



# NATURAL FAMILY PLANNING

## Majority of Hispanic Population Likely to Use Natural Family Planning

A survey was recently conducted with 357 women of reproductive age to determine their interest in using natural family planning (NFP).<sup>1</sup> The women respondents were mostly Hispanic (81.8%). They were recruited among women seeking reproductive health services at an ambulatory clinic in Phoenix, Arizona. While in the waiting room of the clinic, the respondents completed an NFP interest survey which also included questions that ascertained the level of acculturation and other select characteristics of the respondents.

The results showed that 60% of the respondents would be interested in using NFP to avoid pregnancy, and 50% would be interested in using NFP to achieve pregnancy. Lower educated and less acculturated respondents were more likely to use NFP to avoid pregnancy than those with higher education and more acculturation. Those who attended religious services more frequently were more likely to use NFP, but identification with a specific religion had no apparent effect. The aspects of NFP that respondents liked were the fact that NFP is natural (20%); has no side effects (27%); and provides information about the woman's

body (24%). Unappealing aspects of NFP were cited as a perception that it is ineffective (21%) and too difficult to use (11%). The authors concluded that Hispanic women find NFP methods to be an appealing alternative method of family planning.

### Comments

The authors indicated that this was a cross sectional study with a non-random selected sample of mostly Hispanic women. Most of the women were of Mexican origin. The results therefore, cannot be extrapolated to all Hispanic women in the US. The authors noted that expressing interest in NFP does not mean that the respondents will eventually use an NFP method. I would point out that decreasing the barriers to use of these methods, such as providing them with simple to use and easy to learn NFP methods, might help to translate interest to use. (RF)

1. Leonard CJ, Chavira W, Coonrod DV, Hart KW, Bay RC. **Survey of attitudes regarding natural family planning in an urban Hispanic population.** *Contraception*, 2006;74:313-317.

### RESEARCH ON . . .

Natural Family Planning .....	1
Menstrual Cycle .....	5
Fertility .....	7
Contraception .....	11

### Under the Microscope

<i>In Depth—The Rhythm Method and Embryonic Death</i> .....	20
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**Editor:** Richard J. Fehring, DNSc, RN

**Managing Editor:** Theresa Notare, MA

Send all inquires to: DDP/NFP, USCCB, 3211 4th St., N.E. Washington, DC 20017.

Questions: 202-541-3240/3070;

FAX 202-541-3054; nfp@usccb.org

## Male Participation and Cooperation Found to be Important for Correct Use of Fertility Awareness-Based Methods of Family Planning

Used correctly, natural family planning (NFP) and fertility awareness methods (FAM) are very effective when employed to avoid pregnancy. Although this is well known, very little research has been conducted on why women or couples are unable to follow the rules of these methods correctly. Researchers from Georgetown University Institute for Reproductive Health recently conducted a study to determine characteristics that might predict incorrect use.<sup>1</sup> The women participants for this study were those enrolled in the 13 cycle prospective efficacy studies on the Standard Days Method (SDM) and TwoDay Method (TDM) of family planning. The participants were 928 women (average age 29) from 10 different sites in four countries (i.e., Bolivia, Guatemala, Peru, and the Philippines). Of these 928 women, 212 (23%) reported at least one act of intercourse during the estimated fertile phase in at least one menstrual cycle, i.e., they practiced incorrect methodological use for avoiding pregnancy.

Using logistic analysis, the researchers were able to find only two individual characteristics among the women who had intercourse during the fertile phase that were statistically significant compared to those who used the methods correctly for pregnancy avoidance. These characteristics were associated with the housing quality index and having an income generating occupation. Those women who lived in poor housing were more likely to use the methods incorrectly. This was possibly due to the stress of poverty and the energy it takes with the struggles of daily life. Those who had occupations were less likely to be tradition based women and more open to methods of contraception; thus, less committed to FAM. Of the 212 women with incorrect use, 81 (38%) provided reasons for incorrect use. Most (39) said they had intercourse on fertile days because their husbands insisted. Others (18) felt that the length of abstinence and the fertile period were too long. Fifteen of the women felt the daily routine of the methods was too difficult.

The researchers concluded that there were no real clear characteristics that could predict incorrect use of the SDM or TDM. However, they did recommend that difficulties in the use of the methods could be overcome by including the male partner in the teaching of the methods and in follow-up counseling.

### Comments

An interesting side finding of this study was that the couples in the SDM efficacy study had on average 5.5 acts of intercourse per cycle and those in the TDM study 5.6. These rates compare well with world wide data of 5.5 acts per cycle for sexually active married women. In other words, women who follow FAM or NFP methods probably have as many acts of intercourse as women using other methods of family planning. (See next review article that describes this phenomenon in more detail.) More attempts and studies need to be conducted that are prospectively designed to determine characteristics of correct use and male partner dynamics. (RF)

1. Sinai I, Lundgren R, Arévalo M, Jennings V. **Fertility awareness-based methods of family planning: predictors of correct use.** *International Family Planning Perspectives*, 2006;32:94-100.

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## Coital Frequency among Users of Fertility Awareness-Based Methods of Family Planning (SDM & TDM) Increases with Use - Frequency Similar to that Reported by Users of other Methods of Family Planning

There is an assumption and some evidence that users of natural methods of family planning have intercourse less frequently than users of contraception. Researchers from Georgetown University Institute for Reproductive Health (IRH) conducted a study to determine the frequency and timing of intercourse during the menstrual cycle among users of a fixed day method of family planning, called the Standard Days Method (SDM), and users of a simplified form of a mucus-only based method, called the TwoDay Method (TDM).<sup>1</sup> These methods were developed at Georgetown University IRH, and coital records were collected during the efficacy trials of these methods. There were a total of 928 women participants in the two studies between the ages of 18-39 that contributed over 8,000 menstrual cycles of data. These participants were from 4 different countries (Bolivia, Guatemala, Peru, and the Philippines).

Past studies from countries throughout the world have demonstrated that sexually active couples have on average 5.5 acts of intercourse per month. In the Georgetown University IRH study the mean acts of intercourse for the SDM participants was 5.6 and for the TDM couples 5.5. Further analysis showed that the incidence of intercourse during the fertile phase decreased the longer the method was used. The researchers also found the frequency of intercourse increased the longer the methods were used, and that the frequency of intercourse during menses decreased the longer the methods were used. Regression analysis with multiple variables that might influence intercourse frequency demonstrated the only variable that was statistically significant to predict intercourse frequency was age, i.e., frequency of intercourse declines as the age of the women increases. They also found that women using the SDM had a slightly higher frequency of intercourse than those using the TDM.

The authors believe that some of the intercourse trends discovered in their study were due to the learning phase of the methods (on the part of the couple users) and to becoming more confident in determining the estimated fertile days. In particular, the trends in intercourse patterns were reflected in the decrease in intercourse during the fertile phase, the decrease in intercourse during menses, and the overall increase in intercourse over time. They speculated that the differences in frequency of intercourse between the users of TDM and SDM was due to the objectivity of the fixed days of fertility with the SDM as compared to the need to establish confidence in recognizing cervical mucus and the estimated fertile days with the TDM.

### Comments

Data from this study suggest that couples who use simplified methods of natural family planning (i.e., the SDM and TDM), do not experience less intercourse than couples in general. Furthermore, helping couples to quickly gain confidence in estimating the fertile phase with methods of NFP will help to decrease acts of intercourse during the fertile phase, during menses, and increase frequency over time. An interesting comparison: the average frequency of intercourse among the users of the ovulation method as reported in the 5 country World Health Organization efficacy study was 4.8.<sup>2</sup> (RF)

1. Sinai I. Arevalo M. **It's all in the timing: coital frequency and fertility awareness-based methods of family planning.** *Journal of Biosocial Science*, 2006;38:763-777
2. World Health Organization Task Force. **A prospective study multicenter trial of the ovulation method of natural family planning. Psychosocial aspects.** *Fertility and Sterility*, 1987;47:765-772.

## Awareness of Natural Methods of Birth Regulation Low among Nigerian Women

Researchers from the University of Maiduguri, Nigeria, designed a study to determine the level of awareness and use of natural methods of family planning.<sup>1</sup> The Nigerian researchers were interested in this information because of the high birth rate in that region of Africa and because of the low utilization of modern methods of contraception. For these researchers natural methods included the Calendar Rhythm Method (RM), Lactation Amenorrhea Method (LAM), i.e., breastfeeding to space child birth, and coitus interruptus (CI).

The respondents for this study were 886 married women between the ages of 15 and 45 years, that were obtained from 150 households in urban and rural settings in northeastern Nigeria. Their mean age was 27.8, parity 3.2, and mean number of living children 2.5. Most (68.8%) of the respondents were of the Islamic faith. Each respondent was interviewed in person about knowledge, awareness, and use of RM, LAM, and CI. Results showed that 50.7% of the respondents were aware of RM, 42.1% of LAM, and 36.1% of CI. Not surprisingly, a big majority (76.0%) were aware of modern methods of contraception. However, only 25.3% gave a correct description of the RM, 23.7% of LAM, and 29.2% of CI, and only 18.4% utilized RM, 13.0% utilized LAM, and 11.1% used CI. Of the respondents who used these methods, 39% utilized RM incorrectly, 27.7% utilized LAM incorrectly, and only 4% did not use CI correctly.

The authors concluded that there was a relatively low level of awareness and low use of natural methods among this African population, and that among the users many employed the methods incorrectly. They also felt that the provision of correct information about natural methods of family planning will increase use of both natural and modern methods of contraception.

### Comments

I found it interesting that the authors assumed that there was low use of modern methods of contraception among this population because of a high use of traditional natural methods. In fact, they claimed that post-partum sexual abstinence of up to 3 years was a source of reducing fertility among Nigerian couples. However, they found that 76% were aware of modern methods of contraception, a much higher awareness than the natural methods. A better approach would have been to include in the study how many of this sample of Nigerian women used modern methods of contraception and reasons why they might not use these methods. I also found it incongruous that the authors included CI as a method of natural family planning when most definitions of NFP would not include CI. The study lacks a clear conceptual and definitional base for the natural methods. (FR)

1. Audu, B.M., Yahya, S.J., & Bassi, A. **Knowledge, attitude and practice of natural family planning methods in a population with poor utilization of modern contraceptives.** *Journal of Obstetrics and Gynecology*, 2006;6:555-560.

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# MENSTRUAL CYCLE

## Re-analysis of Tremin Menstrual Cycle Data Shows Bigger Shift in Menstrual Cycle Length during Final Year before Menopause

The Tremin Research Program on Women's Health is an ongoing study of menstrual cycles across the lifespan initiated by Alan Treloar, PhD, at the University of Minnesota in 1934. Treloar analyzed data from two cohorts of women to produce the patterns and changes in the menstrual cycle length across the female reproductive lifespan.<sup>1</sup> However, in calculating the length of the menstrual cycle in the final year before menopause, he discarded menstrual cycles that straddled one calendar year to the next. By doing so he skewed the final year's length to shorter cycles since longer cycles had a greater probability of straddling. In addition, he was not consistent in his definition and dating of menopause — sometimes it would be the day of the final menses and sometimes 12 months later. Researchers recently re-analyzed the Tremin data to take into account these inconsistencies and to include the straddled cycles. They did so by counting calendar years backwards from the final menstrual period (FMP). The re-analysis included all menstrual cycles in the Tremin data that had data during the 10 years before the FMP.

The results from the re-analysis showed significant changes in the mean menstrual cycle lengths in the final 5 years before the FMP. The biggest differences were in the 2 before the final menses. The mean menstrual cycle lengths in the final 2 years in the original Treloar data was 57.14 days (SD=35.5) for both years. When the data set was reconstructed by the current researchers and re-analyzed, the mean length of the menstrual cycles was 55.87 days (SD=31.9) in the second year before the FMP and 54.58 (SD=38.4) in the final year. However, the data set with the corrections showed a mean length of 45.15 days (SD=22.1) in the second year before the FMP and 80.22 (SD=56.4) in the final year. The corrected data also showed that women spent >75% of their time in menstrual cycles >40 days in length. Hence, the data showed that the largest increase in mean length did not occur until the final year before menopause. The authors concluded that this re-analysis of menstrual cycle lengths could be useful clinically as well as epidemiologically for assessing menopausal onset.

### Comments

This data is interesting in that it could be helpful for menopausal NFP users and NFP teachers working with these women to help predict menopause. Of interest is that the variability in menstrual cycle length when measured by the standard deviation from the 4th year before the FMP almost doubles in the 3rd year, i.e., from 9.26 to 17.0. So (theoretically), if a woman sees the mean differences in cycle length increase to 7 days, she might suspect her FMP in 2-3 years. The FMP will be especially close when she experiences more than 75% of her cycles being 40 days or more. (RF)

1. Ferrell RJ, Simon JA, Pincus SM, Rodriguez G, O'Connor KA, Holmes DJ, Weinstein M. **The length of perimenopausal menstrual cycles increases later and to a greater degree than previously reported.** *Fertility and Sterility*, 2006;86:1-6.

## Validity of Self-reported Menstrual Cycle Length Questioned

Researchers from Emory University recently investigated the validity of self-reported menstrual cycle lengths.<sup>1</sup> They cited the need for accuracy in reporting of menstrual cycle length since self-reported length can be clinically assessed and linked with important environmental factors (e.g., smoking) and of chronic disease risk (e.g., heart disease). The authors compared the self-reported “usual” cycle length with prospectively determined mean menstrual cycle lengths among 398 women aged 19-41 years.

The researchers found that among 43% of the women participants, self-reported menstrual cycle length varied by more than 2 days from their prospectively determined mean length. The researchers also categorized the lengths into three groupings: cycle lengths < 26 days, cycle lengths between 26-35 days, and cycle lengths > 35 days. They found that 21% of the women’s menstrual cycles were misclassified based on the self-reported lengths. Characteristics of women who had more accurate reporting of cycle length, were older, married, and with higher incomes. Women with short or long mean cycle lengths tended to be less accurate with their self-reported lengths. Their findings led the authors to conclude that their findings showed there was considerable measurement error in self-reported menstrual cycle length.

### Comments

These findings might have some relevance to the Standard Days Method (SDM) of NFP that relies on self-reported and assessed menstrual cycle length to determine best fit with the method. These findings also have relevance to other models and methods of NFP that assess self-reported menstrual cycle lengths to help place the woman client into a reproductive category. However, this study did have some deficits in that the women participants prospectively reported only from 2-6 menstrual cycles. The mean menstrual cycle length might vary considerably with an addition of a year worth of recording, i.e., 13 prospectively produced menstrual cycles. (RF)

1. Small CM, Manatunga AK, Marcus M. **Validity of self-reported menstrual cycle length.** *Annals of Epidemiology*, 2006; (Epub ahead of print).

## Knowledge of Menstrual Cycle and Ovulation Low among Teenagers and Young Adults

Sexual health education is mandatory in the Swedish school system from elementary school through grade 9. Swedish researchers (from the Faculty of Health Sciences at the University of Linköping) recently conducted a survey of Swedish adolescents and young adults to determine their knowledge of reproductive anatomy, physiology and fertility health.<sup>1</sup> The researchers developed a 35 item fertility questionnaire and anonymously distributed the questionnaire to 209 students in the 8th grade through first year of university studies (i.e., students 13-25 years old); 206 of the questionnaires were returned. The mean score of the questionnaire was 28.7 out of 54. The researchers found that women had statistically higher total scores than the men, and older students had higher scores than younger students. Only 24% of the men compared to 63% of the women knew the approximate time of ovulation in the menstrual cycle. However, approximately 91% of the University level males and females were able to identify the female sex organs and 100% of them were able to identify the male sex organs. Most students (88.4%) were able to correctly estimate the length of the female fertile period, while 61.5% were able to correctly identify

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the length of the fertile period for men. About 50% of the respondents were able to correctly identify the mechanisms of contraception. The researchers concluded that the students did not receive adequate knowledge of human reproduction and sexuality in their school system. They felt that the quality of sexual health education in Sweden needs to improve.

### Comments

The authors of this study mentioned in their article that they found no other studies that measured knowledge level of students on reproduction and sexual health. However, a recent study of the sexual health knowledge of college age students (young adults) was conducted in Sweden by researchers at Uppsala University.<sup>2</sup> This study by fellow Swedish researchers was missed in their review. The authors did not provide the actual items for the instrument that they developed, nor did they provide how or if the knowledge questionnaire was validated. I would like to have seen some of the questionnaire items and the answers to the items, for example, the item that asked about the length of the fertile phase for men and women. Teaching fertility awareness methods might help to enhance the sexual health education in Sweden. (RF)

1. Sydsjo G, Selling KE, Nystrom K, Oscarsson C, Kjellberg S. **Knowledge of reproduction in teenagers and young adults in Sweden.** *The European Journal of Contraception and Reproductive Health Care*, 2006;11(2):117-125.
2. Lambic C, Skoog Svanberg A, Karlstrom P, Tyden T. **Fertility awareness, intentions concerning childbearing, and attitudes towards parenthood among female and male academics.** *Human Reproduction*, 2006;21:558-564.

## FERTILITY

### Evidence Shows Early Pregnancy Loss Associated with Elevated Follicular Progesterone Levels

**E**vidence from several studies suggest that the rate of early pregnancy loss (i.e., within the first 5 weeks from fertilization) is from 25%-30% and may be as high as 80%. There are many causes for early pregnancy loss (EPL), including genetic abnormalities, maternal age, maternal behaviors (such as cigarette smoking), and intake of high levels of caffeine and alcohol. Although there is a belief that low levels of progesterone (P) production by the corpus luteum during the luteal phase is a cause for some EPL, the therapeutic evidence does not always support this theory. Therefore, researchers from the US, Germany, and Bolivia recently conducted a study to test the hypothesis that EPL is actually due to elevated follicular P levels rather than low level luteal phase P levels.<sup>1</sup> According to this theory elevated follicular P levels are due to stress induced adrenal P.

The multinational research team collected data from 191 menstruating Bolivian women volunteers between the ages of 19-40. The volunteers were visited every other day to collect saliva samples and every day from day 24-25 of the menstrual cycle to collect urine samples. The urine samples were tested for human chorionic gonadotropin (hCG) as a measure for early pregnancy (until a positive test was detected or until the next menses occurred). The salivary samples were assayed for P levels at Northwestern University. Conceptions that ended within 5 weeks of ovulation were classified as EPL. The day of ovulation was estimated by an algorithm based on a sharp rise in P levels.

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The researchers found that, following the estimated day of ovulation, the P levels were similar in the menstrual cycles with sustained conception cycles (N=32) as compared to those cycles with EPL (N=8). They also demonstrated that follicular P levels were significantly greater in the EPL cycles compared to the sustained conception cycles. The authors concluded that elevated follicular P levels are associated with EPL in normal cycling healthy women.

#### Comments

The authors recognized that the study was limited by the small sample size and the inability to determine whether the elevated follicular P levels were of adrenal or ovarian origin. They also felt the over-the-counter pregnancy (hCG) test utilized in the study might not have been sensitive enough to pick up some EPL. However, the fact that they did not detect elevated follicular P levels in the non-conception cycles of those women with EPL suggests that the elevations were due to some temporary factor. Of note: the median EPL occurred on luteal day 16, and the median duration of cycle length was 30.5. These ranges would fall within normal limits and probably would not be detected by NFP charts. (RF)

1. Vitzthum VJ, Spielvogel H, Thornburg J, West B. **A prospective study of early pregnancy loss in humans.** *Fertility and Sterility*, 2006;86:373-379.

## Higher Estrogen Levels Associated with Achieving Clinical Pregnancy

United States and Chinese researchers recently reported a study to determine how estrogen and progesterone levels are associated with pregnancy and early pregnancy loss.<sup>1</sup> These multinational researches had the opportunity of investigating hormonal variability with a large group of homogenous women seeking to achieve pregnancy. The women were newly married textile workers in China, aged 20-34, and nulliparous, who had permission from the government to have a child. Urine samples were collected from the women each day from the day they stopped a contraceptive method for 12 months or until a pregnancy was confirmed. The women also recorded intercourse patterns for each cycle. The urine samples were assayed for an estrone conjugate (E1G), progesterone (PdG), and hCG to confirm a pregnancy. The report included 601 cycles from 347 healthy women who conceived at least once during the study period.

The results showed that the E1G levels were significantly lower in the 272 non-conception cycles compared to the 266 clinical pregnancy cycles. Furthermore, E1G levels in the 63 early clinical pregnancy loss cycles were lower compared to the 266 clinical pregnancy cycles. However, these differences were not statistically significant. The PdG levels tended to be lower in the 272 non-conception cycles compared to the clinical pregnancy cycles in both the mid- and late follicular phases, but the differences were not statistically significant. It was interesting that the PdG levels tended to be higher in the early luteal phase for both the early pregnancy loss and the non-conception cycles. Again, this difference was not statistically significant. The authors concluded that estrogen concentrations varied from cycle to cycle, and that higher estrogen levels was associated with achieving pregnancy.

#### Comments

The authors speculated that their data might yield a clinically relevant marker (i.e., threshold level of E1G) in the mid-follicular phase that could be utilized to predict the potential for achieving a clinical pregnancy. The total number of days of intercourse in a single cycle was from 1 to 6. The authors speculated, however, that there was underreporting

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of intercourse. They did not find any hormonal patterns that would indicate a libido effect in stimulating intercourse. (RF)

1. Venners SA, Liu X, Perry MJ, et al. **Urinary estrogen and progesterone metabolite concentrations in menstrual cycles of fertile women with non-conception, early pregnancy loss or clinical pregnancy.** *Human Reproduction*, Advanced Access - June 23, 2006.

## The Rate of Infertility is declining in the United States: Or is it?

A professor and demographer at the Georgetown University School of Foreign Service recently analyzed data from the National Survey of Family Growth (NSFG) to determine if there is a decline in infertility in the United States across subgroups.<sup>1</sup> Data were taken from the 1982, 1988, 1995 and 2002 cycles of the NSFG. The NSFG classifies a woman as infertile if she meets a number of categories: she is between 15-44 years old; married; not surgically sterilized; sexually active; not using contraception in the past 12 months; and has not conceived during the past 12 months. Based on these questions the author determined that the infertility rate was 8.5% in 1982, and by 2002 it declined to 7.4%. The lowest level reported was 7.1% in 1995. She also found the odds of infertility for nulliparous women of all ages was significantly higher than for a younger reference group. Among parous women, on the other hand, only those between the ages of 40-44 were significantly more likely to be infertile compared with a younger reference group. Odds of infertility were significantly lower among women with at least a college degree. Hispanic and African-American women were more likely to be infertile compared to non-Hispanic white women. The author speculated that the increase in cohabitation, the decline of marriage, the later average age of marriage, the delay in childbearing, the increase in sexually transmitted diseases, and the introduction of assisted reproductive technology might have influenced the infertility rates. She concluded that the significant decrease in infertility in the United States is a result of several factors and cannot be explained by the changing composition of the population from 1982-2002.

### Comments

A number of critiques of this report were included in the same issue of the journal *Fertility and Sterility* as this article. One critique stated that basing infertility rates on the NSFG has definitional and methodological concerns.<sup>2</sup> These authors felt that the measure of infertility formulated with 5 questions and criteria from the NSFG is faulty because the denominator in the equation includes all women regardless of whether they were trying to have a child or not. They felt that the risk of infertility would be more accurately reflected in the NSFG measure of impaired fecundity. The NSFG measure of impaired fecundity is based on: 1) a 36 month interval without conception, 2) a physical impossibility for the woman to have a child or for her husband to have a child, or 3) a possibility (but physical difficulty) for her or her husband to have a child. Based on this measure, the impaired fecundity in 2002 was around 15% compared with approximately 10% in 1982. Another critique questioned the validity of the data used for the estimates of infertility.<sup>3</sup> These authors believe that the self-reporting of the responses are fraught with recall bias and error. They also believe that to compare a cohort of women from 1982 with 2002 required consistency of techniques, which did not occur with the NSFG.

I would like to see the same authors of these critiques review the contraceptive efficacy rates that are established from the NSFG. I would assume that some of the same difficulties and errors could occur in the NSFG contraceptive efficacy analysis. (RF)

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1. Stephen, EH, Chandra A. **Declining estimates of infertility in the United States: 1982-2002.** *Fertility and Sterility*, 2006;86(3):516-526.
2. Guzick DS, Swan S. **The decline of infertility: apparent or real?** *Fertility and Sterility*, 2006;86(3):524-526.
3. Olive DL, Pritts EA. **Estimating infertility: the devil is in the details.** *Fertility and Sterility*, 86(3):529-530.

## Ninety to One-Hundred Million Women Missing in World

An interesting article was published in the September issue of the *Proceedings of The National Academy of Sciences* on the causes and consequences of abnormal sex ratios in the world population.<sup>1</sup> The "population sex ratio" refers to the total number of males for every 100 females in the population and, based on data from gender neutral Western countries, is approximately 97.9 to 100.3 males for every 100 females.

In many countries the sex ratio is abnormal due to "son preferences." This preference is based on the fact that sons are higher wage earners, they continue the family line, and are generally the recipients of inheritance. Daughters can become a burden because of the dowry system, and the married female becomes a part of the husband's family. Even with these "son preferences," in societies with large families and no contraceptive pressures, there are enough males and females, and there is no concern with sex selection. However, in societies with contraceptive pressures and with population limits, such as China's one child policy, male sex preference becomes a problem. Missing female children are a result of prenatal sex selection abortions, female infanticide, and neglect of the female child. The nations where this is a concern are China, India, South Korea, Pakistan, Taiwan, Iran, Bangladesh, and Afghanistan. Some demographers have estimated up to 100 million "missing females" in the developing world. In China, there are approximately 1 million more males than females born per year over the past 26 years. In South Korea the sex ratio has been as high as 229 male babies for every 100 female babies for the fourth child born as reported in 1992. The 2001 South Korean figures are 128 males for every 100 females for the fourth child born. The male children that result from these population reduction policies and son preferences are now reaching or have reached the age for marriage. The authors point out that marriage is the norm in these societies and single males are a stigma.

Some of the consequences of having a surplus of males include: increased crime and violence, an increase in young men joining military type organizations, women may be valued more highly (which could be positive - women will marry up, but might be more controlled by men due to a higher dowry), possible increase in sex trade, female kidnapping, and trafficking of women.

Governmental solutions include making and enforcing laws outlawing sex selection, providing services for care of older parents, making and enforcing social, economic, and educational equal rights for males and females, and introducing free or low cost basic health care.

### Comments

One of the methods of sex selection that was mentioned in the article was the use of conception early in the menstrual cycle. (RF)

1. Hesheth T, Xing ZW. **Abnormal sex ratios in human populations: causes and consequences.** *Proceedings of The National Academy of Sciences*, 2006;103(36):13271-13275.

## CONTRACEPTION

### Hispanic Women Desire Larger Families and Have More Religious Objections to Using Birth Control than Non-Hispanic Whites

A cross sectional survey of Hispanic women was conducted through two publicly funded reproductive clinics in Houston, Texas.<sup>1</sup> The purpose of this survey was to determine psychosocial factors that were associated with contraceptive decision making, knowledge, attitudes, self-efficacy, and social support. There is an expressed concern that Hispanic women have high fertility rates, high abortion rates, and low contraceptive use rates compared with non-Hispanic white women. A contraceptive questionnaire was administered to 442 women between the ages of 18-50 who sought reproductive health care. Of these 442 women 137 were non-Hispanic whites, 74 were US born Hispanic women, and 231 were non-US-born Hispanic women. About 10% of those women approached for the study refused to participate. The questionnaire contained items on contraceptive knowledge, contraceptive use, perceived barriers to contraception, perceived social support, and contraceptive self-efficacy.

Results showed that Hispanic women (US born and non-US born) had a greater number of pregnancies, desired more children, and had fewer lifetime sex partners and more unwanted pregnancies compared to non-Hispanic white women. Hispanic women also were less likely to use a contraceptive method consistently during the 6 months prior to the survey. The most commonly cited barriers to contraceptive use were: belief that contraceptive use leads to major side effects, belief that birth control was unreliable, partner pressure not to use contraceptives, a belief that it is women's responsibility to use contraception, and the belief that contraception is against their religion. Lower levels of social support from family and friends in using contraception and lower levels of contraceptive efficacy were found among Hispanic women compared to non-Hispanic whites. The authors felt that Hispanic women both US and non-US born are at higher risk for unintended pregnancy.

#### Comments

As in the previous survey on Hispanic women reported in this issue of CMR, these results cannot be generalized to the entire US Hispanic population since it was based on a non-randomized local sample. Of interest is that the contraceptive methods Hispanic women find most ineffective were withdrawal and Rhythm. In addition, it is problematic to label a pregnancy as "unwanted" because it was mistimed or not expected. A mistimed or unexpected pregnancy can actually be wanted by the woman. Researchers ought to take note of these distinctions. (RF)

1. Sange-Haghpeykar H, Ali N, Posner S, Poindexter AN. **Disparities in contraceptive knowledge, attitude and use between Hispanic and non-Hispanic whites.** *Contraception*, 2006;74:125-132.

## Minority Adolescent Women Concerned About Health Risks of Hormonal Contraceptives

Researchers from the University of Pennsylvania and the Division of Adolescent Medicine from The Children's Hospital of Philadelphia recently conducted a qualitative study with minority urban female adolescents to determine their perceptions of hormonal contraception.<sup>1</sup> The researchers were concerned that adolescents have many misperceptions about hormonal contraceptives (HC), and these misconceptions might lead to improper use of HC, discontinuation of HC, and unintended pregnancies. Past research has shown that the biggest reason that adolescents provided for discontinuing HC are "side effects."

The researchers conducted 13 open focus groups with females aged 12 to 18. Each focus group began with the question "What are the things that you have heard about hormonal contraception: the birth control pill, Depo-Provera, and Norplant?" Altogether the 13 focus groups had 72 participants with a mean age of 15.2 (SD=1.9), most (88%) were African American, about 51% were sexually active, and 66% were listed as urban. The focus groups were audio taped and transcripts were typed and analyzed for major themes. The overall comments were directed towards the concern that a disruption in the menstrual cycle was problematic. The researchers developed four major themes based on the responses from the 72 adolescent women:

1. Menstruation is natural and should not be altered in any way.
2. The menstrual period is necessary for cleansing of the body.
3. "Spotting," intermenstrual bleeding and amenorrhea cause doubts about the method's effectiveness and worries about pregnancy.
4. All menstrual irregularity from intermenstrual bleeding to amenorrhea causes worry about the effect on one's physical health and fertility.

Overall, the responses reflected a concern about menstrual bleeding as a sign of health. The authors stated that it was important for the young women to have regular monthly menstrual cycles and having them made them feel clean and healthy. They recommended that health professionals should address these worries by improving contraceptive counseling.

### Comments

The limitation of the study was that the respondents were self-selected from only one geographical area in the US. The results cannot be generalized to the entire adolescent population in the US. Although the responses did reflect some misperceptions and ideas about menstruation, there was a bit of natural wisdom from the respondents that the menstrual cycle is a reflection of their overall health. Counseling might include providing the adolescents with information about reproductive anatomy and physiology, information about their natural signs of fertility and how to chart them, helping them learn about proper vaginal hygiene, what constitutes fertility health, and that the bleeding while on hormonal contraception is not a true menses. (RF)

1. Clark LR, Barnes-Harper KT, Ginsberg KR, Holmes WC, Schwarz DF. **Menstrual irregularity from hormonal contraception: a cause of reproductive health concerns in minority adolescent young women.** *Contraception*, 2006;74:214-219.

## Oral Hormonal Contraceptives Fails to Suppress Ovulation When Administered During Late Follicular Phase

**A**ngela Baerwald and Roger Pierson from the University of Saskatchewan have been studying follicular phase ovarian follicle development for a number of years.<sup>1</sup> They have described in past studies how follicles develop over 2 to 3 waves during the human menstrual cycle. They also speculated that women could experience a double ovulation further apart than 24 hours. This latest study was conducted to determine the effects of initiating hormonal oral contraceptives (OC) during defined stages of ovarian development. Their recent study involved 45 healthy women who have not been on OC for at least one month. They were randomly assigned to receive an OC containing 150 µg of desogestrel and 30 µg of ethinyl daily when follicular development was detected to be at 10 mm, 14 mm, or 18 mm after menses. The volunteer subjects were subjected to daily ovarian ultrasound and serum endocrine blood tests.

The researchers found that there were no ovulations detected when OC were administered at 10 mm follicular development, 4 of 14 women ovulated when administered OC at 14 mm of follicular development, and most (14 of 15) ovulated when administered OC at 18 mm of follicular development. They also found normal levels of estrogen, LH, and progesterone when OC were administered at the 18 mm level of development. They concluded that follicular development, ovulation, and endocrine concentrations are not suppressed effectively when OC are initiated at later stages of follicular development.

### Comments

A practical application of the results from this study is that the “Sunday Start” day of beginning OC use is not recommended since the woman could be at a stage of later follicular development. This study also provides more evidence that women can ovulate while on OCs. (RF)

1. Baerwald AR, Olatunbosun OA, Pierson RA. **Effects of oral contraceptives administered at defined stages of ovarian development.** *Fertility and Sterility*, 2006;86:27-34.

## Best Randomized Control Trial Study Showed a Decrease in Libido with Oral Contraceptive Use

**R**esearchers from Columbia University Medical Center reported a systematic review of the research literature to determine the effects of hormonal oral contraceptive (OC) use on women’s libidos.<sup>1</sup> In their report they elaborated on physiological and psychological reasons why women’s libidos might increase or decrease while on OC. The reasons for increased libidos include: 1) a decrease in fear over an unplanned pregnancy, 2) decrease in pain due to a variety of painful gynecological conditions such as endometriosis, 3) having predictable bleeding periods, 4) experiencing decreased and shortened bleeding during menses (when many couples avoid intercourse), and 5) improved appearance, body image, and self-confidence with the use of OC to treat acne. The decrease in the libido might be a result of losing the element of risk (i.e., the excitement of being fertile), the progesterone compounds used might decrease moods, associated weight gain might decrease body image and attractiveness, and the decrease in androgen production from OC use might decrease the libido.

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The authors were able to collect 156 articles related to OC use and libidos in the medical literature from 1966-2004. Of these articles, only 30 were original research and met their review criteria. There were 17 retrospective studies, 4 prospective studies with uncontrolled cohorts, 4 were prospective or cross-sectional with non-random controls, and 5 were randomized control trials. Many of the studies (in particular the retrospective studies) were poorly designed or the measure of libido was suspect. They concluded, based on the most recent and well designed randomized placebo-control study, that the libido was significantly decreased for women on OC when compared to a placebo group.<sup>2</sup> Overall they found positive effects, no effects, and negative effects on the libido due to OC use. They also concluded that better designed randomized control studies (RCT) are needed.

#### Comments

I did not find any recent RCT that compared libido levels on OC with other methods. There was a 2003 study that showed no difference with a non-random comparison of IUD users with OC users, but they did find that sexual desire decreased in women with a poor quality relationship.<sup>3</sup> Certainly the stability of the relationship is a factor in sexual desire. A study that compared the libido of women using natural family planning compared to use of OC would be desirable. Although this is a relatively old study (2004), I felt that it has some relevance and interest. (RF)

1. Davis AR, Castano PM. **Oral contraceptives and libido in women.** *Annual Review of Sex Research*, 2004;15:297-320.
2. Graham CA, Ramos R, Bancroft J, Maglaya C, Farley TM. **The effects of steroidal contraceptives on the well-being and sexuality of women: a double-blind, placebo-controlled, two-centre study of combined and progestogen-only methods.** *Contraception*, 1995;52(6):363-9.
3. Martin-Loeches M, Orti RM, Monfort M, Ortega E, Ruis J. **A comparative analysis of the modification of sexual desire of users of oral hormonal contraceptives and intrauterine contraceptive devices.** *European Journal of Contraception and Reproductive Health Care*, 2003, 8(3):129-134.

## Majority of Male Volunteers find Injectable Hormonal Contraception Acceptable

The World Health Organization (WHO) and Shering Pharmaceutical Company are in the development stage of an injectable hormonal contraceptive method for males. The contraceptive regimen involves injections of norethistrone enanthate (a progestin) and testosterone undecanoate at 8-12 week intervals. Researchers from WHO, Italy, and the United States recently investigated male attitudes towards and acceptability of the male hormonal contraceptive.<sup>1</sup> The study participants were 200 healthy Italian males who volunteered to participate. Of these 122 (61%) were screened for eligibility and randomly distributed into a treatment group who were to receive the hormonal injection, a placebo group, and a non-treatment group. The final treatment group of 50 participants, the placebo group of 32 participants, and the non-treatment group of 40 participants were provided a self-administered acceptability questionnaire. Most of the participants did not have children, were in some type of stable relationship, and were on average 28 years old.

The results showed that 92% (112/122) felt that both men and women should share in the responsibility for contraception, but only 38% (46/122) were willing to take on the total responsibility (i.e., relieve the partner of the responsibility). Most (75%) would try a new contraceptive if available for men, and 74% welcome the idea. Most (75%) of the participants in the treatment group found the injection regimen acceptable at the beginning of the treatment period and (66%) at the end of the one year treatment period.

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The biggest advantages of the hormonal regimen for the participants were: 30% felt it was an alternative to condoms, 27% indicated it provided control over contraception, and 23% felt it relieved partner of responsibility. The disadvantages were: 32% disliked the injections, 25% perceived a lack of protection from disease, and 16% disliked the length of time for it to become effective, i.e., it takes about 12 weeks for the sperm levels to decrease to contraceptive levels. There was no report of significant decrease in libido or other negative mood states.

The authors concluded that the contraceptive regimen tested in this study was found to be well accepted by the participants. They did express the need to find a non-injectable form of male contraception.

### Comments

An obvious problem with this study was that the participants were self-selected and biased towards accepting male contraception. Furthermore, they were compensated approximately \$2,000 for participating in the study. The fact both WHO and Schering are involved in the development of the male contraceptive compounded the bias through the researchers. No reason was provided why 39% of the healthy volunteers were not eligible for the study. It is interesting that one reason some single males liked the male contraceptive is that it did not interfere with the sexual act and they maintained control over fertility and whether or not they father a children. I wonder what sociological dynamics would result if a large portion of single males utilized a non-condom hormonal form of contraception. (RF)

1. Meriggiola MC, Cerpolini S, Bremner WJ, Mbizvo MT, Vogelsong KM, Martorna G, Pelusi G. **Acceptability of an injectable male contraceptive regimen of norethisterone enanthate and testosterone undecanoate for men.** *Human Reproduction*, 2006;21(8):2033-2040.

## Marriage is a Predictor of Satisfaction with use of Hormonal Contraceptives

**A**ttention rates have often been used as an indicator of dissatisfaction with contraceptive methods. Currently about 44% of women will discontinue a reversible method of family planning over a 12 month time period. In order to get a better picture of what constitutes satisfaction with hormonal methods of contraception (i.e., the number one reversible method of contraception), researchers have developed a self-administered satisfaction tool that can be used as a standardized measure of contraceptive satisfaction. The developers of this tool recently conducted a study to determine the sensitivity of this measure of satisfaction and to determine factors that contribute to satisfaction among women who recently switched to a new hormonal method of contraception.<sup>1</sup>

The tool they develop, called the ORTHO Birth Control Satisfaction Assessment Tool (ORTHO BC-SAT), is a 42 item questionnaire that has 8 sub-scales: Ease of Use and Convenience; Compliance; Lifestyle Impact; Symptom and Side Effect Bother; Menstrual Impact; Future Fertility Concerns; Assurance and Confidence; and Overall Satisfaction. The evidence for the reliability and validity of the tool has been gathered.

The 56 female participants for this study were selected from the private practices of 4 gynecologists and ranged in age between 18 and 50 years (mean age 26). Of these participants, 21 were married, 48 had some college level education, most (46) were Caucasian, and only 5 were using a non-hormonal method of contraception. The participants were all seeking a different or new method of contraception. The ORTHO satisfaction tool was administered at enrollment into the study and 3 months later.

The participants reported a statistically significant improvement in satisfaction from enrollment to the 3 month measurement. The greatest positive change (among all participants) was in Overall Satisfaction and Assurance/Confidence. The sub-group of women

(Continued on p. 16)

(Continued from p. 15)

with the greatest improvement in satisfaction were married women and those who previously used a non-hormonal method of contraception. Women who were on non-hormonal contraception at baseline also experienced less satisfaction at 3 months with the Lifestyle Impact sub-scale. The authors concluded that the ORTHO BC-SAT is a good measure to detect differences in satisfaction with hormonal contraception among female users.

#### Comments

Although the idea to develop and test a standardized measure of satisfaction for users of hormonal contraception is a good one, there were a number of weaknesses in this study. First of all, the number of participants that exhibited some of the studied contributing factors were very small (e.g., only 5 women were using non-hormonal contraception). Second, there was no comparison group to see if a group of woman who were not switching contraceptive methods or who were using a non-hormonal method also exhibited change. Third, the fact that the participants knew they were being studied, knew that they were being measured for satisfaction, had a baseline measure of satisfaction, and were paid \$25 for the response could easily have biased the responses. Finally, the participants were rather homogeneous, i.e., educated, fairly well off white women. A study to compare users of natural family planning with women using hormonal or barrier contraception would be of interest. However, I would want to modify the tool to reflect some of the benefits of natural methods, e.g., increased understanding of the menstrual cycle, communication, sexual satisfaction, and spiritual well-being. (RF)

1. Mathias SD, Colwell HH, LoCoco JM, Karvois DL, Pritchard ML, Friedman AJ. **ORTHO birth control satisfaction assessment tool: assessing sensitivity to change and predictors of satisfaction.** *Contraception*, 2006;74:303-308.

## Consistent Use of Condoms by Males Reduces Rate of Human Papillomavirus Infections among their College Age Women Partners

Previous studies have shown that use of condoms by males does not reduce the rate of acquisition of human papillomavirus (HPV) as among their female sexual partners. However, most of the past studies have been cross-sectional in design, and the existing prospective studies were not specifically designed to investigate the HPV infection rate with condom use. Researchers from the University of Washington, Seattle, recently reported the results of a longitudinal prospective study that was specifically designed to determine the relationship between condom use and HPV infection.<sup>1</sup>

The participants for this study were 82 University of Washington undergraduate female students between the ages of 18-22 who either had never had vaginal intercourse or had engaged in 1st-time intercourse with a male within the previous 3 months. The researchers obtained their sample by sending out invitational letters to 24,201 female students within that age range. Of these students 243 eligible students replied, of these, 33 declined to participate, and 210 enrolled in the study. Of the 210, 65 reported no vaginal intercourse, 60 reported first vaginal intercourse 2 weeks before the study, and 3 did not provide any sexual behavior information. All participants kept web-based sexual behavioral diaries every two weeks, and received a gynecological exam by a nurse practitioner every four months for the purpose of taking cervical samples to detect HPV infections. The diaries included data on vaginal intercourse, frequency of condom use by their partner, and the number of new partners.

Of the 42 participants who reported their male partners used the condom 100% of the

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(Continued from p. 16)

time, the HPV infection rate was 37.8 per 100 patient years of risk. This risk increased to 62.3% with 50-90% use of the condom, 159.9% with 5-49% use, and 89.3% risk with less than 5% use. The rate of HPV infections was 0 when the male partner had no previous sex partner, but increased to 73.9 per 100 patient years of risk when there was greater than one male partner reported. Auxiliary data showed that the 82 women who obtained a HPV infection during the course of the study, 30 different types of HPV were detected. The authors concluded that among newly sexually active women, consistent use of condoms by their male partners significantly reduced the incidence of cervical and vulvovaginal HPV infections.

### Comments

Although this study was prospective and designed specifically to investigate the temporal relationship between condom use and HPV infections, the design was not without flaws. To truly determine the HPV infection rate with condom use you would need to have virginal women who had intercourse with male partners that already had the HPV infection. We do not know how many of the males partners in this study had HPV or how many sexual acts occurred with partners infected with HPV. Most of the sexual acts were probably with non-infected partners. According to the authors, the male infection rate on the University of Washington, Seattle campus, is around 33%, therefore, the rate of infection among the 100% users is higher.

Other important facts to ponder are: 1) the rate of HPV infection was reduced but not eliminated, i.e., more than a third of the women participants still were infected with HPV with 100% use of the condom by their male counterpart; 2) with the infection rate of 37 per 100 patient years of use, all of these women with infected male partners will eventually obtain an HPV infection even with 100% use; 3) the odds that they will be with male partners that practice 100% condom use over time is not likely; 4) those women who had intercourse with virginal male partners had an infection rate of 0.

Another consideration is the ethics of conducting such a study. By having a study in which the researchers invited infection free college age virgin women to participate in a study on condom use and sexual intercourse legitimizes having at risk sexual intercourse outside of a committed relationship. Since a university body sanctioned this study, they are also sanctioning sexual intercourse outside of marriage, or at minimum saying that studying this phenomenon is worth the risk of students obtaining an HPV infection. From a research standpoint, the results from this study have little generalization beyond the participants described in the article. Furthermore, the participants, by virtue of being in the study, most likely will change their behaviors to increase the use of condoms by their partners. These behaviors would not match those found in the real world where the participants would not be influenced by researchers and the study protocol. (RF)

1. Winer RL, Hughes JP, Feng Q, O'Reilly S, Kiviat NB, Holmes KK, Koutsky L.A. **Condom use and the risk of genital human papillomavirus infection in young women.** *The New England Journal of Medicine*, 2006;354:2645-2654.

## Bone Mineral Density Loss Significant with Long Term Use of Depot Medroxyprogesterone Acetate (DMPA)

**B**ased on short term studies (i.e., < 2 years) that have demonstrated significant bone mineral density (BMD) loss with use of depot medroxyprogesterone acetate (DMPA) the Food and Drug Administration has placed a black box warning on the labeling of Depo-Provera Contraceptive Injection (Pfizer, New York, NY). The warning states that users

(Continued on p. 18)

*(Continued from p. 17)*

of DMPA may have significant bone loss which might not be completely reversible. However, there is very little data on long term use and recovery of bone loss with use of DMPA. Two studies have recently been published that investigated the long term effect of DMPA on BMD.

The first study was conducted to describe BMD changes from the time of initiation of DMPA through 48 months of follow-up, including information about BMD recovery.<sup>1</sup> The participants for this study were 323 women aged 18-35 years, of which 178 were new users of DMPA, and 145 were control participants not using hormonal contraceptives. Of these participants, 139 (78%) in the DMPA group and 114 (78.6%) in the control group completed the first 2 years of the study. All participants had BMD evaluations (hip and lumbar spine) measured by dual energy roentgen absorptiometry approximately every 3 months for < 48 months. There was no statistical differences between the control and users on age, ethnicity, race, BMD, body mass index, weight, self-reported calcium consumption, cigarette smoking, physical activity or age at menarche.

Results: The hip BMD declined by 7.7% and the spine BMD by 6.4% among the DMPA users compared to only a 1.6% decrease for the hip and 0.5% for the spine among the controls. Most of the BMD loss occurred during the first 24 months of use with 75% of the hip loss and 90% of the spine BMD loss occurring during the first 24 months of use. After discontinuation of DMPA, BMD increased by 0.3% to 2.0% per year, but the hip BMD took longer than the spine to recover. However, the longer the use of DMPA, the longer it took for BMD to recover.

The authors of this study indicated that there is substantial BMD loss with use of DMPA, but that over time most of the loss is recovered. They recommended that menopause should be considered in the administration of DMPA with the long BMD recovery time.

The second study was a retrospective investigation of the long term use of DMPA on BMD loss and included bone remodeling as another outcome measure.<sup>2</sup> This study was designed and implemented by researchers at Cairo University, Egypt, and involved 60 women between the ages of 21-44, of which 40 were users of DMPA and 20 served as non-hormonal controls. The DPMA users were divided into a group of 20 who used DMPA less than one year, a group of 10 women who used DMPA for 1-2 years, and a group of 10 women who used DMPA for > 5 years. BMD was measured at the spine (i.e., lumbar vertebrae) with the use of dual energy roentgen absorptionmetry. They measured bone formation by use of a biological marker serum osteocalcin (SOC) and bone resorption with urinary levels of deoxyuridinoline (DPD). The DMPA users were statistically equal to the control participants with regard to mean age, parity, body mass index, previous use of contraceptives, and breastfeeding.

The results showed that the SOC levels were significantly elevated among the DMPA users compared to the controls, with a mean percentage increase of SOC of 70% among the < 1 year DMPA users, 133% among the 1-2 years users, and 224% among the > 5-year users of DMPA. The mean urinary DPD levels were significantly higher than the controls for users of DMPA for 1-2 year users, and the > 5 year users, but not for the less than 1 year users of DMPA. They did not find a significant lower spinal BMD in the less than 1 year users of DMPA, but the 1-2 year users and > 5 years users of DMPA had a significantly lower BMD levels. The lumbar spine BMD percentage decrease was 9% for the 1-2 year users and 17.8% for the > 5 year users. The authors pointed out that the BMD loss did not reach the level that would indicate osteoporosis.

The authors concluded that long term use of DMPA results in significant loss of BMD and induced significant increases in bone turn over (i.e., bone formation and resorption). They urged caution in using DMPA for women older than 40 years and recommended BMD and bone resorption markers measurements with these women.

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(Continued from p. 18)

### Comments

Both of these studies demonstrated significant BMD loss compared to the controls. The Cairo study, however, did not show the significant loss of BMD in the first year of use as compared to the first study. Part of the reason for the difference might be due to the retrospective nature of the Cairo study and, in particular, the low number of participants (i.e., 10-20 women in each group). The Cairo authors did not include a power analysis for their study. I doubt that they had enough power to show differences and enough subjects to make generalizations. Both studies, however, have results that demonstrate significant health concerns for prescribers and users of DMPA and in particular among older women. These significant health concerns with use of hormonal methods of contraception add to the attraction of using natural methods of birth control. (RF)

1. Clark MK, Sowers MF, Levy B, Nichols S. **Bone mineral density loss and recovery during 48 months in first-time users of depot medroxyprogesterone acetate.** *Fertility and Sterility*, 2006, (Epub ahead of print).
2. Shaarawy M, El-Mallah SM, Seoudi S, Hassan M, Mohsen IA. **Effects of the long-term use of depot medroxyprogesterone acetate as hormonal contraceptive on bone mineral density and biochemical markers of bone remodeling.** *Contraception*, 2006; 74:297-302.

## Progestogenic Components in Oral Contraceptive Preparations Influence Skeletal Growth in Young Women

Optimal bone development for adolescent girls is important for the prevention of osteoporosis in later life. After menarche, the ovarian production of estrogen is significant for bone formation. How hormonal contraceptives influence the bone formation process in adolescent girls is important to know. Therefore, German researchers conducted a study to determine the influence of two hormonal oral contraceptives (OC) on bone and skeletal formation in young adolescent girls over a 12 month time period (i.e., 13 cycles of use).<sup>1</sup> The two OC of interest were 20 µg ethinylestradiol with either 100 µg of levonorgestrel (LEVO) or 150 µg of desogestrel (DESO).

The participants for the study were 52 women between the ages of 18-24 years who were randomly distributed into either the LEVO or DESO group. Another 27 women served as controls and had spontaneous menstrual cycles. All participants had bone mass, bone geometry, and bone metabolism measures at 1, 3, and 6 months from the start of the study.

Women in the LEVO group did not lose bone mass but the participants in the DESO group had a decrease of 1.5% of spinal bone mass density. Furthermore, the volumetric bone mass density was increased with the use of DESO at the distal radius and tibia but the radial trabecular volumetric bone density decreased by 1.4% with the DESO group but stayed the same with the LEVO group. A side finding was that the women in the LEVO group became significantly taller than those in the control and the DESO group. The researchers concluded that the immature bone structures of the younger adolescent girls will be especially vulnerable to the androgenic side effects of progestogenic OC components.

### Comments

As with the previous studies on the effects of progestogenic agents on bone mass density, this study had a low number of participants in each group, therefore, the power to detect significant change was decreased. The authors stated that they viewed this study as a pilot and encouraged large scale prospective studies to address this important issue. I agree

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that there needs to be a further review of the health effects of hormonal contraceptives on young women who are most vulnerable to the side effects of these drugs. (RF)

1. Hartland M, Kleinmond C, Luppa P, Zelger O, Egger K, Wiseman M, Weissenbacher ER, Felsenberg D, Erben RG. **Comparison of the skeletal effects of the progestogens desogestrel and levonorgestrel in oral contraceptive preparations in young women: controlled, open, partly randomized investigation over 13 cycles.** *Contraception*, 2006 (Epub ahead of print).

## UNDER THE MICROSCOPE

### IN DEPTH - The Rhythm Method and Embryonic Death

Last June (2006) the *Journal of Medical Ethics (JME)* published an article by Professor Luc Bovens from the London School of Economics titled "The Rhythm Method and Embryonic Death." In the article, Bovens makes a claim that couples who use Rhythm will cause early embryonic death due to intercourse on the fringes of the fertile phase that leads to aged and damaged gametes. This assumption was that couples who practice Rhythm often have intercourse at the edges of the fertile phase. His article was partly in response to claims that hormonal contraception can act as an abortifacient. He argues that the practice of Rhythm can be considered a means of early embryonic death and, as such, an immoral practice.

Bovens' article received press in the media world wide. A number of people responded to the article and the responses were published in the on-line version of the journal. I responded as well. My response is printed below. I encourage the reader of CMR to access the online version of *JME* and read other responses. Of interest is Bovens' response to the responders. In his response, he provides more rationale that is not in his original article and argues for a need to essentially separate procreation from the act of intercourse through in-vitro fertilization.

*Dear Editor,*

Luc Bovens' assumption that intercourse on the fringes of the fertile phase of the menstrual cycle by users of Rhythm will result in increased embryo loss is not based on convincing evidence (*Journal of Medical Ethics*, 2006;32:355-356). In fact, some scientific evidence points to the opposite conclusion. Researchers at the US National Institutes of Health Science reported they found no evidence for this association based on single acts of intercourse during the fertile window.<sup>1</sup> In a subsequent study they did find a significant increase in pregnancy loss from acts of intercourse on the estimated day of ovulation, but the study had severe limitations due to imprecise timing of intercourse and in estimating what acts of intercourse actually caused the pregnancy.<sup>2</sup> But neither of these studies involved couples using Rhythm or what is commonly known as natural family planning (NFP).

Researchers from Johns Hopkins and Georgetown University conducted a prospective study that included 373 unplanned and 367 planned pregnancies which occurred from women who were taught natural family planning (NFP) at 5 centers worldwide.<sup>3</sup> The researchers found no significant differences in adverse pregnancy outcomes including spontaneous abortion rates between the two groups of women. Although these same researchers found some evidence of poor pregnancy outcomes from unintended pregnancy compared to NFP couples who intended pregnancy, the poor pregnancy outcomes were only

(Continued on p. 21)

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from couples who had a history of early pregnancy loss.<sup>4</sup> The largest study to test the hypothesis that users of NFP with unintended pregnancies have different pregnancy outcomes than couples that practice spontaneous intercourse resulted in no difference in pregnancy outcomes.<sup>5</sup>

Bovens's assertion about ageing gametes with use of Rhythm and resulting spontaneous embryo wastage is not new. In fact moral theologians postulated this possibility in the 1970s.<sup>6</sup> Back then, their assertions were based on poorly designed research studies and circumstantial evidence. One of the studies was a thesis that involved a retrospective assessment of parents of mentally handicapped children from one Dutch village who were asked, up to 10 years later, to recall when the conception intercourse occurred. These couples practiced a calendar-based system of NFP, not the more modern methods that rely on biological markers of fertility. The same researcher also provided circumstantial evidence of an increase of Downs Syndrome by young Catholic mothers using NFP.<sup>7</sup> Guerrero and Rojas tested the ageing gamete theory and seemed to show an increase in the spontaneous abortion rate and possibly malformations based on the recordings of the basal body temperature thermal shift and timing of artificial insemination.<sup>8</sup> However, we now know that the thermal shift is a very imprecise method of estimating the fertile phase, and conclusions based on this biological marker are fraught with error. Poor scientific studies result in poor outcomes and false conclusions.

Physiological mechanisms in the human being facilitate fresh gametes for the process of fertilization. During the fertile phase of the cycle, estrogen stimulated cervical mucus serves the purpose of filtering out defective sperm. Only the most robust succeed in reaching the ovum. Furthermore, the ovum is viable only about 12 - 24 hours. Approximately 50 -75% of spontaneous abortions are a result of chromosomal abnormalities of the embryo, and most of these occur by chance.<sup>9</sup> How much of this chromosomal damage is due to ageing gametes from intercourses on the fringes of the fertile phase has not been documented. Other factors contributing to early embryonic loss include uterine abnormalities, immunologic disorders, bleeding disorders, endocrine disorders, infections, and environmental factors such as smoking. The more troublesome ageing factor is oocytes from older women, especially when they have intercourse with older men. Women in modern developed countries tend to delay (largely by use of hormonal contraception) having children until later in life, often at an age when their fertility is in decline and their oocytes are diminished and genetically old.<sup>9,10</sup>

In fact, it could be postulated that couples using hormonal contraception will contribute to higher spontaneous abortion rates and poorer pregnancy outcomes than couples using other forms of family planning. Many couples who are on hormonal contraception will eventually discontinue the contraceptive pill to achieve a pregnancy. (Please note that couples do not stop using NFP when they want to achieve a pregnancy - in fact, NFP helps couples to target the fertile phase). Couples who discontinue hormonal contraception often experience irregular menstrual cycles, delayed ovulation, longer follicular phases, and shortened luteal phases.<sup>11</sup> Longer follicular phases and shortened luteal phases have been cited as factors that could contribute to oocyte ageing and early spontaneous embryo loss.<sup>12</sup> Millions of women discontinue hormonal contraception each year to achieve a pregnancy. Should we ask them to avoid achieving a pregnancy until their cycles normalize?

The highest probabilities of pregnancy from an act of intercourse during the fertile window are the two days before the day of ovulation.<sup>13</sup> We do know that there are factors that decrease this probability such as poor quality cervical mucus, the age of the woman and the man (not the age of the gametes), and smoking.<sup>14,15</sup> If we were to accept absolute numbers of natural preimplantation losses of 50%, then it is likely that these will occur much more (in absolute terms) with intercourse during the days of highest fertility. That is, if 50% of all zygotes fail to implant, since there are many more zygotes formed at days of peak fertility, there will be many more failed implantations during the high fertile time. This is true even

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(Continued from p. 21)

if the percentage of failed implantations on the extreme margins of the fertile period were to be slightly higher (say 1% or 5% more) - a possibility that we can't entirely exclude.

From an ethical standpoint, even if we were to hold the assertion that fertilization on the margins of the fertile time result in embryo loss, that doesn't mean that NFP use causes embryo death in any morally relevant sense. This is the case for at least two reasons, first, intercourse at these times is not unique to NFP users. Where is the evidence that NFP users have intercourse on the edges of the fertile phase significantly more than the general population? Research has indicated couples have intercourse more frequently on the weekend when there is more time and less stress.<sup>16</sup> Weekend intercourse will result in intercourse anytime during the fertile phase, including the fringes. Second, having intercourse at these times does not equal doing anything (either "action" or "omission") to the woman or the embryo to cause the embryo's death - as is the case when a woman uses an abortifacient drug or device. The parallel Bovens tries to draw between the two cases just doesn't work. The point is basically the same as one would make in distinguishing between [non- abortifacient methods of] contraception and NFP. They both avoid fertilization, but contraception does so by doing something to the act of intercourse - either an "action" or [in the case of withdrawal] an "omission" - that takes away as much as possible of the fertility it would otherwise have. NFP does nothing of the sort.

NFP helps couples to monitor, understand, and live with their fertility. Contraception works to block, suppress, or destroy fertility — actions that are contra-fertility and, at times contra-life. Fertility for many couples is a precious and awesome gift. Human life is precious and at the most vulnerable during the passage from the fallopian tubes to the womb. The assumption that intercourse on the edges of the fertile phase leads to the utilization of aged gametes and increased embryonic destruction is plausible, but there is scant evidence of this among human beings. The assumption that practicing NFP results in the use of aged gametes and increased embryonic death has no good evidence and in fact some good evidence to the contrary. The use of NFP is not an action or omission against embryonic human life anymore than normal human living and loving. Taking Bovens's notion to the extreme would mean that couples should not have intercourse at all - since, it might result in a spontaneous abortion. Perhaps the real absurdity is the thinking that what is natural is bad and what is destructive of fertility is good.

Separating sexuality from fertility is a dualistic system counter to the natural intent of the sexual act. It only works in a fantasy world with a false sense of sexual freedom by use of condoms, hormonal contraception, emergency contraception, abortion as a backup, IVF when a perfect child is wanted, and sterilization when fertility is no longer desired. This dualism creates a false representation of human beings, human relations, human bonding, and the transmission of human life.

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(Continued from p. 22)

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