occurs as a result of P-mediated inhibition of LH secretion to levels that allow follicular development to proceed to the antral or late antral stage, but do not allow the LH surge and ovulation to occur."

Comment

This article caused "waves of astonishment" among NFP users, teachers, and promoters around the world. Not because what was said in the article but rather what was reported about the article in the news and electronic media. Essentially the news media reported that women could ovulate more than once in a menstrual cycle and that NFP does not work. The news media based this erroneous notion on one speculative sentence in the study that mentioned, "it could, therefore, be speculated that follicles developing in the luteal phase of the cycle have the potential to ovulate in the presence of an LH surge" and by later remarks attributed to one of the authors, Dr. Roger Pierson (see below). There was no evidence (whatsoever) in this study that any of the 63 women had more than one ovulation or ovulated in the luteal phase, or had an ovulation other than LH-stimulated. The authors made no mention how their findings applied to NFP. Furthermore, as the authors stated, in order to ovulate you need to have an LH surge, and an LH surge does not happen when a woman is in the luteal phase because of the suppression of LH from the high levels of progesterone secreted by the corpus luteum. In interviews with the media one of the authors speculated on the use of NFP. For example, Dr. Roger Pierson stated in the Women's Health Matters Network web site (http://www.womenshealthmatters.ca/news) "up to 40 per cent of women may not be able to use natural family planning methods. That's because for women who experience two or three waves of dominant follicle growth per month there is no 'safe' time to have intercourse during the cycle — there may always be a follicle capable of ovulating." And he made a disparaging remark about NFP to the Canadian Broadcasting Corporation (CBC) "Dr. Pierson, the lead researcher on the study quipped, 'We have a word for people using natural family planning methods...parents.'" (http://www.cbc.ca/stories/2003/07/08/ovulate030708) These remarks are uncalled for and unprofessional.

The study itself is objective. It has a good theoretical base, clear definitions, and a well-documented method of identifying, classifying and tracking the follicles. This was only one study with a relatively small number of women participants who generated only a small number of cycles. It is interesting that although the women were healthy and in regular cycles, 13 of the cycles had ovarian irregularities. In the "methods" section of the study they stated that ultrasound scans were initiated 12 days after menses indicating that this would be before the first ovulation. I wonder if they missed any early ovulations. The study was hard to follow with regard to which follicles were included in a count and which were tracked on a day-to-day basis. The "waves of follicular development" are not obvious in the figures provided in the article. I also wondered if they were biased towards what they previously

had seen in animal models and in particular the bovine model. The model is also based purely on observations of follicles and not on the hormonal functioning of those follicles.

Although the wave model of follicular development is interesting and provides a different way of viewing the menstrual cycles and the role of the follicles, I did not find a lot new in the article. The fact that follicles develop as cohorts of 11-12 over several cycles is not new.[2] Furthermore it is known that smaller antral follicles, produce only small amounts of estrogen and greater amounts of androgens.[3] The larger antral follicles and in particular the mature graafian follicle secretes larger amounts of aromatase and estrogen. It is speculated that the differences in the secretion levels between the small and large follicles produces a balance of androgens and estrogens in the microenvironment of the ovary and may be instrumental in the selection of the dominant follicle and the regression of other smaller follicles.

1. Baerwald, A.R., Adams, G.P., & Pierson, R.A. **A new model for ovarian follicular development during the human menstrual cycle.** *Fertility and Sterility.* 2003;80:116-122.
2. Palter, S.F., & Olive, D.L. **Reproductive physiology.** Chapter in *Novak's Gynecology* (J.S. Berek Editor) 13th Edition; Philadelphia: Lippencott Williams & Wilkins, 2002. p. 165.
3. Carr, B.R. **The normal menstrual cycle.** Chapter in *Textbook of Reproductive Medicine.* (Edited by Carr, B.R., & Blackwell, R.E.) Second Edition. Stamford, Connecticut: Appleton & Lange, 1997. p. 235.

ISOFLAVONES LENGTHEN MENSTRUAL CYCLE AND MAY HELP PREVENT BREAST CANCER

One of the known risks of women developing breast cancer is the frequency of menstrual cycles over a lifetime and the proliferation of breast tissue during the luteal phase of the menstrual cycle. Women in modern developed countries have almost double the amount of menstrual cycles over a lifetime (either naturally or hormonally induced) than women from developing countries or women from earlier times. This is due to the greater number of pregnancies and the greater frequency of breast-feeding among women in developing countries and from earlier times. Both pregnancy and the practice of breast-feeding lower risks for breast cancer. It is also known that women in Japan and Asia have a much lower rate of breast cancer than women in developed western countries. A big reason for the lower Asian rates is dietary patterns (and in particular the use of soy products) and the increased length of their menstrual cycles. Soy products contain isoflavones that act as phytoestrogens, or, that is, weak estrogens. The estrogenic properties of the soy products in theory can help lengthen the follicular phase of the menstrual cycle.

Researchers at the University of South Florida tested this theory by investigating the effects of one of the major forms of isoflavones called genistein among 66 healthy premenopause, omnivorous women that ranged in age from 25 years to 55 years.[1] The researchers conducted a double blind randomized study by randomly distributing the 66 women into two groups. One group received a soy product (i.e., 40 mg of genisten per day) for 12 weeks and the other group of women received a placebo over a 12-week period (or three menstrual cycles). The researchers measured dietary patterns (through a 4-day diet recall), menstrual cycle lengths (including having the women participants utilize urinary LH tests kits to determine the follicular and luteal lengths of the cycles). The researchers also measured serum levels of estrone, estradiol, and serum hormone-binding globulin (SHBG) at baseline and at the end of the study.

The results showed that women participants who consumed the soy supplement for 3 menstrual cycles significantly increased their cycle length by a mean of 3.52 days and that the control group women decreased their mean length by 0.06 days from baseline to the third menstrual cycle. The mean follicular length of the soy supplement group increased a mean

of 1.46 days compared to a decrease of 0.14 days for the women taking the placebo. The results also showed that SHBG increased by 41.4% in the soy group (as compared to 37.5% in the controls), free estradiol decreased 53.8% in the soy group (as compared to 37.5% in the control) and estrone decreased 55.5% in the soy group (as compared to 42.8% in the control group). The authors concluded that the intake of the soy product influenced estrogen metabolism and menstrual cycle and follicular phase length. They also concluded that genisten intake is a potential means to reduce the risk for breast cancer. They indicated that this is an important finding, because an increase in menstrual cycle length would decrease the number of menstrual cycles over a lifetime, reduce the exposure of breast tissue to estrogen, and the breast tissue would spend more days in the follicular phase of the cycle when proliferation of breast tissue is at the lowest.

Comment

I liked this study for two reasons; one is that is was good from a scientific standpoint, in that the authors used a randomized double blind control group methodology. And two, it involved looking at how lifestyle (and in this case use of nutritional supplements) can effect the menstrual cycle and hormonal production. (RJF)

1. Kumar, N.B., Cantor, A., & Allen, K., et al. **The specific role of isoflavones on estrogen metabolism in premenopausal women.** *Cancer.* 2002;94:1166-74.

VITAMIN C FOUND TO INCREASE PROGESTERONE LEVELS AND CORRECT LUTEAL PHASE DEFECT

Up to 10% of women with primary or secondary infertility and up to 35% of women with repeated or habitual (miscarriages) have a luteal phase defect. The cause of the infertility and pregnancy loss is thought to be a result of an inadequate maturation and development of the endometrium. The reason for the retarded development of the endometrium is thought to be in part due to inadequate levels of progesterone production by the corpus luteum. A reason for poor progesterone production could be due to oxidative stress, free radicals, and high levels of lipoperoxide. Ascorbic acid (Vitamin C) and other anti-oxidative substances helps to prevent oxidative stress and the production of free radicals that interfere with progesterone production. Furthermore, low plasma levels of ascorbic acid (i.e., Vitamin C) have been found in women who habitually miscarry. Ascorbic acid deficiency produces ovarian atrophy and extensive follicular atresia.

Japanese researchers (from Sapporo Medical University School of Medicine) recently tested the effects of Vitamin C on the serum progesterone levels and pregnancy rates of women who have documented luteal phase defects.[1] One hundred fifty patients with a luteal phase defect were randomly assigned to either a control group with no treatment or daily vitamin C (750 mg). The luteal phase defect was defined as having two consecutive menstrual cycles with serum progesterone levels (taken three separate days during the mid-luteal phase) of less than 10 ng/mL. Subjects in the treatment group started daily vitamin C on the first day of the third cycle until pregnancy was confirmed or 6 months after the study was started. All subjects had serum progesterone levels taken at mid-cycle until pregnancy was confirmed or 6 months had lapsed. There were 76 patients in the vitamin C group and 46 in the control group. Twenty-eight patients withdrew from the control group when they found out they were not to be treated.

Prior to the initiation of treatment (i.e., at the first and second cycles) there was no significant difference in the mean mid-cycle serum progesterone levels. After the first cycle of treatment, serum progesterone levels were significantly elevated in the treatment group

but not in the control group. Ten (22%) of the control group subjects and 40 (53%) of the treatment group subjects had mid-cycle serum progesterone levels that increased to at least 10 ng/mL. Nineteen of the treatment group (25%) and 5 subjects (11%) in the control group had a clinically confirmed pregnancy. There was no difference in the miscarriage rate with 16% in the vitamin C group and 20% in the control group. Based on these findings, the researchers concluded that vitamin C supplementation is an effective treatment for some patients with luteal phase defects.

Comment

The findings from this small preliminary study are encouraging. The use of a vitamin C supplementation to help treat low progesterone levels and luteal defects would be easy and inexpensive. However, because of the small number of subjects and the fact that 28 patients withdrew from the control group places some hesitancy on the findings. The Japanese researchers did not show a statistically significant difference in the mean serum progesterone levels between the two groups (even though there was a large mean post treatment difference in progesterone levels, i.e., 104 ng/mL for the control group and 138.7 ng/mL for the treatment group). The lack of statistical significance is probably a reflection of the relatively small number of subjects. A better design would be to have a double blind study, i.e., a study in which the subjects and the researchers did not know which group of subjects were getting the treatment (i.e., the control group would receive a placebo). A double blind study would prevent bias on the part of the researchers and would also help prevent subjects from leaving the study when they find out that they are not receiving the treatment.

1. Henmi, H., Endo, T., Kitajima, Y. et al. **Effects of ascorbic acid supplementation on serum progesterone levels in patients with a luteal phase defect**. *Fertility and Sterility*. 2002;80:459-461.

CONTRACEPTIVES

USE OF ORAL CONTRACEPTIVES LINKED TO BREAST CANCER IN FINNISH STUDY

Studies on the link between the use of oral contraceptives (OC) and breast cancer continue to give a mixed picture, i.e., some studies show a correlation and some studies do not. Much of the mixed results are due to the multifaceted nature of breast cancer, the age of initiation, length, and type of OCs used, whether OCs were used before the first birth, whether there is a familial/genetic risk, lifestyle factors, how many pregnancies brought to live birth, how many abortions, and whether the women breastfeed or not and the length of breastfeeding. The quality and methodology of the research is also another reason for the mixed results, especially when comparison groups are not randomized (which is difficult or impossible to do with such a study).

In any case, the first generation of OC users from the 1960s and early 70s usually initiated use of OCs after the birth of their first child and at a later age. This pattern of use has changed radically over time with now many teenage girls initiating use at a young age and continuing until their first child at a much later date. Many women are now continuously on OCs for 10 or more years. A case controlled study in Finland was conducted to determine whether women who initiated the use of OCs at a young age and before their first child have an increased risk for breast cancer.[1] There were 37,153 recorded cases of breast cancer among Finnish students born between 1946 and 1960. For each of these cancer cases they randomly selected 5 aged-matched controls that did not have cancer. Of these cases, those who used the Helsinki Student Health Service at least three times yielded 150 cases with breast cancer and 316 control subjects for final analysis. The reason that the researchers used those who attended the student health services is that they

were able to obtain records that detail the use of OCs.

The results showed that women who had used OCs had a statistically higher risk for breast cancer (the adjusted odds ratio was 2.1) than those few women who never used OCs. However, the researchers were not able to find a statistically higher risk among women who started OCs at a young age compared to those who were older at initiation of use and there was no difference in the risk between those who started OCs before their first birth and those who started after. The main reason there were no differences is that there were too few subjects who started OCs before 20 or who did not use OCs before their first birth. The authors concluded that the impact of early initiation of OCs cannot be answered until around the year 2010 when those women who were born after the 1960s are in their 40s and 50s. These women will more likely reflect the early use of OCs than the previous generation of OC users.

Comment

The Finnish researchers were only able to find 15 cases who never used OCs among the breast cancer group and 57 among the control group. The fact that they could find so few women who have never used OCs makes this type of research more difficult to detect significant differences.

1. Hemminki, E., Luostarinen, T., & Pukkala, E., et al. **Oral contraceptive use before first birth and risk of breast cancer: a case control study.** *BMC Women's Health.* 2002;2:9 (**http://www.biomedcentral.com/1472-6874 /2/9**)

CONDOM USE ERRORS COMMON AMONG COLLEGE MEN

There have been numerous studies on the consistent and correct use of condoms, but none have investigated a comprehensive range of condom use errors and problems. Correct use of condoms is essential for their efficacy in preventing both pregnancy and sexually transmitted diseases. In order to investigate the prevalence of a comprehensive range of condom use errors, researchers at Indiana University conducted a cross-sectional survey, with a 3-month recall period among 158 heterosexual male students.[1] The male students were selected (by convenience) from introductory health science classes at Indiana University. Three hundred sixty-one students filled out the questionnaire but only 158 men met the study criteria of being heterosexual, never been married, sexually active and reported putting condoms on themselves within the last 3 months. The students were provided a questionnaire that evaluated 24 condom use errors and 4 potential condom related problems. The questionnaire had a section on technical errors, availability errors, communication error, and another section on "other problems."

The four highest ranked technical errors in condom use (based on percentage of the sample reporting the events) were: 1) did not check condom for visible damage (74.5%); 2) did not check expiration date (61.4%); 3) put condom on after starting sex (42.8%); and 4) did not hold tip and leave space (40.4%). Under the availability error section, 42.4% reported that they "wanted a condom but did not have one." Almost 60% reported that they did not discuss condom use before initiating sex. Under the "condom problems" section, 29% reported that the condom broke, 13.1% reported that the condom slipped off during sex, 21.6% lost their erection before the condom was put on, and 19.6% reported that they lost their erection after the condom was on and sex had begun.

The authors admit that the findings are limited since the male student participants were mostly white, educated and heterosexual, and used retrospective recall to provide the information requested by the questionnaire. The authors concluded that a substantial proportion of college men reported a variety of errors and problems that could contribute to

Current Medical Research, a supplement of ***NFP Forum (Diocesan Activity Report)***, is published biannually. Richard Fehring, DNSc, R.N. is the editor. Theresa Notare is the managing editor. The purpose of the supplement is to serve the Roman Catholic diocesan NFP programs of the United States through providing them with up-to-date information on research within the field of fertility, family planning, and related issues. The diocesan NFP teacher should be equipped to understand the various methods of contraception and be able to explain their incompatibility with the practice of the natural methods of family planning.

condom failure. Their answer to this problem (besides more research) is further or more education on correct condom use as a public health strategy.

Comment

I find it fascinating that correct condom use entails more than 24 behaviors. In fact some of the behaviors recommended in government literature were not even listed in the questionnaire, such as removal and disposal of the used condom. I am not sure how providing more education on the use of condoms will increase the ability to properly use condoms during intimacy and the emotional intensity involved with human sexual intercourse. I also find it fascinating that the use of abstinence is not a viable option among unmarried male college students. (RJF)

1. Crosby, R.A., Sanders, S.A., & Yarber, W.L., et al., **Condom use errors and problems among college men.** *Sexually Transmitted Diseases.* 2002;29:552-57.

CONTRACEPTIVE SPONGE IS BACK ON THE MARKET BUT CONTAINS NONOXYNOL-9

According to an article in The Alan Guttmacher Institute's journal, *Perspectives on Sexual and Reproductive Health*, the Today contraceptive sponge is back on the market.[1] The Today sponge is a polyurethane type intravaginal device that is placed over the cervix. The sponge contains and releases the spermicide Nonoxynol-9. The Today sponge was taken off the market in 1995 because the manufacturer failed to meet Food and Drug Administration (FDA) standards. Another manufacturer has bought the copyrights for the Today sponge and is currently shipping the device to Canadian markets. The new manufacturer does not yet have FDA approval but the device is available on the Internet.

Of interest is a recent study showing that multiple use of Nonoxynol-9 could cause toxic effects and actually enhance the HIV-1 infection rate. Belgium researchers tested the effectiveness of a vaginal gel spermicide with Nonoxynol-9 to prevent sexually transmitted diseases among 892 female "sex workers" in four countries (Benin, Cote d'Ivoire, South Africa, and Thailand).[2] The researchers randomized the workers into a Nonoxynol-9 group (N = 449) and a placebo gel group (N = 443). The primary outcome was the rate of HIV-1 infection. They also followed the rates of gonorrhea and chlamydia infections between the two groups. Among the workers who used the gel at least an average of 3.5 times a day there was almost twice the rate of HIV-1 infections among the Nonoxynol-9 gel users than the placebo group. When the rate of use dropped to less than 3.5 times a day there was no difference between the two groups in HIV infections. The researchers also found no differences in the rate of gonorrhea and chlamydia infections. The researchers concluded that the nonoxynol-9 gel could cause toxic effects that enhance HIV-1 infections and that the drug should no longer be considered a potential protection from HIV infection.

Comment

If Nonoxynol-9 can cause toxic effects on the cervix and vagina I would think twice about using the Today sponge as a contraceptive method. The FDA should take into account these findings before approving the Today Sponge for use in the US.

1. Hollander, D. **The sponge bounces back.** *Perspectives on Sexual and Reproductive Health.* 2003;March/April.
2. Van Damme, L., Ramjee, G., & Alary, M, et al. **Effectiveness of COL-1492, a nonoxynol-9 vaginal gel, on HIV-1 transmission in female sex workers: a randomized controlled trial.** *Lancet.* 2002;360:962-3.