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Retrospective clinical trial of contraceptive effectiveness of the electronic fertility indicator Ladycomp/Babycomp

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Abstract

The Babycomp/Ladycomp (Valley Electronics Ltd., Eschenlohe, Germany) is an electronic device that combines the temperature method and calendar method for planning and preventing pregnancy by identifying the fertile and infertile phases of the menstrual cycle.

In a retrospective clinical trial, the system was tested as a contraceptive aid. A total of 648 women from Germany and Switzerland have participated: 597 women with 10 275 months of use used the device for contraception. Thirty-three unplanned pregnancies were identified, giving a total pregnancy rate of 3.8 use effectiveness according to the Pearl Index. Six method-related pregnancies occurred, producing a method Pearl Index of 0.7. Calculating the cumulative pregnancy rates by life-table analysis, it was found that, after about one year of exposure, the probability of an unintended pregnancy was 5.3% (0.053), after 2 years it was 6.8% (0.068) and after about 3 years of exposure it was 8.2% (0.082). The mean length of the identified fertile period was 14.3 days with a standard deviation of 4.6 days in all cycles reported. The acceptance of the device by the woman and her partner was good. In fact, 21 of the 33 women who became pregnant would still recommend the device for further use (63.6%).

Introduction

Today it is possible to avoid pregnancy effectively with natural family planning, i.e. with the so-called symptothermal method. However, for some women self-observa-

tion of their body to detect the fertile phase is inconvenient and therefore makes NFP methods unacceptable [1–3]. This is why, over the past decade, specific devices and tests have been developed to detect ovulation and the fertile phase [4–7]. Some of these technologies use a combination of basal body temperature (BBT) measurement and calendar calculation to identify the fertile and infertile phases in the menstrual cycle. The names of these temperature computers are Bioself, Ladycomp/Babycomp and Cyclotest.

This paper deals with the temperature computer Babycomp/Ladycomp (BC/LC). Some efficacy-finding studies (EFS) with this computer have been published [8,9]. Until the present time, no study has been reported dealing with the contraceptive effectiveness of the device. We report on a retrospective non-comparative effectiveness study (rES) which gives some idea of the value of this device in preventing unwanted pregnancy [see also Reference 10].

In addition to examining the effectiveness, questions concerning the length of the fertile phase detected by the computer, and the possible influence of the body-mass index of the user on the fertile phase in a cycle have been investigated. The temperature computers, which store the cycle data electronically, make it easy to answer various questions concerning the menstrual cycle and to statistically evaluate these data from several gynecological aspects.

Materials and methods

Materials

BC/LC is developed and manufactured by Valley Electronics and is sold in pharmacies throughout Germany, Switzerland and Austria. It is a portable electronic device that measures BBT orally in 30–60 s, and checks and stores the temperature values, as well as the length and other information about the woman's menstrual cycle in a large data base. A microprocessor uses an evaluation program to identify the change in BBT following ovulation in order to indicate the user's daily fertility status by means of colored lights: a green light indicates 'infertile', a red light indicates 'fertile' and a yellow light indicates 'unsure'. The actual fertility status and the daily temperature are shown on the display. Inaccurate temperature readings are indicated on the display and with an acoustic signal. All data are stored and evaluated for 4 months and some specific cycle data are stored for 5 years. If there is no free memory, the oldest data are removed from the memory of the device and new data are entered. Using a special interface, the data of the device can also be shown on a PC screen.

Babycomp (BC) differs from Ladycomp (LC) in that it includes the option of entering the date of intercourse, as well as incorporating an additional program level which shows the optimal conception time and the probable sex of the offspring following intercourse on a particular day of the cycle relative to ovulation. The expected day of delivery is calculated from the ovulation day and is shown on the screen of the device.

Methodology

After tracing the addresses of purchasers of BC/LC over the past 3 years, we sent questionnaires (Appendix 1) to 800 German purchasers. One hundred and eighty-two letters came back unopened as the addressees had moved and the new addresses were not known. Sixteen customers had bought devices but had not used them. Consequently, 602 were able to answer the questionnaire. Of these, 538 returned the questionnaires, a response rate of 89.7%. In the same way, 110 questionnaires were returned to us from Switzerland. Thus, for the statistical analysis, a total of 538+110 = 648 questionnaires were included in the study.

The most important question referred to the occurrence of pregnancy while using the device. When we heard about a pregnancy, we examined the type of pregnancy according to the opinion of the user: Did it occur during the use of the device? Did the BC/LC show a green, red or yellow light? When had intercourse taken place? The cut-off date for the study was August 31, 1995.

The size and the weight of the participant were recorded on the questionnaire, so we were able to determine the body-mass index of the user, which is defined by BMI = body weight/height × height [kg/m^2].

Some socioeconomic characteristics of the volunteers were computed from the questionnaires (Table 1). Table 2 shows contraceptive usage prior to the use of the device. BC/LC was used according to the manufacturer's instructions without any special training.

Table 1. Sociodemographic characteristics of the participating women

	n	%
Age		
<19	2	0.3
19–29	441	68.6
30–39	183	28.5
40–45	15	2.3
>45	2	0.3
Number of children		
None	384	59.3
1	138	21.3
2	87	13.4
3	30	4.6
4	9	1.4

Table 2. Prior contraceptive usage (one answer – main method)

Method	*% of use*
Pill	86.5
Condom	5.7
Diaphragm	0.2
Natural method	3.7
IUD	1.7
Others	2.2

Pregnancy classification

a) Method-related unplanned pregnancy: the pregnancy was the result of an unprotected intercourse on a 'green day' shown by the computer.

b) User-related unplanned pregnancy: the pregnancy was the result of intercourse on a 'red' or 'yellow' day

c) Unsure: the available information did not enable us to classify the unplanned pregnancy into (a) or (b).

Statistical analysis

Contraceptive efficacy was assessed in terms of pregnancy rates in two ways:

a) We used the Pearl Index [11] which gives the number of pregnancies that would occur per 100 woman years of being exposed to the risk of pregnancy. The Pearl Index is computed as the number of pregnancies divided by the number of cycles multiplied by 1200 (or 1300 if data are collected by cycles).

b) As the Pearl Index is flawed because it suffers from duration bias (in general, the longer a study runs, the more effective a method will appear), we also calculated the pregnancy rate applying methods commonly used for the analysis of survival times. The cumulative pregnancy rates for different groups of subjects were calculated by the life-table or (in this case equivalently) the Kaplan–Meier method [12] and the proportions of subjects pregnant within one, two or the first three years.

Results

Participants

Questionnaires from 648 women were available from Germany and Switzerland. These can be divided into 493 German women with 8284 months of use and 104 Swiss women with 1991 months of use who used the devices for contraception. The remaining 51 women used the system in order to achieve pregnancy. Some socio-economic characteristics are shown in Table 1 and prior contraceptive usage is incorporated into Table 2, respectively.

Contraceptive efficacy

Pearl pregnancy rate

When the BC/LC was used for contraception, 33 unplanned pregnancies were identified in 10275 months of use. Therefore the total pregnancy rate or use effectiveness is $33 \times 1200/10275$, which gives a Pearl Index [11] of 3.8.

Counting only the pregnancies which occurred as a result of intercourse when the computer showed a green light, we found 6 pregnancies, giving a method pregnancy rate of 0.7 according to the Pearl Index.

Life table probability of the risk of pregnancy

Table 3 shows the actuarial curve according to Kaplan–Meier [12].

Column 2 shows the number of women exposed, and column 3 the number of unintended pregnancies reported. From this table, it can be seen that, after one year of exposure, the cumulative probability of an unintended pregnancy is 5.3% (0.053), after 2 years of exposure it is 6.8% (0.068), and after 3 years 8.3% (0.083).

Table 3. Rate of unplanned pregnancies (actuarial curve, Kaplan–Meier)

Ordinal cycle number	*Women exposed*	*Unplanned pregnancies (cumulative)*	*Cumulative months of use*	*Cumulative pregnancy rate (%)*
1	524	2	524	0.57
3	514	6	1552	1.34
6	485	14	3511	2.90
12	288	23	5274	5.29
18	183	26	6759	6.78
24	106	26	7297	6.78
36	38	27	8051	8.26

Length of the fertile phase

The last cycle of the users showed a mean length of fertile period of 16.3 days with a standard deviation of 4.6 days. A single yellow day at the beginning and the end of the fertile phase is included in this figure. However, often, three or more days of a cycle were yellow. In our opinion, it is a problem that the pregnancy risk of the yellow days is not explained to the user. The fertile phase would be longer if all yellow days were included. In the user's instructions, it is written that, in up to 20% of cycles, there is yellow from the end of the red phase up to the end of the cycle. With the exception of anovulatory cycles (about 3% of the women concerned), these are probably cycles where the postovulatory phase is not detected and the yellow days are potentially fertile.

The distribution of the length of the red phase relative to cycle length is shown in Table 4. With normal cycles of 26–30 days' duration the mean length of the fertile phase was 13.5. Figure 1 underlines these relationships and Figure 2 shows the distribution of the length of the red phase of all participants in the last cycle reported.

Table 4. Cycle length and mean length of the fertile phase (red phase)

Cycle length (days)	*Mean length of fertile phase (days)*	*SD (days)*
⩽20	9.9	Only one value
21–25	12.4	0.76
26–30	13.5	0.87
31–35	16.4	1.61
36–40	17.5	3.2
⩾41	27.4	7.67

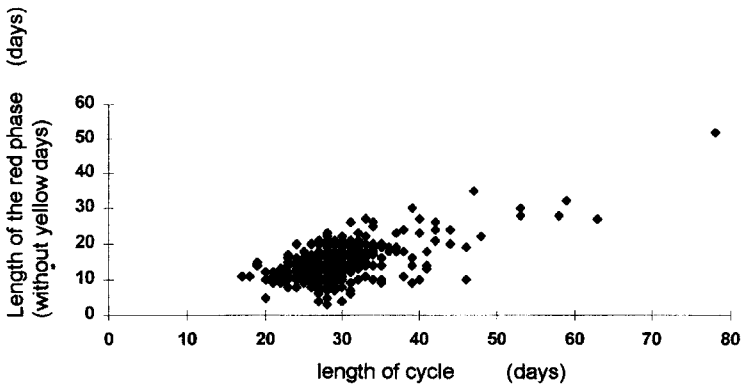

Figure 1. Correlation of the fertile phase to the length of cycle

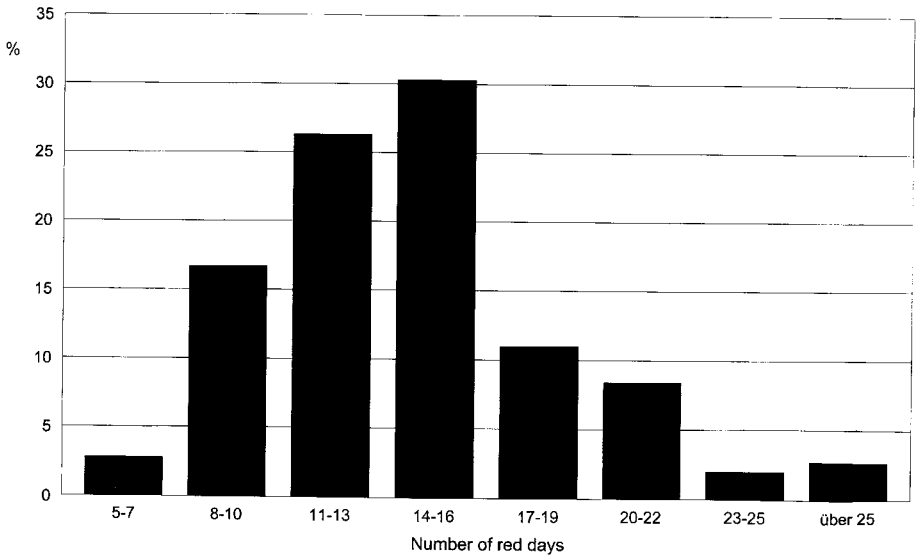

Figure 2. Length of the red phase in the last cycles of use in all participants

Assessment of the device by the user

It was interesting that 90% of the questioned users would recommend the device to their friends or other interested people. They were happy that they had found an effective method without side-effects. Surprisingly, 21 of the 33 women who became unintentionally pregnant while using the temperature computer would still recommend the device for future use (63.6%).

As with other behavioral methods, the partner's reaction is key. Therefore, we also asked for an assessment of the device by the partner. It is interesting that, at the start, 70.9% of the partners were in favor of the device compared with 79.0% after use. At the beginning, 4.9% of partners were against using the device compared with 5.0% at the end.

Risk of pregnancy and body-mass index

As we had information about the weight and the height of the users we were able to determine the BMI. The number of ovarian function disturbances increases if a woman exceeds a normal BMI (19–24).

We found that 71 women hoping to prevent a pregnancy had a BMI > 24, providing a total of 1161 cycles. With 6 pregnancies, the PI amounts to 6.2. Among 548 women with normal BMI, we found a PI of 3.3 in 8839 preventing cycles. The difference is statistically significant (Student's *t*-test).

Appendix 1: Questionnaire

A)

How did you become aware of Ladycomp/Babycomp?	newspaper article/ advertisement/ physician/ pharmacy/ friend
date of purchase	.....
Have you used BC/LC right up to today?	Yes/ no If no: I have used it for .....months Why did you stop using it?
If no: send the questionnaire back after this answer.	

B 1)

How many times did you forget to measure during one cycle?	About ..... days			
What is your partner's opinion of BC/LC?		positive	undecided	negative
	at the beginning	( )	( )	( )
	today	( )	( )	( )
Did you use other methods of contraception prior to BC/LC?	If yes, specify type and duration of use			
Do you have children?	If yes, how many?			
In how many days of your last cycle did the BC/LC show	red/ green/ yellow?			
Did you experience an unwanted pregnancy during the time of use?	Yes/ no			
Do you have problems with too many red days?	Yes/ no			

B 2) Getting pregnant

Did you use BC/LC to get pregnant?	Yes/ no
	If no, continue with B 3)
How long have you been trying?	.....
Did BC/LC show you the conception optimum?	Yes/ no
Did you use the optimum?	Yes/ no
Did you get pregnant?	Yes/ no If yes: how long have you been trying? If no: was a reason found by your doctor?
Did BC/LC indicate the pregnancy?	Yes/ no
Did BC/LC give you an accurate sex prognosis of the offspring?	Yes/ no If yes was it a boy/ a girl?
When was the expected day of delivery according to BC/LC?	date
Which day did the obstetrician calculate?	date
When was the baby born?	date

Was an induction of labour performed?	Yes/ no
Did you have a miscarriage?	Yes/ no
If yes, did BC/LC inform you?	Yes/ no
Did BC/LC indicate the miscarriage prior to the event?	Yes/ no

B.3) General information

Did you have problems taking temperature reading using the device?	Yes/ no
Other problems?	.....
Would you recommend the device to friends?	Yes/ no
What is your age?	19..
body weight?	kg
height?	cm
What is your occupation/ profession/ job?	.....

If you have any questions please phone!

Discussion

The contraceptive effectiveness of a device is a function of accuracy of the indicators and the rules which form the algorithm of the device and of the behavior of the user. The system we have used (BC/LC) has already been demonstrated to locate the fertile time in a woman's cycle rather accurately in efficacy-findings studies (EFS) [8,9]. However, its usefulness as a contraceptive device or as a system aimed at helping women to get pregnant has never been tested.

This is a retrospective study with all the disadvantages entailed in such studies. However, we believe that it is possible to give an idea of the effectiveness of the system, as experienced in daily use. Under these circumstances we found that the system displayed a total effectiveness of 3.8 (PI) and a method effectiveness of 0.7 PI.

These results cannot be compared with the results of prospective studies of original methods of natural family planning (NFP). Prospective studies (pES) of the symptothermal method of NFP showed a user effectiveness of 2.8 PI in Germany, and a method effectiveness of 0.3 with 758 women and 14 870 cycles [13]. We are sure that the motivation of a NFP user is different from that of a user of a new technology (NT) like the temperature computer. NT users may not pay as much attention to abstinence or may not adjust it so carefully to the stage of the cycle. Therefore, we think that the use effectiveness of 3.1 PI is overestimated because of the retrospective character of the study.

Compared with hormonal computers, NT uses well established parameters, such as temperature. Another temperature computer, Bioself 110, was studied prospectively [14–16]: 131 women contributed 1238 cycles. One pregnancy occured on a green day, one pregnancy occurred on a day which the woman thought was a green day. Eleven pregnancies occurred due to barrier method failure and another 11 when the volunteers knowingly had unprotected intercourse during the red phase. There were five planned pregnancies in this study. Calculating the pregnancy rates in the usual way, the total pregnancy rate was 23.3 PI, whereas the method pregnancy rate was 1.9 PI. Discounting barrier method failures, we still have a total pregnancy rate of 12.6 PI. However, the results cannot be compared as the type of study (retrospective/prospective) varies. For the new generation of Bioself 2000 and Cyclotest 2 plus, the only available results are from efficacy-finding studies [9,17].

With the personal system of hormonal monitoring, Persona, two parameters are used to determine the fertile time in a cycle: estriol glucuronide (E3G) and luteinizing hormone (LH) in urine. A multicenter prospective efficacy trial was carried out using this system to determine the method effectiveness of personal hormone monitoring in preventing pregnancy used in conjunction with abstinence from sexual intercourse during the identified fertile period. The trial was carried out in Germany, the UK and Ireland. The German results have already been published [18]. The calculated method pregnancy rate was 6.2%, resulting in an effectiveness for Persona, when used with abstinence on red days, of 94%. However, when comparing these with the figures for temperature computers, it must be pointed out that a prospective study is being compared with a retrospective study.

With all methods of periodic abstinence [1,13,19], the couple's motivation to abstain from intercourse is essential for the success of the method. In the present study about two-thirds of the women had no problems obeying the rules, one-third declared that they had some problems. Interestingly, these figures were related to the age of the participants: 6.6% (14 out of 213) of the 21–25 year age group admitted to having problems; the figure concerning problems with abstinence rose to 14.5% (18 out of 124) in the 31–35 year age group; over 35 years, the figure was only 2.3% (1 out of 42). These figures correspond well with known figures for NFP users. We know that, in the course of time, the problems decrease, but do not disappear [20].

Obviously many people were satisfied with this technology: more than 90% of the participants would recommend it to their friends: 21 out of 33 with an unplanned pregnancy would still do so.

We conclude that the present technology of BC/LC can produce reasonable results in users who like this kind of technology. Compared with the symptothermal method or with the hormonal monitoring system, the length of the fertile time is increased. We do not think that clients using original NFP methods are the same as those using new technologies [2,3,19]. However, they both belong to the group of women who do not want to interfere with their bodies by supplying hormones or introducing mechanical or chemical substances.

In the present age, we must be aware that this kind of contraception does not protect against venereal diseases like STD or HIV. This means that it is most suitable for couples in stable relationships.

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Resumé

Le Babycomp/LadycompTM (Valley Electronics Ltd., Eschenlohe, Allemagne) est un dispositif électronique qui associe la méthode des températures et la méthode du calendrier pour planifier et éviter des grossesses en cernant les phases fertiles et infertiles du cycle menstruel.

Ce système a été testé comme moyen contraceptif lors d'une étude clinique rétrospective. Y ont participé 648 femmes en Allemagne et en Suisse. 597 femmes, représentant 10 275 mois d'utilisation, ont eu recours à ce dispositif à des fins contraceptives. 33 grossesses non planifiées ont été recensées, soit un pourcentage total de grossesses de 3,8 lié à une utilisation effective selon l'indice de Pearl. Six grossesses liées à la méthode se sont produites, soit un indice de 0,7 de la méthode Pearl. En calculant les taux cumulés de grossesses par une analyse des tables de survie, on a constaté que la probabilité d'une grossesse non

intentionnelle était de 5,3% (0,053) après environ un an d'application, de 6,8% (0,068) après 2 ans et de 8,2% (0,082) après environ 3 ans. La durée moyenne de la période fertile identifiée était de 14,3 jours, avec un écart-type de 4,6 jours, pour tous les cycles considérés. Ce dispositif était bien accepté par les femmes et par les partenaires. En fait, 21 des 33 femmes chez qui une grossesse s'est déclarée continueraient à recommander l'utilisation de cette méthode (63,6%).

Resumen

El Babycomp/Ladycomp (Valley Electronics Ltd., Eschenlohe, Alemania) es un dispositivo electrónico que combina el método de la temperatura y el método del calendario para planificar y prevenir el embarazo, identificando la fase fecunda e infecunda del ciclo menstrual.

En un ensayo clínico retrospectivo, el sistema fue sometido a prueba como medio anticonceptivo, con la participación de 648 mujeres de Alemania y Suiza. Este dispositivo fue utilizado a efectos anticonceptivos por 597 mujeres con 10 275 meses de uso. Se identificaron 33 embarazos no planificados, cifra que da una tasa total de embarazo de eficacia de uso de 3,8 según el índice de Pearl. Hubo seis embarazos relacionados con el método, cifra que da un índice de Pearl del método de 0,7. Calculando las tasas acumulativas de embarazo mediante el análisis con tablas de vida, se descubrió que, al cabo de aproximadamente un año de exposición, la probabilidad de un embarazo no intencional era 5,3% (0,053), al cabo de 2 años, 6,8% (0,068) y al cabo de 3 años de exposición, 8,2% (0,082), respectivamente. La longitud media del período fecundo identificado era 14,3 días, con una desviación estándar de 4,6 días en todos los ciclos notificados. La aceptación del dispositivo por parte de la mujer y de su compañero era buena. En efecto, 21 de las 33 mujeres que quedaron embarazadas continuarían recomendando el dispositivo para seguir utilizándolo (63,6%).