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Natural Family Planning

German Computer-Thermometer (Cyclotest 2+) Compared with Sympto-Thermal Method

A German company called UEBE has developed and marketed a very precise electronic thermometer called the Cyclotest 2 plus for the purposes of family planning. The electronic thermometer has a built in algorithm that follows the rules of the temperature method of natural family planning (NFP). A group of researchers from the Academic Teaching Hospital of the University of Dusseldorf, Germany tested the efficacy of the Cyclotest by comparing the fertile time in a woman's cycle as detected by the Cyclotest with the fertile time determined by the sympto-thermal method (STM) of NFP.(1) Two hundred seven women used the device for 13 cycles which yielded 4,430 cycles of comparison. In 120 women (58%) the beginning of the fertile time (FA) was on the same day for both methods, in 57 women (27.5%) there was a difference of 1-3 days, in 3 women the FA was four days later with the Cyclotest. In only one woman did the computer/thermometer detect the beginning of the fertile time 6 days later than the STM. The authors considered this as "risky". The end of the fertile time (FE) as detected by the Cyclotest was on the same day as the STM with 127 women (61.4%), the FE was 1-2 days earlier than the STM day with 4 women, and with only 1 woman did the device show the FE 3 days earlier than the STM day. From this data the researchers predicted that the device would detect a "wrong" FE in about 1 in 200 women and have a "dangerous" reduction in the fertile time in 2 out of 207 woman cycles. The authors concluded that the Cyclotest 2 plus has a medium degree of reliability when used to avoid pregnancy and that there is a need for further studies to determine the actual efficacy of the device.

Comments

Of interest is that the researchers from the University of Dusseldorf used a method of NFP (i.e., the rules of the Sympto Thermal Method) as a standard for comparison of the fertile time of a woman's cycle as opposed to hormonal tests and /or ultrasonography of the follicle. The researchers also propose that there are levels of efficacy for devices or methods that determine the fertile and infertile times of a woman's menstrual cycle. The first level they called the Efficacy Finding Studies (EFS) in which a device or method is compared with a known accurate indicator of fertility (e.g., luteinizing hormone in the blood or urine). If a device or method shows an acceptable level of EFS then you would proceed to a retrospective efficacy study (rES) (on the effectiveness of avoiding and achieving pregnancy) with multiple users who have used the method or device in the past. The final level (what they call the "Gold Standard") is the prospective efficacy study (pES) in which a statistically significant sample size of woman are asked to test the effectiveness of a device or method. I would add another level or type of efficacy and that is determining how accurate a woman makes an observation with a device (e.g.,

thermometer) or her own bodily signs (e.g., the sensation of slipperiness).

Freundl, G., Frank-Herman, P., and Bremme, M. **Results of an efficacy-finding study (EFS)** with the computer-thermometer Cyclotest 2 plus containing 207 cycles. *Advances in Contraception* 14 (1998): 201-207.

Effectiveness of Personal Hormone Monitoring in Determining the Fertile Period

Researchers from Germany, Ireland, and the United Kingdom recently collaborated on the first European study to determine the effectiveness of a personal hormone monitoring device to help women to delay pregnancy.(1) The personal hormone device was developed by Unipath Ltd. (Bedford, England) and was a prototype of the Persona (R) fertility monitor now marketed in Europe. The data collected in this three country study helped to refine the algorithms used for the current Persona hormone fertility monitor. The hormone monitor that was used in the collaborative European study consisted of a hand held electronic device and disposable test strips that were designed to detect urinary luteinizing hormone (LH) and a urinary metabolite of estrogen, i.e., oestrone-3-gluconeride (EG) from early morning urine samples. The monitor picks up a rising threshold level of urinary estrogen as the beginning of the fertile period and the urinary LH + 3 days surge as the end of the fertile period. The monitor displays a green light to indicate the infertile days and a red light to indicate fertile days.

The researchers recruited 710 volunteer women (median age 30 years, with regular menstrual cycles) through press advertisements from the general population of England, Germany and Ireland to use the fertility monitor (without training) for the purpose of avoiding pregnancy. The volunteer subjects also recorded all acts of intercourse and their interpretation of the monitor's status on a daily basis. At completion of the study, there were 67 method related pregnancies (i.e., a pregnancy resulted from having intercourse on a "green light" day , 92 user related pregnancies (intercourse on "red light" days,) and 3 unsure pregnancies, from 7209 cycles of use. A 13 cycle life table analysis yielded a method pregnancy rate of 12.1 percent. After changing the algorithm to a more conservative formula the method related pregnancy rate dropped to 6.2 percent. The revised algorithm is what is currently used in the Persona (R). The authors calculated the method effectiveness based on the new algorithm for the Persona as 93.8 percent and concluded that personal hormone monitoring is simple to use and of value for women trying to avoid pregnancy.

Comments

Other data of interest from the study is that there was a 78% continuation rate after 13 cycles of use. Only 35 of the volunteers found the monitor to be unsuitable and usually for the reason that there were too many red light days. After three cycles of use, there was a median of

10 red light days and with the revised algorithm 11 days. Of interest is that the authors subclassified pregnancies that resulted from a change of intention (i.e., knowingly used a red day to achieve pregnancy) but kept them in the user category. The authors admit that the success of the use of the fertility monitor depends on the sexual behavior of the couple. The authors are currently conducting a randomized controlled study to determine the method and use effectiveness of the Persona. The control/comparison group are couples using the male condom.

Bonnar, J., Flynn, A. and Freundl, G. et al. **Personal hormone monitoring for contraception.** *The British Journal of Family Planning* 24 (1999): 128-134.

Fertility and Pregnancy

Does Moderate Alcohol Intake Decrease Fertility?

Researchers from the Department of Growth and Reproduction at the National University Hospital in Copenhagen Denmark conducted a nationwide study to determine the effect of alcohol consumption on the probability of conception.(1) (Alcohol is known to decrease steroid hormone concentrations, inhibit ovulation and decrease sperm transport in the fallopian tubes.) They recruited couples who had no known fertility problems and who were trying to conceive for the first time from members of a National trade union that represented office workers, nurses, metal workers, and day care workers. They obtained a total of 430 couples who reported after each menstrual cycle their daily and weekly consumption of smoking, caffeine and alcohol until they became pregnant or for six menstrual cycles. After six cycles of reporting, 65% (179) of the women with a weekly intake of 5 or fewer drinks conceived and 55% (75) of the women with a higher intake conceived. They also found a decrease in fecundity (after adjusting for a number of variables) in women with 5 or fewer drinks per week compared to women with no alcohol consumption. The authors concluded that even moderate alcohol consumption (5 or fewer drinks) is associated with a decreased fecundability but that their findings need further corroboration.

Meanwhile, researchers from the Institute of Pharmacological Research and the University of Milan, Italy examined the relationship between alcohol intake and difficulties in conceiving among 1769 women who gave birth on randomly selected days at the largest obstetric hospital in Milan.(2) All of the subjects had a previous history of having difficulty in conceiving. After interviewing these women, they found that 135 women had difficulty in conceiving while 1634 had no difficulty in conceiving. When comparing the two groups they found no relation between alcohol drinking and difficulty of conceiving.

Comments

Of the two above studies, the Denmark one is the strongest. The Milan study was retrospective (recall information) and the subjects were chosen from women from one setting who had difficulty in conceiving and then successfully gave birth. The findings of the study, however, agree with the results of previous studies on the relation of alcohol and conception. Like the Milan study those studies were retrospective, and had small and biased samples.

The Denmark study was prospective, subjects were selected from a National population pool and data was collected on a cycle to cycle basis. There was some bias in the sample in that they all were trying to conceive and some might have some difficulty in conceiving or suspected infertility, i.e., only 65% became pregnant in a 6 month period. The study could have been enhanced if the subjects were charting their cycles on a daily basis, were knowledgeable about the optimal time of fertility and recorded the frequency and timing of intercourse.

- Jensen, T. K., Hjollund, N. H. and Henriksen, T. B. et al. Does moderate alcohol consumption affect fertility? Follow up study among couples planning first pregnancy. *British Medical Journal* 317 (August, 1998): 505-510.
- 2. Parazzini, F., Chatenoud, L. and Di Cintio, E. et al. Alcohol consumption is not related to fertility in Italian women. *British Journal of Medicine* 318 (February, 1999): 397.

Researchers Discourage Use of Salivary Ferning Test For Predicting Fertility

Small hand held miniature microscopes continue to be manufactured and marketed as fertility monitors in the United States, Canada and Europe. Researchers from the Department of Obstetrics and Gynecology from the University Hospital in the Netherlands recently studied the accuracy of salivary ferning as detected through the use of a miniature microscope and a regular light microscope.(1) The subjects for this study were 36 women with regular menstrual cycles. The day of ovulation was determined through the use of serial ultrasound of the ovaries, serum luteinizing hormone or the shift in basal body temperature. The researchers also compared salivary samples of estradiol levels with serum estradiol levels and asked 10 post menopausal women and 10 men to perform salivary ferning tests.

They found that there was a strong correlation between salivary estradiol and serum estradiol levels but did not find a significant correlation between salivary estradiol levels and ferning patterns. They also found a positive ferning pattern in 8 of the 10 menopausal women and all of the men. They concluded that the use of salivary ferning is an unreliable test for predicting fertility and discouraged the use of miniature microscopes as fertility monitors.

Comment

The 1999 Spring/Summer issue of *Current Medical Research* had a short review article on miniature microscope fertility monitors. The article also concluded that these microscope fertility monitors should not be used as predictors of fertility. In a study, published by this author, on the accuracy of the "Lady Free Biotester", there was no discernable beginning or end of the fertile period using salivary ferning as a marker.(2) This author, like the men in the above Netherlands study, was also able to detect beautiful ferning patterns with his own saliva.

- 1. Braat, D. D., Smeen, J. and Manger, A. P., et al. Saliva test as ovulation predictor. *Lancet* 352 (October 17, 1998): 1283-84.
- Fehring, R. and Gaska, N. Evaluation of the Lady Free Bio-tester in Determining the Fertile Period. *Contraception* 57(1998): 325-28.

Planned/Unplanned Pregnancy: The Male Factor

Researchers at the University of Utah conducted a qualitative study in order to determine how women define the intention status of their pregnancy (i.e., whether the pregnancy was intended, planned, and wanted or not).(1) In depth interviews were conducted with 18 pregnant women volunteers obtained from a variety of clinical sites in Salt Lake City, Utah. Three themes emerged from the interviews: 1) the definition of the terms (wanted, intended, and planned) varied among the women and circumstances, 2) the terms wanted and unwanted were distinct from the terms planned and unplanned, and 3) the attitudes of the male partner were influential in how the women defined their pregnancies. The authors concluded that when determining pregnancy status a woman's relationship with her partner, her partner's attitude about the pregnancy and the level of family support should be assessed. Further research with a great variety of women volunteers (e.g., women placing their child for adoption) and determining how pregnancy attitudes change across time was recommended.

Comment

The Utah researchers indicated in their article that they believed that an emphasis should be placed on men's involvement and responsibility in reproductive behavior. NFP and chastity teachers are in an ideal situation to foster this responsibility and involvement before conception takes place.

Fischer, R. C., Stanford, J. B. and Jameson, P., et al., **Exploring the concepts of intended**, **planned**, **and wanted pregnancy**. *The Journal of Family Practice* 48 (February, 1999): 117-122.

Timing of Implantation and Pregnancy Loss

Very little research evidence exists on the actual timing of implantation of the human embryo into the endometrium of the uterus. Researchers from the National Institute of Environmental Health Sciences recently conducted a study to determine the timing of implantation and the outcome of pregnancy in healthy woman with no known infertility problems.(1) The NIH scientists obtained 221 voluntary couples who were planning to have children. The 221 woman subjects were asked to collect daily specimens of urine through eight weeks of clinical pregnancy or up to six months if pregnancy does not occur. The estimated day of ovulation was determined by a algorithmic ratio of urinary metabolites of estradiol and progesterone. Pregnancy and the estimated day of implantation was determined by urinary chorionic gonadotropin levels. The researchers detected 199 conceptions of which 189 (95%) they had sufficient data for analysis and of which 126 resulted in a live birth. Of the 189 conceptions, 48 pregnancies or 25% ended in early loss. Of the pregnancies that lasted 6 weeks or more, implantation occurred from 6 to 12 days after ovulation. The researchers also found that the risk of pregnancy loss increases with later implantation. Among the 102 human embryos that implanted by the ninth day, 13% ended in early loss; 26% on the tenth day; 52% on day 11, and 82% after day 11. The authors concluded that in the most successful pregnancies, implantation occurs between 8 - 10 days after ovulation and that the risk of pregnancy loss increases with later implantation.

Comments

The authors did point out that although the biological markers for ovulation, pregnancy and implantation were valid and precise, there is still some possible error in measurement and therefore, the window of implantation might be even narrower. Of interest is that they found no pregnancies that implanted later than 12 days after ovulation. This indicates that there is a short window of opportunity for implantation of the blastocyst. The authors speculated that the narrow window of receptivity of the endometrium to implantation might act as a gating mechanism to screen out impaired embryos. They also suggested that interventions aimed at extending the time of implantation proceed with precaution.

1. Wilcox, A. J., Baird, D. D. and Weinberg, C. R. **Time of implantation of the conceptus and loss of pregnancy.** *New England Journal of Medicine* 340 (June 10, 1999): 1796-9.

Contraception

Mortality Associated with Contraceptive Use

Members of The Royal College of General Practitioner's have conducted a prospective longitudinal study to determine the risk of death among long term users of oral contraception.(1) In 1968-69, 46,000 British women were recruited into the study, half of which were using oral contraception. At the end of the 25 year study the median age of the volunteers was 49 years and 1,599 deaths were recorded. The researchers found that there was no difference in the relative risk of mortality among those women who were ever users of oral contraception and those that were never users. However, the relative risk of death from ovarian cancer, cervical cancer, and from cerebrovascular disease was increased among current and recent (within 10 years) users of oral contraception. There was no increased risk of death among women who stopped using oral contraception for 10 or more years. The authors concluded that oral contraceptives seem to have their major effect during current use and within ten years after cessation.

Comments

The results found in this study might not apply to women today. The women they recruited in 1968-69 were taking different oral contraceptives than women did in the 1980s and 1990s. (2) Only 1% of the women in the above study took oral contraceptives before the age of 20 and 54% after the age of 30, whereas as many as 42% of women in the 80s and 90s have taken the pill before the age of 20 and only 2% after the age of 30. This is of concern because many of these women are taking oral contraceptives before having their first child. This is important because developing breast cells are most vulnerable to carcinogen before a woman has a baby.

The authors do not develop the data they reported that showed the relative risk of liver cancer was (5.0), cerebral vascular disease (1.5) and accidents and violence (1.6) among ever users. They do not report current users. Even after 19 years there was still an increased risk of mortality for cerebrovascular disease and after 20 years the relative risk of liver disease is 1.8. (3,4) The authors seem to be giving the Pill a clean bill of health but that does not seem to be quite the case.

 Beral, V., Hermon, C. and Kay, C., et al. Mortality associated with oral contraceptive use: 25 year follow up of cohort of 46 000 women from Royal College of General Practitioners' oral contraceptive study. *British Medical Journal* 318 (January 9, 1999): 96-100.

Menstrual Cycle/Menopause

Calcium Reduces Symptoms of PMS By 48%

Many remedies have been suggested and tested to treat the numerous symptoms of premenstrual syndrome (PMS). Research has determined that most therapies, including progesterone and Vitamin B6, are not effective. Scientific literature has indicated that a disturbance in calcium regulation might be the pathological cause of PMS and that calcium replacement might be an effective treatment. Researchers from Colombia University recently conducted a multi center prospective double blind study to test the effectiveness of calcium carbonate to reduce PMS symptoms during the luteal and menstrual phases of the menstrual cycle.(1) Four hundred and sixty-six healthy pre-menopausal women were recruited from 12 outpatient clinics throughout the United States and validated to have PMS. These 466 women participants were randomly assigned to either receive 1200 mg of calcium per day or a placebo for 3 menstrual cycles. PMS symptoms, adverse effects and compliance with medication were monitored daily. By the third treatment cycle, there was a 48% decrease in PMS symptoms among the calcium treated group compared with 30% among the placebo group. The researchers concluded that calcium supplementation is a simple and effective treatment in PMS.

Comment

The 1200 mg of elemental calcium in this study reduced all four categories of PMSrelated symptoms, including mood swings, bloating, food cravings, and pain. Two *Tums E-X tablets* have the equivalent of 600 mg of elemental calcium.(2) So taking two Tums twice a day should be an effective and inexpensive treatment for many women who suffer from PMS. There is a "Calcium Calculator" web site at www.calcium.com for women who are interested in evaluating their dietary intake of calcium.

- 1. Thys-Jacobs, S., Starkey, P. and Bernstein, D., et al. Calcium carbonate and the premenstrual syndrome: Effects on premenstrual and menstrual symptoms. *American Journal of Obstetrics and Gynecology* 179 (August, 1998): 444-52.
- Jellin, J.M. (Ed.). Women's Health. Calcium supplements seem to work well for PMS. Prescriber's Letter 5 (September, 1998): 53.

Does Progesterone Cream Provide Adequate Protection Levels in Postmenopausal Women?

Postmenopausal women who use long term estrogen replacement therapy (ERT) for the purpose of reducing the risk of cardiovascular disease and bone loss (osteoporosis) have a concern that the ERT increases their risk for endometrial cancer. This increased risk is thought to be due to the unopposed proliferative endometrium that is constantly being stimulated by ERT. To decrease the risk imposed by a chronic proliferative endometrium, women take some form of progesterone. The progesterone is administered either inter-muscularly (IM), vaginally (suppository), orally with the now available micronized natural progestin, nasally (available in Europe - as a progestin spray) and percutaneously with a cream. There is concern with all the routes of administration that adequate serum levels of progesterone are absorbed for the protective effect (a secretory type endometrium) to take place. Only scant research exists on the absorption rate and levels obtained with use of progesterone creams.

Three researchers (Drs. Burry, Patton and Hermsmeyer) from the Departments of Obstetrics and Gynecology and Medicine from Oregon Health Sciences University evaluated the serum progesterone levels among 6 healthy postmenopausal women volunteers who applied progesterone cream to the skin on a daily basis for 4 weeks. The 6 women received ERT by use of a transdermal estradiol patch that was applied two days before the use of the progesterone cream and continued to be used throughout the experiment. Progesterone cream (Pro-Gest) at a concentration of 30 mg/g was self-applied (either on the chest, arms or legs) once a day for 2 weeks and twice a day for 2 weeks. Serum estradiol and progesterone levels were measured 9 times per day on day 1 and at weekly intervals for the 4 week duration of the study. Results showed that there was a significant increase in serum progesterone levels in all 6 women subjects. The serum levels of progesterone also closely resembled the variations and absorption levels of estradiol. The authors concluded that the percutaneous (skin) application of progesterone cream appears to be a safe and effective route of administration.

Comments

In order to obtain the proper (effective) serum levels with use of a progesterone cream, the cream needs to have an adequate amount of progesterone in it (at least 30 mg/g). Many over the counter creams have little (e.g., 5 mg /ounce) or none at all. The creams that are made from Mexican yams are not metabolized to progesterone by women. The cream used in the above study (Pro-Gest) contains pure United States Pharmacopeia progesterone. It is regulated by the Food and Drug Administration and the dose of 450 mg/oz is tightly controlled. The authors plan further study to determine through endometrial biopsy if the serum absorption levels of the progesterone creams block proliferation of the endometrium.

 Burry, K. A., Patton, P. E. and Hermsmeyer, K. Percutaneous absorption of progesterone in postmenopausal women treated with transdermal estrogen. *American Journal of Obstetrics and Gynecology* 180 (1999): 1504-11.

Under the Microscope

Review and Analysis of the Peak Day

The "Peak Day" is an important indicator of fertility for modern methods of natural family planning (NFP). The Peak Day is not only important for the Ovulation Method (OM) (also referred to as the Billings Method) or variants of the Ovulation Method such as the Creighton Model System but also for the Sympto-Thermal Methods (STM) that combine the shift of basal body temperature (BBT) with the observation of the peak in cervical mucus. The "Peak Day" is thought to coincide closely with the peak of fertility and the day of ovulation. For couples trying to achieve pregnancy, having intercourse on that day is probably the optimal time for conception. The Peak Day is also a marker for the beginning of the end of fertility. Once a woman ovulates, the egg she releases only lives about 12 to 24 hours. When a woman detects her Peak Day, she knows that after three or more days there is little or no chance of being fertile until her next menstruation.

There is, however, a lot of variation as to what the "Peak Day" is among the various systems of NFP. For some methods, the "Peak Day" is primarily a heightened sensation of slipperiness at the vulva; for others it involves observable characteristics of cervical mucus and for others a combination of the above. For some systems of NFP the definition is very precise and for others the definition changes according to different circumstances. There is also a lot of variation among the methods of NFP regarding how a woman should observe her cervical mucus and/or vulvar sensations in order to determine what is the Peak Day. Some methods emphasize sensation only; that is, whether the woman feels wet or dry. Some methods request that the woman wipe the vulvar area with toilet tissue, lift the mucus off and observe between the fingers. "Sensation" for most methods is determined only at the vulvar area. However, some observe this during wiping with toilet tissue, while others encourage obtaining cervical mucus internally at the os of the cervix. Still other NFP systems suggest that women sense the mucus (determine the sensation) between the fingers. The frequency of checking and the time of day for checking also vary among NFP methods.

For the Peak Day to be a good marker of fertility it needs to be accurate in indicating the time of peak fertility, i.e., how close it is to the day of ovulation. Correlating how close the Peak Day is to some other standardized/objective marker of fertility, such as the serum or urinary surge in luteinizing hormone (LH) or to the day of the ripened or collapsed follicle as observed through serial ultrasound are common ways researchers determine accuracy of a given marker of

fertility. What characteristics of the Peak Day are the true indicators of fertility and how accurate and consistent are woman in being able to detect the characteristics of Peak Day are also important for the accuracy of the Peak Day to detect fertility. As a marker of fertility then, the Peak Day relies on a number of different types of accuracy. One type would be the accuracy and consistency of a given woman in observing the signs of peak fertility and then determining what is the Peak Day, i.e., observational accuracy. Another type of accuracy would be how accurate are the characteristics of the Peak Day in actually detecting the peak of fertility (i.e., the actual day of ovulation) or how close do these characteristics coincide with other valid and reliable indicators of fertility. A final type of accuracy would be how effective are these indicators of the Peak Day in helping woman/couples to either avoid or achieve pregnancy. This column will review some of the various definitions and characteristics as an accurate marker of peak fertility and offer comments.

Characteristics, Definitions and Methods to Determine the Peak Day

The following definitions and means of observing the Peak Day are taken from current books on methods of NFP.

Billings, L and Billings, J. J. (1)	when the vulva is slippery, swollen and has a heightened sensitivity(p.2)
Billings, E. L. (2)	The last day of the slippery sensation is the most fertile day in the cycle and is termed the Peak because it is the peak day of fertility and is associated with a heightened sensitivity and swelling of the vulva.(p. 8)
Billings, E. L., Billings, J. J. and Catarinich, M. (3)	The last day on which the mucus is slippery and wet is referred to as the day of "the Peak of the mucus symptom" and marks the peak of fertility.(p. 4) It is the lubricative quality that is the most accurate index at the peak of fertility and at the time of ovulation, so it is therefore the last day of lubricative mucus which is the day of the Peak symptom.(p. 4)
Clubb, E. and Knight, J. (4)	Peak day denotes the LAST day on which this highly fertile-type slippery, transparent, stretchy mucus is either seen or felt.(p.43)
Hilgers, T.W. (5)	The last day of any mucus discharge that is clear, stretchy or lubricative.(p. 32.)

Table 1: Definitions of the Peak Day

Huneger, R. J., Fuller, R (6)	Peak Day is usually the last day of any trait of egg white mucus (EW-M) or lubrication (L). But if no EW-M or L can be observed, Peak Day is the last day of any sticky mucus (M) or if moistness is felt.(p. 34) Peak Day is the last day of any trait of the most fertile sign, usually EW-M or L (the last day that any transparent (T) or part opaque part transparent (OT), the tissue glides (G), the mucus stretches an inch or more (1") or L was present). If no EW-M or L could be observed, Peak Day is the last day of any mucus or moistness.(p. 53)
Kass Annese, B., and Danzer, H.C. (7)	The last day of the wet vaginal feelings and slippery, stretchy, wet mucus is the peak day.(p. 79)
Kippley, J. (8)	Peak day is the last day of the more-fertile mucus before the drying-up process starts, even if the more-fertile mucus was present only for part of that day.(p. 71) These types of mucus are the "more-fertile" types: produces feelings of lubrication or wetness; stretches more than one-half inch; like raw egg white; clear or cloudy.(p. 71) Peak Day is simply the last day on which you notice any of the more-fertile types of mucus before the mucus starts to dry up.(p. 71)
Nofziger, M. (9)	The term "peak" refers to the last day of Spinnbarkeit or wet mucus.(p. 24)
Weschler, T. (10)	Generally speaking, this is considered the last day that you produce fertile cervical fluid or have a lubricative vaginal sensation for any given cycle.(p. 83) Your Peak Day is the last day of either: -egg white-quality cervical fluid (which is slippery and usually stretchy) -lubricative vaginal sensation (which is wet and slippery, but may not be accompanied by any cervical fluid), or -any midcycle spotting.(p. 83)
Winstein, M. (11)	The last day of any mucus is sometimes called the "Peak day."(p. 33)

Wilson, M. (12)	The last day of clear, elastic mucus is referred to as the Peak day, so called because that day is thought to be the day of peak fertility, as well as the time most closely related to peak levels of the ovarian hormones.(p. 33)
Wilson, M. (13)	The last day on which the woman feels wet and slippery, is the "PEAK DAY."(p. 13)
WHO (14)	The last day of wetness or lubrication is called the Peak Day, and occurs when the estrogen is at its highest.(p 16.)

As can be seen in Table 1 there are a variety of definitions, symptoms and characteristics of the Peak Day among the various methodologies of NFP. Peak Day symptoms include sensations (slippery, lubricative, sticky, tacky), water content (wetness, moistness), elasticity (stretchy, elastic), lack of color (transparent, clear), cloudiness, gliding of the tissue, swelling and heightened sensation of the vulva and spotting. The most common symptoms listed are wetness or wet, slippery sensation, stretch of the mucus and transparency. For one system of NFP there are "split" peaks and "double" peaks. The only universal component of the definition of Peak Day is that the above symptoms are on the "last day."

Billings, L and Billings, J. J. (1)	Sensations at the vulva. Woman are asked "How does the vulva feel?" during normal activities, for example walking, etc. No internal examinations are made. Woman describes her own patterns.(p.2)
Billings, E.L. (2)	Mucus is observed at the vulva:1) by the changing sensations of the vulva over the whole day.2) by direct inspection of visible mucus from time to time. (p.1)
Billings, E.L., Billings, J. J. and Catarinich, M. (3)	 The observations are twofold: 1) How the vulva feels; 2) What the woman sees. It is a mistake to overemphasize the visual appearance of the mucus. Women are not instructed to feel the mucus between her fingers. No internal exams. Be attentive to sensations at the vulva throughout the day. Wet slippery fish analogy.(p. 9)

Clubb, E. and Knight, J. (4)	 Recognition of cervical mucus by sensation, appearance and by testing with the finger. 1) Sensation at the vulva throughout the day, 2.) Appearance (and color) of the mucus after blotting or wiping the vulva with soft white toilet tissue, 3) Observing mucus (and stretch of mucus) lifted from tissue between finger and thumb.(p.41)
Hilgers, T.W. (5)	Sensation at the vulva while wiping with toilet tissue, observation of the mucus (if any) lifted off of the tissue, and finger testing the mucus at eye level. Observations are made before and after every time woman voids and before going to bed.(p. 15-17)
Huneger, R.J., Fuller, R (6)	Tissue-Paper Exam -each time going to bathroom to urinate: wipe from front to back; look at the tissue; test between thumb and finger to see color and stretch. (p. 19) Vaginal sensations are observed during the day.(p.23)
Kass Annese, B., and Danzer, H.C. (7)	Recognize vaginal sensations and observe cervical mucus when you wake up in the morning. Observe mucus by wiping with toilet tissue and finger testing it off of the tissue -observe quality, color, amount and feel. (p.45)
Kippley, J. (8)	You can observe your cervical mucus in two places : 1) externally at the outer lips of the vagina or 2) internally at the cervical os. Can make external observations before and after urination and bowel movements by 1) wiping with toilet tissue and 2) by being aware of sensations at the vulva. Tissue paper exam includes sensations while wiping and finger test(p. 33-35)
Nofziger, M. (9)	When you use the bathroom, gather mucus from the vaginal opening with clean finger and then observe the characteristics of the mucus.(p. 24)
Weschler, T. (10)	Check vaginal sensations throughout the day. Check cervical fluid each time using the bathroom and do Kegel's exercises. Check cervical fluid at least three time a day. Check cervical fluid either with tissue or with fingers. Note cervical fluid on underwear. You can check internally by using index and middle finger. (p. 78-81)

Winstein, M. (11)	Check vaginal sensations throughout the day. Check cervical fluid each time using the bathroom and do Kegel's exercises. Check cervical fluid at least three time a day. Check cervical fluid either with tissue or with fingers. Note cervical fluid on underwear. You can check internally by using index and middle finger. (p. 78-81)
Wilson, M. (12)	Throughout the day the mucus secretion (or its absence) can be observed by wiping the vulva after urination -no internal exam -the consistency, color, and sensation or wetness or lubrication are the items to be observed.(p 24)
Wilson, M. (13)	It is not necessary to check the mucus with the fingers or to do any kind of internal examination. Its presence and changing pattern can be observed when the vaginal opening is wiped with tissue after urination.(p. 12)
WHO (14)	Women must learn to recognize the characteristic changes in the cervical mucus discharge that occur during the cycle, -most women experience a sensation of dryness -then they notice the appearance of mucus -vagina feels increasingly wet. (p 16)

Table 2 shows that the various systems of NFP use a variety of ways to observe the symptoms of the Peak Day. For example, some focus on the mental awareness of the vaginal/vulvar sensations, other by actually observing the cervical mucus by finger testing it and some by doing internal exams to check for mucus at the os of the cervix. One system recommends checking the underwear for mucus symptoms. The frequency of making observations and the times to do so also vary from method to method. Some systems of NFP recommend only checking once (as the first activity in the morning), other systems recommend that the symptoms be observed before and after voiding and then making a special check at the end of the day after bearing down. Most of the above systems of NFP instruct women to subjectively observe both the sensations and the physical characteristics of the cervical mucus.

Published Research On the Peak Day

The first published research study in a referenced scientific journal on the accuracy of self-assessment of cervical mucus characteristics in association with the estimated day of ovulation was published in 1972 by Billings, Brown, Billings and Burger. (15) In this study 22 woman volunteers were taught how to "recognize a pattern of vaginal mucous discharge" and to record their observations in a daily record. The "peak symptom" was defined as "the occurrence of clear, slippery, lubricative mucus, having the physical characteristics of raw white of egg" (*Spinnbarkeit*)....It characteristically lasts for 1-2 Days , and the last day of its occurrence is

referred to as the day of the peak symptom in the results presented. The day of ovulation was estimated through serial measurement of plasma LH, i.e., the day after the LH surge. They found that ovulation occurred a mean of 0.9 days after the peak symptom, with a range of 3 days after to 2 days before.

Since the Billings, et al study, there have been a number of similar studies that have verified the Peak symptom of cervical mucus in relation to the estimated day of ovulation. (16, 17, 18, 19) Flynn and Lynch published a study in 1976, in which they correlated cervical mucus ratings with plasma LH, estradiol and progesterone with 9 healthy woman subjects who generated 29 menstrual cycles. (16) The peak day was defined as the day of maximum mucus grading (MMG). The MMG was based on a cervical mucus grading system developed by Dr. James Brown. Scores of the rating system ranged from -1 (Dry sensation) to 9 (wet, slippery, variable amount). The MMG occurred a mean of 0.45 days before the estimated day of ovulation by plasma LH, with a range of 2 days before and one day after.

Hilgers, Guy, Abraham and Cavanaugh studied the relationship of the peak symptom with the estimated day of ovulation with 24 healthy woman subjects.(17) The estimated day of ovulation was determined by predetermined peri-ovulatory serum progesterone levels. The peak symptom was defined as "the last day of the clear, stretchy, and or lubricative discharge." Hilgers et al., also used a scoring system that numerically ranked the consistency, color and change in vaginal discharge. The study yielded 65 cycles out of 75 cycles with a hormonal confirmation of ovulation. They found that ovulation occurred from 3 days before to 3 days after the peak symptom with a mean of 0.31 days before the peak symptom.

Cortesi, Rigoni, Zen and Sposetti conducted a similar study to determine the correlation of ovarian steroid hormones with the peak in cervical mucus in 27 healthy young Italian women.(18) They defined the Peak Day as "the last day on which the mucus was observed to be slippery, stringy and/or lubricative" and the estimated day of ovulation was determined as the day after the plasma LH surge. In 31 of 32 ovulatory cycles they found that ovulation occurred from one day before to one day after the peak symptom with a mean of 0.0 days.

This author conducted a study in which a self-detected urinary LH surge was correlated with the Peak Day with 20 young healthy women who were taught the Creighton Model system of NFP. Twenty-eight of the 38 cycles yielded a detected LH surge and Peak Day. The Peak Day was defined according to the Creighton Model system as "the last day of mucus that was clear, stretchy and/or lubricative." In the 28 cycles, the LH surges occurred either on the Peak Day or within 3 days before the Peak Day.

Conclusion

The above review of the published research on the accuracy of the Peak Day as determined by self-observation of characteristics of cervical mucus is not comprehensive, nevertheless, the three most common characteristics of Peak Day studied in the above articles are the last day of clear, stretchy, and/or slippery/lubricative mucus. In all of the studies, the selfdetection of Peak Day was an accurate subjective indirect indicator of peak fertility and ovulation. There is no indication in the research on how to self-observe these characteristics or how often they need to be observed in order to maintain the accuracy of detecting the Peak Day. One study had the subjects observe for mucus before and after each micturition, another in the course of normal daily activity and another indicated the use of white toilet tissue. Future research could help determine the best ways or way to make observations and how often observations need to be made. Other research might discover ways of making the observation of the Peak Day more objective. For example, there might be a simple accurate and reliable device to measure some physical property of cervical mucus.(20) Further research might also determine if there are more accurate characteristics of Peak Day then others, e.g., slipperiness vs stretch. In the final analysis, research might also show that there are multiple ways of determining the Peak Day and that the subjectivity of the woman's observations need only the patience and guidance of a good NFP teacher.

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