Natural Family Planning

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NATURAL FAMILY PLANNING

Mucus Observations Are Useful for Predicting Days of High Probability for Conception

An existing data set was used by a group of researchers from the United States, France, Germany, and Italy to determine the influence of cervical mucus observations on day- specific probabilities of pregnancy within the 6-day fertile window.[1] The data set was obtain from the 1992-1997 European Study of Daily Fecundability in which 782 women between the ages of 18-40 recorded their daily observations of cervical mucus and basal body temperature (BBT). The cervical mucus observations were rated on a 1-4 scale that ranked the characteristics of sensation and appearance: with the rating of 1 = Dry, rough, and itchy - Nothing felt and nothing seen; 2 = Damp - Nothing seen; 3 = Damp - Mucus is thick, creamy, whitish, yellowish, or sticky; 4 = Wet, slippery, smooth - Mucus is transparent, like raw egg white, stretchy/elastic, liquid, watery, or reddish. The estimated day of ovulation was considered to be the day of the BBT shift. The BBT shift was determined by the 3 highest consecutive temperatures over the previous 6.

There were 6,724 cycles of data available with 487 pregnancies. The researchers were able to use only 1,473 cycles of data with 353 pregnancies, due to incomplete data (i.e., missing BBT, mucus, or intercourse readings). From this data set they determined that there was clear evidence for an increase in the probability of pregnancy with the increase in the mucus rating within the 6-day fertile window. Furthermore, there was a steady increase in pregnancy probability with each increase of the mucus rating. In fact, the highest mucus score was more predictive of pregnancy than having intercourse 3 days before the estimated day of ovulation. The researchers concluded that (within the fertile window) the type of mucus observed on the day of intercourse was more predictive of conception than the timing of intercourse. In addition, the highest rated mucus occurred most often on the 2 days before the estimated day of ovulation. They also remarked that self-monitoring of cervical mucus provides additional information about fertility that is not provided by other methods or indicators of fertility, such as, ultrasound and urinary LH testing.

Comments:

The results of this study make clinical and physiological sense. The estrogen rise before ovulation stimulates cervical mucus production and higher levels of estrogen produces better quality and quantity of mucus. Because of this, it would be expected to anticipate a strong association between quality mucus and the probability of

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pregnancy with an act of intercourse. However, I have some problems with the results of the study.

The BBT shift is not a very precise estimator of ovulation and can be off by a large margin. Basing research assumptions and probabilities of pregnancies on this imprecise measure of peak fertility is questionable. Second, 78% of the data cycles and 134 pregnancies were discarded due to incomplete information. I wonder if the discarded data charts had poor temperature, mucus, and/or intercourse patterns because of confusing information that these biological markers were providing the women observers. Third, they did find a probability of pregnancy within the fertile window when there was no mucus, when there was a damp sensation but no mucus, and when damp thick whitish type mucus was observed. In fact, the probability of pregnancy 3 days before the estimated day of ovulation when thick whitish type mucus was observed was higher than 0.20. No mucus seen or felt and a damp sensation without mucus are considered by some NFP systems to be an equivalent of a dry infertile day. Furthermore, the level 3-type mucus (thick white damp) is often a type of mucus observed with a basic infertile pattern. The application of these findings for women trying to achieve pregnancy with cervical mucus observations might be encouraging but are questionable for those couples avoiding pregnancy based on mucus observations.

1. Bigelow, J.L., Dunson, D.B., Stanford, J.B., Ecochard, R., Gnoth, C., & Colombo, B. **Mucus observations in the fertile window: a better predictor of conception than timing of intercourse**. *Human Reproduction.* 2004;19:889-892.

Biologists Confirm Cervical Mucus Classifications and Propose Four New Structural Types

Cellular biologists from the University of Murcia, Spain confirmed the Odeblad morphological classification system of cervical mucus by using light (LM) and scanning electron microscopy (SEM) to view 230 samples of cervical mucus from 195 women participants.[1] The samples were placed on glass slides and either air-dried or fixed (i.e., prepared) with a chemical called gluteraldehyde. One hundred eighty of these samples were taken from the core of the cervix by use of an insulin syringe. Another 50 samples were taken from various crypts from the cervix by use of a small pipette.

The Spanish biologists were able to identify four mucus types previously described by Odeblad. These four types are based on characteristic ferning patterns of dried cervical mucus and include: *L mucus*; *S mucus*; *G mucus*; and *P mucus*. They were able to identify 3 subtypes of *S mucus*, (i.e., S1, S2, and S3) and 5 subtypes of the *P mucus* (i.e., P6B, Pa, P2, P4, and Pt). They also confirmed that various zones and crypts in the cervix produce a specific type of mucus, i.e., the Zone of the L crypts produced mostly *L mucus*, the Zone of the S crypts produced *S mucus*, the Zone of the G crypts produced *G mucus*, and the Zone of the P crypts produced *P type mucus*.

What is new is that the biologists were able to observe and describe 4 different structural types of cervical mucus. They are:

Type I mucus is compact looking with large plain surfaces and small pores. This type came from samples with a high percentage of G mucus.

Type II mucus appeared not as compact as Type I. The structure of this type looked similar to a marine sponge, with slightly bigger pores. This type came from samples that had a high percentage of L mucus.

Type III mucus had a network of parallel and crossing fibers with large diameter pores. The pores were large enough for sperm to penetrate. This type was identified primarily from samples with S type mucus present.

Type IV mucus had plain surfaces and parallel folds. The diameters of the pores were smaller than those found in Type III. This type came from samples that had at least 50% of P type mucus.

The Spanish researchers concluded that they did not view cervical mucus as a homogeneous entity, but rather as a mosaic of four different types in various proportions during the menstrual cycle. They also concluded that specific mucus types are located in specific areas of the cervix. They cautioned that further studies are needed to determine if these different mucus types have biochemical differences.

Comments:

The authors stated that the cyclical changes in the ferning patterns of the mucus, depending on the day of the menstrual cycle that the mucus sample was taken, could be expressed in percentages. Furthermore, they said that this quality (and technique of observing air dried mucus through a microscope) would allow for use in natural family planning.

I would caution that this methodology would have to be demonstrated through research before there was any application for family planning purposes by couples outside of a laboratory setting. The biologists in this study used very sophisticated and powerful microscopes with grids in the field of vision to estimate the percentages of the various types of mucus. The handheld lip-stick size microscopes that are available in the market place would in no way match that precision. Furthermore, researchers would have to verify the accuracy of identifying these mucus types in correlation with other valid markers of fertility.

1. Menarguez, M., Pastor, L.M., & Odeblad, E. **Morphological characterization of different human cervical mucus types using light and scanning electron microscopy**. *Human Reproduction*, 2004;18:1782-1789.

Natural Family Planning Failure in the United States

The 14th and latest edition of the book *Contraceptive Technology* was recently published.[1] This book is considered by some to be the contraceptive "bible" for health care professionals. Two of the chapters were written by James Trussell, a professor of economics at the Princeton University Office of Population Research and a well-known expert in contraceptive effectiveness. He has also published an article on contraceptive effectiveness based on his two chapters in *Contraceptive Technology*.[2,3] What is relevant about this article is that the effectiveness rates provided for each method of family planning will be commonly cited in textbooks, journal articles, in professional conversations, and for contraceptive decision- making on the part of health professionals and their clients. What is directly relevant for NFP providers and NFP users are the effectiveness figures provided on NFP methods. Other information provided in this article that is important for NFP providers and users are the terms and definitions used to express contraceptive effectiveness.

Trussell points out that in the epidemiology literature there are two terms that refer to "how well a method works." The term *efficacy* refers to how well an intervention works (i.e., a method of contraception) in clinical trials and the term *effectiveness* refers to how well an intervention works in actual practice by the consumer. These terms are often used interchangeably.

Three terms and definition are provided on contraceptive efficacy. These terms and

definitions are useful for couples and health providers to make decisions on choosing a method of family planning. They are:

1. Typical use – refers to the failure rate (i.e., the effectiveness) of a method of contraception (or NFP) during actual use (both inconsistent and incorrect use)
2. Perfect use – refers to the failure rate or the effectiveness of a method of contraception during perfect use as defined by following the directions for use.
3. Imperfect use - reflects how ineffective a method is when used incorrectly or inconsistently.

The percentage of perfect users of a given method of contraception reflects how hard it is to use a method of family planning correctly and consistently. The difference between failure rates during imperfect use and perfect use reflect how forgiving a method of contraception is and how hard it is to use. NFP methods are "un-forgiving" in that if a person uses it incorrectly (i.e., has intercourse during the fertile period) she will most likely become pregnant. So too, NFP methods are relatively difficult to use, since there is a rather large difference between perfect use failure rates (i.e., 1-9%) and typical use failure rates (i.e., 10-25%).

Typical use of a contraceptive method is based on how well the average person uses the method. It is assumed that the average person will not always use the method correctly or consistently. It could also mean that the person might not have been using the method in that typical use is based on self-report. Trussell admits that this concept of typical use is controversial and difficult for some to accept.

Trussell provides figures for Typical and Perfect use of 21 methods of family planning and the percent of women continuing use of these methods at 1 year. For NFP methods the following figures are provided:

TABLE 1: EFFECTIVENESS RATES OF NFP METHODS

Typical Use	Perfect Use	% Continuing
Periodic Abstinence	25	51
Calendar	9	
Ovulation method	3	
Sympto-Thermal	2	
Post ovulation	1	

Trussell determined these effectiveness rates based on the data provided from the 1995 National Survey of Family Growth (NSFG). This survey involves in-person interviews with a random selection of women between the ages of 14 and 45 in the United States. The typical use rates of NFP provided in the Trussell article and in the up-coming edition of *Contraceptive Technology* are based upon self-report use and "failure" i.e., achieving a pregnancy when not intending to. Many (around 50%) of the women who report the use of a periodic abstinence method in the NSFG actually list calendar rhythm and not one of the modern methods.

Trussell mentioned that there are many factors that can influence contraceptive effectiveness, including the age of the users, the frequency of intercourse, the expertise of the investigators, user characteristics, and the inherent efficacy of the methods. For example

methods that require little behavior change on the part of the user, like sterilization or the IUD, will show very consistent efficacy rates as determined by different investigators with different subjects. Whereas methods that require modification of behaviors, like NFP or use of condoms, will have a lot more variability in efficacy rates between various efficacy studies. Efficacy rates can also be influenced by methodological problems in conducting efficacy studies. Trussell mentioned the importance of using life-table analysis in calculating efficacy rates rather than Pearl Index rates so that the distorting effects of duration of use are controlled for. Trussell also recommended that pregnancy tests be conducted once a month on all subjects to report true pregnancies (and early pregnancy loss) rather than just having the woman user report a pregnancy.

Comment:

I have difficulty in comprehending and accepting some of Trussell's interpretation of efficacy rates — especially typical use failure rates. I wonder how valid efficacy rates are when based only on self-report use of a given method of contraception and self-report of failure rates. As he mentioned and admits, a person is counted in typical use effectiveness rates even if that person is not using the method. Women respondents in the NSFG often reported that they use Calendar Rhythm. But as seen in a number of studies, women will often report that they are using Rhythm, but in actuality not even know how it works (see study in this issue of CMR on ethnic Chinese use of "Rhythm"). I would be more comfortable with the typical use failure rates in a good clinical study of a method of family planning. I wonder why some of the good NFP efficacy studies are ignored. He uses small clinical studies for other methods of contraception and in doing so, the comparison of pregnancy rates among the various methods are not justified.

1. Hatcher, R.A., Trussell, J., Stewart, F., et al. *Contraceptive Technology.* Eighteenth Revised Edition. New York: Ardent Media, 2004.
2. Trussell, J. **Contraceptive failure in the United States**. *Contraception.* 2004;70:89-96.
3. Trussell, J. **The essentials of contraceptive efficacy, safety, and personal considerations** and Trussell, J. **Contraceptive efficacy**. In Hatcher, R.A., Trussell, J., Stewart, F., et al., editors. *Contraceptive Technology.* Eighteenth Revised Edition. New York: Ardent Media, 2004.

Screening and Monitoring for the Standard Days Method is Important for Maintaining Efficacy

The Standard Days Method (SDM) of family planning was developed at the Georgetown University Institute for Reproductive Health (IRH) for the purpose of providing a simple but effective natural method of family planning. The Georgetown IRH has a mission of providing cost effective simple natural methods of family planning for developing countries. The SDM is a fixed-day calendar system in which days 8-19 are considered fertile. The method is to be used for women with menstrual cycles that fall within a 26-32 day range. If the woman user has two cycles out of this range then she is advised to use another method. The effectiveness of this method was tested at 5 different sites in three developing countries with 787 women participants and was found to have a 1-year correct use non-pregnancy rate of 95% and a 1-year typical non-pregnancy rate of 88%. This method has been described in past issues of *CMR* and has been published in the peer reviewed scientific literature.[1] The method is currently implemented by use of a colored bead system called CycleBeads. The bead system helps in the maintenance of the system in that there are reference beads that indicate if cycle length is within the defined parameters of the method.

The current screening procedures to determine whether the SDM would work for a potential woman user is based on recall of menstrual cycle history and asking the potential user 3 questions: 1. Have your last 3 periods come approximately when you were expecting them? 2. When was the first day of your most recent menstrual period? 3. When do you

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expect your next period to start? If the potential woman user indicates that her past 3 periods occurred when expected and her current cycle length was expected to be 26-32 days in length then they can be confident in the use of SDM.

The IRH researchers evaluated the screening and monitoring procedures for the SDM by applying its rules to an existing data set from the World Health Organization (WHO) study of the Ovulation Method.[2] The WHO study was conducted in 5 countries, involved 726 participants, and generated over 8,000 cycles of data.[3] Criteria for entering the study included having cycle lengths between 23-35 days in the past 6 months. The IRH researchers applied the SDM method fixed days (8-19) to the WHO data and utilized the peak day of mucus as an estimate for the day of ovulation. The framework for analysis was a 12-day theoretical fertile phase that included the 8 days before and 3 days after the Peak day of mucus.

The IRH researchers analyzed the probabilities of pregnancy within those 12 days in 4 different theoretical scenarios in order to determine if screening and monitoring (for cycle lengths between 26-32 days) was necessary.

Scenario A involved women from the WHO study who all had cycles within the 26-32 day parameter. There were 1,377 cycles from 25.7% of the women participants. The highest probability of pregnancy with these cycles was 0.007 on Peak day minus 6. These results indicate from a theoretical standpoint that the SDM is an effective method.

Scenario B included only women who had no more that 2 cycles outside of the 32-day range within a year. This involved 51.4% of the women and 4,072 cycles. The highest probability of pregnancy was again only 0.007 on Peak day minus 6. These results show that the SDM criteria for having no more than 2 cycles outside of the established range of 26-32 days is valid for maintaining efficacy.

Scenario C included all (100%) of the women in the WHO study, but analyzed only those cycles (n = 4,803) up to and inclusive of the 2nd out of range cycle. The probabilities of pregnancy increased somewhat in the 8-day fertile phase, but only to a high of 0.009 on Peak day minus 4. The authors suggested that this somewhat higher level of probability indicated that the screening interview for use of the SDM is important.

Scenario D involved only those WHO study women (49.7%) who had menstrual cycles (n = 2,789) after the second out-of-range (i.e., longer than 36 days). With this scenario, the day specific probabilities of pregnancy increased considerably to a high of 0.014 on Peak day minus 4. The authors speculated that this much higher potential pregnancy rate indicated that the monitoring of 2 cycles outside of the range clearly affects method efficacy for the SDM.

Another statistic of interest was that 77.5% of the cycles in the WHO data set were within the 26-32 day range compared to over 90% of the cycles in the SDM method study. This statistic indicates that screening for cycle length helps to determine the best users of the SDM. The researchers also found that only 56.4% of the women in the SDM study who had one cycle out-of-range had another one out-of-range within 6 months, compared to 78.2% of the women in the WHO study. This data again suggests that the SDM screening method reduces the likelihood of this event occurring with SDM users. Finally, they also found that 18.3% of cycles in scenario A are shorter than 26 days or longer than 32, compared to 29.1% of those in scenario B. The differences confirm the importance of cycle monitoring with the SDM.

The authors concluded that the results show the importance for and the effectiveness of the SDM screening and monitoring protocol. They also pointed out that with more intensive screening procedures or with having potential women users to actually compile a menstrual cycle history, they then could rule out more women and thus have greater efficacy. So too they could loosen or tighten the monitoring rules for the SDM for a lower or higher efficacy. For example, they could recommend only 1 cycle be out of the range to induce greater efficacy or allow more than 2 cycles out of the range to slightly decrease the efficacy. The authors felt that the current screening and monitoring criterion for the SDM were a good balance.

Comments:

This study illustrated the continued systematic research on the SDM by the Georgetown University IRH group. This is a good model for the development and systematic testing of new methods of NFP. Testing of the SDM with various populations by researchers other than the Georgetown group would be welcome.

1. Arevalo, M., Jenning, V., & Sinai, I. **Efficacy of a new method of family planning the Standard Days Method.** *Contraception* 2002;65:333-338.
2. Sinai, I., Jennings, V., & Arevalo, M. **The importance of screening and monitoring: the Standard Days Method and cycle regularity**. *Contraception,* 2004;69:201-206.
3. World Health Organization (WHO). **A prospective multicentre trial of the ovulation method of natural family planning. III. Characteristics of the menstrual cycle and of the fertile phase**. *Fertility and Sterility* 1983;40:773-778.

Misperceptions about Condoms, Withdrawal, and Rhythm

The notion that women who claim to use Rhythm as their primary method of family planning often do not understand their menstrual cycles or actually use a Rhythm (calendar) method was given more credence by a recent study conducted by Canadian researchers.(1) The study involved interviewing 40 ethnic Chinese women living in Vancouver who presented to a family planning clinic with an unintended pregnancy and with the desire to have an abortion. These 40 women participants had an average age of 25.4 years (range 17-39), 12 (30%) were married, 5 (12.5%) were living in a common law relationship, and the rest were single and sexually active. The women were provided in-depth hour-long interviews with open-ended questions about their contraceptive practices and contraceptive decision-making. All interviews were taped and analyzed using qualitative methodologies.

Four major themes were formulated from the analysis of the interviews. These are: 1. negotiation, 2. power within relationships, 3. lack of knowledge, and 4. plans for future contraception. The "negotiation" theme involved dynamics that occur between a woman and her male partner about the type of contraception to use and when to use it. One of the quotes given as an example for this theme dealt with whether to use a condom or not based on the male partner's desire to have satisfying intercourse. The "power within relationship" theme involved the women participants feeling that they did not have control over their contraceptive methods – when the method of family planning involved cooperation with the male partner, especially when they had to use condoms, withdrawal, or Rhythm. The "plans for further contraception" theme essentially entailed a plan to use either hormonal contraception or condoms.

The "lack of knowledge" theme was revealing. This theme essentially indicated a lack of knowledge of the menstrual cycle, the fertile phase and ovulation. It also indicated the lack of knowledge in how to use a calendar-based family planning method. The women participants commonly indicated that they considered their menses and 7 days after as infertile (i.e., what they called safe days), which means that they were having intercourse up to the 12th to 14th day of the cycle. Furthermore, only 2 women said that they abstained during what they considered the fertile phase. Most of the women used condoms or withdrawal during what they considered the "unsafe" time of their menstrual cycles. An example quote that was given that formulated the "lack of knowledge" theme is as follows:

> "It's not really clear. Actually, other people just told me when it is safe, so I don't know if it is really safe, just approximately. Not as sure — especially since I got pregnant. I don't feel a sense of security with it."

The authors concluded that the use of non-medical methods of family planning required communication between the sexual partners. They also indicated that since 50% used

calendar systems, that it was important to educate women and their partners about the relative risk of pregnancy at different times during the menstrual cycle.

Comments:

The authors did not think about offering to teach or refer the married women clients and their partners to a NFP teacher to learn how to use modern methods of NFP, including the newer calendar-based methods. They also did not consider helping the single women participants to live chaste lives or consider the dangers of living with serial sexual partners.

1. Wiebe, E.R., Janssen, P.A., Henderson, A., & Fung, I. **Ethnic Chinese women's perceptions about condoms, withdrawal and rhythm methods of birth control**. *Contraception*, 2004;69:493-496.

Intercourse Found to be Most Frequent During the Fertile Window – But Might Accelerate Ovulation

Researchers at the National Institutes of Environmental Health Sciences (NIH) have confirmed in a number of studies that there are only 6 days in the menstrual cycle in which pregnancy can occur with a single act of intercourse.[1] The 6-day fertile window includes the day of ovulation and the 5 days before. NIH researchers recently discovered that intercourse patterns among couples occur most frequently during the 6-day fertile window and in particular the day before ovulation.[2] That day is statistically the most fertile day in the menstrual cycle. These same researchers have also provided some evidence that intercourse might stimulate ovulation.

In order to determine if there are any biological influences regarding intercourse patterns around the time of ovulation, NIH researchers analyzed existing data from 68 women who were using an IUD or who had been sterilized by tubal ligation. The 68 women provided data on 171 menstrual cycles in which they collected daily urine samples that were analyzed for metabolites of estrogen and progesterone. The day of ovulation was estimated by estrogen progesterone ratios. The NIH researchers also tested a secondary hypothesis to determine if intercourse accelerated ovulation by analyzing existing data from 217 women (696 cycles of data) who were trying to achieve a pregnancy. The 6-day fertile window was the physiological framework for their study. Days of bleeding (menses) were not included in the data set.

The researchers found that the overall frequency of intercourse on non-bleeding days was 0.29 per day or about twice a week. They also found that the frequency of intercourse was above the mean of 0.29 / day during the fertile window and below during the luteal phase of the cycles. Furthermore, the frequency increased during the 6-day fertile window, with the most frequent day of intercourse being the day before the estimated day of ovulation. The frequency of intercourse during the 6-day fertile window was 24% higher than during non-bleeding days outside of the fertile window. Researchers also discovered that couples were most likely to have intercourse on weekends.

To determine if intercourse accelerated ovulation, it was speculated that ovulation would occur most frequently 1-2 days after intercourse. By combining 2 data sets (for a total of 285 women participants and 867 cycles of data) they found a small (but statistically weak) rise in the frequency of intercourse after weekend intercourse. They also found that those couples who had a strong pattern of intercourse on weekends had a statistically higher frequency of ovulation post weekend intercourse compared to those couples that had no pattern of weekend intercourse (54% compared to 41%).

The researchers speculated that the results might be explained by some of the following mechanisms: 1. a woman's libido (sexual interest) is higher during the 6 day fertile window (i.e., the follicular phase leading up to the day of ovulation); 2. a man's sexual interest is

stimulated by behaviors and chemicals (pheromones) from the woman that increases her sexual attractiveness during the fertile window; and, 3. ovulation is accelerated by sexual intercourse. The researchers concluded that one or more of these mechanisms serve as a silent partner in facilitating the optimal timing of intercourse to achieve a pregnancy.

1. Wilcox A.J., Weinberg C.R., & Baird, D.D. **Timing of sexual intercourse in relation to ovulation: effects on the probability of conception, survival of the pregnancy and sex of the baby.** *New England Journal of Medicine.* 1995; 333: 1517-1521.
2. Wilcox A.J., Baird, D.D., Dunson, D.B., McConnaughey, D.R., Kesner, J.S., & Weinberg, C.R. **On the frequency of intercourse around ovulation: evidence for biological influences.** *Human Reproduction.* 2004;19:1539-43.

INFERTILITY

Decline in fertility with increased age due to increased infertility rather than sterility

Biostatisticians recently determined that the decline in fertility with increased age, through the 20s and 30s, among European couples was due to increasing rates of infertility rather than an increased rate of sterility.(1) Sterility was defined by the investigators as the inability to achieve a pregnancy naturally in the absence of clinical intervention. Infertility was defined as the inability to conceive with unprotected intercourse over a 12-month period. The biostatisticians were also able to determine the length of time to conceive (by gender) and the expected rates of infertility among these age groups.

The data set utilized was generated by 770 couples from 7 European NFP centers in which the women were between the ages of 18 and 40 years. The researchers analyzed data from a total of 7,288 menstrual cycles. They adjusted the data set for the timing and frequency of intercourse and utilized a statistical model to estimate the probability of sterility and infertility. They calculated that the rate of sterility among these couples was around 1% and that this rate did not increase with age of the couple. However, the rates of infertility did increase with age. Among couples that had intercourse at a frequency of 1 and 2 times per weeks the proportion of women unable to conceive within 12 months can be seen in Table One.

TABLE 1: PROPORTION OF COUPLES FAILING TO CONCEIVE WITHIN 12 MONTHS BY FREQUENCY OF INTERCOURSE AND AGE OF WOMAN PARTNER

AGE OF WOMAN	INTERCOURSE 2X/WEEK	INTERCOURSE 1X/WEEK
19 – 26	8%	15%
27 – 34	13-14%	22-24%
35 – 39	18%	29%

As can be seen, the rates of infertility increased substantially with a decrease in the frequency of intercourse. Having intercourse only once a week enhanced the likelihood the couples will miss the 6-day fertile window. The researchers did not find a significant decrease in infertility with an intercourse frequency of 3 times per week. They did however

see a significant increase of infertility when the male partner's age approached 40. This was particularly pronounced when the woman's age was over 35. For example, when the woman is 35 years of age and the male partner is 35, the percent of infertility is around 18%; however, if the male partner is 40 the rate of infertility increases to 28%.

The researchers also calculated the probabilities of pregnancy when infertile couples continue to try to achieve pregnancy for two years. They found that when the woman is between the ages of 19 – 26 and the male partner is 35 years or less then the percent of couples achieving pregnancy was 63; when the woman was between 27 – 34 and the male partner was age 35 or less, the percent was 55%; when the woman was between 35 – 40 and the male partner was 35 or less, than the percent was 51; and when the woman was between 35 – 40 and the male partner was 40, the percent decreased to 43. The researchers concluded that many infertile couples would achieve pregnancy if they continue to have natural intercourse for another year.

1. Dunson, D.B., Baird, D.D., & Colombo, B. **Increased infertility with age in men and women.** *Obstetrics and Gynecology*. 2004;103:51-56.

Negative Lifestyle Factors are found to be Associated with a Significant Reduction in Fertility

Researchers from the United Kingdom found that time to pregnancy (TTP) was significantly longer if the woman participant or her partner smoked > 15 cigarettes per day, the partner consumed > 20 alcohol units per week, the woman was overweight, she or her partner drank > 6 cups of caffeinated tea or coffee / day, or if they were socially deprived.[1] They also found that lifestyle factors had a cumulative effect on TTP.

Researchers at the Postgraduate Medical Institute from the University of Hull, England conducted an observational study in which they administered a lifestyle and TTP (i.e., the interval of exposure to unprotected intercourse from discontinuing birth control methods until conception) questionnaire to 2,112 pregnant women who attended antenatal clinics in Hull and East Yorkshire England. They had a 099% response rate to this questionnaire.

Overall, they found that 57.1% of the women conceived within 3 months and 81.2% by the end of 12 months. Of the 372 (18.8%) sub-fertile couples, 190 or 9.6% conceived by the end of the second year. The sub-fertile couples compared to the fertile couples were significantly older, more obese, smoked more cigarettes, and consumed more alcohol.

More specific results showed that heavy smoking women (>15 cigarettes / day) compared to light smoking or non smoking women had a 2-fold longer TTP. Heavy smokers were more likely to be sub-fertile among the men and women. Heavy alcohol consumption among the male partner was associated with a 2-fold increase in TTP. Moderate alcohol consumption, among women and their partners was found to have no effect on TTP. Women who drank >5 cups of tea or coffee per day had a longer TTP and were more likely to be sub-fertile. Women who were over and under weigh had problems with fertility. Underweight women had a 4-fold longer TTP and women who were overweight had a twofold longer TTP. Underweight women were 3.5-fold and obese women were 3.8-fold more likely to be sub-fertile. Women participants who had a lower living standard had a longer TTP and were more likely to be sub-fecund than those women who had high living standards. Finally, recreational drug use and coital frequency had no significant effect on TTP or sub-fecundity. However, the incidence of recreational drug use was low and thus statistical power to determine risk was decreased.

The researchers also found that as the number of negative lifestyle factors increased there was a significant and progressive increase in TTP and a significant reduction in fecundity. The mean TTP with 2 negative lifestyle variables was 2.5-fold, 3.7-fold with 3 variables, and

4.4-fold with 4 variables. Couples who had more than 4 negative lifestyle variables had a 7.3-fold longer TTP compared with couples that had none. The researchers recommended promoting healthy lifestyles to couples planning for or trying to achieve a pregnancy. Based on their results they concluded that couples who lead healthy lifestyles should cut the rate of sub-fecundity in half.

Comments:

Helping couples lead a healthy lifestyle will not only help them to have better general health but also increased fertility. This could lead to a substantial decline in medical referrals and treatment for infertility and thus a substantial reduction in health costs.

1. Hassan, M.A.M. & Killick, S.R. **Negative lifestyle is associated with a significant reduction in fecundity.** *Fertility and Sterility*, 2004;81:384-392.

Natural Pregnancy and Deliveries after the Age of 45 Are Rare and Constitute Only 0.2% of Total Deliveries

Israeli researchers observed the records of all women who delivered naturally after the age of 45 at 4 major hospitals in Jerusalem during the years 1995-2000.[1] They found only 209 women out of 104,659 who delivered a baby were 45 years or older or i.e., 0.2% of the total. What is most remarkable about these women is that they were exceptionally fertile and had on average 9.6 children. The researchers analyzed the gravidity, parity, and spontaneous abortion rates (SAB) of these women in order to determine: 1. Whether parity exerted a protective effect on the rate of SAB and Down's Syndrome (i.e., aneuploidy) and 2. Whether the women in the study differed from the general population in the rate of SAB and Down's Syndrome? The protective effect of parity is theoretically due to the ovaries being in a state of quiescence when women are pregnant, and during this state of quiescence the follicles and oocytes are protected from demise and genetic alterations.

The researchers found that the 209 women who delivered a healthy child after the age of 45 had a mean gravity of 11.5 ($\pm$4.5) and a mean parity of 9.6 ($\pm$4) children. Most of the women (81%) were classified as grandmultiparas with 6 or more deliveries, and 46% were grand-grandmultiparas and had greater than 11 deliveries. The mean number of SABs for the entire group was 1.9 ($\pm$1.9). There was no difference in the SAB rate between the women with a low parity (less than 6) than those with a higher number. They concluded that the increased parity was found to have no effect on SAB rate. However, when compared with the general population the study group had a significantly lower SAB rate. For example, the rate for the study group was 9.1% at age 45 or older, compared with 53.2% in the general population.

There were 6 cases of Down's syndrome among the 209 deliveries for a rate of 2.8%. There was no significant difference in the Down's Syndrome rate among the lower parity study group women compared to the higher parity women. They also did not find a significant difference in the Down's Syndrome rate when the study group was compared to the general population, i.e., a 2.80% rate compared to a 3.33% rate. The researchers concluded that this evidence shows that multiparity does not have a protective effect on ovarian senescence through periods of ovarian rest. However, they did speculate that the study group might possess some type of genetic propensity that affects ovarian demise and prolongs fertility.

Comments:

Although the hypothesis of ovarian protection was not supported, it also was not necessarily rejected. The reason is that the researchers did not have enough participants to have adequate statistical power to detect small changes in the levels of parity. There might also be behavioral reasons for the differences, in that many modern couples or women do wish to have babies after the age of 40 most often are either sterilized or are using some type of contraceptive.

Of interest is that the population of women who delivered a baby when they were 45 years or older were essentially from an ultra-orthodox Jewish sect in the greater Jerusalem area who are proscribed from using conventional contraceptive measures. The authors mentioned that these women encourage natural conception and view fecundity as a blessing. The authors do not mention the use of natural family planning by this group of women.

1. Laufer, N., Simon, A., Samueloff, A., Yaffe, H., Milwidsky, A., & Gielchinsky, Y.. **Successful spontaneous pregnancies in women older than 45 years.** *Fertility and Sterility*, 2004;81:1328-1332.

CONTRACEPTIVES

Offering Advanced Supplies of Emergency Contraception Found Not to Reduce Abortion Rates

Theoretically the widespread use of emergency contraception (EC) should reduce abortion rates among a population of sexually active women. Researchers in Scotland undertook a community intervention study designed to test whether the widespread distribution of EC to a large number of women would influence abortion rates.[1] The study was conducted in the county of Lothian in South East Scotland. The plan was to have all women aged 16-29 years who lived in Lothian to receive 5 courses of the English version of EC called PC4 which consists of 4 tablets of ethinylestradiol (a synthetic estrogen) and levonorgestrel (a synthetic progestin). Two tablets are taken 12 hours apart within 72 hours of intercourse.

Every household in Lothian was mailed a postcard inviting women to ask their healthcare provider for a free package of PC4. In addition, publicity materials were distributed to all general practice physicians, all participating health clinics, libraries, cinemas, hairdressers, community pharmacies, nightclubs, pubs and discotheques. Posters advertising the free EC were placed in public toilets. There was a local and national press conference to launch the study. All heath care providers who prescribed contraception were asked to participate. Contraception can be obtained free of charge from a primary health care provider in Scotland. EC has been available since 1984.

Eighteen months after the launch of the study, a questionnaire was mailed to 6,486 Lothian women between the ages of 16-29 registered with a primary heath care provider. Reminder postcards were sent to non-respondents. From the survey, 2,817 women responded with a rate of 50.8% (940 questionnaires were returned undelivered). During the time period of the study (September 1, 1999 to December 31, 2001) 17,831 women had received a supply of EC and at least 22,603 women had access to EC without needing to see a doctor. It was estimated that at least 8,081 courses of EC were used during the time period of the study.

Of the 647 women who completed and returned a questionnaire and received the free EC, 36 (5.5%) reported the occurrence of an unintended pregnancy. When countywide abortion rates (per 1000 women) from 1998-1999 were compared with the rates in 2000-2001 there were no differences. There also were no differences in abortion rates in Scotland as a whole and in 3 other counties as a comparison. Furthermore, there were no significant differences in the mean number of women referred for abortion among the 10 general practices that distributed the most packages of EC.

The researchers concluded that the provision of advanced supplies of EC appears to have no effect on abortion rates in Lothian, Scotland. The rationale that the researchers gave to explain the results are that with the supply of EC so easily available this encouraged women

to take risks with unprotected intercourse or even when the women had the supply of EC at home that they failed to use it. A final explanation given was that possibly EC was not as effective in preventing pregnancy as is believed, since efficacy is based on rather unreliable data.

Comments:

The common perception among health providers is that if contraception is made more readily available then there will be a lower rate of abortions. This assumption comes from the Alan Guttmacher data that 50% of women who have abortions are not using any contraception. This study diminishes that notion. There must be some other factors that contribute to abortion rates.

Some of the authors did a follow-up study to evaluate the county-wide distribution of EC and to determine why it did not lower abortion rates.[2] They interviewed 44 primary health care workers (both physician and nurses) who participated in the original intervention study and 22 women who received the free packets of EC. The interviews were transcribed and analyzed utilizing qualitative techniques. The researchers found some of the health care workers were reluctant to be pro-active in distributing free EC because they felt it provided a contradictory message, i.e., you need to be responsible with your sexual behavior and plan ahead and use safe (condom) sex — and not have chaotic sexual practices. They also felt that it was not always appropriate to bring up the use of EC with women clients that come to them for other medical reasons. And some felt that their clients might view offering EC as an immoral affront.

The women users who were interviewed were hesitant about offering free EC to every woman. For example, they felt that the offer of ECs would not be appropriate for them (i.e., they did not engage in un-safe chaotic sexual behaviors) but might be appropriate for those that did engage in such behavior. They also felt that there would be a judgment about their morality if they asked for ECs.

The authors concluded that the health care providers needed to be more pro-active in offering EC and needed to help women overcome their reluctance to ask for ECs. The authors also suggested that EC packages should include condoms. Supposedly this would make the use of EC or asking for EC more responsible in terms of behavior and help the women respondents suppress their sense of morality!

1. Glasier, A., Fairhurs, K., Wyke, S., Ziebland, S., Seaman, P., Walker, J., & Lakha, F. **Advanced provision of emergency contraception does not reduce abortion rates.** *Contraception,* 2004;69:361-366.
2. Fairhurst, K., Ziebland, S., Wyke, S., Seaman, P., & Glasier, A. **Emergency contraception: why can't you give it away? Qualitative findings from an evaluation of advance provision of emergency contraception.** *Contraception,* 2004;70:25-29.

Increased Risk of Breast Cancer Found with Increased Duration of Use of Progestin-Only Contraception

Researchers from a number of institutions investigated whether progestin-only contraception in the form of implants or injectables have a link to the development of breast cancer.[1] The study was coordinated through the National Institutes of Child Health and Human development. Called the Women's Contraceptive and Reproductive Experiences (CARE) Study, it involved 4,575 randomly sampled women (mean age 49.5) with primary breast cancer from 5 metropolitan areas in the United States. These participants were compared with 4,682 control subjects (mean age 49.8) (i.e., women without breast cancer) that were randomly sampled from the same metropolitan areas. All were interviewed in person and questioned as to their use of contraception, length of use, when initiated and questions about numerous lifestyle behaviors and demographics.

A total of 99 women in the cancer group and 117 in the control group were exposed at some time to either depot medroxyprogesterone acetate (i.e., injectable progestin), an unknown form of injectable contraception, or Norplant (progestin implant). The researchers found no significant increase or decrease in breast cancer among women ever exposed to progestins and those who were not. The risk of breast cancer was not increased among women who were exposed to injectable contraception within one year, or 5 years within the date of the interview. There was a slight significant increase of breast cancer with duration of use, but risk was not increased among women with 24 months of use compared to those women who never used progestins. The authors concluded that the study data does not support an increased risk of breast cancer associated with the use of injectable or implanted progestin-only contraception between the ages of 35-64.

Comments:

As admitted by the authors this study had a lot of limitations. Chief among them is that there were not enough women who ever used progestins (implanted or injected) and not enough had used it long enough to have enough statistical power to determine differences. Other problems mentioned include the probability of recall bias in the use of contraception and the fact that they only interviewed women over the age of 35.

Finally, there is the difficulty that this is not a prospective random control study of women who have never used progestins versus those who have been exposed. A prospective randomized trial is the most powerful design to determine differences. That is why recent hormone replacement studies have found significant differences. One also needs to ask, how can the researchers tease out the effects of being exposed to other forms of hormonal contraception? Over 90% of the control group of women and 86% of the cancer group of women were exposed at sometime to combination estrogen and progestin type contraception.

1. Strom, B.L., Berlin, J.A., Weber, A.L., et al. **Absence of an effect of injectable and implantable progestin-only contraceptives on subsequent risk of breast cancer.** *Contraception*, 2004;69:353-360.

Return to Ovulation Following Subcutaneous Injection of Depo-Provera Can Take Up to 12 Months

Researchers from the University of California and University of Wisconsin Schools of Medicine recently compared the efficacy and duration of ovulation suppression and the return to ovulation between Depo-Provera (150 mg/mL) given intramuscularly (IM) and a lower dose formula of Depo-Provera (104 mg/0.65 mL) that is given by subcutaneous injection (SC).[1] The IM route of providing Depo-Provera (i.e., medroxyprogesterone acetate) has been available in the United States for over 10 years. Researchers, however, wanted to determine if the lower dose SC route would be just as effective. The reason for the lower dose of Depo-Provera and the SC route is that the researchers felt it would be better tolerated and easier to provide. Women could potentially give themselves an SC injection every 3 months.

Nineteen women received the usual IM Depo-Provera and 39 received the lower dose SC version of Depo-Provera. Serum levels of estrogen, progesterone, LH and FSH, and serial sonography of the developing follicles were used to determine ovulation suppression and return to ovulation. Both the usual IM dose of Depo-Provera and the SC low dose of Depo-Provera provided immediate suppression of ovulation and in both groups ovulation was suppressed over the 13 week dose interval. The earliest return to ovulation among the SC users was at 15 weeks. The median return time was 30 weeks. The 1-year cumulative return to ovulation for the SC group was 97% and for the IM group 95%. The researchers concluded that the low dose SC formulation of Depo-Provera was an important new option for effective, reversible contraception.

Comments:

Whether the new SC formulation of Depo-Provera is acceptable to women users remains to be seen. For NFP teachers, they can advise women who want to learn NFP and have just discontinued the use of either the SC or the IM version of Depo-Provera that it will take up to one year before ovulation and normal cycles return. Furthermore, it might take up to a year or more for them to be able to achieve a pregnancy if that is desired.

1. Jain, J., Dutton, C., Nicosia, A., Wajszcuk, C., Bode, F., & Mishell, D. **Pharmacokinetics, ovulation suppression and return to ovulation following a lower dose subcutaneous formulation of Depo-Provera**. *Contraception* 2004;70:11-18.

UNDER THE MICROSCOPE

Book Review

The Medical and Surgical Practice of NaProTECHNOLOGY.

T.W. Hilgers. Pope Paul VI Press, Omaha, Nebraska, 2004. Hardcover, 1244 pages, $209.95. ISBN 0-9744147-0-0.

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The Medical and Surgical Practice of NaProTECHNOLOGY, by Thomas W. Hilgers, MD, is a unique book. It is safe to say that no other medical textbook quotes from the Bible, the Catholic papal encyclicals *Humanae vitae, Fides et ratio,* and *Evangelium vitae,* John Paul II's Theology of the Body, and Elvis Presley, all within the Preface! No doubt many "objective" scientific readers will look at the abundant references of faith and dismiss the entire book as a work based in religion, rather than science. But to dismiss the meticulous and illuminative science of this book would be a grave mistake.

As explicated in *Fides et ratio*, in order for there to be moral clarity, there must be scientific clarity. Likewise, in order for there to be scientific clarity, there must be moral clarity. The ignorance or rejection of this principle is at the source of many of the morally objectionable practices in medical science today, including abortion, contraception, and artificial reproductive technology. Just one example: the countless women who are told that the oral contraceptive pill is the only available answer for their particular medical condition (such as abnormal bleeding, PMS, ovarian cysts, and the list goes on).

To learn about medically sound and morally acceptable medical practice in women's health with scientific depth and rigor, there is no better source than this textbook. It contains a comprehensive summary of the data and insights of 30 years of devoted service by Dr. Hilgers and colleagues, resulting in the science of NaProTECHNOLOGY (natural procreative technology). In keeping with his own dedicated role, 80 of the book's 90 chapters are written by Dr. Hilgers himself, without whom the book, the data, and the key elements of the science wouldn't exist. Yet others have made important contributions to the field and will help NaProTECHNOLOGY develop into the future.

NaProTECHNOLOGY is defined in the book as a new women's health science which has the main principle of working cooperatively with the woman's menstrual and fertility cycle. A simple concept, but revolutionary in today's medicine. NaProTECHNOLOGY is medicine at the service of the whole human person. It is a balanced system in which the patient's role

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

is as critical and as respected as the physician's. It starts with detailed medical evaluation to establish the correct diagnosis. As needed, treatment includes natural hormones, drugs, or surgery, all with the goal for supporting or restoring the natural reproductive processes.

This textbook is not meant for the lay reader. Other than the first few chapters, I would not recommend it to someone without formal medical or scientific training. Weighing in at 1244 pages filled mostly with technical information (including 460 tables, 672 figures, and 830 medical photographs), it is not a casual read. But it is an invaluable medical reference that should be studied carefully by every physician and health professional seeking to care for women and families in the realm of reproductive health, rightly understood.

Some physicians who come from the background of other NFP methods might question the emphasis in the book on the Creighton Model Fertility*Care*™ System. I would simply ask them to give the benefit of the doubt and don't allow this approach to get in the way of what can be learned. Many of the key insights into diagnosis and treatment simply would not have been developed without the standardized interpretation of the fertility biomarkers available within the Creighton Model system. The Creighton Model is explained in the early book chapters in sufficient detail to understand how it is used as the basis for NaProTECHNOLOGY. This forms Part I of the book (15 chapters).

Part II of the book (6 chapters) describes the fundamentals of medically evaluating the fertility cycle with hormonal profiles and ovarian ultrasound, based always on the woman's or couple's observation of their own biomarkers. In Part III (13 chapters), medical approaches to diagnosis and treatment are introduced. Particularly important chapters detail the differences between natural (human identical) and artificial hormones, and the crucial concept of cooperative hormone replacement therapy. Part IV (14 chapters) is devoted to the evaluation and treatment of infertility, where particularly important advances have been made with NaProTECHNOLOGY. Part V (10 chapters) addresses the perinatal period, with particularly important insights on the prevention of miscarriage and preterm birth. Part VI (21 chapters) is devoted to techniques of surgical NaProTECHNOLOGY, complete with many intraoperative color photographs. Part VII (8 chapters) describes the integration of NaProTECHNOLOGY into medical practice from the perspectives of the obstetrician-gynecologist, the family physician, the nurse, and the Creighton Model Fertility*Care*™ Practitioner (teacher). A particularly useful reference chapter is the summary of medical protocols found throughout the remainder of the book.

The textbook is extensively referenced to the medical literature, with over 2000 references. Yet I expect that some physicians who have adopted the values of evidence-based medicine will object that there are, as yet, no randomized trials specifically in the realm of NaProTECHNOLOGY. I wish to point out that no new field in medicine begins with randomized trials. In many ways, NaProTECHNOLOGY builds on the best of medical research in the 1950s, prior to the diversion of reproductive medicine into approaches that seek to suppress, destroy, or bypass natural human reproductive function. Of course, this was also prior to the current emphasis on randomized trials. NaProTECHNOLOGY is a field at its beginning, not its apex. As such, it has a future that surely must include the randomized trials to confirm and develop and improve many different aspects in years to come.

The publication of *The Medical and Surgical Practice of NaProTECHNOLOGY*, by Thomas W. Hilgers, MD, is a landmark event. It is a crowning achievement of Dr. Hilgers' work, but it is only the opening statement for a reproductive science that must grow in years to come, if there is to be hope for a renewed respect for the divinely appointed miracle of human procreation. Dr. Hilgers has blazed a trail that must become a highway for physicians and scientists in years to come, a highway that will play a critical role in building the culture of life. I believe that the ultimate impact for medicine and society will be beyond anything we currently imagine.