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FERTILITY

Determination of the fertile window: Reproductive competence of women – European cycle databases

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Abstract

Objectives. The objective of the present paper is to review the main results of recent European cycle databases on ovulation detection and determination of the fertile window performed by the women themselves.

Methods. The ongoing German Long-term Cycle Database currently comprises 32 788 prospectively collected cycle charts of 1551 women, the I European Cycle Database (10 countries) 1328 women/19 048 cycles, the II European Cycle Database (six countries) 782 women/6724 cycles, and the World Health Organization Database (one European country) 234 women/2808 cycles. The women record cycle parameters (cervical mucus changes, temperature rise, etc.), family planning intention and sexual behavior.

Results. With the symptothermal method of natural family planning it has become possible to determine the fertile window in order to avoid pregnancy with a method effectiveness of 0.3%. According to a small sub-study, the ovulation time observed by the women themselves correlates closely with ovulation detected by ultrasound and measurement of luteinizing hormone (correlation within 1 day in 89% of the 62 cycles). Fertility awareness methods can be integrated into the management of sub-fertility. They seem to shorten the time to pregnancy.

Conclusions. Self-observation of the fertile window puts women into a position to develop a high level of reproductive competence that could be used much more in different areas than is currently the case.

Keywords: *Natural family planning, fertile window, efficacy, infertility, symptothermal method, ovulation detection*

Introduction

Usual clinical methods of exact ovulation detection (daily sonography and hormone measurements) are expensive and time-consuming and may cause physical and psychological stress for women. For this reason, attempts have been made for some time to obtain the same result reliably but less expensively using symptoms the women are able to observe themselves (cervical mucus, basal body temperature, etc.). Recent work has shown that cycle monitoring, sometimes with support from hormonal home-use methods, enables women to determine the time of ovulation and the fertile window. That work was based on the evaluation of large cycle databases, two of which we set up ourselves over the last 20 years, i.e., the German Long-term Cycle Database (> 30 000 cycles) and the I European Cycle Database [1–9].

The advantages of cycle monitoring performed by the women themselves are obvious. It puts them in a position to develop a high level of reproductive competence starting in puberty and reaching into the menopause. It may comprise the following aspects:

(1) Simple and early hints at cycle pathologies (anovulation, dysmucorrhea, irregular bleedings, metrorrhagia, corpus luteum insufficiency) [7];
(2) Prevention of unintended pregnancy [3,10,11];
(3) Higher probability of conception, especially in cases of sub-fertility [8,12];
(4) Increased reproductive competence and improved compliance with necessary medical treatment [10];
(5) Possible time- and cost-effectiveness by basing diagnosis and therapy on cycle monitoring;
(6) Possibility of cycle research with a large number of subjects [1,3,13]; and
(7) An excellent opportunity for physicians to give competent advice to women who are trying to achieve or avoid pregnancy [10].

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The purpose of the present paper is to review new European data gathered mainly in the last two decades regarding the detection of ovulation and the fertile window.

Material and methods

Databases for cycle monitoring

The most comprehensive databases on the fertile window in terms of number of cycles and variables have been developed mainly in Europe (Table I).

The German Long-term Cycle Database. Twenty years ago, we set up a cycle database on the symptothermal method (STM) with prospectively collected cycle charts. We have continuously maintained it until the present day [1]. Cycle records as part of natural family planning (NFP) mainly originate from healthy women, as they have been recruited from the general population. This means they are ideally suited for the investigation of epidemiological questions about fertility and the cycle. The participants record different cycle parameters, among others their cyclical cervical mucus secretion and basal body temperature changes. In addition, they specify their family planning intention for the next cycle as well as their sexual behavior (Figure 1).

In this way, a large number of long-term records have accumulated in which the woman is registered initially for avoidance of pregnancy; subsequently, the exact shift from avoiding to trying for pregnancy, conception, breast-feeding and returning to avoiding pregnancy can be observed. The database currently comprises 32 788 cycles of 1551 women. The loss-to-follow-up rate is 7% (Table I).

With the support of the World Health Organization (WHO) and the German Health Ministry, various types of data analysis have been performed and the new data management system has been published [1–3,6–8,20].

I European Cycle Database. Together with ten participating countries, we set up a prospective European database (1328 women, 19 048 cycles) based on the structure of the German database [5,9,21].

II European Cycle Database (FERTILI). For the special purpose of analyzing the daily probability of conception in natural cycles, the FERTILI database was set up to prospectively collect STM charts in six European countries (782 women, 6724 cycles) [13,18,19].

World Health Organization Database. In Europe, there are comparatively few data on the Billings ovulation method (OM). The WHO carried out a multicenter study on OM in five countries, one of them in Europe [14,15].

Italian OM. A database to collect Italian OM charts prospectively was started in 1996. No results have emerged so far.

Methods of cycle monitoring

Cycle monitoring is based on women observing cyclical changes of their body symptoms and recording them (charting). The most common modern

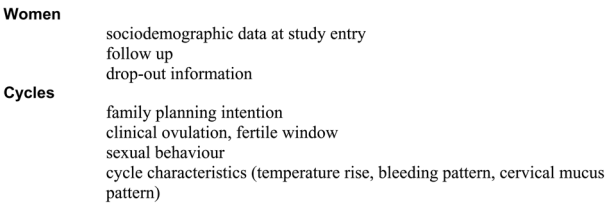

Figure 1. Design of the German Cycle Database prospective.

Table I. The use of prospective European databases in published research: A review of the last two decades.

	Database (chronological order)	No. of cycles	No. of women	No. of pregnancies	NFP method	Participating countries	Reference
WHO	WHO Database (1974–1979)	2808	234	38	OM	Five countries, one European: Ireland	[14–16]
Germany	German Long-term Cycle Database (1984 to date)	32 788	1551	439	STM	Germany	[1–4,6,7]
Europe	I European Cycle Database (1989–1995)	19 048	1328	222	STM	Austria, Belgium, France, Germany, Great Britain, Italy, Ireland, Spain, Switzerland, Czech Republic	[5,9,17]
Europe	II European Cycle Database (FERTILI) (1992–1996)	6742	782	487	STM	Belgium, France, Germany, Great Britain, Italy, Switzerland	[13,18,19]

NFP, natural family planning; WHO, World Health Organization; OM, Billings ovulation method; STM, symptothermal method.

Table II. Daily estimates of conception probabilities in cycles with one oder more acts of intercourse in the fertile window, 0 = peak day of the cervical mucus.

Intercourse day vs reference day	Mucus reference day		
	Probability of conception	Lower-Upper 90% Confidence Interval	
		L	U
8	0.003	0.000	−0.011
−7	0.000	0.000	– 0.004
−6	0.045	0.026	– 0.071
−5	0.078	0.046	– 0.118
−4	0.181	0.131	– 0.238
−3	0.114	0.068	– 0.173
−2	0.203	0.145	– 0.270
−1	0.177	0.126	– 0.237
0	0.135	0.089	– 0.192
1	0.067	0.035	– 0.109
2	0.020	0.005	– 0.049
3	0.005	0.000	– 0.015
No. Of cycles	3265		
No. of pregnancies	435		
k	0.301		

method of cycle monitoring in Europe is the STM. In some southern European countries, the OM is also used to a certain extent [10].

Symptothermal method. At least two parameters are monitored in the STM:

(1) Secretion of cervical mucus (observation externally at the vulva); and
(2) Basal body temperature.

Both the beginning and the end of the fertile phase are identified using the double-check principle (Figures 2 and 3). For the first year of application special rules are used to determine the onset of the fertile phase.

The STM version presented above has been developed by scientific consensus among the German NFP working group, based on the findings of the WHO, Döring, Rötzer, Flynn and others [10,22–24]. It has now been translated into 11 languages [25]. Groups in Austria, Belgium, Great Britain, Italy, Spain, Switzerland and Tschechia are using this STM or a very similar one.

Billings ovulation method. The OM is a single-check method based on self-monitoring of the cervical mucus symptom. The entire bleeding phase is considered potentially fertile for two reasons:

(1) The peak mucus symptom as an estrogen marker is no proof of ovulation and any bleeding could therefore also be caused by ovulatory bleeding; and

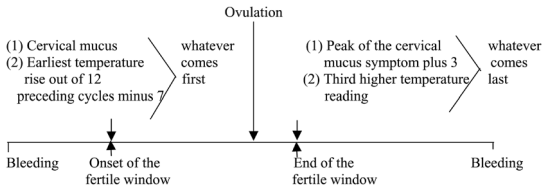

Figure 2. Determination of the fertile phase according to the symptothermal method.

(2) The end of menses could mask the beginning of the mucus symptom.

Subsequently, up to the onset of the mucus symptom, intercourse should take place only every other night as the seminal fluid could mask the mucus symptom. The fertile phase ends on the morning of the fourth day after the peak of the cervical mucus symptom [26].

Symptothermal method versus Billings ovulation method. The OM has the advantage of relying exclusively on physical observation without any device. Therefore, it is suitable for use in developing countries, especially in simplified form [10,27].

The STM approach is clearer and more physiological in so far as the cycle starts with an infertile phase followed by a fertile phase and then returns to an infertile phase up to the end of the cycle. In the case of the OM, the cycle starts off with a potentially fertile phase, followed by a phase in which only every other evening is considered to be infertile, followed by the proper fertile phase, which may repeat several times in prolonged cycles due to changing estrogen levels during a disturbed follicular phase. The advantage of the slightly shorter periovulatory fertile phase in the OM is largely cancelled out by the limitation of intercourse to 'every other night' in the preovulatory phase and the non-menstrual days.

For reasons of effectiveness, the STM combines mucus observation with temperature measurements. However, today it is no longer necessary to take temperature measurements throughout the whole cycle owing to flexible and clear method rules.

Results

Determination of the fertile window to avoid pregnancy

The rate of unintended pregnancy is still the main indicator of the efficacy of a family planning method. This efficacy can be determined using three different methods:

(1) The Pearl index (PI), which is the simplest and very common method;
(2) The life-table or Kaplan–Meier curve (actuarial curve); and
(3) The perfect/imperfect use approach.

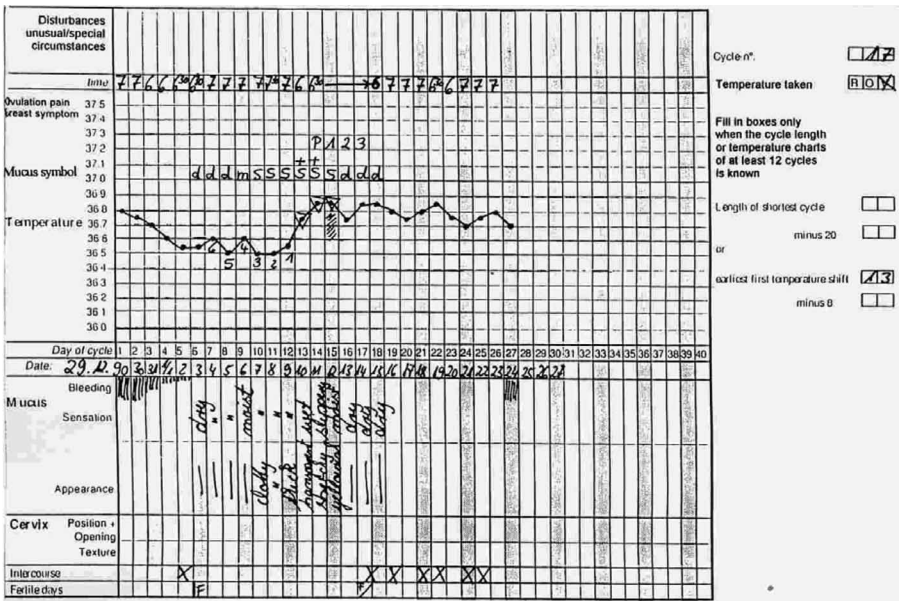

Figure 3. Correlation of cycle parameters to objective ovulation ($n = 62$).

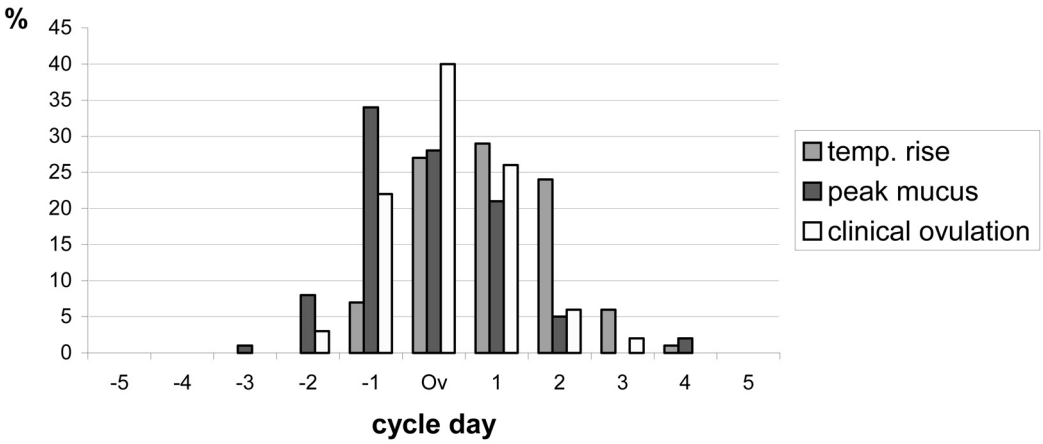

Figure 4. Charting with the ovulation method. OV = ovulation (ultrasound + LH measurement). Synopsis: clinical ovulation determined according to temperature rise and peak mucus.

Pearl index and life-table approaches. Why is a PI (or a 12-month life-table value) of 2–3 not a particularly good rating for a family planning method?

A PI of 2–3 means that two or three of 100 women become pregnant during the course of 1 year. However, two or three out of the remaining 97 or 98 women will get pregnant in the following year and another two or three in the next year, etc. After 10 years, 20–25% will probably have become pregnant, i.e., one in four or five women. For a contraceptive method to be rated highly efficient, it would therefore need to have a PI of 0.3–0.5, so that only one unintended pregnancy occurs per 100 women over 2–3 years. That is only *one* pregnancy in 3600 cycles or four or five pregnancies in 10 years (of course, it is impossible to extrapolate the PI in a linear way because the remaining population changes with time). The main problem is that the PI has an observation time bias towards less fertile and experienced users. The life-table or Kaplan–Meier approach additionally accounts for the time of observation.

Effectiveness of natural family planning. In general, the cycle databases show that NFP is highly effective, provided the effective variants of the STM are used (Table III). If the onset of the fertile window is identified by mucus observation alone, efficacy is reduced [5,17]. In the German study, some of the couples used barrier methods in the fertile window. There was no loss of efficacy for mixed method use [3].

The WHO five-country study is commonly referred to as evidence of the efficacy of the OM. While the efficacy of the OM was very high in the three developing countries, it was much lower in the two

Table III. Effectiveness of different natural family planning (NFP) methods in Europe.

Study, country, year of publication	NFP method	No. of cycles/ months (no. of participants)	No. of unintended pregnancies	Method effectiveness (life table, 12 months)	Use effectiveness (life table, 12 months)	Comments
Frank-Herrmann et al. [3], Germany, 1997	(1) STM (double-check)	8052 (396)	18	0.26	2.25	NFP beginners, prospective
	(2) plus occasionally barrier methods	6818 (362)	10			pregnancy classification, loss to follow-up 2.4%, indication of sexual behavior in the fertile phase
European multicenter study [5], 10 countries, 1993 interim results	(1) different STM	3208	7	0	2.6	Same study design as the German study
	(2) plus barrier methods	4196	8	0	2.3	
	(3) CLER method	677	10	1.8	17.7	participating countries: Austria, Belgium, Czech Republic, France (CLER method: preovulatory: mucus only), Germany, Great Britain, Ireland, Italy, Spain and Switzerland; loss to follow-up 3.0%
WHO five-country study [14,15], Ireland (Ire), 1981	OM	Ire: 2808 (234)	38	3.4	16.3	Additional participating countries: New Zealand, El Salvador, India, Philippines

industrial countries (effectiveness of method: PI = 3.4 in Ireland) [14,15]. There exist only few European data on mucus methods, surely also due to the fact that mucus methods are not widespread in Europe. Barbato and Bertolotti found in their prospective study on the STM (8140 cycles, 460 women) that all of the 12 method-related pregnancies occurred when determining the fertile window with mucus observation alone [11].

A relatively large number of additional rules have emerged over time in order to raise the efficacy of the OM. In addition, attempts have been made to train women how to become more and more sensitive to vaginal perceptions, however with limited success in some women. Despite sensitive and competent monitoring of the onset of the cervical mucus symptom, pregnancy sometimes occur as a result of intercourse on the so-called 'dry days' [5,10].

Furthermore, large discrepancies between method effectiveness and use effectiveness may suggest that the complexity of the method also impairs efficacy (Table III).

Perfect/imperfect use. The PI and life-table calculations have major inherent weaknesses:

(1) To calculate method effectiveness is difficult because one has to distinguish between method- and use-related pregnancies;
(2) When calculating the efficacy of the method, the so-called method-related pregnancies are separated from the use-related pregnancies and only the former are factored into the 'failure rate', *but* calculated on the basis of the *total* number of cycles of the whole study population, which automatically improves the method-related pregnancy rate; and
(3) Unintended pregnancies are widely explained as user failure as soon as it is thought that the user failed to obey one detail of a method rule, although the pregnancy probably or certainly would have occurred if this detail had also been observed.

Trussell and Grummer-Strawn criticize this fundamental situation and suggest an interesting alternative, which is to calculate the pregnancy rates in relation to the proper risk set: effectiveness during perfect use or imperfect use, i.e., efficacy in relation to sexual behavior [16]. Across the world, this idea has been realized only in the WHO and German databases [3,16], because sexual behavior needs to be recorded on all of the charts. Only the cycles with a particular sexual behavior are included in the pregnancy rates and all the pregnancies during these cycles, i.e., all cycles with sexual abstinence in the fertile phase and all the pregnancies in that group (Table IV).

Table IV. Pregnancy rates in relation to sexual behavior according to the German Long-term Cycle Database [3] (statistical approach according to Trussell and Grummer-Strawn [16]).

Sexual behavior	Cycles (*n*)	Cycles (%)	Unintended pregnancies (*n*)	Pregnancy rate (% per annum)*
Abstinence in the fertile window	7866	52.9	3	0.50
Protected intercourse in the fertile window	2917	19.6	1	0.45
Unprotected intercourse in the fertile window	2364	15.9	17	8.96
Unprotected and protected intercourse in the fertile window	882	5.9	3	4.33
Genital contact in the fertile window†	841	5.7	4	4.54

*Calculated with the formula: $100 \times [1-(1-P)]$, where P is probability of conception per cycle; †including coitus interruptus.

The method effectiveness of the STM is at least 0.5 (per 1300 cycles) if unprotected intercourse does not occur in the fertile phase. The method effectiveness of the OM is 2.8 according to this approach.

Ovulation detection

Sixty-two cycles of the German database were studied with daily ultrasound and urinary luteinizing hormone measurements and compared with the observations of the women [20]. Individually, the peak day of the mucus symptom and the temperature rise each show a relatively good correlation with ovulation. However, more precisely correlated to ovulation is the synopsis of both symptoms, i.e., when the temperature rise *and* the peak of the cervical mucus pattern is used and determines ovulation. The synopsis of the two cycle parameters results in clinical ovulation, which corresponds within 1 day to the objective ovulation in 89% of the cycles. Ovulation was detected in all of the cycles. In 40% of the cycles the self-observed ovulation coincides with the 'objective' ovulation day.

Similar results were found in Europe earlier by Barbato and Pravettoni [28] (correlation of the peak mucus day to ovulation = 0 ± 1 day in 57/70 cycles, correlation to the day before the temperature rise = 0 ± 1 day in 58/70 cycles), and Flynn and Lynch [24] (correlation of the peak mucus day to ovulation = 0 ± 1 day in 26/29 cycles).

In the German database, clinical ovulation (according to cycle parameters) has been determined in 28 377 cycles. The rate of anovulatory cycles is at the expected level for age (2.5% for women aged 25–30 years, 0.9% for 35- to 40-year-olds and 6.4% for women older than 40), also suggesting a high accuracy of ovulation detection.

Determination of the fertile window to achieve pregnancy

In the German database we observed 346 unselected women starting with the first cycle in which they used natural methods to conceive. Up to this point the women had used natural methods to avoid pregnancy. Eighty-one percent of the women had become pregnant after 6 months and 92% after 1 year (cumulative probabilities of conception). This constitutes a fairly short time to pregnancy in women having fertility-focused intercourse based on NFP [8]. Surprisingly, for those who finally conceived these results did not depend on age.

In the II European Cycle Database the daily probabilities of conception around the peak day of cervical mucus were calculated (Table V). It shows that women can monitor the increasing probability of conception up to the fertility optimum, by observing the changing quality of the cervical mucus secretion. A recent retrospective US study by Stanford and colleagues had similar findings [29].

Discussion

The results and experiences gained so far, which are based on large international databases, suggest that women can acquire a high level of reproductive competence that could be used much more than is currently the case. Today, it is possible for women to reliably determine the fertile window as well as the fertility optimum in the cycle without much effort – all it takes is a few instructions. This competence about their bodies could be used in several ways.

Integration into the management of sub-fertility

Recent studies show that live birth rates in untreated sub-fertile couples reach nearly 55% in 36 months [30]. During this period, self-observation with natural methods may be all that is necessary, especially in cases of unexplained infertility, and gives the couple the opportunity to wait actively and experience their own fertility irrespective of whether or not they achieve pregnancy. On the other hand, the woman may get hints at cycle disorders earlier and have them investigated.

Therefore, it is useful to integrate modern fertility awareness methods into the management of infertility. We proposed such a concept in previous publications [12,31]. The integration of this kind of competence of women into the management of infertility may contribute to avoid both over-treatment and under-treatment.

Table V. Daily estimates of conception probabilities in cycles with one or more acts of intercourse in the fertile window, 0 = the peak day of cervical mucus (FERTILI database [18]).

	Mucus reference day	
Intercourse day vs. reference day	Probability of conception	90% confidence interval
−8	0.003	0.000–0.011
−7	0.000	0.000–0.004
−6	0.045	0.026–0.071
−5	0.078	0.046–0.118
−4	0.181	0.131–0.238
−3	0.114	0.068–0.173
−2	0.203	0.145–0.270
−1	0.177	0.126–0.237
0	0.135	0.089–0.192
1	0.067	0.035–0.109
2	0.020	0.005–0.049
3	0.005	0.000–0.015
No. of cycles	3265	
No. of pregnancies	435	
k	0.301	

Family planning

STM based on the double-check principle seems to be suitable for application in Europe as it shows high method effectiveness. The German NFP working group has suggested such a symptothermal method. Other types of STM are possible if they use two parameters each to determine the beginning and the end of the fertile window. In terms of efficacy, this type of STM can be similarly successful to oral contraceptives. The few existing results on methods determining the onset of the fertile window by cervical mucus observation only do not reach that high efficacy. Therefore the STM seems to be more adequate for the European situation in meeting the high efficacy expectations of many women in industrialized countries. The precondition is the motivation to learn the method and to have no unprotected intercourse in the fertile phase.

Use in scientific studies

With this method of cycle monitoring, it seems possible for the first time to detect ovulation accurately in large populations and continuously over extended periods and to improve the imperfect measures of ovulation used previously [32,33]. The greatest accuracy to determine ovulation is provided by methods based on a synopsis of the peak cervical mucus symptom and the temperature rise. This could considerably improve the state-of-the-art of cycle research in the different reproductive phases.

Rational diagnosis and therapy for cycle irregularities and hormonal disorders

Through cycle monitoring, women may support medical diagnosis and therapy. Recently, we introduced a project on 'fertility awareness in the endocrinological clinic' at the University of Heidelberg. Women with hyperprolactinemia, hyperandrogenemia, post-pill amenorrhea, endometriosis, premenstrual syndrome and dysmenorrhoea, premenopause, micro-mosaic Turner syndrome etc. are carrying out fertility charting provided they are not currently in need of hormonal therapy. The cycle monitoring seems to help applying diagnostic measures at the right time in the cycle (i.e. diagnosis of the luteal phase insufficiency).

Initial results suggest that integration of the patients' reproductive competence can make an interesting contribution to gynecological endocrinology. Different European NFP groups have started projects to integrate NFP into the health system [5,34].

Psychological/emotional benefits for women

It would certainly be interesting to investigate the psychological and emotional aspects of the physical perception of fertility and infertility symptoms, as well as the possible influence on female sexual identity, especially if this type of competence becomes part of sex education.

Conclusion

By self-monitoring of the fertile window, women are able to develop a high degree of reproductive competence which may be used to observe the variability of the cycle and its disorders in everyday life, especially when the women want to achieve or avoid pregnancy.

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