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PREFACE

According to a survey carried out by the Emnid Institute, there is a common desire among the majority of women and their partners for a safe, simple and harmless method of contraception. Lady-Comp and Baby-Comp have a Pearl Index of 0.7. All that is required is 30 seconds and a press of a button. Furthermore, there are absolutely no side effects. Even the excretion of hormones into the water cycle, which occurs when taking the pill, is avoided. All this is possible thanks to high technology, computer programming and state-of-the-art scientific knowledge.

Over a period of more than two years, 686 users in Germany, Switzerland and Mexico were questioned about their experiences with Lady-Comp/Baby-Comp. The women came from a broad range of income and vocational groups, although a large number worked in the medical or paramedical sector. The average cycle length amounted statistically to 29.2 ± 5.4 days. Unusual cycles were also represented in the survey. Correspondingly, there was a considerable fluctuation in the days identified as being fertile. The computer programme proved to be reliable and generally indicated the shortest time span that could still be considered to be safe. The key result: 0.7 pregnancies per 100 women and years.

The user sample was put together by chance, the cycles were arbitrary. Eighty-six per cent of the women had previously taken the pill. Obese women proved to be twice as likely to have turbulent cycles. Partners showed an increasing tendency to be in favour of the use of the device. There was a general improvement in the sense of peace of mind. According to the statistical process illustrated by the Kaplan-Meier Survival Curve, the long-term stability is high. Long-term use of Lady-Comp and Baby-Comp results in constant safety.

Ninety per cent of those questioned would recommend the device to others. This makes the recommended behaviour methods a viable choice for those who, up to now, have found them to be too time-consuming and unreliable. Now it is up to you to recommend this new but proven method to your patients and other interested parties. Upon request, we would be glad to send you the complete study comprising 80 pages. Yours faithfully Dr H. Rechberg

MATERIAL AND METHOD

1.1. Participants

The data of 686 users from Germany, Switzerland and Mexico were evaluated for the period from 1992 to 1995 (fig. 1). The average usage time was 16 months. In contrast to previous research (Toncaboni, 1992), the users questioned had not received instructions about the BBT* method, its physiological background or its application. Most of the women had heard about the minicomputer from a friend, ordered it and received the product information from the manufacturer.

Mexico 6%

Switzerland 16%

Germany 78%

1.2. Baby-Comp/Lady-Comp

The Baby-Comp (BQ) and Lady-Comp (LQ) devices were developed as part of a collaboration between information scientists, designers, social scientists and gynaecologists.

The concept and objective of this invention were: 0 to facilitate contraception/family planning using the BBT method*, to facilitate the keeping of temperature graphs and their evaluation. 0 to eliminate the interpretation errors which frequently occur with inexperienced users. 0 to create a safe, non-invasive** alternative to other methods of family planning. * BBT= Basal Body Temperature/ ** invasive = disturbing the surrounding tissue

In this context, a futuristic-styled device was developed in the form of a 3 cm high disk with a diameter of 14 cm, and weighing 200 g. A detachable temperature sensor with a spiral cable is integrated into the side of the device. The BC/LC device has a temperature display, a clock and alarm function and three lights in the colours of the traffic lights: red, yellow and green. The user is awoken by an acoustic signal at the time that she has set on the alarm. This must be within a timespan of 3 hours before or 3 hours after the time set on the previous day. The sensor is placed under the tongue. A button is pressed to start the temperature reading. Within 30 seconds, the sensor takes the user's temperature and automatically enters it into the computer.

The computer is equipped with an algorithm of the temperature method. This calculates whether each day is a fertile (red), infertile (green) or uncertain (yellow) day using the survival limit of the egg, the fertilising ability of the sperm cells and the definition of a rise in temperature from the actual temperature recorded. The integrated learning programme brings about a reduction in the preovulatory* red phase in the course of use. In order to accelerate the learning phase, it is possible to enter the cycle length of the previous cycles when setting the device into operation for the first time.

To monitor the efficiency of BC&C, it is possible to print out the BBT graph for the previous 120 days.

BC differs from LC in that it has an additional computer level with data concerning the optimum day for conception and a prognosis of the sex of offspring. This indicates the prognosis before ovulation and the actual expected sex of the offspring if fertilisation has taken place. The first indication that a pregnancy has occurred is already provided 5 days after conception. Both the date of conception and the calculated birth date are shown.

* preovulatory = the time before ovulation

**algorithm = calculation procedure/ BBT = Basal Body Temperature

RESULTS

2.1. General data

There were 686 completed questionnaires available for evaluation. The study took into account a total of 10 975 user months. BC/LC was used by 633 women as contraception for 10 601 months. The mean age of users was 27.9 years. The average age of the Mexican women was 26.6 years, making them younger than the German and Swiss women participating whose average age was 28.

The average cycle length for 419 cycles containing complete information was 29.2 ±5.4 days.

Of the 686 users, 392 had no children (57.1 %), 160 had one child (23.3 %), 89 women had 2 children (12.9%) and 44 women (6.4%) 3 or more children. One woman did not supply information.

German and Swiss women had an average of 0.7 children, whereas the Mexican women had 1.1 children.

In all countries, there was a similar distribution of education level and professional groups. However, the largest number of users worked in the field of medicine and paramedicine (table 1). activity housewife worker hotel, agriculture, truck driver paramedical, social activity ... of whom nurses non-medical practitioner flight attendant office worker cosmetic and manual worker professional, managerial employee free-lancer teacher, social worker, psychologist graphic artist, designer, artist doctor, biologist business economist, information technologist and other engineers lawyer architect student scholar.

Table 1: Occupational groups, data from 626 users.

Number
174
12

8
82
40
7
7
120
22
62
16
40
26
9
12
4
6
15
4

Five hundred and sixty-nine women (83 % of all those questioned) had used the temperature computer exclusively for contraception; of this group, 7 women who did not yet have a cycle because of lactation were excluded from the evaluation of the contraceptive reliability of the device. A total of 46 women had used the device exclusively for conception planning; 71 women (10.3 %) had used it for contraception, as well as for conception planning.

In this study, BC/LC was used for contraception by 633 women during 10601 months. The sample was made up of 493 Germans with 8284 months, 104 Swiss with 1991 months and 36 Mexicans with 326 months of contraception.

2.2. Previously used methods of contraception

There is a marked difference in the previous types of contraception used by the Mexicans and those used by the Europeans. Whereas the Europeans mainly used oral contraception before (fig. 5a), the majority of Mexicans who answered this question had used NFP* methods: 16 women did not answer; 10 women had relied on the "Billing" method (21 years together) and one had used another device (2 years). Eleven women had taken the "pill" (17 years) (fig. 5b). Of the 648 European women, a total of 557 (86 %) replied to this question. Of these, 478 women (86%) had used oral contraceptives exclusively or in addition to other methods. Only 27 women (4 % of BC/LC users) had previously used a NFP method (fig. 5a).

2.3. Reliability of BC/LC as a method of contraception

Reliability continues to be the most important criterion in the evaluation of a method of family planning. In the questionnaire about family planning behaviour in the Federal Republic of Germany in 1985 and 1989 (Freundl and collaborators, 1991), there were indications that the need for reliability had even increased. Correspondingly, during this period of time, the number of answers stating reliability as the main priority in a method of contraception rose from 89 % to 94.1 %.

2.3.1. Evaluation according to the Pearl Index

The reliability of a method of contraception is usually expressed using the Pearl Index. The formula developed by Pearl is calculated as follows (Pearl, 1933):

unwanted pregnancies x 1200 user cycles

This produces an index for the statistical probability of pregnancy occurring in 100 women years (1200 months) when using the method being tested.

In the present study, 39 unplanned pregnancies occurred in 10601 months; among the Germans and Swiss, there were 33 unplanned pregnancies in 10 275 months of contraception. This includes those that occurred on <> (= fertile) days, and those that occurred on <> (= infertile) days.

This means that the following calculation can be made: $39 \times 1200 : 10\ 601 = 4.4$; if the Mexicans are excluded, we have the following calculation: $33 \times 1200 : 10\ 275 = 3.8$.

The Pearl Index for pregnancies occurring on "red" and "green" days in this survey amounts to 3.8 for the Europeans.

2.3.2. Usage safety and method reliability

Unplanned pregnancies can be divided into two categories, depending on their genesis: An unintended conception can either occur when correctly adhering to the rules of the method, i.e. observing

abstinence during the days identified as "fertile" (= red) and "uncertain" (= yellow), or when not adhering to the rules by having unprotected coitus during the time identified by the device as being "fertile".

Correspondingly, we talk of user reliability. This takes into account all unintended pregnancies and therefore reflects the everyday efficiency of a method. For the Germans and Swiss in the present study, this corresponds to a Pearl Index of 3.8 in the period under observation (see above calculation).

This is distinguished from the method reliability. Only those pregnancies which occurred when green was displayed are taken into account here. If the women had not entered the information on the questionnaire, telephone enquiries made it possible to ascertain that 6 of the 33 unplanned pregnancies in Europe could be traced to method errors and 27 to user errors. This means that for method reliability, a Pearl Index can be calculated of $6 \times 1200 : 10\,275 = 0.7$.

SATISFACTION

3.1. General

The number of potential advocates of this technology was remarkable: 90% of users of BC/LC would recommend this device to others; many of them also expressed their satisfaction at finally finding a reliable method of contraception that did not involve side effects (fig. 12.).

2.4. Conception planning

In our questionnaire, 113 of 648 Europeans said that they had also or exclusively used BC/LC for conception planning (table 3). In this context, the device displayed the optimum time to conceive in 106 cases, which was used by 100 couples. Conception took place in 81 cases (81 %). There was a broad distribution of user time period and often conception already occurred in the first cycle, whereas for 2 women it only took place after 24 months. The mean user time period to achieve conception was 4.5 months.

used for conception planning:	used conception optimum:	number of pregnancies:	% proportion of pregnancies:
113	100	81	81% (71%)

Table 3: Use of the device for conception planning.

Only Baby-Comp, costing 35 % more than Lady-Comp, provides a sex prognosis. Of the 81 pregnancies, Baby-Comp with sex prognosis was used in 19 cases in which the children have already been born. The sex prognosis was accurate in 10 cases; in the other 9 cases, the device either showed an equally high probability for "boy/girl" or the prognosis was inaccurate.

2.5. Length of the fertile phase

The average length of the fertile phase indicated by BC/LC was 14.3 ± 4.6 days. For more than 50 % of users, the length of the fertile phase lay between 11 and 16 days (fig. 9). The mean cycle length (data from 419 women) in our study was 29.2 ± 5.4 days.

3.2. Attitude of the partners

Since the success of a behaviour method is decisively influenced by the involvement of both partners, the questionnaire included questions concerning the partner's attitude.

Users were asked about their partners' attitudes when starting to use BC/LC and "now". In the course of the period of use, there were a few partners whose attitudes were described as deteriorating from uncertain towards negative.

There were only limited differences between the Europeans and the Mexicans concerning this point. The majority of partners were on the whole "positive". However this trend generally increased among the Europeans and declined among the Mexicans up to the present time (fig. 13).