

Regarding the Reliability of the Temperature Method for the Prevention of Conception

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Introductory Note

Doctor & Professor Gerhard K. Doering's research report that was first published in 1967 has special relevance for the work of NFP International and other groups that teach the cross-checking Sympto-Thermal Method of natural family planning.

1. This study provides support for the three-day temperature-only rule to determine the start of post-ovulation infertility. It provides even more support for the more conservative rules used by NFP International, that is, the four-day temperature-only rule and the Sympto-Thermal Rule K that requires only two days of mucus dry-up to cross-check three days of well elevated temperatures as described in this research report.

2. When Dr. Doering shows examples of pregnancies conceived on the second day of elevated temperatures, he also demonstrates why all of NFPI's STM and Temperature-only rules require at least three days of elevated temperatures.

3. His comments about the inclusion or exclusion of imperfect-use pregnancies are still highly relevant some 43 years later. It is still a problem.

4. His comments on the 18-day rule used by Dr. John Marshall help to explain why Dr. Prem and others led us to use a 21- or 20-day rule.

5. This study was published approximately 13 months before the publication of Humanae Vitae, the papal encyclical that reaffirmed the Christian Tradition against the use of unnatural forms of birth control. It must have given great encouragement to the Pope Paul VI as he prepared his encyclical.

6. Regarding terminology, when Dr. Doering uses "conception prevention" or "prevention of conception," he is using the term in a very broad way that encompasses both natural and unnatural ways to avoid conception.

7. Occasionally I have inserted explanatory notes in [italics and brackets].

—John F. Kippley, President, NFP International.

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The prevention of conception, i.e., the attempt of a married couple to manage the number of births and the time periods between pregnancies in accordance with the particular circumstances and conditions of the mother, is now a basic principle in practice. For several years now, the concern with questions regarding the prevention of conceptions has no longer been a taboo topic of discussion.

Despite the unsurpassed reliability of ovulation inhibitors, and in spite of the success of the newer IUDs in many parts of the world, there is great interest in the methods of birth control by periodic abstinence. This was shown in 1966 by a scientific study of the World Health Organization (WHO) whose particular focus was the biology of fertility control by periodic abstinence.

The advantages of a method of periodic abstinence are obvious:

1. The ease with which it can be confirmed as no other method of control can be.
2. The ready applicability of this method, which is not encumbered with any technical or chemical aspects, has led to it being the only one accepted under certain conditions by the Catholic Church.
3. If the question of reliability is considered, then the abstinence method must be considered thoroughly reliable, even in the age of the pill. This paper aims to contribute to the clarification of this question.

The opinions as to the value of periodic abstinence as a method of birth control have previously been divided. They range from an enthusiastic evaluation of the method to a complete rejection of the concept altogether. It is generally unknown how great the differences are between various methods of periodic abstinence. An objective comparison of the data of participants based on recognized statistical principles (Table 2) clearly indicates that only the temperature method can be viewed as reliable.

Methodology – The Temperature Method

About 150 years ago, de Bordeau (item 1 in the references) described the variations of morning body temperature in the monthly cycle. Van de Velde (22) was the first in 1904 to ascertain the relationships between the basal temperature and the ovarian function. Already in 1932 it was recommended by Harvey and Croquett (7) to make use of the fluctuations in temperature for contraceptive purposes. In Europe Ferin was the first in 1957 (5) to provide an exact methodology. In German-speaking countries the temperature method was made known by means of a publication by Doering in 1954.

There are two types of temperature methodology:

1. The strict form [is for use] when optimal reliability is the goal. This is illustrated in Figure 1, showing the time from the 3rd day of the hyper-thermal phase to the beginning of the following menstrual period, which is from the 17th to the 28th day of the cycle.

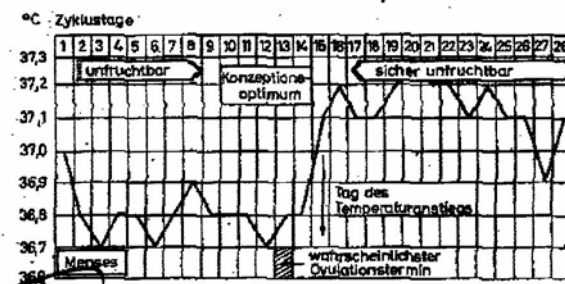


Figure 1

Figure 1. Typical basal temperature curve of a sexually mature woman. The temperature is low at first – 36.7 to 36.8 degrees C. [98.1 to 98.2 F. These seem high from our typical American experience. The German custom is to measure rectally, which produces temperatures about 0.5°C higher than with oral measurement.] The temperature rises on the 15th day of the cycle and moves higher on the 15th day of the cycle to 37.1 to 37.2 degrees C. [98.8 to 99.0 F., again high from our typical American experience with oral temperatures].

2. The combined form of the temperature method requires a smaller number of abstinence days. In this second plan, the post-menstrual infertile time period is used in addition to the infertile hyper-thermal phase. The time period here is figured from [the start of] menstruation to six days before the earliest registered rise of temperature.

When, for example, in at least six simultaneous cycles the rise in temperature takes place between the 15th and 18th days, then the calculation is $15 \text{ minus } 6 = 9$. This means in this example that the first 8 days of the cycle are infertile.

[Dr. Doering's calculation yields the first day of Phase 2, the fertile time. In NFPI, we phrase it so that it yields the last day of Phase 1 in this way: "Earliest day of temperature rise minus 7 = Last day of Phase 1." The result is exactly the same. In the present case, $15 \text{ minus } 7 = \text{Day } 8$, the last day of Phase 1]

The fixing of the beginning of the hyper-thermal phase is not often something that is problematic. The following definition generally allows for a reliable interpretation of the curve of this course. It was formulated by the aforementioned WHO group in 1966 and presents a modification of the Holt Rule (8): "A significant rise of temperature is registered when it takes place within 48 hours or less and if the temperature in the next 3 days is at least 0.2 C higher than in the previous 6 days." The first of the 3 days with higher temperature represents then the rise in temperature. *[0.2 C = 0.4 F]*

Statistical Principles

For the evaluation of the effectiveness, that is the reliability, of this method, the 1932 Pearl Formula needs to be taken into consideration (14). According to this formula, the number of unintended conceptions per 1,200 cycles is considered the failure rate, i.e., per 100 years of application, or, as it is usually defined, per 100 woman-years. The meaning of this formula illuminates the fact that in every cycle in which an unintended conception occurred, only one conception can take place. Less meaningful are the attempts to indicate the number of the undesired conceptions per patient, or the number of cohabitations *[marriage acts]*.

In accordance with bio-statistical demands, those unintended conceptions that are a result of an erroneous application of the method have to be counted as failures. The rate of patient-caused mistakes belongs to the most important criteria for the evaluation of the usefulness of this method. What use is such a method, whose theoretical reliability is outstanding, but whose practical application is not because of the possibility of patient-caused mistakes? As an example, I would like to refer to the study of C.G.

Hartman (6) that was based on the Pearl Formula and published by Latz and Reiner (10). The failure rate of the Ogino-Knaus-Method amounted to 1 per 100 years of application, excluding patient-caused mistakes, but was 30 per 100 years of application with the inclusion of such mistakes.

The demand raised by bio-statisticians that the mistakes of patients be included is something often not taken into consideration by prominent authors.

The Ideal Data

From the bio-statistical standpoint the ideal data would be that which would meet the following criteria, based on Tietze and Lewit (19).

1. The registration of observations should take place on a regular basis, above all in order to exclude the most well known disadvantages of retrospective surveys.
2. The data should come from a specific number of women, whose results are recorded accurately and without any gaps for a particular time period. The number of cycles for the evaluation of reliability of the method should be at least 2,400.
3. Before the beginning of the planned-for study there should be easily understood rules, by means of which the most accurate application of a contraceptive method can be vouched for.
4. The study should only involve women who have already given birth, so that there is no doubt as to their fertility and who are also not older than age 40.
5. If possible, all relevant demographic and sociological data should be known.
6. For figuring out the years of application, so as to determine the failure rate, the months should be counted in which the application of the investigated method were doubtful for some reason. The cycles should not be counted in which other contraceptive methods were used or in which there was no cohabitation.
7. In case it cannot be clarified if a conception was intended or unintended, it should be counted as an unintended conception and therefore as a failure.

Our Data

59,566 cycles of 996 women were evaluated, who made use of the basal temperature method. This was a study almost exclusively involving patients who made

use of their private consultation with their doctor for the purpose of discussing conception prevention, or they were postpartum or post-abortion consultations. The longest period of observation was 19 years and the average time was 4 years and 10 months. The average age of a patient was 29 years and 9 months.

Through the unique nature of the temperature method, especially the daily registration of temperature in a record book, it becomes a question of taking a systematic survey of information. As it was not possible to follow all patients who had been advised to follow this method, the statistical demand for controlled statistical entity could not be attained.

The data had to be divided into two entities for statistical analysis: 1. For women who had held to the strict method of the temperature method, and, 2. For the women who made use of the combined form of the temperature method. The first group was essentially smaller: 307 women made use of the former for a total of 11,352 cycles. On the other hand, 689 women made use of the latter method for 48,214 cycles. The strikingly greater number making use of the combined method can be explained by the fact that this was the original form of the temperature method, which I described in my 1954 monograph on the topic. The particular advantages of the strict form of the method only became known in the course of time, so that the experience with this particularly reliable form of the temperature method is not as extensive.

Results

Combined Form of the Temperature Method

Almost four-fifths of the entire data relates to the combined form of the temperature method, that is the use of the pre-menstrual as well as the post-menstrual infertile days. In the evaluated material, this method was used by 689 women for a total of 48,214 cycles. In this period of observation there were 125 unwanted conceptions. Figuring the failure rate according to the Pearl Formula resulted in the following:

Failure rate = the number of unwanted conceptions X 1200 divided by the number of months of application/cycles which equals 125×1200 divided by 48,214 = 3.089 per 100 woman-years.

[Rounding], the failure rate of the combined form of the temperature method resulted in 3.1 per 100 woman-years of application in the data that was studied.

Strict Form of Temperature Method

307 women used the strict form of the temperature method for a total of 11,352 cycles; that is, the time from the 3rd day of the hyper-thermal phase to the following menstruation was considered as infertile. In the period of observation there were 8 unwanted pregnancies. *[Rounding]*, the Pearl Formula yields a failure rate of 0.8 per 100 woman-years of application: 8×1200 divided by $11,352 = 0.845$.

The Cause of the Failures

In clarifying the failures of the combined method, various causes were found. We have to say that this older form of the temperature method was too generous in defining the infertile time period. At that time, the fluctuation of the time period between ovulation and the rise of temperature was less well known, so that for example in my instructions from the year 1954 the beginning of the infertile pre-menstrual phase was placed on the 2nd day of the hyper-thermal phase. In the meantime, it has become known that conception occasionally occurs on this day. For this reason, the start of the infertile phase with the strict form of the temperature method has been placed on the 3rd day of the hyper-thermal phase.

The source of the mistakes for the combined form of the temperature method comes from the definition of the post-menstrual infertile days. That the infertility of these days is less reliable than the pre-menstrual days was something I emphasized in 1954 as follows: "The determination of this second infertile time period is, however, more difficult. By fluctuations of the cycle length there can occur an unintended conception more often than in the first described time span, between the rise of temperature and the beginning of the following period, which can be considered as definitely infertile." (3)

With the strict form of the temperature method there was not a single case of a purely methodological failure. In the time from the 3rd day of the hyper-thermal phase to the following menstruation not a single conception was registered. The few failures that

occurred using the strict temperature method almost all go back to mistakes made by the patients. (Table 1).

In individual cases it is at times difficult to delimit the methodological mistakes of patients, so for example, when the inter-menstrual rise of temperature was not the beginning of the hyper-thermal phase of the cycle, but rather the consequence of a cold (Figure 2). If one accordingly counts the unwanted conceptions exclusively as failures then one avoids the temptation of cleaning up the material in these cases. The noted biologist C.G. Hartman (6) laments in his book *Science and the Safe Period* that the importance of many valuable publications has been overshadowed by the fact that too many failures have been “explained away.”

In the following several examples will be provided that show typical mistakes.

Example 1

Figure 2 shows an unwanted conception that came from a misreading of the inter-menstrual rise in temperature. Colds, headaches, etc. can lead to a slight rise in temperature as on the 12th and 13th cycle day in Figure 2. When this rise is confused with the beginning of the hyper-thermal phase of the cycle, it can result in an unintended conception. This patient had cycle intervals of 31 to 32 days with habitually late ovulations. Normally, there was a rise in temperature with her from the 16th to the 18th cycle day, so it would have been advised to observe the rise of temperature on the 12th cycle day with a greater degree of skepticism.

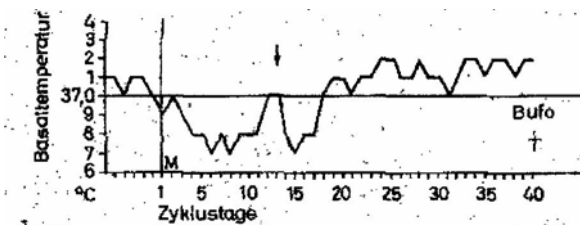


Figure 2

Figure 2: The basal temperature curve of a 27 year old woman with 31-32 day menstrual cycles and late ovulations. The higher temperatures on the 12th and the 13th cycle days came from a slight cold and were falsely interpreted as the beginning of the hyper-thermal phase. This resulted in conception on the 13th cycle day as a result of cohabitation.

Example 2

Figure 3 [below] shows one of the rare conceptions on the second day of the hyper-thermal phase. To be exact, it was a case of a methodological mistake, because in the older instructions for the temperature method the beginning of the infertile pre-menstrual phase was spoken of as soon as the 2nd day of the hyper-thermal phase had been reached. This was a mistake related to the methodology, when the variability of the time period between ovulation and the rise in temperature was not known exactly.

On the 3rd day of the hyper-thermal phase a conception has never been observed [and recorded in the literature], so that later the strict form of the temperature method was formulated in such a way that not until the 3rd day of the hyper-thermal phase could infertility be counted on.

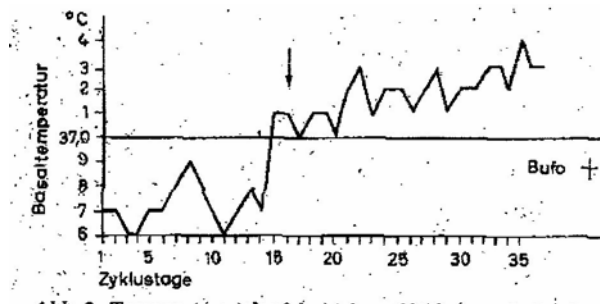


Figure 3

Figure 3: The temperature curve of a 32 year old patient with 26/28 day cycle intervals. The consultation took place in 1952 when the conception on the second day of the hyper-thermal phase was unknown to the author. After cohabitation on the day after a rise in temperature a conception took place.

Example 3

A 24 year old woman, who has already given birth twice, made use of the combined temperature method for two years with no problems. The menstrual cycles were 27 to 31 days, the rise in temperature fluctuated between the 15th and 17th days of the cycle, so that the post-menstrual infertile time lasted till the 8th day of the cycle. In the illustrated cycle (Figure 4 below) an injection of 10 mg. of Estradiol valerianat was given by the doctor due to circulatory disturbances on the 8th day of the cycle. Thereafter, there was a delay of ovulation. A rise in temperature was first registered on the 23rd day of the cycle and menstruation began on the 35th day. The following cycle resulted in an

early ovulation that was obviously in compensation for this. The temperature already started to rise on the 8th day of the cycle and conception took place after cohabitations on the 6th and 7th day of the cycle.

Such shifts in the cycle also can take place due to a change in climate, especially when there are such nuisances as bodily ills or emotionally charged dreams. However, these are not the usual course of events. Conception at the end of the post-menstrual infertile phase accounts for about 10% of the failures of the combined temperature method (table 1).

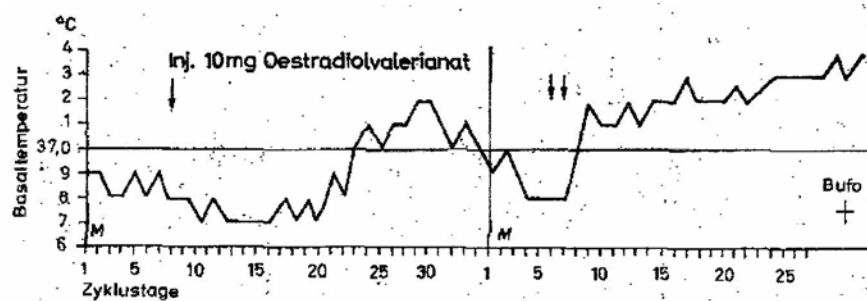


Figure 4

Figure 4: The basal temperature curve of a 24 year old woman. Cycle intervals of 27-31 days, temperature elevation between the 15th and 17th cycle day. An estrogen injection resulted in the shift of the cycle with early ovulation in the following cycle and conception after cohabitation on the 6th and 7th cycle day.

The data confirms the supposition that the majority of the failures of the temperature method were a result of mistakes made by the patient. In spite of instructions regarding the fertile and infertile days of the cycle and in spite of the regular measuring and recording of temperatures, it occurs that for some reason all of the relevant principles are forgotten, resulting in cohabitation in the midst of the fertile period. The lack of discipline, especially for young couples, appears to be the reason here. There is no doubt that even these purely user mistakes must be counted as failures because the source of the failures is a disadvantage intrinsic to the method itself.

Table 1 shows that the measuring and recording of unintended pregnancies was incomplete in a significant way. These unintended conceptions must also be counted as failures.

Table 1: Causes for failure in the temperature method

A. Combined form of the temperature method	Total of 125 conceptions
Conception on 2 nd day of the hyper-thermal phase	6 conceptions
False interpretation of temperature rises due to illness	12 conceptions
Conception at the end of the post-menstrual infertile days	13 conceptions
Patient failures (cohabitation in the fertile phase)	56 conceptions
Incomplete measurements of temperature	36 conceptions
B. Strict form of the temperature method	Total of 8 conceptions
False interpretation of temperature rises due to illness	1 conception
Patient failures (cohabitation in the fertile phase)	5 conceptions
Incomplete measurements of temperatures	2 conceptions

In conclusion Table 1 shows that in a significant number of unwanted pregnancies the recording of temperatures was incomplete. These unwanted conceptions must also be classed as “failures”.

As a result of the critical observation of the results we come to the conclusion that a faultless delineation between the methodological mistakes and those of the patients is not always possible, apart from the purely patient-caused mistakes. It is just as difficult to speak about the purely methodological mistakes, of which one can speak clearly only of conception on the 2nd day of the hyper-thermal phase. In all other causal areas the methodological weaknesses and human inadequacies merge together.

Discussion of the Results

The results stand in contrast to the widespread opinion regarding the unreliability of periodic abstinence as a method of contraception. There is no doubt that this negative view relates only to the calendar methods, which are known in the German-speaking countries as the Ogino-Knaus-Method. There are only a few publications on the reliability of the calendar methods as contraceptive measures and which satisfy bio-statistical requirements. Tietze and colleagues (20) report a failure rate of 14.4 per 100

years of application in Boston in 1951. Westoff and colleagues (23) reported in 1961 in a very extensive study drawn from seven of the largest cities in the U.S. that they found a failure rate of 38,5 per 100 woman-years. At a scientific congress of the WHO in Geneva Rendu (16) reported in 1966 regarding a rate of 40 unwanted pregnancies per 100 woman-years.

The figures for the low failure rate of the temperature method agree with the few publications available on the topic. Traissac and Vincent (21) reported in 1961 about a rate of 0.8 per 100 woman-years of application. Marshall (12) reported at the aforementioned congress of the WHO in 1966 a rate of 7.5 per 100 woman-years of application with the use of the combined temperature method. This method distinguishes itself from the combined method discussed above in that the post-menstrual infertile days are not calculated with the aid of checking the temperature, but rather with the help of calendar methodology. For the strict form of the temperature method Marshall (12) reports a failure rate of 1.3 per 100 years. Rendu (16) reports at the same congress regarding a failure rate of 3.2 per 100 woman-years with the use of the combined temperature method and of a rate of 1.0 per 100 woman-years of application for the strict form of the temperature method. In Table 2 the failure rates for the temperature methods are displayed as are the calendar methods for comparative purposes. The numbers clearly indicate the superiority of the temperature method in relation to the calendar method.

Table 2: Comparative Table of the Failure Rates of the two temperature methods and the calendar methods. The superiority of the strict form of the temperature method is clear.

Method	Author	Year	Cycles	Unintended Conceptions per 100 woman-years
Calendar Method	Latz and Reiner (10) calculated by Hartman (6)	1942	2,353	30.1
Calendar Method	Tietze et al.(20)	1951	7,287	14.4
Calendar Method	Westoff et al (24)	1961	4,179	38.5
Temperature Method	Traissac and Vincent (21)	1962	4,556	4.5 Subjective 0.8 Objective
Temperature Method	Marshall (12)	1966	2,713	7.5 Combined method 1.3 Strict method
Temperature Method	Rendu (16)	1966	18,656	3.2 Combined method

Temperature Method	Döring	1967	48,214 11,352	1.0 Strict method 3.1 Combined method 0.8 Strict method
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The differences in the reliability of the combined form of the temperature method between the data of Marshall (11) with 7.5 per 100 woman-years of application and our data with 3.1 per 100 years probably relates to the difference in the applied methods: The calculation of the pre-menstrual infertile days is the same. A difference exists only with the determination of the post-menstrual fertile days. According to Marshall (11) the beginning of the fertile phase of the cycle is determined in such a way that 18 days are subtracted from the shortest menstrual cycle. According to Doering (2, 3, 4), the fertile phase begins 6 days before the earliest observed rise in temperature. Perhaps the calculation of the post-menstrual fertile days that is based on the course of the basal temperature curve is more in accord with the individual peculiarities of the cycle than the calculation aided by the calendar method. In any case, the difference in the failure rate between Marshall's (11) published results and our own data speaks for a greater reliability of the combined form of the temperature method based on basal temperature.

Our own results for the strict form of the temperature method are a little bit better than those published by Marshall (11, 12) and Rendu (16). Perhaps this small difference is due to the data that in a certain respect presents a positive selection, as it only relates to private patients. It is well known that factors relating to economic status, education, self-discipline, etc. exert an influence on the reliability of pregnancy prevention measures (18, 19, 20). The excellent results of Roetzer (17), however, show that with rural or industrial populations one can count on very good results with the temperature method.

In short, the question we asked at the beginning of this article regarding the reliability of the temperature method is one that can be answered here in the affirmative. With regard to the strict form of the temperature method it has been shown that our data as well as those published by others has proven to be favorable. The failure rate varied around 1 per 100 woman-years of application (Table 2). It is therefore lower than the failure rate of the newer IUD's and only a bit above the failure rate of the ovulation

inhibitors. This means that the temperature method in its strict form as a contraceptive measure can compete with them.

Summary

The criteria and relevant data and statistical calculations were explained. The results of our data were drawn from 59,566 cycles of 996 women.

[Combined form:] Of them there were 689 women who made use of the combined form of the temperature method during 48,214 cycles, that is, they used the post-menstrual phase as well as the pre-menstrual infertile phase. In the period of observation there were 125 unintended pregnancies. *[Of these, only 13 were perfect-use end-of-Phase-1 pregnancies. All others were imperfect-use pregnancies of which 56 were from marriage acts clearly in the fertile time. See Table 1.]* According to the Pearl Formula, this shows a failure rate of 3.1 per 100 woman-years of application.

[Strict form, Phase 3 only:] 307 women made use of the strict form of temperature control during 11,352 cycles, with which only the time from the 3rd day of the hyper-thermal phase to the following menstruation was judged as infertile. Here the failure rate was only 0.8 per 100 woman-years of application. *[All eight of these were imperfect-use pregnancies. See Table 1.]*

The typical mistakes of the temperature method were systematically explained and graphically presented. In the discussion of the results, our own data was compared with those of previous publications regarding the calendar method and the temperature method. This demonstrates that the strict form of the temperature method can definitely compete with the ovulation inhibitors as a birth control measure.

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