



# NATURAL FAMILY PLANNING

## Gap Technique More Accurate than Coverline Technique in Interpreting BBT Chart

Researchers at Emory University School of Medicine in Atlanta have developed a method of estimating the day of ovulation and post-ovulatory infertility by having both a woman and her male partner take their waking body temperatures.<sup>1</sup> Their theory is that the woman and her partner will experience the same influences on body temperature but the woman's will substantially rise after ovulation. When a substantial "gap" in the difference between the woman's and man's body temperature occurs, they identified that as a sign of ovulation and the beginning of the woman's post-ovulatory infertile phase. The "gap" needs to be at least 0.2° F greater than the largest temperature difference from the first 10 days of the menstrual cycle. This temperature elevation is what the authors term the "crucial gap."

Emory University researchers compared the "Gap" technique with the Coverline technique in interpreting both the post-ovulatory "final fertile phase" (FFP) and the "initial infertile phase" (IIP).<sup>2</sup> The FFP was defined as the last day a couple could have intercourse

if they were trying to achieve a pregnancy and the IIP was the first day it was safe to have intercourse if they were trying to avoid pregnancy. For the Coverline technique, the FFP was the first day that the temperature was above the Coverline, for the Gap technique the FFP was the first day the differences in female-male temperatures were as large as or greater than the "crucial gap." A Coverline is established by taking the highest temperature from the first 10 days of the menstrual cycle and then adding 0.15° F to that temperature. The IIP for the Coverline technique was the third consecutive day that the women's temperature was above the Coverline temperature, and for the Gap technique the IIP was the third consecutive day that the temperature was equal to or greater than the crucial gap. The researchers used the urinary luteinizing hormone (LH) surge as the gold standard to compare the two techniques and to estimate the day of ovulation.

The Basal Body Temperature (BBT) charts used for comparing the Gap technique with the Coverline technique came from a previous study in which the researchers collected 33 complete BBT charts that

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reflected ovulatory menstrual cycles.<sup>1</sup> The women who produced the BBT charts used a urinary LH test kit to estimate the day of ovulation. The end of the fertile period was defined to be the morning of the third day after the urinary LH surge.

The results showed that the Gap technique identified the FFP correctly + 1 day of the LH-identified FFP in 13 of the 33 cycles (39%); the Coverline technique correctly identified the FFP in 10 of 33 menstrual cycles (30%). A chi square test ( $\chi^2 = 13.4$ ;  $p = 0.44$ ) showed no statistical difference in the ability of the two techniques to identify the FFP. However, the Gap method estimated the IIP to be within + 1 day of the LH-defined IIP in 13 of 33 cycles, as compared to the Coverline technique, which correctly identified the IIP in only 4 of 33 cycles. There was a statistical difference in the proportion of correctly identified IIPs between the two techniques ( $\chi^2 = 13.4$ ;  $p < 0.001$ ). Neither method underestimated the fertile period but the Gap technique overestimated the fertile period by a median of one day and the Coverline by a median of four days. The authors concluded the Gap technique was a more accurate method of determining the initial post-ovulatory infertile phase than the Coverline technique.

#### COMMENTS

The authors stated they compared the Gap technique to the Coverline technique because the Coverline technique is the simplest and most commonly used method to determine post-ovulatory infertility with the BBT. This is questionable because a different temperature technique is used by many BBT and Sympto-Thermal Method users. Many use the "3 over 6" rule, i.e., the highest 3 temperatures at least 0.2°F over the previous 6 lower temperatures. Furthermore, the Coverline method as described by Vollman consists of obtaining an average of all the temperatures from the previous menstrual cycle and using that average as the Coverline temperature for the following cycle. Another Coverline technique method utilizes the average temperature from the first six days of the menstrual cycle.

It should be noted that the Gap method is a shared method in that both the woman and her partner take daily temperatures. Whether there is greater satisfaction and compliance in use of this technique because it is being shared by both remains to be seen. The fact that this method has been used and evaluated by only a very small number of female participants indicates the need for a larger study. Furthermore, the fact that a woman and her male partner must take daily temperatures increases the chance for temperature variance 100-fold. The authors assume that the man and woman both experience the same variances and that a false rise in temperatures (for example due to a fever) can be more easily identified than if just the woman used BBT. This assumption needs to be verified with a much larger and diverse population of women and men. (RF)

1. Dunlop, A.L., Allen, A.S., & Frank, E. **Involving the male partner for interpreting the basal body temperature graph.** *Obstetrics and Gynecology*, 2001;98:133-138.
2. Dunlap, A.L., Schultz, R., & Frank, E. **Interpretation of the BBT chart: using the "Gap" technique compared to the Coverline technique.** *Contraception*, 2005;71:188-192.

## Turkish Couples Report Satisfaction with Use of Standard Days Method

The Standard Days Method (SDM), a fertility-awareness based method of family planning developed at Georgetown University Institute for Reproductive Health (IRH), was recently introduced to couples living in a region of Istanbul, Turkey.<sup>1</sup> The SDM was designed for women who generally experience menstrual cycle lengths between

26-32 days. The SDM estimates fertility to be between days 8-19 of the menstrual cycle and utilizes a bead system (called Cyclebeads) designed to help track days of the menstrual cycle. After the SDM was introduced to couples in Turkey, researchers at the Marmara University School of Medicine (Istanbul, Turkey), in collaboration with the Georgetown University IRH research group, conducted interviews to determine demand, satisfaction, and continuation with the method.

Participants for use of the SDM were solicited from one neighborhood in Istanbul by a systematic cluster sampling method. Trained research assistants interviewed an initial sample of 657 couples, of which 346 were eligible for the study. Of these 346 couples, 204 (58.9%) were eligible for use of the SDM, 166 (47.9%) were interested in learning about the method, 151 (43.6%) were interested in using the method, and of these, 132 (38.1%) were actually taught the method and given the tracking beads. Eligibility for the study included current use of a traditional method of family planning (i.e., withdrawal or douching after intercourse), inconsistent condom use, or no method between the ages of 18-39, in a stable relationship, and a desire to avoid pregnancy. Eligibility for use of the SDM included not having used oral hormonal contraception in the last 3 months, not having used injectable hormonal contraceptive in the last 6 months, having 4 or more cycles since the last child was born, having the last 3 periods when expected, and having menstrual cycle regularity between 26-32 days.

At the first one-month follow-up interview, 105 (84.0%) of the 132 original SDM participants were using the method and at the second follow-up (4 months later), 67 couples (or 50.7% of the original 132 couples) were still using the method. Fourteen of the 132 couples were lost to follow-up and 6 couples achieved a pregnancy. At each follow-up interview, the women participants were asked (by use of an open ended question) their level of satisfaction with the method. The researchers categorized the responses into 4 themes as follows:

1. Happiness with being able to have unprotected intercourse during the infertile days
2. Happiness knowing when the days of menses and possible fertility would occur
3. Trust in the method
4. Happiness with no side effects

Although most users were satisfied with the method, those who discontinued gave the following reasons:

1. Lack of trust in the method
2. Too much abstinence (i.e., the 12 day fertile phase)
3. Time consuming to track cycle
4. Husband not satisfied with using condoms during fertile phase
5. Preferred to use withdrawal because it felt cleaner

Of interest is that 41% of the potential users of the SDM (i.e., those who met the eligibility requirements) could not use the SDM due to cycle irregularity. According to the Turkish researchers, some were due to breastfeeding or postpartum, but most because of irregular cycles. Since the potential demand for use of the SDM was around 80% and that 50% of those who were taught continued with the method at 4 months of use, the researchers concluded that the SDM be added to the family planning options for Turkish women.

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## IMPORTANT NOTICE

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**Thank you!**

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#### COMMENTS

As the authors of this study mentioned, it is worth noting that the reason why some couples discontinued the SDM and were not satisfied with the method was because their husbands continued to use withdrawal even during the infertile phases of the cycle. They were habituated to use of withdrawal. Furthermore, some discontinued because withdrawal was a cleaner method for the woman. By clean is meant that the semen did not remain in the vagina. Withdrawal is one of the traditional methods of family planning for Turkish couples, along with douching after intercourse. It seems that vaginal cleanliness might have some type of cultural component in the choice of family planning methods for these couples. A quote from one of the Turkish couples in the study illustrated some of the thinking for use of withdrawal.

*"My husband practiced withdrawal for 17 years. He made it a habit. He says if he becomes accustomed to this freedom, then he would not control himself anymore."*

An interesting study would be to find out how often US couples use withdrawal along with their method of NFP. I am afraid that withdrawal can be habit forming and is more widely used in the US than expected. The ever use of withdrawal by US women has increased over 100% since 1982, and is currently the primary method of family planning for about 1.5 million women in the US. Use of withdrawal is certainly a dynamic that NFP teachers will encounter in a large practice. (RF)

1. Kalaca, S., Cebeci, D., Cali, S., Sinai, I, Karavus, M., & Jennings, V. **Expanding family planning options: offering the Standard Days Method(tm) to women in Istanbul.** *Journal of Family Planning and Reproductive Health Care*, 2005;31:123-127.

## THE MENSTRUAL CYCLE

### ***Shorter Menstrual Cycle Length Linked to Stress among Peri-Menopausal Women***

It is known from past studies that severe stress (e.g., being in a war zone) can cause amenorrhea and anovulation. The effect of chronic daily stress on menstrual cycle variability, however, is less clear. Some studies have shown that high stress (e.g., stressful jobs) can cause menstrual cycles to lengthen, shorten, and /or become anovulatory. Other studies have found no effect of stress on the menstrual cycle. Furthermore, there has been little study on the effects of stress on the menstrual cycle among peri-menopausal women, since these women already experience considerable menstrual cycle variability. Researchers at Penn State University published a prospective study to determine the relationship of chronic life stress and menstrual cycle characteristics among peri-menopausal women.<sup>1</sup>

The sample for their study came from participants in the Tremin Research Program on Women's Health, which is an ongoing longitudinal study of menstrual cycle characteristics that was started by Alan Treloar back in 1934. The current study utilized a 1990 subgroup (n = 505) of women participants that were between 35-55 years old and still menstruating. In 1992, 206 (40.8%) of these participants responded to their stress survey, and in 1993, 159 of these women were still menstruating and responded to a second stress survey. The mean age of the 1992 subset was 48.2 and the 1993 subset was 47.8. As part of the Tremin study, the participants kept calendar cards in which they recorded the beginning and end of each

menses. These participants were also asked to complete a stress survey based on life changes experienced over a year (e.g., death of a spouse, marriage, moving, new job, etc.). Each life change was ranked on a 4-point scale with the possible range of scores 0-36. The researchers chose the scores of 13 and above as "high stress." The 1993 subset was surveyed in 1992 and 1993 to yield a stress score change.

Results showed no significant relationship between menstrual cycle characteristics (i.e., menstrual cycle length and length of menses) and stress levels, nor were there significant differences in menstrual cycle length between low and high stress women. However, the researchers did find that women who experienced an increase greater than 4 point in their stress scores from 1992-1993 had a significantly shorter cycle length (i.e., on average 0.2 days) and significantly shorter menses (i.e., on average 0.1 days) than those women who had low stress scores. The researchers concluded that in the long term there is little evidence to suggest that there is a relationship between stress and menstrual cycle changes in perimenopausal women, except if there are marked changes in overall stress. They also commented that it was difficult to conduct such a prospective study, since so many women are on some type of exogenous hormones during the peri-menopause.

#### COMMENTS

The study is questionable due to several problems. First, it is curious that the study was conducted in 1992 and 1993 and yet published in 2004: the results were published 11 years after the data was collected. The authors provide no explanation for this delay. The types of life stress that women experience today (e.g., with cell phones, the Internet, etc.) might be very different than those cited 10 years ago. Second, the researchers did not look at individual menstrual cycles and the effect of stress. It would be more accurate to measure stress levels for each menstrual cycle to determine the effects of stress. Looking at overall length and overall stress scores is a crude method of determining effects on the menstrual cycle. Third, their measure of stress was questionable. Instead of using the Social Readjustment rating scale as was intended, they ranked each life change item on the same 1-4 scale. The original tool ranked 50 life changes from death of a spouse to minor traffic ticket, with marriage being the middle score (50) life event. The original tool therefore, had a better weighting system, was more sensitive, and had much greater variability in scoring range and thus a better measure of stressful life events. Finally, there were only 30 women in the subgroup that experienced a life change score of 4 or more from 1992-1993. To statistically compare them with the total of 150 is a violation of the statistical test that they used. The study of the effects of stress on menstrual cycle variability is important (especially among perimenopausal women) but this study lends little to that knowledge. (RF)

1. Barsom, S.H., Mansfield, P.K., Koch, P.B., Gierach, G., & West, S.G. **Association between psychological stress and menstrual cycle characteristics in peri-menopausal women.** *Women's Health Issues*, 2004;14:235-241.

## Monitoring Menstrual Cycle is Helpful for Predicting and Treating Menstrual Migraines

**A**ccording to the literature, 50% of migraine headaches experienced by women are associated with menstruation. Furthermore, migraine attacks are more severe and last longer around menstruation than at other times of the menstrual cycle. Peak migraine incidence is two days before menstruation through the first three days of the following cycle. Based on this information, researchers from London, England theorized it

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would be best to predict the first day of menstruation and then to time prophylaxis treatments (e.g., use of estradiol gel) around that day.<sup>1</sup> To test this idea, they used a fertility monitor (the ClearPlan Easy Fertility Monitor, Unipath Limited, Bedford, UK) to estimate ovulation and predict the first day of menses. Menstrual migraines for this study were defined as migraines on days -1 to +3, with day one being the first day of menstruation in at least two-thirds of cycles with no migraine at other times of the cycle.

Forty women were recruited for this study, but only 27 (67.5%) remained to complete the study and generate 174 cycles of usable data. The mean age of these women was 43 years (range = 29-50). The subjects monitored their menstrual cycles, with use of the ClearPlan fertility monitor. The ClearPlan monitor (also known as ClearBlue) is a hand held fertility device that measures a threshold level of urinary estrone-3-glucuronide (E3G) and luteinizing hormone (LH). The participants collected first morning urine samples for the study. The first day of the LH (peak) was used as the marker for estimating the first day of the next menses and for the initiation of treatment with estradiol gel. The treatment algorithm was to use the gel on day 10 (first day of LH surge +9 days) and continue until day 2 of the next menstrual cycle.

The mean length of the 174 cycles generated for the study was 28 days, with the length range of the follicular phase from 5-22 days, and the luteal phase 7-18 days. The investigators found 25 of the 27 women participants able to apply the algorithm (day LH surge +9 days) accurately, i.e., they applied the treatment gel prospectively 5 to 6 days prior to day one of menstruation. They also found the ClearPlan monitor accurately detected 90.2% of the LH surges (in comparison with laboratory analysis of the urine samples). Subjective comments indicated 97% of the participants experienced the monitor useful in predicting menstrual migraines.

#### COMMENTS

This study illustrated the potential health benefits of self monitoring menstrual cycles (outside of use for family planning purposes). The authors pointed out that the algorithm they tested could also be used for non-pharmacological treatments of migraines and be useful in alerting the migraine patient to avoid environmental triggers during the perimenstrual time period. (RF)

1. MacGregor, E.,A., Frith, A., Ellis, J., & Aspinall, L. **Predicting menstrual migraine with a home-use fertility monitor.** *Neurology*, 2005; 64:561-563.

## MALE FERTILITY

### *Conditions for High Scrotal Temperatures*

**A** study was recently conducted at Liebig University, Germany to determine the effect different types of undergarments and activity had on scrotal temperatures.<sup>1</sup> The reason for the study was to test scrotal temperatures which are closely related to testicular temperatures. When testicular temperatures are too high (i.e., near body core temperature) spermatogenesis and semen quality are reduced.

Fifty healthy volunteer males between the ages of 18-45 with no history of infertility took part in the study. Each volunteer had electronic temperature sensors attached to each testicle. They were then randomly assigned to one of two activities, either walking for 45 minutes on a treadmill or sitting in a fixed position for 45 minutes, using three types of undergarments,

i.e., cotton jockey briefs, cotton boxer shorts; or no undergarments. They all wore standard cotton pants and a cotton shirt. Each participant had scrotal temperatures recorded with each type of undergarment while either sitting or walking in a climate controlled room.

The results showed that scrotal temperatures were significantly lower (1.5 to 2.2° C) during walking than sitting. Researchers also found significantly higher scrotal temperatures while the subjects wore jockey briefs than with boxer shorts either walking or sitting. Moreover, scrotal temperatures were significantly higher with boxer shorts than with wearing no undergarments. The researchers concluded that wearing tight fitting undergarments is associated with higher scrotal temperatures and subsequently higher testicular temperatures than when wearing loose fitting undergarments or none.

#### COMMENT

Although there were significantly higher scrotal temperatures for male participants when wearing tight fitting undergarments, there is no evidence of the effect type of undergarment has on sperm production or semen quality. Further research will need to be conducted to determine those effects. (RF)

1. Jung, A., Leonhardt, F., Schill, W.B., & Schuppe, H.C. **Influence of the type of undertrousers and physical activity on scrotal temperature.** *Human Reproduction*, 2005;20:1022-27.

## Laptop Use Causes Significant Increase in Scrotal Temperatures

Researchers in the Department of Urology at State University of New York (SUNY) also were concerned about elevated scrotal temperatures and its effects on male fertility, especially among young males using laptop computers.<sup>1</sup>

Laptop computers generate considerable heat while in use and if balanced on the lap, can potentially cause increases in scrotal temperatures. To test the effect of laptop computer use on scrotal temperatures SUNY researchers recruited 25 healthy male subjects with no known infertility problems. The subjects were fitted with temperature sensors on the left and right testicles and were measured at 3 minute intervals in two experimental conditions: 1) one hour in a sitting position with legs positioned as if a laptop computer was in place, and 2) one hour in a sitting position with a laptop computer in use. Subjects were in climate controlled rooms during testing.

Results showed a significant increase in both left and right scrotal temperatures with use of the laptop computer and a significant increase in the left scrotal temperature in a sitting position without a laptop computer. However, laptop use scrotal temperatures were significantly higher than those taken in the sitting position without the laptop. The left and right scrotal temperatures increased by 2.8° C and 2.6° C respectively with one hour use of the laptop computer. SUNY researchers concluded that repetitive use of laptop computers and repetitive increases in scrotal temperatures could result in negative effects on sperm production.

#### COMMENT

Of interest is that both the German study (described above) on activity and scrotal temperature and this study found just being in a sitting position caused elevation in scrotal temperatures. Like the German study, there is no evidence that the sitting position or use of the laptop computer positioned on the lap will decrease sperm production and semen quality. However, the SUNY researchers point out, based on data from previous studies, sperm concentrations can

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decrease by 40% per 1° C increase in median daytime scrotal temperature. (RF)

1. Sheynkin, Y., Jung, M., Yoo, P., Schulsinger, D., & Komaroff, E. **Increase in scrotal temperature in laptop computer users.** *Human Reproduction*, 2005;20:452-455.

## Antioxidants (Vitamins C, E, and $\beta$ -Carotene) Are Associated with Better Semen Quality in Healthy Males

**P**ast studies have indicated that dietary intake of anti-oxidants such as vitamins C, E, and  $\beta$ -carotene and micronutrients, such as folate and zinc, is important for sperm production and semen quality. Furthermore, semen quality and sperm concentrations are known to decrease as men age. Researchers from the School of Public Health at the University of California, Berkeley and the Lawrence Livermore National Laboratory (California) conducted a study to determine whether normal daily dietary and supplement intake of anti-oxidants (vitamins C, E, and  $\beta$ -carotene) and micronutrients (folate and zinc) were associated with semen quality and whether vitamin and nutrient intake can modify age-related decline in semen quality.<sup>1</sup>

The investigators recruited 97 healthy male volunteers from employed and retired workers at Lawrence Livermore National Laboratory. The male volunteers were enrolled so that approximately 15 males represented each decade from 20 to 60 years of age and another 25 males from 60 to 80 years of age. The volunteers could not have any infertility problems or be current cigarette smokers. The 97 volunteers completed a 100 item dietary food frequency questionnaire to estimate average daily intake of nutrients and provided a semen specimen for analysis of sperm concentration and semen quality. The target vitamins and micronutrients were categorized by the researchers into 1 of 3 categories, i.e., 1 = low intake, 2 = moderate intake, and 3 = high intake.

The mean age of the volunteers was 46 and the age range was 22 to 88, with a median age of 44. The results indicated that neither zinc nor folate intake was associated with improved measures of semen quality. However, high intake of antioxidants was associated with improved semen quality. More specifically, vitamin C intake was associated with higher sperm count, vitamin E with progressive sperm motility, and  $\beta$ -carotene with higher sperm concentration and sperm motility. When the 3 antioxidants were calculated together, they were significantly associated with higher sperm concentrations and more progressively motile sperm. However, the amount of nutrient and vitamin intake did not eliminate the age related decline in semen quality. There was some evidence that the slope of decline decreased with higher intake of nutrients. The researchers concluded that among a convenience sample of healthy non-smoking males, higher anti-oxidant intake was associated with higher sperm numbers and motility. They suggested a healthy diet with supplements may be an inexpensive and safe way to improve semen quality.

### COMMENT

Although this study found a positive association between anti-oxidant intake and semen quality, this type of research design produces only relational results, not cause and effect. A study in which a group of healthy males are randomly distributed into a treatment group (with intake of supplemental anti-oxidants) with a control group of males that receive no supplemental intake of anti-oxidants would be a stronger design to show the effects of these nutrients on semen quality. There are many co-factors that could affect semen quality in a relational study, including the retrospective recall of dietary nutrients. (RF)

1. Eskenazi, B., Kidd, S.A., Marks, A.R., Slotter, E., Block, G., & Wyrobek, A.J. **Antioxidant intake is associated with semen quality in healthy men.** *Human Reproduction*, 2005;20:1006-1012.

## Optimal Cervical Mucus Minimizes Effects of Male Age Related Reduction in Fertility

As was mentioned in the previous study, as the quality of semen and sperm concentration decrease as men age, so does their reproductive capacity. However, biostatisticians from the National Institute of Environmental Health Sciences and the University of North Carolina, Chapel Hill, sought to determine if lowered fertility in men in their late 30s and early 40s is related to quality of cervical mucus on the day of intercourse.<sup>1</sup> It is well known among natural family planning (NFP) teachers that quality cervical mucus is crucial for sperm survival and transport through the female reproductive tract.

In collaboration with a European NFP group and researcher, the US biostatisticians were able to obtain data produced by 782 couples who were taught an NFP method and recorded daily observations of cervical mucus quality and acts of intercourse. The European NFP couples produced 1,459 menstrual cycles of data, of which 342 ended with a documented pregnancy. The researchers were then able to determine day-specific probabilities of pregnancy in relation to cervical mucus quality on the suspected day of intercourse that resulted in a pregnancy with male reproductive age.

Controlling for the female partner's age, researchers found that as the quality of cervical mucus increased, the effect of male age on fertility decreased. Specifically, among men in their late 30s and early 40s, there was a 50% less likelihood of pregnancy from an act of intercourse when no mucus was observed. On days when a damp sensation was recorded the less likelihood of a pregnancy decreased to 21%. On days of thick mucus the less likelihood decreased to 11% and on days with the most fertile-type mucus to only 4%. The researchers concluded male age decline in fertility can be offset with intercourse on optimal mucus (i.e., clear, stretchy, and slippery type mucus) days of the menstrual cycle.

### COMMENTS

These results and conclusions confirm the information that many NFP teachers already provide to couples: the most optimal time to achieve a pregnancy is when couples have intercourse on good quality mucus days. It is satisfying to have data to support these practices and advice. (RF)

1. Dunson, D.B., Bigelow, J.L., & Colombo, B. **Reduced fertilization rates in older men when cervical mucus is suboptimal.** *Obstetrics and Gynecology*, 2005;105:788-793.

## CONTRACEPTIVES

### Majority of Men Willing to Use Male Birth Control "Pill"

Men have been using condoms as a male-controlled method of birth control for many years. Condoms, however, are often not effective, can be messy, and are disruptive of the act of intercourse. Researchers have been interested in the idea of developing other male birth control options (such as a pill, injection, or implant). Of special concern has been an interest in creating a method that does not interfere with the act of

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intercourse. Within the next five years new male birth control options will become a reality. Phase II clinical trials of male fertility control (MFC) products are currently being conducted. Since male fertility control (MFC) products are soon to be available, researchers from the Center for Epidemiology & Health Research in Berlin, Germany and from Schering, AG (a German based pharmaceutical company that is currently conducting phase II trials of a male birth control product) conducted a large survey study to determine knowledge, attitudes, and acceptability of MFC products.<sup>1</sup> They also wished to determine the best-accepted route of administration for MFC products.

Researchers through the Centre for Epidemiology & Health Research, Berlin, surveyed males between the ages of 18 and 50 in nine countries on four continents. They used a combination of random and quota sampling methods and obtained the following sample sizes in each of 9 countries: 1000 Argentina, 1000 Brazil, 1000 Indonesia, 1024 Mexico, 1021 Germany, 1049 Spain, 1023 Sweden, 725 France, and 1500 in the USA. France was the only country that did not meet the target goal of 1000 participants. The overall response rates ranged from 36% to 68%. A multiple choice MFC product attitude questionnaire was distributed in person by trained interviewers. The median age of the respondents ranged from 29 years in Mexico to 40 in the USA. Most (at least 60% in each country) were married and most (>70%, except in the USA, Germany, and Indonesia) listed their religion as Roman Catholic.

The results showed that overall the respondents had good knowledge of contraceptive methods. The male condom was the male contraceptive with which respondents had the most experience, with an average ever-use of 79.4%. The overall percentage of respondents who expressed personal experience with female contraceptive methods was as follows: oral contraception (66.4%), Calendar Rhythm (28.3%), IUD (21.8%), breastfeeding (17.2%), and sterilization (11.7%). Very few respondents disapproved use of contraception, with the heavily Muslim country of Indonesia and the USA as the only two with at least a 10% disapproval rate. The main result of the survey was that, overall, 55.1% of respondents expressed willingness to use some type of MFC product and only 20.7% expressed an unwillingness to do so. There was no association found between religious commitment and willingness to use male contraception. However, willingness to have a vasectomy was a strong predictor of a favorable response to use a MFC product. Finally, daily oral intake of a birth control pill was the most favored route of administration followed by yearly implant and monthly injection. The researchers concluded that with over 9000 male respondents in 9 different countries on 4 continents there was general wide acceptance of MFC products.

#### COMMENT

The Schering pharmaceutical company funded this study and Schering researchers are conducting studies on MFC products. Therefore, there is a strong potential for bias towards the favorability of MFC products in the survey questionnaire and in the interpretation of the study results. In fact, the MFC product that Schering is closest to bringing to market is a combination annual implant with monthly injections. Furthermore, the non-response rate in some of the target countries was 40-65%. The opinions from these large groups of non-respondents might change the scope of the results. I also wonder if some of the potential side effects of taking a monthly injection of testosterone and estrogenic implant (e.g., atrophy of the testicles) were included in the survey items, and if that would change the willingness of the male respondents to take these products. I personally cannot see males wanting to have monthly clinic visits for an injection of testosterone and an annual visit for a gestagen implant. However, the influence of the female partner might change the dynamics. She might

point out that the male partner should participate in the contraceptive burden. In fact 40-80% of the respondents indicated that they consulted with their wives about how to respond to the questionnaire. Finally, it is a sad commentary that the majority of respondents that were willing to use MFC products are Roman Catholic. (RF)

1. Heinemann, K., Saad, F., Wiesemes, M., White, S., & Heinemann, L. **Attitudes toward male fertility control: results of a multinational survey on four continents.** *Human Reproduction*, 2005;20:549-556.

## Obesity Decreases Efficacy of Oral Contraceptives

Researchers from the University of Washington School of Public Health and Community Medicine recently conducted a federally funded study to determine the effects of body mass index (BMI) and weight on hormonal oral contraceptive (OC) effectiveness, i.e., the risk of pregnancy while on OCs due to weight.<sup>1</sup> The researchers designed a case control study in which they obtained female enrollees from a Seattle based Group Health Cooperative who had positive pregnancy tests between May 1, 1998 and February 28, 2001 and who had received prescriptions for OCs. They were able to find records of 756 women during that time period and of these women, 546 (72.2%) agreed to participate but only 280 fit the requirements of the study (257 said they did not use OCs during the time period). These women were matched with randomly selected OC-using enrollees from the same health cooperative during the same time period that did not have a positive pregnancy test. The researchers were able to contact 945 matched control women, of which 701 (74.2%) agreed to participate, but only 536 met the study requirements. Body weight was ascertained from all participants by in-person interviews and validated through medical records. Only women who had laboratory-confirmed pregnancies were included in the study. Overweight was defined as a BMI over 27.3 (which is the 85th percentile of 20-29 year old women) and severely overweight was defined as a BMI over 32.2 (which is the 95th percentile of US women 20-29 years old).

Researchers found an increased risk of pregnancy of nearly 60% for those OC users in the highest BMI percentile (i.e., BMI > 27.3) and a >70% increased risk for pregnancy among women in the higher end of the highest BMI percentile (i.e., BMI > 32.2), compared with women in the lowest 3 BMI quartiles. The investigators also discovered there was a threshold weight before risk of pregnancy increased significantly (i.e., no increased risk of pregnancy with BMI categories below 27.3).

The authors gave three biological reasons why there is an increased risk of pregnancy with high BMI: 1) a higher body weight is associated with a high basal metabolic weight and therefore a shortened duration of action of OCs; 2) drugs such as OCs have an increased liver clearance with obesity, which may lead to insufficient serum levels of OCs; and 3) lipophilic OCs might be sequestered in the increased volume of fat tissue in obese women and therefore lower OC serum levels. The researchers concluded that being overweight may increase an obese women's risk of unintended pregnancy while on OCs. They also mentioned a 60% increased risk translates into 2 more pregnancies per 100 women-years of use.

### COMMENTS

The authors recommended overweight women might consider an additional contraceptive method or an effective alternative method. From a health standpoint I would

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recommend weight loss, not using a hormonal method of family planning, and learning natural family planning. (RF)

1. Holt, V.L., Scholes, D., Wicklund, K.G., Cushing-Haugen, K.L., & Daling, J.R. **Body mass index, weight, and oral contraceptive failure risk.** *Obstetrics & Gynecology*, 2005;105:46-52.

## EMERGENCY CONTRACEPTION

### *Chinese Hong Kong Women Do Not Favor Over-the-Counter Distribution of Emergency Contraception*

The Family Planning Association of Hong Kong recently conducted a survey to determine knowledge, use, and attitudes towards more liberal approaches in delivering emergency contraception (EC).<sup>1</sup> Chinese women attending one of eight birth control clinics and one of three youth care centers run by the Hong Kong Family Planning Association were asked to complete a questionnaire on attitudes and knowledge of EC. Over a 6-week study period, 2454 were asked to complete the questionnaire, 1725 took the questionnaire, 1675 returned the questionnaire, and 1405 questionnaires were suitable for analysis (i.e., a 42.5% participation rate). The mean age of the participants was 32.4, 58.9% were married, and 75.2% had no religion.

Results showed 63.7% of the respondents were aware of EC. Higher awareness of EC occurred in the younger age group (73.4%), the more educated (i.e., university education) (81.3%), and being single and cohabitating (71.3%). Among the subjects that heard of EC, 81.3% knew that EC had to be taken within 72 h of intercourse. Forty-four (4.9%) thought the EC pill acted as an abortifacient. Few (15.7%) of the respondents have used EC and 56.6% found EC easy to obtain. Less than half (46.3%) supported EC to be widely advertised and less than half (48.7%) supported advanced provision of EC. A quarter (25.7%) supported having EC available over-the-counter. Reasons for not supporting over-the-counter use were concerns that EC should only be issued under a doctor's supervision, EC might be misused, and EC distribution might promote irresponsible sex. The authors indicated the respondents for this study were rather conservative in their attitudes towards EC and lacked adequate knowledge of EC.

#### COMMENT

The low support among respondents for wider advertising, advanced provision, and over-the-counter distribution of EC was rather surprising. These respondents (for the most part) were attending family planning clinics for either contraception or abortion services and certainly were not anti-birth control or pro-life advocates. Of interest is that 75% had no religion and knowledge of EC was highest among single cohabitating women - a group that EC would serve well to support that type of lifestyle. Replication of this study among US women would be of interest. (RF)

1. Wan, R.S.F. & Lo, S.S.T. **Are women ready for more liberal delivery of emergency contraceptive pills?** *Contraception*, 2005;71:432-437.

# UNDER THE MICROSCOPE

## Staging the Menopausal Transition: TREMIN and STRAW

In July of 2001, the Stages of Reproductive Aging Workshop (STRAW) was held in Park City, Utah for the purpose of addressing the absence of a relevant staging system for female reproductive aging.<sup>1</sup> The specific goals of the workshop were threefold: 1) to develop an objective and useful staging system; 2) to revise the nomenclature related to reproductive aging; and 3) to recommend areas of research. The workshop was sponsored by the American Society of Reproductive Medicine, the National Institute on Aging, the National Institute on Child Health and Human Development, and the North American Menopause Society. The participants for the workshop were 27 invited experts who had extensive clinical or research experience in reproductive aging. The model of female reproductive aging they developed is called the STRAW staging system and was based on four criteria: 1) it relies only on objective data; 2) it uses only inexpensive reliable tests; 3) it allows women to be placed in the appropriate stages prospectively; and 4) inclusion in one stage precludes placement in another stage. The final system had seven stages. They are as follows:

<b>THE STRAW STAGING SYSTEM</b>		
<b>Stage -5</b>	<b>Early Reproductive Stage</b>	follows menarche; menstrual cycles are variable to regular in length; the FSH levels are normal; length of this stage is variable
<b>Stage -4</b>	<b>Peak Reproductive Stage</b>	menstrual cycles are regular (i.e., 25-35 days in length); the FSH levels are normal; length of this stage is variable
<b>Stage -3</b>	<b>Late Reproductive Stage</b>	menstrual cycles are regular but FSH levels are elevated; duration of this stage is variable
<b>Stage -2</b>	<b>Early Menopausal Transition</b>	(also the beginning of the peri-menopause) the variability of cycle lengths are greater than seven days different from normal (e.g., her regular cycles are now every 24 days instead of every 31 days); the FSH levels are elevated; the duration of this stage is variable
<b>Stage -1</b>	<b>Late Menopausal Transition</b>	this stage is marked by two or more skipped menstrual cycles and an interval of amenorrhea greater than 60 days; elevated FSH levels and is variable in length; vasomotor symptoms are most likely to occur (still part of the peri-menopause); stage duration is variable
<b>Final Menstrual Period (FMP) = 1 year = amenorrhea for 12 months = final 12 months of the peri-menopause</b>		
<b>Stage +1</b>	<b>Early Postmenopause</b>	begins with the FMP and last for four more years, i.e., lasts a total of five years, there are no menstrual cycles, the FSH remains elevated
<b>Stage +2</b>	<b>Late Postmenopause</b>	begins the sixth year after the FMP and ends at the death of the individual, FSH levels continue to be elevated

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In 1934, Alan Treloar began collecting prospective menstrual diaries (at first he used students at the University of Minnesota) and continued for the next 50 years.<sup>2</sup> He became the director of what was originally known as the Menstrual and Reproductive Health or Tremin Trust Program (what is now known as the TREMIN Program). This program is thought to be the longest and largest project study of menstruation and women's health and now includes over 5,000 participants that have contributed over 58,296 menstrual records. Dr. Treloar is known for first describing the concept of the peri-menopause, (i.e., the time period of up to 11 years before menopause when irregular menstrual cycles are normative).

The TREMIN project is now housed at Pennsylvania State University and researchers there recently conducted a study to examine the STRAW model of reproductive staging. The study was particularly interested in whether or not menopausal transition is experienced in discrete stages from pre- to peri-menopause, and then from peri- to post-menopause.<sup>3</sup>

To conduct an evaluation of the STRAW model, the Penn State researchers utilized 505 participants of the Midlife Women's Health Survey (MWHs) who: 1) reached menopause during the course of the study; 2) had minimal missing data; and 3) had provided health report data in the 3-12 years prior to the report of menopause. Of the 505 female participants in the MWHs, 100 (19.8%) met the criteria for the evaluation study. These women were mostly white (99.2%), college graduates (93.8%), and married or living with a partner (80.8%). Their mean age was 46.6 years and 75% were between 45-49 years old. Each of the 100 participants completed a health report and completed menstrual calendar cards. They were also asked to respond to the following four menstrual situations to determine and categorize their menopausal status: 1) I am menstruating in my regular pattern = regular or "R" status; 2) I am menstruating, but my periods are changing (for example, in length, spacing, amount of bleeding, etc.) = changing or "C" status; 3) I am not sure I'm still menstruating, since I haven't had a period in at least 3 months, also = changing or "C" status; and 4) I am postmenopausal (no period for 1 full year or more) = menopausal or "M" status. The year of menopause (M) became the final year of the data set for that participant and the years prior to that were -1 for one year prior, -2 for two years prior, and so forth. The minimal number of years contributed was three and the maximum was twelve.

The researchers used this process and menstrual cycle grading status to describe overall menstrual cycle patterns participants exhibited as they moved through the menopausal transition. What they discovered were eight menopausal stage patterns. The most predominant pattern experienced by 53 of the 100 women participants was R-C-M, (i.e., regular cycles, to changing cycles, to menopause), followed by 28 participants with a C-M pattern, 15 moved back and forth from R to C back to R before reaching M, three women reached M and then experienced more bleeding, and one woman went from R to M without experiencing changes in her menstrual patterns.

The researchers then narrowed the analysis to the five years before menopause. Ninety-one of the 100 participants were able to contribute that amount of data. They then discovered 23 distinct patterns of menopausal transition. The most common pattern experienced by 41 participants was five years of C followed by M (i.e., the C-M pattern). They found twelve different patterns that began with R (regular cycling) and ending with M. Most (21) experienced the R-C-M pattern, but one experienced only C-M, and four women showed what they called "flip flop patterns" of moving back and forth from R and C before M (example, R-C-R-C-C-M). Finally, they found four women who reached M and then experienced menstrual bleeding again. Example patterns are C-C-C-M-C-M and C-C-M-M-C-M.

The researchers concluded that there is enough evidence of diverse menopausal transitions to reject the assumptions of a regular progression to menopause as in the STRAW staging model. Although many of the women experience a transition of regular cycles to variable cycles to menopause, there were enough women that experienced flip-flopped stages to warrant review or revision of the STRAW model. The authors mentioned that physiologically follicular activity can continue after menopause and that if hormonal levels rise to a threshold level, menses could ensue.

#### COMMENT

The results from the Penn State study would have been more convincing if the participants charted more than a gross measure of the menopausal transition, i.e., more than just regular (R), changing (C) and menopause (M). The evidence would be stronger if the subjects charted length of cycles, length and amount of bleeding during menses, and some biological marker or markers of ovulation, such as peak mucus, a BBT shift, or ideally, urinary E3G and LH levels. Without these minimal biological markers I am not convinced the bleeding from the four women who went in and out of menopause were actually experiencing ovulatory cycles. (RF)

1. Soules, M.R., Sherman, S., Parrott, E., Rebar, R., Santoro, N., Utian, W., & Woods, N. Executive summary: **Stages of reproductive aging workshop (STRAW)**. *Fertility and Sterility*, 2001;76:874-878.
2. Treloar, A.E., Boyton, R., Behn, B.G., & Brown, B.W. **Variation of the human menstrual cycle through reproductive life**. *International Journal of Fertility*, 1967;12:77-126.
3. Mansfield, P.K., Carey, M., Anderson, A., Barsom, S.H., & Koch, P.B. **Staging the menopausal transition: data from the TREMIN research program on women's health**. *Women's Health Issues*, 2004;14:220-226.

## OF INTEREST

### **Randomized Control Study Found Adolescent Abstinence-Only Pregnancy Prevention Program Effective**

There is a current debate as to the effectiveness of abstinence-only based programs versus abstinence based programs that teach use of contraception and condoms in preventing teen pregnancy and sexually transmitted infections. The debate is of particular import in the United States because of federally-funded teen abstinence programs. One of the problems is the lack of good research studies that compare these two approaches or that compare each approach with a randomized control group. Researchers from Chile recently reported results from a randomized control study on the effectiveness of an abstinence-only based teen pregnancy prevention program.<sup>1</sup> The specific purpose of their study was to compare pregnancy rates among female students who participated in an abstinence-only sex education program (called TeenSTAR) with pregnancy rates from students who did not participate in the program.

The Chilean researchers were able to enroll into their study 1259 students from a public high school that randomized freshmen students into ten classes of 30 to 35 students. The

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students were all white female Hispanics from low or middle income households. The researchers included three cohorts of students in their study, i.e., all students who entered the high-school in 1996, 1997, and 1998. The 1996 group of 425 students did not receive any sex education program and served as a control group. The abstinence-only program was applied to 210 of the 423 students in the 1997 cohort and to 328 of the 411 students in the 1998 cohort.

The TeenStar program is a 45 hour abstinence-only based curriculum with 14 units that cover topics such as reproductive anatomy and physiology, fertility awareness, marriage and family, and other psychological and personal aspects of human sexuality. The program was offered over the entire school year by faculty who were trained to implement the TeenSTAR program at the high school. The control classes did not receive any sex education program.

The 1996 cohort of 425 student controls had a total of 53 pregnancies during the four year high-school time period. This is an average of 13.2 per year, and a pregnancy rate of 3.86%. In the 1997 cohort, there were only 6 pregnancies (1.5 per year average) among the intervention group and 35 (8.75 per year average) in the control group. The average pregnancy rate in the intervention group was 0.87% and in the control group 4.87%. For the 1998 cohort, there were 13 pregnancies over four years in the intervention group (a 3.2 per year average) and 17 in the control group (4.25 per year average). The overall pregnancy rate for the intervention group was 1.16% and for the control group 5.88%. The researchers found a clear protective effect for pregnancy among those students who received the abstinence only program. They concluded that the TeenSTAR adolescent abstinence-only sex education program was effective in preventing unintended pregnancies and that properly trained regular high school teachers were effective in implementing the program.

#### COMMENT

Readers should be aware that the developer and promoter of the TeenSTAR program is Hanna Klaus, M.D., Ob/Gyn, the former president of Billings Ovulation Method Association and former editor of *Current Medical Research*. See <http://www.teenstar.org> or the Chile web site at [www.teenstar.cl](http://www.teenstar.cl) for a description of the TeenSTAR program.

An important question I would ask the researchers is whether the results from the Chilean study apply to adolescents in the United States. Would the TeenSTAR program be as effective in a public high school in the US as it was in a public high school in Chile? My guess is that the results would be the same, but this is unknown until a randomized control study is conducted in the US. There is a limitation to the current study (as mentioned by the authors) because there is no record of abortion rates among the student participants since abortion is illegal in Chile. Theoretically, the pregnancy rates in the intervention group could be lower than the controls because these students were obtaining undocumented abortions. However, that does not seem to be a likely scenario. I would agree with the authors that this limitation does not affect the principle findings of the study. (RF)

1. Cabezón, C., Vigil, P., Rojas, I., Leiva, M.E., Riquelme, R., Aranda, W., & García, C.. **Adolescent pregnancy prevention: an abstinence-centered randomized controlled intervention in a Chilean public high school.** *Journal of Adolescent Health*, 2005;36:64-69.