

Natural Family Planning
CMR
Current Medical Research

Winter/Spring 2010 • Vol. 21, Nos. 1 and 2

Richard J. Fehring, PhD, RN, FAAN – Professor, Marquette University College of Nursing

In this issue ...

Natural Family Planning 2

Menstrual Cycle 7

Of interest 10



Current Medical Research is a publication of the Natural Family Planning Program of the United States Conference of Catholic Bishops. © Washington, DC: USCCB, 2011. The managing editor is Theresa Notare, PhD, Assistant Director. Permission is granted to reproduce in whole or in part, in print and/or electronically, with the following statement: *Current Medical Research*, NFPP/US Conference of Catholic Bishops, Washington, DC, volume # (year): page#. Used with permission.

Natural Family Planning

Natural Methods of Family Planning not Recommended by European Researchers

European researchers recently conducted a systematic review of the literature to determine a comprehensive and objective summary of evidence for the efficacy of contraceptive methods (D. Mansour, P. Inki and K. Gemzell-Danielsson, 2010, "Efficacy of contraceptive methods: A review of the literature," *The European Journal of Contraception and Reproductive Health Care* 15: 4-16). This review was intended to help health professional in their decisions for providing contraceptive services and to help women with their decisions in their use. The authors stated that effectiveness was the single most important reason that women choose a form of contraception.

The authors of this review selected all contraceptive efficacy studies from January 1990 through February 2008, by accessing the Ovid search engine and reference lists from articles. They also used the criteria of having at least 400 participants in the efficacy studies and at least 6 months of use. Based on these criteria they were able to review 139 studies of which eight were listed as natural family planning. Their review ranked the efficacy of contraceptive methods as follows: 1) female sterilization and long-acting hormonal contraceptives, 2) the copper IUD with a surface area of $> 300 \text{ mm}^2$, 3) the copper IUD with $< 300 \text{ mm}^2$ of surface area and short acting hormonal contraceptives, such as the injectables, the oral hormonal contraceptives, the patch, and the vaginal ring, and finally, 4) barrier methods and natural family planning. The authors stated that they would not recommend the use of natural methods for women with serious reasons to avoid pregnancy.

Comments

The eight natural family planning studies reviewed by the authors are presented in Table One.¹ It is difficult to compare these studies, since they use different methods of NFP and inconsistent ways of presenting the efficacy of the methods to avoid pregnancy. Some of the studies actually mix what they call "natural" methods. Some studies are prospective, some retrospective and some by recall. The typical use ranges from 2.5 to 25.6 unintended pregnancies per 100 women over 12 months of use. They also cite the 86.4 unintended pregnancy rate from the study by Trussell and Grummer-Strawn in which they reanalyzed data from a large World Health Organization Study of the Billings Ovulation Method and calculated the imperfect use pregnancy rate.² Based on this study, Trussell and Grummer-Strawn concluded that the use of NFP was very "unforgiving" of incorrect use. Imperfect use usually entails knowingly having intercourse during the estimated fertile phase. Therefore, it is not too surprising when a couple achieves a pregnancy through imperfect use.

The authors of the review study made it very clear and were very careful to point out that they wished to analyze efficacy for separate types of hormonal oral contraception. It is too bad

that they did not do so for natural methods. Furthermore, they also failed to include some of the more recent studies on efficacy that meet their criteria of at least 400 participants over at least 6 months of use, such as the Howard and Stanford study of the Creighton Model System and the Frank-Herrmann et. al. study of the European Double Check method of natural family planning.^{4,5}

Table 1: Classic and Recent NFP Efficacy Studies: Correct Use and Total Survival Rates* per 100 Women Over 12 Months of Use

Study	No Participants	Indicators	Correct	Typical
Arevalo et al.	478	Fixed Calendar	4.75	12.0
Bonner et al.	710	E3G/LH/Monitor	6.2	25.6
Che et al.	154,642	Periodic Abstinence		23.6
European Group	1328	Double check (STM)		2.6/8.5
Freundl et al.	597	Computer Temp/Calendar	0.7	5.3
Thapa et al.	850	3 Cervical mucus methods	2.5	10.3/11.5
Xu et al.	688	Billings Mucus	1.0	7.0
Trussell et al.	725	Billings Mucus	3.1	86.4**

* Survival rate = percent of women per 100 that did not have an unintended pregnancy.

** Imperfect use pregnancy rate.

1. M. Arevalo, V. Jennings and I. Sinai, "Efficacy of a new method of family planning: the Standard Days Method," *Contraception* 65 (2002): 333-338; J. Bonner, A. Flynn, G. Freundl, R. Kirkman, R. Royston and R. Snowden, "Personal hormone monitoring for contraception," *The British Journal of Family Planning* 24 (1999): 128-134; Y. Che, J. G. Cleland, M. and M. Ali. "Periodic abstinence in developing countries: an assessment of failure rates and consequences," *Contraception* 69 (2004): 15-21; The European Natural Family Planning Study Group, "European multicenter study of natural family planning (1989-1995): efficacy and drop-out," *Advances in Contraception* 15 (1999): 69-83; G. Freundl, P. Frank-Herrmann, E. Godehardt, R. Klemm and M. Bachhofer, "Retrospective clinical trial of contraceptive effectiveness of the electronic fertility indicator Ladycomp/Babycomp," *Advances in Contraception* 14 (1998): 97-108; S. Thapa, M. V. Wonga, P. G. Lampe, H. Pietojo and A. Soejoenoes, "Efficacy of three variations of periodic abstinence for family planning in Indonesia," *Studies in Family Planning* 21 (1990): 327-334; J. X. Xu, J. H. Yabn, D. Z. Fan and D. W. Zhang, "Billings natural family planning in Shanghai, China," *Advances in Contraception* 10 (1994): 195-204; J. G. Trussell and L. Grummer-Strawn, "Contraceptive failure of the ovulation method of periodic abstinence," *Family Planning Perspectives* 22 (1999): 65-75.

2. J. Trussell and Grummer-Strawn, "Contraceptive failure of the ovulation method of periodic abstinence," (1999).
3. M. P. Howard and J. B. Stanford, "Pregnancy probabilities during use of the Creighton Model Fertility Care System," *Archive of Family Medicine* 8 (1999): 391-402.
4. P. Frank-Herrmann, J Heil and C. Gnoth et al., "The effectiveness of a fertility awareness based method to avoid pregnancy in relation to a couple's sexual behavior during the fertile time: a prospective longitudinal study," *Human Reproduction* 22 (2007): 1310-1319.

Only 0.1% of US Women Currently Use Modern Methods of Natural Family Planning

In 1973, 1976, 1982, 1988, 1995, and 2002, the National Center for Health Statistics conducted the National Survey of Family Growth (NSFG) for the purpose of collecting population based data on factors related to birth and pregnancy rates in the United States. One of the most important factors related to pregnancy rates is the use of contraceptive methods by women of reproductive age (i.e., 15-44). The latest NSFG was conducted from 2006-2008 and involved in-person interviews with 13,495 men and women. On May 26, 2010, the first report on this national survey was released for the purpose of providing results collected on the 7,356 women in the study and their use of contraception (W. D. Mosher and J. Jones, "Use of contraception in the United States: 1982-2008," *Vital and Health Statistics Series 23, Number 29* (2010):1-77).

According to this report, the number one method of contraception by current use (i.e., within the month of interview) was the oral hormonal contraceptive pill. This method was used by an estimated 10.7 million women (17.3%) and was the number one method used by women under 30. The second most frequent method of contraception was female sterilization, used by 10.3 million women (16.7%). However, sterilization was the number one method used by women aged 30 and older. Furthermore, if you added the women who listed "male sterilization" as their method of contraception, i.e., 6.1% or 3.7 million, then sterilization (male and female) is by far the most frequent method of contraception used by couples in the United States. Furthermore, female sterilization is the most frequent used method of contraception among Hispanic (20%) and Non-Hispanic Black (21%) women.

There were only 0.1% of women in the study who listed natural family planning (NFP) as their current method of family planning or about 62,000 women in the United States. This number is down from the 0.2% or about 124,000 in 2002 who listed NFP as their current method of family planning, the 0.2% (120,000) in 1995, and the 0.3% in 1982 (162,000). Reported current use of periodic abstinence or calendar rhythm is also down. In the current 2006-2008 study, 0.5% listed calendar rhythm as their current method of contraception (or about 309,000

women). This frequency of use of calendar rhythm is down from 1.8% in 1982 (or about 978,000 women). It should be noted that calendar rhythm for most women in this National survey is most likely a self-devised “blanket type” method, whereby the woman guesstimates when fertility begins and ends within her menstrual cycles. It is not based on traditional calendar formulas or the modern Standard Days Method developed by researchers at the Georgetown University Institute for Reproductive Health.

Comments

The researchers at the National Center for Health Statistics stopped reporting on the use of contraceptive methods by religion of the participants in 1988. However, this data is still collected and the data on Catholic women is accessible and will be reported on in future issues of *Current Medical Research* and *The Linacre Quarterly*. However, it is unlikely that Catholic women will differ in their use of contraceptive methods in comparison to US women in general. A sad state of married life in the United States is that sterilization is the number one method among married women and once a woman has two children, the rate of sterilization is around 35%, and with three children, 59%.

Menstrual Cycle

Cervical-Vaginal Fluid Die Swell Parameters Correlate with Fertile and Infertile Phases of the Menstrual Cycle

Researchers from Texas Tech University recently set out to determine if measures of viscosity and elasticity of cervical vaginal mucus correlated with the fertile and infertile phases of the menstrual cycle (J. Wang, S. J. Usala and F. O’Brien-Usala et al., 2009, “The fertile and infertile phases of the menstrual cycle are signaled by cervical-vaginal fluid die swell functions,” *The Endocrinologist* 19: 291-297). They were interested in measuring the physical properties of cervical-vaginal mucus when the mucus is forced through a die swell device developed by the Texas Tech research team. The device includes a capillary tube in which the fluid is forced through with a collection syringe and a video system that is connected to a computer that records and measures the die swell ratio, i.e., the greatest diameter of the fluid as it passes the capillary tube in relation to the diameter of the tube. They also measured the position of the die swell from the orifice of the capillary tube and called this measure the DisMax.

The researchers recruited two women volunteers (one age 26 and the other 28) who collected their daily cervical vaginal mucus with a syringe type device and who measured their urine for the luteinizing hormone (LH) surge. Blood levels of LH were also collected to confirm the day of the urinary LH surge. The women volunteers recorded a total of eight menstrual cycles of data. The first positive urine LH reading was recorded as the estimated day of

ovulation. What the researchers discovered was that the three highest DisMax readings coincided with the estimated day of ovulation and the two days before. The smallest die swell diameter coincided with the estimated day of ovulation and the two days before. The greatest amount of cervical-vaginal mucus collected by the syringes also coincided with the same peri-ovulatory days. The researchers concluded that the die swell diameter and the DisMax were good objective measures of the visco-elasticity properties of cervical vaginal mucus and, therefore, good objective markers to estimate the fertile phase of the menstrual cycle. They speculated that a small die swell device could be developed for use in the office or home setting to help women differentiate the fertile phase of the menstrual cycles, especially for women who have difficulty with self-observations of cervical vaginal mucus for family planning purposes.

Comments

The results of this small study make sense since it is well known that the most abundant and most liquid (i.e., watery) cervical–vaginal mucus coincides with the day of ovulation and the two days before. The more watery mucus would have a smaller diameter and lower level of swell compared to thicker type mucus. It remains to be seen whether women would be willing to suction mucus from the vagina with a small syringe on a daily basis.

Luteal Phase Defects and Anovulation Occurred in 50% of Menstrual Cycles of Exercising Women

It is well known that extreme exercise and/or extreme dieting will cause cessation of ovulation and menstruation among young women. The cause is thought to be due to the body conserving energy for vital functioning and not having enough energy reserve for reproductive processes. Prolonged anovulation among young women can lead to decreases in bone mineral density, fractures, and endothelial dysfunction. What is not known are the effects of regular recreational and competitive exercise on menstrual cycle function as compared with sedentary type activities. Exercise science researchers sought to determine if there were more subtle effects on the menstrual cycle, i.e., luteal phase defects and/or amenorrhea in exercising women with regular length menstrual cycles (M. J. De Souza, R. J. Toombs, J. L. Scheid, E. O'Donnell, S. L. West and N. I. Williams, 2010, “High prevalence of subtle and severe menstrual disturbances in exercising women: confirmation using daily hormone measures,” *Human Reproduction* 25: 491-503). The point of the study is to determine if there are more subtle changes in the menstrual cycle with exercising rather than just gross changes (i.e., anovulation,) determined only by menstrual cycle length.

The researchers were able to obtain daily prospective menstrual cycle records from 67 exercising women and 20 sedentary volunteer women between the age of 18-30 from two data

collection sites, i.e., Connecticut and Toronto. The exercising women were involved in a variety of activities including recreational running, stationary cycling, aerobic classes, field hockey, tennis, soccer, rugby, volleyball, and dance. The sedentary women had less than two hours of purposeful exercise per week. All participants contributed at least two menstrual cycles of data that included daily urinary measures of estrone, pregnanediol glucuronide and luteinizing hormone. Based on the results of these hormones, the researchers were able to categorize the menstrual cycles as ovulatory, luteal phase defect, anovulatory, oligomenorrheic and amenorrheic. A luteal phase defect was defined as a luteal phase of less than 9 days in length.

The researchers found that there were no statistical differences between the two groups in age, weight, body mass, and age of menarche. However, the women in the sedentary group had only two anovulatory menstrual cycles i.e., 46/48 (95.8%). In contrast, 60 of the 120 menstrual cycles in the data set (i.e., 50%) of the exercise group were observed as anovulatory. Furthermore, as many as 50% of the menstrual cycles of the exercise group were categorized as abnormal, with 29.2% classified as having luteal phase defects, 20.8% as anovulatory, 3.5% displayed oligomenorrhea, and 33.7% amenorrhea. There were no amenorrheic or oligomenorrheic menstrual cycles among the sedentary group. The researchers concluded that approximately half of exercising women experienced menstrual cycle disturbances and that having exercising women just report menstrual cycle intervals is not sophisticated enough to pick up the subtle (but significant) menstrual cycle disturbances.

Comment

The authors also pointed out that due to the health problems (e.g., bone loss) and infertility that could be experienced by exercising women, these women should be assessed more closely in the clinical setting. They did not point out how this would be done. Obviously, having women learn how to monitor natural indicators of fertility through natural family planning methods would be one simple and cost effective way.

Characteristics of Menstrual Bleeding and Fecundity

Both the American Pediatric Association and the American Academy of Obstetrics and Gynecology have recommended monitoring parameters of the menstrual cycle as a fourth vital sign (American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 2006, "Menstruation in girls and adolescents: using the menstrual cycle as a vital sign," *Pediatrics* 118: 2245-2250). In other words parameters of the menstrual cycle could be used in the detection, diagnoses and treatment of women's health problems. The more we know about the normal and abnormal characteristics of the menstrual cycle, the better health professionals can use this information to inform women about potential and actual health problems. Therefore, researchers sought to describe patterns of menstrual bleeding based on

measurement of bleeding patterns developed by a cohort of women seeking pregnancy (R. T. Mikolajczyk, G. M. Buck Louis, M. A. Cooney, C. D. Lynch, R. Sundaram, 2009, “Characteristics of prospectively measured vaginal bleeding among women trying to conceive,” *Paediatric and Perinatal Epidemiology* 24: 24-30).

The data for this study came from a subset of 74 women who had participated in the New York State Angler Cohort Study and were asked to participate in a prospective pregnancy study. The 74 participants were asked to provide daily diaries designed to capture any vaginal bleeding rated from 0-3, (with 0 = none, 1 = spotting, 2 = light bleeding, 3 = moderate bleeding, and 4 = heavy bleeding) for at least two menstrual cycles. The 74 participants (mean age 30.0, range 18-40 years) produced a total of 430 bleeding episodes.

From the data generated, the researchers were able to describe four distinct bleeding patterns: 1) spotting of 1-3 days (10% of the menstrual cycles), 2) bleeding lasting 3-6 days in length (40% of the menstrual cycles), 3) bleeding of 6-8 days in length (33% of the menstrual cycles), and 4) bleeding lasting 8-12 days (17% of the menstrual cycles). They also found approximately 8% of the menstrual cycles had non-menstrual bleeding based on the interval until the next menstrual bleed. The normal length of menstruation was considered 4-7 days. They also found a positive correlation between length of menstrual cycle and intensity of bleeding, i.e., the longer the cycle the more intense the bleeding. The researchers suggested that this ruled-out the notion that there was some type of compensatory mechanism with shorter menstrual flows having more intense bleeding. They concluded that there was considerable variability in menstrual bleeding patterns.

Comments

One of the most common questions that natural family planning (NFP) teachers and health professional get are about bleeding patterns found on NFP charts, and in particular length, intensity, and unusual bleeding questions. The more research is done on patterns of menstrual bleeding, the better health professionals will be able to discern normal from abnormal patterns. Women who chart their menstrual cycles in NFP charting systems can contribute to this endeavor. The authors of this study called for more research to determine the association of bleeding patterns with fecundity.

Inverse Relationship Exists Between Dietary Fiber and Estrogen Levels among Healthy Menstruating Women

Higher dietary fiber has been associated with reducing the health risk for heart disease, stroke, breast cancer, and colon cancer; however, studies also have shown that high fiber diet reduces the estrogen intake in older (i.e., peri-menopausal) women. Due to this, researchers

sought to determine if dietary fiber has an influence on estrogen levels and ovulatory function among young healthy women (A. J. Gaskins, S. L. Mumford and C. Zhang et. al., 2009, "Effect of daily fiber intake on reproductive function: The BioCycle Study," *The American Journal of Clinical Nutrition* 90: 1061-1069).

The participants for this study were 259 healthy menstruating women between the ages of 18-44 years who monitored their menstrual cycles for one to two menstrual cycles with use of an electronic hormonal fertility monitor that measured estrogen levels and luteinizing hormone (LH) in the urine. The women also had blood samples taken on days 2, 7, 12, 13, 14, 18, 22 and 27 of their menstrual cycles to measure estrogen, progesterone, follicle stimulating hormone (FSH), and LH. They also provided a 24 hour dietary recall on days 2, 7, 14, and 22 with a nutrition data system software program that was developed at the University of Minnesota. Menstrual cycles were classified as anovulatory if the peak progesterone levels was less than or equal to 5 ng/mL across the menstrual cycle.

The researchers discovered that both estrogen and progesterone levels (and LH and FSH) had an inverse relationship with the amount of dietary fiber. They also found that as the amount of dietary fiber increased by 5 ng, the odds ratio of anovulation (i.e., the risk of anovulation) increase was 1.78 (95% CI: 1.11-2.84). The 5 ng amount of dietary fiber could be found in one large apple or two slices of whole grain bread. The authors speculated that dietary fiber reduces the amount of estrogen and other reproductive hormones from being reabsorbed in the intestines and that dietary fiber binds with the reproductive hormones. A limitation of the study was the small number of participants and that only 42 of the 259 participants had anovulatory menstrual cycles. The researchers recommended further study before any recommendations could be made.

Comments

Although the authors controlled for weight by recording the body mass index (BMI) you wonder whether the participants who had higher dietary fiber were also those who exercised more and thus more anovulatory cycles. The Harvard Fertility diet recommends high levels of dietary fibers through fruits and whole grains.

Of interest . . .

Approximately 1 in 4 US Female Adolescents Have Sexually Transmitted Infections

Untreated sexually transmitted infections (STI) among female adolescents can lead to pelvic inflammatory disease, infertility, and cervical cancer. Community based studies have indicated there are high rates of STI among certain subpopulations of adolescents. However, there are few in-depth population based studies that have investigated the magnitude of STI among US adolescents and important sub-groups of this population. Therefore, researchers at the Center for Disease Control (CDC) set out to determine the magnitude of common STI among US adolescents and large sub-groups of this population (S. E. Forhan, S. L. Gottlieb and M. R. Sternberg et al., 2009, "Prevalence of sexually transmitted infections among female adolescents aged 14 to 19 in the United States," *Pediatrics* 124: 1505-1512).

The CDC researchers were able to use data collected from females aged 14 to 19 who participated in the National Health and Nutrition Survey (NHANES). This national survey involved 10,122 randomly selected participants and had a 79% interview response rate. The female participants in this national survey provided urine, serum, and vaginal specimens to determine if they currently had five common STI, i.e., chlamydia, gonorrhea, herpes simplex virus type 2, trichomonas, and human papillomavirus (HPV). There were 820 female participants of the total NHANES who were between the ages of 14 to 19. Of these 820 participants, all had at least one STI laboratory result available and 590 had all five tests for STIs.

The researchers found that the prevalence of STIs among the 14-19 year old adolescents was 24.1%, however, the rate was 37.7% when the data included only sexually active teens. The most prevalent STIs among the sexually active were HPV (29.5%), followed by chlamydia (7.1%). Of the sub-groups, African-Americans had the highest rate at 43.9%, and Mexican-American had the lowest rate at 18%. When sexual behaviors were analyzed those adolescents who had 3 or more sexual partners had a STI rate of 53.5% and those with sexual activity of greater than or equal to 2 years had a rate of 49.2%. The data also showed there was a rapid acquisition of acquiring an STI soon after sexual initiation, i.e., the prevalence was 26% among adolescents who's age at sexual debut was the same or one year greater than their age at initiation. The authors discussed the need to educate adolescents about sexual issues, well before sexual initiation. They also recommended sexual infections screening, quality parent-adolescent communication, and counseling about safer sex, i.e., condom use.

In a related study, researchers from Indiana University sought to determine the time interval from first intercourse and the attainment of the first sexually transmitted infection (STI) and to determine the time interval from the first STI until a subsequent infection among female adolescents (W. Tu, B. E. Batteiger and S. Wiehe et al., 2009, "Time from first intercourse to

first sexually transmitted infection diagnosis among adolescent women,” *Archives of Pediatric and Adolescent Medicine* 163:1106-1111). They also wished to recommend screening frequency for STIs among adolescent patients.

The researchers were able to obtain 386 study participants between the age of 14 and 17 from three adolescent medical clinics that primarily served an inner-city population. Each participant was interviewed by a trained researcher about sexual activity and had cervical and vaginal specimens taken every three months during the course of the study. The specimens were tested for chlamydia, gonorrhea, and trichomonas. Enrollment in this study started in 1999 and continued for eight years.

The researchers discovered that 25% of the participants obtained a STI within one year from the initiation of intercourse and 50% within two years of initiation. They also found that time to re-infection was short, i.e., within 3.6, 6, and 4.8 months 25% of the participants were re-infected with chlamydia, gonorrhea, and trichomonas respectively. They also found that there was a considerable time gap from first intercourse until the first testing for an STI. The researchers recommended a three to four month time interval for STI testing among sexually active adolescents.

Comments

In both studies “sex” was defined as vaginal, oral or anal sex. The fact that 6.6% of the adolescents in the CDC study who indicated that they never had sex obtained an STI makes you wonder if either the adolescents were underreporting sexual activity or if sexual activity also included hand to genital or genital to genital activity. Furthermore, as the authors in the CDC study pointed out, they did not check for syphilis or HIV, so that the results presented could be underreporting the actual infection rates. The Indiana University study did not mention testing for HPV, which was the most prevalent STI in the CDC study. Both studies found a 25% rate of infection within the first year of initiating intercourse.

Abstinence-Only Intervention to Reduce Sexual Activity among African-American Adolescents More Effective than Condom-Based “Safe-Sex” Intervention

Sexual activity among African-American adolescents is higher than White and Hispanic American adolescents. As a consequence, the rates of sexually transmitted infections (STI) and unintended pregnancy are higher among African-American adolescents as well. The efficacy in the use of abstinence only interventions versus safe-sex condom based interventions for decreasing sexual activity, STI, and pregnancies are hotly debated and often have political undertones. Some feel that teaching abstinence-only interventions to adolescents would not only be ineffective but also reduce the use of condoms when sexual activity takes place. However,

there have been few randomized control trials to compare the efficacy of abstinence-based versus safe-sex type interventions to lower STIs and pregnancy rates among adolescents and in particular African-American adolescents. Researchers at the University of Pennsylvania, therefore, conducted a study to compare abstinence-based versus safer-sex type interventions on the pregnancy and STI rates of African-American adolescents (J. B. Jemmott, L. S. Lammott and G. T. Fong, 2010, "Efficacy of a Theory-based abstinence-only intervention over 24 months," *Archives of Pediatric and Adolescent Medicine* 164:152-159).

Participants for this study were 662 sixth and seventh graders from four schools in a primarily low income area of a city in the US. The age range of the participants was 10 to 15 years with a mean of 12.2. The participants were randomly assigned into an abstinence only group (N = 129), a safe sex group (N = 125), a health promotion control group (126), a comprehensive safe sex plus abstinence 8 hour program (134), or a comprehensive safe sex plus abstinence 12 hour program (N = 131). In addition, all participants were randomly assigned to receive either a booster intervention at 6 weeks and 3 months after the initial intervention or to receive no booster intervention. The authors pointed out that the abstinence program was theory-based and did not use a moralistic tone or portray the view that condoms were ineffective.

The major interest of the researchers was the differences in outcomes between the abstinence-only intervention and the safe-sex intervention groups. The abstinence only group had a 32.6% intercourse rate at 24 months follow-up, the safer sex group 51.8%, and the control group 46.6%. Based on relevant risk analysis, the abstinence-only group reduced sexual initiation with a probability of sexual intercourse in 24 months at 33.5% compared to 48.5% in the health-promotion group. Three months after the completion of the intervention, 29.5% in the abstinence group had sexual intercourse, 40.0% in the safer sex group, and 37.5% in the control group. Of concern by safe-sex critics is the accusation that abstinence-only education leads to unprotected sex among adolescents. However, in this study there was essentially no difference in the use of condoms during the last three months of the study among those sexually active, i.e., 73.8% among the safe-sex group, 75.8% among the abstinence-only group, and 78.0% among the control group. The authors concluded that theory-based abstinence only interventions can have positive effects on adolescent sexual behavior and that it would not decrease condom use.

Comments

The authors were careful to point out that their abstinence-only intervention did not include any morality and did not disparage the efficacy of condoms. The fact that they mentioned to the participants that they should delay intercourse until they are more prepared to handle the consequences of sex is a moral statement. To tell sixth and seventh graders that they should not be sexually active (until marriage) is a good practice from both a health and development standpoint. To not let them know that condoms are not effective protection against many sexually transmitted infections and, for that matter, only 80% effective when used consistently for preventing pregnancy, is not being truthful.

Prolonged Use of Oral Hormonal Contraceptives Decreases Bone Mass Density among Young US Women

The number one method of contraception among adolescents and young women in the United States is oral contraceptives (OCs). Furthermore, OC use is highest and most prolonged among women when they are undergoing a critical time of bone growth. Previous study results are mixed on the effects of OCs on bone growth in young women and adolescents. Few of the studies are population based. Therefore, researchers sought to determine the relationship of OC use, duration, and estrogen dose on bone mineral density (BMD) among a population based sample of women between the ages of 14 to 30 years (S. Scholes, L. Ichikawa and A. Z. LaCroix et al., 2010, "Oral contraceptive use and bone density in adolescent and young adult women," *Contraception* 81: 35-40).

The participants for this study were selected from a large cooperative group medical practice in the Pacific Northwest. The researchers sent invite letters requesting participation to 1,549 women who had current OC prescriptions and 1,199 comparison women. From these women, they enrolled 389 current OC users and 217 non-users. Of these, 301 were 14-18 years old and 305 were 19-30 years. All participants completed a questionnaire on their health, reproductive and family planning history and had their BMD measured at the hip, lumbar spine and whole body with a dual-energy X-ray absorptiometry.

The researchers found that the mean BMD levels at all anatomic sites among the 14-18 year old participants did not differ significantly. However, among the 19-30 year old group, mean BMD was significantly lower with duration of use of OCs for the spine and whole body. For example, the BMD was 5.9% lower at the spinal site with greater than 24 months of use of OCs. They also found that the BMD was significantly lower with OCs with lower doses of synthetic estrogens, i.e., less than 30 mcg. Furthermore, the OC group showed significantly lower (5.2%) mean spine BMD. The authors pointed out that among postmenopausal women a 5% decrease in BMD is associated with 50% more osteoporotic fractures. They concluded that prolonged use of OCs may impact the BMD of young women using these methods of family planning.

Comments

The authors recommended further study on the optimal dose and duration of OCs for young women in regards to bone health. However, they also pointed out that the risk of a lower BMD must also be weighed in the context of the risk for an unintended pregnancy. There was no mention of the use of non-hormonal (condoms or natural family planning) and chastity among unmarried adolescents and young adults.

Risk of Mortality Less Among Users of Hormonal Contraception

Two large British cohort studies were recently published that provided evidence “ever-users” of oral hormonal birth control have less mortality due to multiple causes (e.g., cancer, circulatory disease, digestive disease, and violence) than “never-users” of hormonal contraception. The first study involved ongoing data from The Royal College of General Practitioners’ Oral Contraceptive Study -- one of the largest studies in the world to investigate the health effects of oral hormonal contraception (P. C. Hannaford, L. Iversen, T. V. Macfarlane, A. M. Elliot, V. Angus and A. J. Lee, 2010, “Mortality among contraceptive pill users: cohort evidence from Royal College of General Practitioners’ oral contraceptive study,” *British Medical Journal* c927: 340). The Royal College study started in 1968 when 1,400 general practice physicians recruited approximately 23,000 women participants who were using oral hormonal contraception and an approximate number of women who have never used hormonal contraception and followed them until they left the study or died. Deaths were followed by having the participants “flagged” in the National Health Service that registers all cancers and deaths. After forty nine years of follow-up, there remained 46,112 women participants and 378,006 women years of observation among ever users and 819,175 women years of observation among never users of oral hormonal contraception. The end date for this study report was June of 2007. As a result, the researchers found 1,747 deaths among never users of hormonal contraception and 2,864 deaths among ever users. Based on relative risk (RR) analysis, this resulted in a significant lower rate (i.e., 12%) of deaths among the ever users (RR = 0.88, 95% confidence interval 0.82 to 0.93). They found a lower rate of death from all cancers and all circulatory disease among the ever users but a higher rate of death due to violence. They estimated that the ever users of hormonal contraception had approximately 52 fewer deaths per 100,000 woman years. They concluded that use of oral contraception was not associated with an increased long term risk of death.

The second study was an update of mortality of the Oxford Family Planning Association contraceptive study, which, like the Royal College study, also started in 1968 (M. Vessey, D. Yeates and S. Flynn, 2010, “Factors affecting mortality in a large cohort study with special reference to oral contraceptive use,” *Contraception*, Article In Press). From 1968 through 1974, 17,032 married women between the age of 25-39 years who used oral hormonal contraception, a diaphragm, or an intrauterine device were recruited by the staff of family planning clinics in England and Scotland. Deaths were recorded by annual contact by the staff of the clinics or by being flagged in the National Health Service registry. When the participants reached the age of 45 they were allocated into three groups, i.e., women participants who never used oral hormonal contraceptive, women who used oral hormonal contraceptive for 8 or more years, and women who had used oral hormonal contraception for less than 8 years. The current study updated the

results by follow-up of the participants until March of 2009. As of this date, the Oxford researchers had 602,700 women years of observations with 22% of the participants having 8 plus years of contraceptive use.

The Oxford University researchers found a similar rate of reduction in mortality by ever users of oral hormonal contraception as in the Royal College study, i.e., a 13% reduction in mortality (RR = 0.87, 95% confident interval, 0.79 to 0.96) when compared to never users of oral hormonal contraception. However, unlike the Royal study they did find an increase in deaths due to cervical cancer, i.e., a 7.3% increase among the ever users of hormonal contraception, but they found no differences in the rate of breast cancer among the two groups. They did find a reduction in risk of death due to uterine and ovarian cancer among the ever users. Of interest, death from breast cancer was not increased by duration of use. They also found that death due to circulatory causes were not increased among the ever users of hormonal contraception. Like the Royal College study, these researchers also concluded that long term use of oral hormonal contraception has no adverse effects on overall mortality and actually might reduced the risk of death.

Comments

The design of both of these studies is a prospective cohort comparison. This type of research design can provide good evidence for comparisons or relative rates of risk but this design does have weaknesses that can results in false findings. A more powerful design is a randomized comparison of two groups, for example, women who are randomized into a oral hormonal group compared to a placebo group or group that does not receive the hormones. The authors of the first study mention this and point out the differences when hormonal replacement therapy was studied by cohort comparison as opposed to a randomized design. In the large cohort studies of hormonal replacement therapy, the use of hormones was found to be healthier than not taking the hormones. However, once a well designed large randomized control trial was conducted, the opposite was found (with the Women's Health Initiative study), i.e., increased rates of cancer and heart disease among users of hormonal replacement therapy (G. Heiss, R. Wallace and G. L. Anderson et al., 2008, "Health risks and benefits 3 years after stopping randomized treatment with estrogen and progestin," *Journal of the American Medical Association* 299:1036-45). These conflicting results will occur when comparison groups in cohort studies have some type of built in bias or, i.e., the comparison groups not equal groups due to some confounding factor.

In the two cohort studies described above, the differences might have nothing to do with taking hormonal contraception but rather healthier women might be taking hormonal contraception. Women who have a history of cancer in the family or have some type of circulatory disease would be less likely to be on hormonal contraception. Just this fact alone

might explain the differences found in both of these cohort comparison studies. Another factor that might confound the study is that women who take hormonal contraceptives today do so differently than the married women in the Royal College study. In that study women were married and often did not start taking the oral contraceptive pill until they had children or completed their family size. They started taking hormonal contraception later in life. Parity and breastfeeding could decrease the effects of the pill. Women, in this current time period, take the pill at a much younger age, before they have children, and for longer periods of time. The younger users in these studies had greater risk for death. Finally, the authors of the Royal College study were unable to speculate as to why there was an increase risk for violent death among the oral hormonal contraceptive users.