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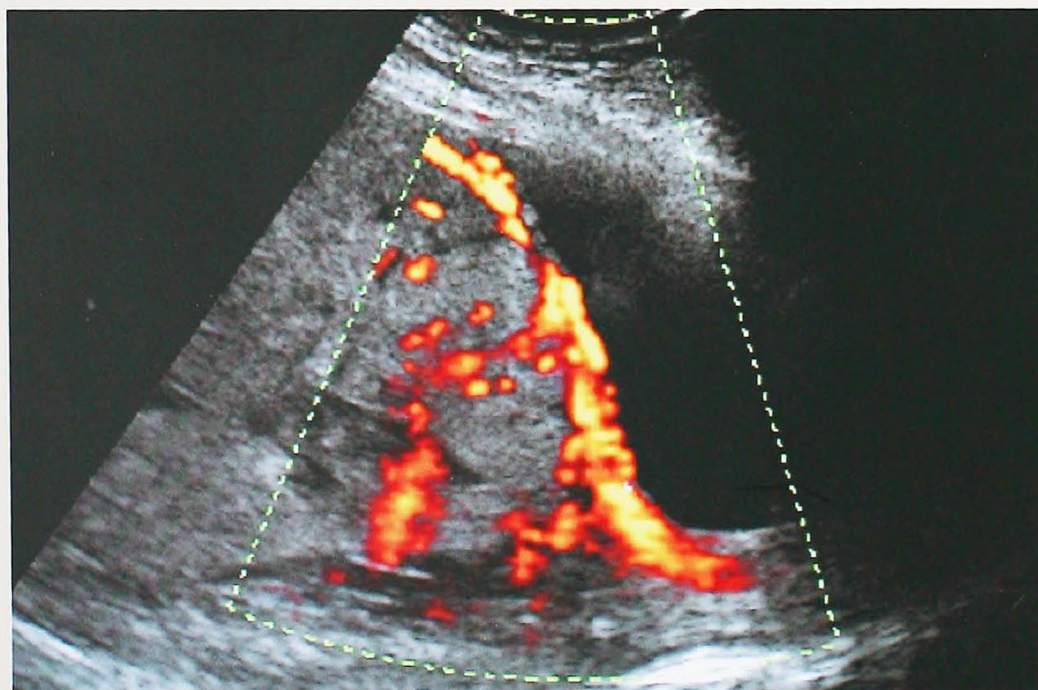
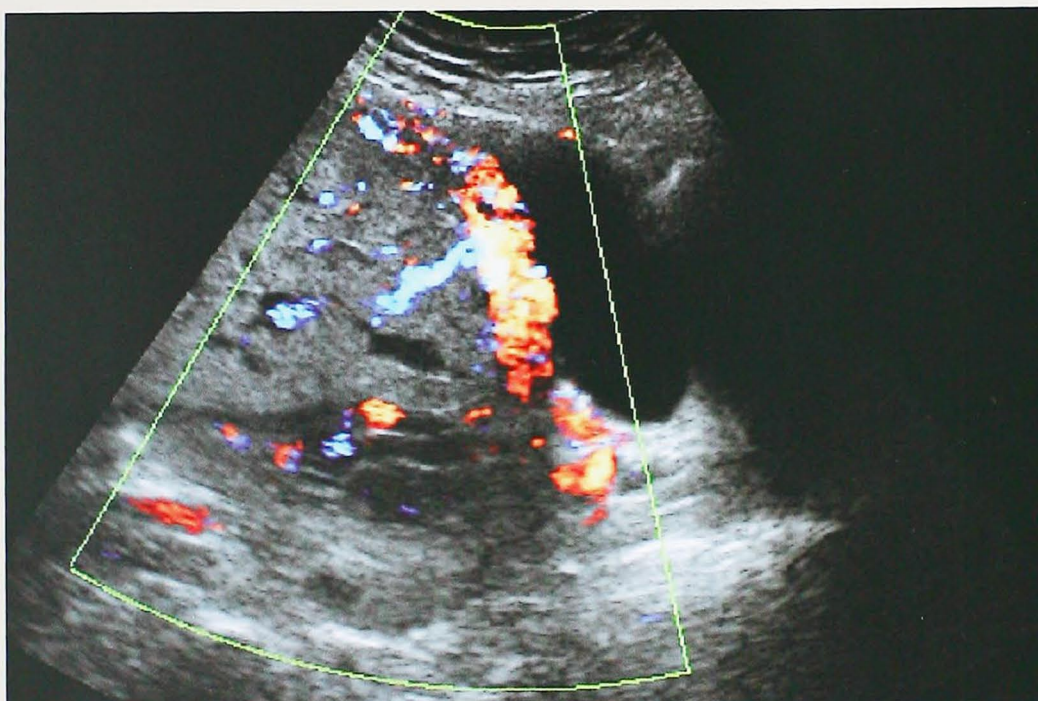
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Indeks Pearl'a komputerów cyklu Lady-Comp, Baby-Comp i Pearly stosowanych jako metoda antykoncepcji

The Pearl Index of Lady-Comp, Baby-Comp and Pearly cycle computers used as a contraceptive method

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Streszczenie

Komputery cyklu Lady-Comp, Baby-Comp i Pearly to urządzenia medyczne wykorzystujące zaawansowane metody statystyczne i własną bazę danych produkowane i dystrybuowane na całym świecie od ponad 25 lat przez firmę Valley Electronics GmbH (Eschenlohe, Bawaria, Niemcy). Służą do precyzyjnego określania fazy płodnej i niepłodnej w cyklu kobiety na podstawie pomiarów temperatury w jamie ustnej.

Cel. Celem badania było określenie skuteczności antykoncepcyjnej urządzeń przez wyznaczenie indeksu Pearl'a.

Materiał. Na podstawie danych adresowych dystrybutora urządzeń wybrano losowo próbę 510 Polek, które stosowały urządzenia w okresie dłuższym niż 1 rok lub powyżej 13 cykli.

Metoda. Badanie przeprowadzono za pomocą techniki ankietowej. Wykorzystano metody statystyki opisowej w zakresie obliczenia średniej arytmetycznej, wariancji, odchylenia standardowego oraz statystyki pozycyjne w zakresie obliczenia mediany i dominanty. Indeks Pearl'a wyliczono na podstawie ilorazu liczby nieplanowanych ciąży i całkowitej liczby cykli stosowania metody przez kobiety objęte badaniem, a następnie otrzymaną wartość pomnożono przez 1300.

Wyniki. Otrzymano 139 prawidłowo wypełnionych ankiet. Uzyskano dane o 3332 cyklach. W toku dalszej analizy odrzucono 290 cykli pochodzących od użytkowniczek nie stosujących się do wskazań komputera cyklu oraz 1002 cykle, które pochodziły od użytkowniczek stosujących równolegle inną formę antykoncepcji (w grupie tej nie obserwowano żadnej nieplanowanej ciąży). W grupie 2040 cykli zaobserwowano 1 nieplanowaną ciążę. Wyliczony indeks Pearl'a wynosi 0,64, czyli niecałe 7 użytkowniczek z 1000 może zajść w nieplanowaną ciążę w okresie 1 roku stosując prawidłowo komputer cyklu w celach antykoncepcji. Wyliczono także prawdopodobieństwo zajścia w ciążę u kobiet stosujących w fazie płodnej cyklu prezerwatywy. Spośród 100 kobiet stosujących w okresie 1 roku komputery cyklu i prezerwatywę w fazie płodnej, w nieplanowaną ciążę zajdzie nieco ponad jedna kobieta.

Wnioski. Uzyskana wartość indeksu Pearl'a, czyli skuteczności antykoncepcyjnej komputerów cyklu jest porównywalny z indeksem Pearl'a antykoncepcji hormonalnej. Wysoka skuteczność metody pozwala na jej rekomendowanie kobietom, szczególnie tym, które nie chcą lub nie mogą stosować innych form antykoncepcji.

Słowa kluczowe: indeks Pearl'a, antykoncepcja, metoda termiczna, komputer cyklu

Abstract

Introduction: Lady-Comp, Baby-Comp and Pearly cycle computers are medical devices that use sophisticated statistical gathering methods, as well as a comprehensive database, to precisely determine fertile and infertile phases of a menstrual cycle on the basis of everyday basal body temperature measurements. They have been produced and distributed worldwide by Valley Electronics GmbH (Eschenlohe, Bavaria, Germany) for over 25 years.

Objectives: The aim of the study was to calculate the Pearl Index of cycle computers to determine their contraceptive effectiveness.

Material and methods: 510 Polish women, randomly chosen from the database of the distributor, who had been using the device for over one year or during 13 menstrual cycles, received a questionnaire. The Pearl Index was calculated as a quotient of the number of unplanned pregnancies and the total number of cycles during which cycle computers were used and the obtained value was then multiplied by 1300. Statistics methods were applied to analyze data from the questionnaires and calculate the Pearl Index. Unplanned pregnancy odds ratio for women using additionally condoms during the fertile phase of the cycle was also calculated.

Results: 139 properly filled questionnaires were the source of data about 3332 cycles. After the initial analysis, 290 cycles were declined because the respondents had not complied with the computer instructions and 1021 cycles were declined because the respondents had been using other contraceptive methods at the same time - no unplanned pregnancy was noted in that group. In the investigated group of 2040 cycles of correct cycle computers usage, one unplanned pregnancy was observed. Calculated Pearl Index for this group amounted to 0.64; it means, that less than 7 out of 1000 users of cycle computer as a contraceptive method may become pregnant within one year. The odds of pregnancy in women using a cycle computer and condoms on fertile days amounted to 1,035%; it means that 1 out of 100 users of the combined methods may become pregnant within one year.

Conclusions:

The Pearl Index value of cycle computers is comparable with the Pearl Index of hormonal contraceptives. Cycle computers offer an effective and drug-free method of contraception to all women who wish to limit interventions in their bodily functions and do not want or cannot use other contraceptive methods.

Keywords: Pearl Index, contraception, thermal method, cycle computer

Introduction

Advances in the field of information technology and quantitative methods in the last decades have enabled to introduce new technologies which are applied to determine the fertile phase of a woman's menstrual cycle. Nowadays it is possible to avoid unplanned pregnancy or to plan the pregnancy precisely due to accurate identification of subsequent phases of a menstrual cycle. Cycle computers, created solely for that purpose, are medical diagnostic devices whose main function is to determine the phases of the cycle on the basis of basal body temperature measurement. The devices identify the possibility of conception at a given time by analyzing the obtained data. The aim of the study was to estimate the Pearl Index and determine the effectiveness of cycle computers used as a contraceptive method.

Material

139 anonymous questionnaires returned by users of cycle computers from all over Poland were used for the study. 510 questionnaires were sent altogether at the end of April, 2010. The respondents were randomly chosen from the database of the Polish distributor of Valley Electronics GmbH products. The questionnaires were anonymous and did not include any personal data, including age, which might help to identify the respondent. 100 is the required number of questionnaires necessary to calculate the Pearl Index correctly. On the basis of the information regarding average time duration of using cycle computers by Polish women, namely two years (25 cycles), the following assumption was made: 100 (20%) of returned questionnaires would comprise the study group of 2600 cycles. In the end, 139 questionnaires (3523 cycles) were returned which resulted in data on 3332 cycles from 119 respondents using the device for ≥ 13 cycles .

Methods

Cycle computers are CE Approved Medical Devices (CE 0124 DEKRA Certification; no. 51210-16-00), produced for over 25 years by Valley Electronics GmbH (Eschenlohe, Bavaria, Germany) and entered into the Polish Register of Medical Devices and Persons Responsible for Placing Them on the Market and Putting into Service, in accordance with Art. 54 of 20 April 2004 Act on medical devices (Journal of Laws 93/896, as amended), recorded under number PL/DR 019246 for Baby-Comp, PL/DR 019028 for Lady-Comp and PL/DR 019245 for Pearly [1].

Cycle computer operation (presented in the table below) is based on determining the fertile and infertile cycle phases of a menstrual cycle on the basis of basal body temperature measurements (thermal contraceptive method).

Table I. Comparison of cycle computers

	Pearly	Lady-Comp	Baby-Comp
Effectiveness	99,3%	99,3%	99,3%
Pregnancy	Confirms pregnancy 18 days after conception	Indicates probability of pregnancy 15 days after conception; Confirms pregnancy 18 days after conception	Signals the possibility of pregnancy 4 days after conception; Indicates probability of pregnancy 15 days after conception; Confirms pregnancy 18 days after conception
Data available	from 99 days	from 180 days	from 250 days
Cycle statistics	Not available	Number of cycles Average length of a cycle Average temperature peak Ovulation range	Number of cycles Average length of a cycle Average temperature peak Ovulation range Average length of the luteal phase Information on anovulatory cycles Information on corpus luteum insufficiency Information on intercourse
Dimensions	Oval shape; 7x10 cm; 2,5 cm / Height	Round shape; 14cm / Diameter; 3cm / Height	Round shape; 14cm / Diameter; 3cm / Height
Weight	52gr	200gr	200gr
Power source	Built-in battery with lifetime of 2 to 3 years	Built-in rechargeable battery; power adapter	Built-in rechargeable battery; power adapter
Display	LCD (Non-backlit) display	Backlit color display	Backlit color display
Software	Not available	Possibility of converting the device into Baby-Comp	Not available

Each device has a built-in software that had been generated on the basis of basal body temperature measurements collected from cycle computer users in over one million cycles over the last twenty five years. In the course of the first two to three cycles, the device ‘learns’ to identify fertile days of the cycle computer user by means of an algorithm that had been created on the basis of validation group. The temperature is taken every day immediately upon waking up in the oral activity with a sensor that constitutes an integral part of the device. The cycle computer diagnoses when the fertile phase starts, predicting it six days prior to ovulation and taking into account the 5-day sperm survival. The user, equipped with knowledge of her fertility on a given day, may influence her fertility by having intercourse only during the infertile phase of the menstrual cycle or abstaining from it, using a contraceptive barrier (condom) during the fertile phase of the cycle. The applied mathematical model, capable of learning and adaptation, ensures that the devices are not influenced by irregular life style of the users, infections, stress and lack of some measurements, etc., [2].

Research method

Evaluation of the cycle computers effectiveness was based on the Pearl Index calculation. According to literature, there are two methods of calculating the index:

- 1: the number of unplanned pregnancies from the study is divided by the total number of months the women had been using a given method; the result is multiplied by 1200 (the obtained number indicates the number of women with an unplanned pregnancy which occurred within a year of using cycle computers in a group of 100 women)
- 2: number of unplanned pregnancies from the study is divided by the total number of cycles of the users of a given method; the result is multiplied by 1300 (the obtained number indicates the number of women with an unplanned pregnancy which occurred within a year of using the device (13 cycles of 28 days) in a group of 100 women).

In the present study the second method, based on the number of cycles, was used to calculate the Pearl Index due to the fact that the respondents supplied information on the number of cycles [3].

The ratio between the number of unplanned pregnancies from the study group and number of cycles of all respondents who participated in the study and used cycle computers properly, was taken to calculate the Pearl Index. However, the number of unplanned pregnancies taken into consideration when calculating the Pearl Index must result from an absolute method error. That is, the pregnancy must be the direct consequence of an incorrect cycle computer indication that mistook the fertile phase for an infertile one (intercourse takes place during the infertile phase which the computer signals by displaying green color on the fertility display). Unplanned pregnancies resulting from user error, namely having sexual intercourse during the fertile phase, regardless of whether the user resorts to additional contraceptive methods, cannot be taken into account when calculating the Pearl Index.

The questionnaire included the following questions:

1. Which cycle computer do you use?
 - Pearly,
 - Lady-Comp,
 - Baby-Comp.
2. For how many cycles have you been using the cycle computer?
3. Have you been using any other contraceptive methods while using cycle computers?
 - YES (if yes, please answer questions 3.1. and 3.2.),
 - NO (if no, go to question 4).
- 3.1. Have you been using the additional contraceptive method:
 - throughout the entire time of using cycle computers – both in the fertile and infertile phase of the menstrual cycle,
 - only during the fertile phase of the menstrual cycle.
- 3.2. What additional contraceptive methods have you been using?
4. Do you always follow the instructions of the cycle computer?
 - YES
 - NO
5. During the time of using a cycle computer, did an unplanned pregnancy happen?
 - YES
 - NO

The abovementioned questionnaire was devised to evaluate method error, that is an unplanned pregnancy occurring as a result of having sexual intercourse during the fertile phase of the cycle which the computer signals with green color on the fertility display.

Cycle computers differentiate between the fertile and infertile phase, thus enabling safe intercourse without additional protection during the infertile phase. They also inform the user about the necessity to resort to temporary reversible contraceptive methods when having intercourse during the fertile phase or abstaining from sex altogether at that time.

All cases when the respondents reported resorting to additional contraceptive methods throughout the entire cycle were excluded from the study due to the fact that cycle computers effectiveness may not be assessed then. Moreover, all cases when unplanned pregnancy happened as a result of having intercourse during the fertile phase of the cycle and using temporary reversible contraceptive methods, were excluded as well as it is impossible to state which of the methods failed.

All in all, two groups of respondents were included into the study: women who did not have intercourse during the fertile phase and did not use any other contraceptive methods and those

who did not have intercourse during the fertile phase or used condoms only during the fertile phase (2040 and 2905 cycles, respectively).

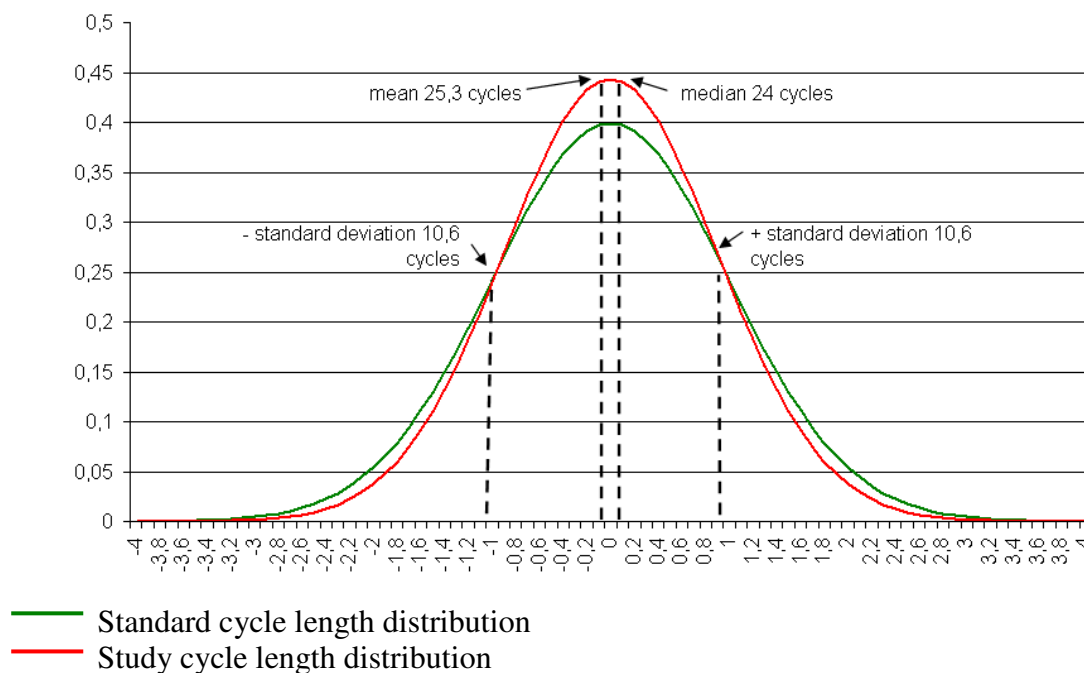
The responses were accepted as true, assuming that if a respondent gives the affirmative answer to question 4, it is in accordance with the actual state of things.

Results

139 properly filled questionnaires were returned. 139 respondents were using different cycle computers: 47 Pearly (34%), 70 Lady-Comp (50%) and 22 Baby-Comp (16%). The total number of cycles was 3523. 20 respondents (191 cycles in total) declared they had been using the device for <13 cycles and their data were not taken into account when calculating the Pearl Index regardless of the fact that, according to the distributor, the respondents had been in possession of the device for over one year.

The distribution of cycles from the study is similar to a normal distribution, with arithmetic mean of 25,3 cycles, median 24 cycles, standard deviation 10,6. The lengths of the cycles are centered around the value of 24-25 days, whereas the majority of measurements is taken between 13 and 39 cycles. The chart visualizing the study cycle length distribution is slightly more convex than normal distribution, with marginal asymmetric distribution on the right side.

Chart 1. Schematic comparison of the analyzed cycle length distribution and normal distribution



As far as the answers to question 3 are concerned, 41 respondents (35%) answered YES, meaning they had been using a different contraceptive method along side the cycle computer, whereas 78 respondents (65%) answered NO, meaning they had not been using any additional protection along side the cycle computer.

Out of the 41 respondents using additional contraceptive methods, 5 (12%) used the method during the fertile and the infertile phase of the menstrual cycle (3 – condom, 1 – coitus interruptus, 2 – no answer). The abovementioned 5 cases were excluded from the group for which the Pearl Index was calculated. Unplanned pregnancy happened in none of the 5 cases and each of the respondents stated she always followed the instructions of the cycle computer. 137 cycles altogether were excluded from the study. The remaining 36 women who took additional precaution (condom) only during the fertile phase of the cycle were included into

the calculation of odds ratio for pregnancy when using both methods, cycle computer + condom during the fertile phase.

107 (90%) respondents gave the affirmative answer to question 4. 12 (10%) women gave the negative answer, which meant they had had intercourse without any other protection also during the fertile phase of the menstrual cycle. Out of the respondents who declared they did follow the instructions of the cycle computer, 4 stated they had been using condoms. In the whole group of cycle computer users who did not follow the instructions of the device, 4 cases of unplanned pregnancy happened, 1 of them despite having used a condom.

5 (4%) respondents gave the affirmative whereas 114 (96%) the negative answer to question 5. Out of the 5 women with unplanned pregnancy which happened while they were using cycle computers, 4 declared they did not follow the instructions of the device (negative answer to question 4). Therefore, the unplanned pregnancy cannot be blamed on the faulty reading of the cycle computer (these respondents did not take into account the instructions of the device) and had sexual intercourse despite the fact the computer signaled the fertile phase of the cycle.

In the remaining 1 case, the respondent declared she had always followed the instructions of the cycle computer but got pregnant nevertheless.

Essential data for calculating the Pear Index are presented in Table 2.

Table 2. Source data from the questionnaires

Total number of cycles from the survey:	3523
Number of cycles of respondents using cycle computers for <13 cycles in the course of <12 months:,	191
Number of cycles of respondents using cycle computers > 13 cycles:	3332
Number of cycles of respondents that did not follow the instructions of the cycle computer:	290
Number of cycles of respondents that followed the instructions of the cycle computer:	3042
Number of cycles of respondents that followed the instructions of the cycle computer and used additional contraceptive methods, among them:	1002
Number of cycles during which the respondents used additional contraceptive methods throughout the entire menstrual cycle	137
Number of cycles during which the respondents used additional contraceptive methods only during the fertile phase of the menstrual cycle	865
Number of cycles of respondents that followed the instructions of the cycle computer and did not use any additional contraceptive method (1 unwanted pregnancy)	2040

The effectiveness of cycle computers measured by the Pearl Index was calculated in the following way:

$$\text{Pearl Index} = \frac{1}{2040} \cdot 1300 = 0,64$$

The obtained result signifies the effectiveness of the method is 0.64, what might be interpreted in the following way: out of 100 women using only cycle computers as a

contraceptive method in the course of one year (13 cycles), an unplanned pregnancy will happen to 0,7 woman. In other words, 7 out of 1000 users of cycle computers using the device as a contraceptive method in the course of one year (13 cycles) will become pregnant without planning.

Complementing the fraction (which is the result of the Pearl Index calculation) to a full number allows to say that the effectiveness of the method in absolute terms is 99,3% [4,5,6]. Due to the fact that every third user of cycle computers as a contraceptive method declares she had been using additional protection (condom) during the fertile phase of the cycle, the effectiveness of the method may be calculated as product of probability of both methods. Taking into account the period of time during which each method is used, joined theoretical probability of pregnancy in the entire cycle will be the weighted average of both probabilities, with the quotient of time of using a given method and the average total cycle length (28 days) as weights, as presented in the diagram below.

Phase of the cycle	infertile phase	fertile phase
Average number of days	20	8
Contraceptive method	only cycle computer (no additional protection)	condom
Pregnancy odds ratio	0,0064	0,02

Assuming that 2% is the mean value of the odds ratio of unplanned pregnancy while using condoms (advertised by the manufacturers for the entire cycle, the fertile and infertile phase) it is possible to calculate the probability of unplanned pregnancy while using cycle computers and condoms during the fertile phase:

Unplanned pregnancy odds ratio using a cycle computer and condoms during the fertile phase

$$= \frac{20}{28} \cdot 0,0064 + \frac{8}{28} \cdot 0,02 = 1,029\%$$

1,029% is the obtained result of calculating the probability of pregnancy while using a cycle computer and condoms during the fertile phase and it means that a little over 1 woman out of 100 users of cycle computers and condoms during the fertile phase of the menstrual cycle will in fact get pregnant.

Discussion

The result of the Pearl Index calculation obtained in the present study (0,64) is comparable to that advertised by the manufacturer. Freundl et al., reported a slightly higher result of 0,7 [4]. There are two reasons for the improved effectiveness of cycle computers. First of all, it has been over 10 years since the research of Freundl et al. was carried out. In the last decade, the cycle computers software has been significantly modified and the amount of historical data has risen. Second of all, the present study group (139 questionnaires, 3332 cycles) was rather small what might have influenced the efficiency. However, taking into account the distribution of the cycle length, almost identical to the normal distribution, the study sample was properly selected and is representative of the entire population.

The obtained result proves high effectiveness of cycle computers used as a contraceptive method. It needs to be emphasized that the Pearl Index from the present study (0,64) and the result advertised by the manufacturer (0,7) are highly satisfactory and comparable with the effectiveness of other contraception methods. Literature on the subject reports the Pearl Index of a contraceptive pill to be between 0,0 – 2,5 (gestagenic mini-pills 2,0-2,5), contraceptive patch: up to 1,0, intrauterine device: 0,5 – 3,0, contraceptive implant: 0,2 - 0,3 and condom: approximately 2,0 [7]. The lower value of the Pearl Index refers to ideal usage of the method and the higher value to normal usage, allowing for minor mistakes of the users. The calculated value for cycle computers means they are highly effective in recognizing the phases of a menstrual cycle and their usage is connected with risk similar to that of other known contraceptive methods [8,9]. High effectiveness of cycle computers applies also to pregnancy planning. Correct identification of the fertile phase enables couples struggling to get pregnant to increase the probability of achieving pregnancy by precise identification of the fertile phase and the ovulation. Correct identification of the fertile phase allows the intercourse to take place at the time when the probability of effective conception is highest. Knowledge of fertility makes it possible to influence the date of birth by planning the conception. Conception planning is particularly important because it allows to avoid seasons of the year when the risk of systemic infections, that might influence the proper development of the fetus in the first trimester of pregnancy, is increased.

What is more, cycle computers are eco-friendly devices as their usage does not influence the environment in any way, contrary to hormonal methods. The hormones that are removed and excreted from the body are non-biodegradable and in the process of sewage treatment they find their way to surface waters, influencing the fauna and flora directly, and human beings indirectly.

All of the abovementioned arguments are the reason why cycle computers are more frequently used in countries where care for the environment and health of the citizens is taken very seriously, chief among them Scandinavian countries, particularly Norway, where the ratio between cycle computers sale and population is the highest.

Cycle computers are sold in over 30 countries all over the world. Country members of the European Union have had continuous rise in the sales of these devices, with Germany and Switzerland at the top of the list. Also USA, Canada, Australia and New Zealand [10] have the highest result of cycle computers sales. Recently, China and Japan have joined the group of countries where cycle computers are sold.

Conclusions

On the basis of the result of the present study it is safe to conclude that cycle computers proved to be a safe method of contraception. Proper usage of cycle computers, in compliance with the device instructions, allows to avoid unplanned pregnancy.