ORIGINAL ARTICLE

CONTENTS

Effectiveness of using ferning of the dried saliva crystallization to determine the fertile window in women with idiopathic infertility

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ABSTRACT
Aim: To evaluate the effectiveness of determining the fertile window in women with idiopathic infertility based on the results of crystallization of saliva samples obtained using the Ovul portable device with a mobile application by comparing them with the results of urine test strips and folliculometry data.
Materials and Methods: The menstrual cycles of 42 women with idiopathic infertility were analyzed: Group I - 21 women who took drugs to induce ovulation, Group II - 21 women with natural menstrual and ovarian cycles. Ovulation was confirmed or excluded based on the results of the Ovul device, urine test strips, and folliculometry.
Results: Although ovulation detection using the Ovul device and urine test strips has 100% specificity, the sensitivity of the device is 97.4%and the accuracy is 97.6% (if the positive result is ovulation or the fertile window), while for urine test strips the sensitivity is 94.9% and the accuracy is 95.2% if we consider a positive result not only to be the same as the day of ovulation according to folliculometry, but also a positive result within the next 72 hours (mainly 12-24).
Conclusions: Ovulation detection using the Ovul device is a highly accurate, 100% specific and highly sensitive method that can be used at home, will optimize diagnostics, make it more convenient and cheaper for patients who want to get pregnant or, on the contrary, who are trying to avoid pregnancy.

KEY WORDS: infertility, saliva, ovulation, female fertility, folliculometry, ferning

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INTRODUCTION

The prevalence of infertility among couples of reproductive age is 17.5% worldwide, meaning that approximately one in six people in the world have trouble conceiving [1], which demonstrates the urgent need to expand access to affordable, high-quality fertility treatments for all who need them. The new data show no significant differences in infertility prevalence rates by world region. In high-, middle-and low-income countries, the rates are comparable, meaning that infertility is a serious health problem for all countries and territories. It can cause considerable stress, stigma, and financial hardship and negatively impact mental and social well-being [2]. WHO Director-General Dr. Tedros Adhanom Ghebreyesus stated in his annual report 2023 that the vast number of people who have infertility highlights the need to expand access to fertility treatment and to take steps to ensure that this topic is no longer sidelined in research and health policy, allowing access to safe, effective and affordable types of fertility care that will help all those who want to become parents [1].

The inability to make a specific diagnosis of infertility is related to the depth of testing, i.e. this diagnosis is made as an exception to proven pathology (male infertility, anovulatory infertility, fallopian tube obstruction, endometriosis, uterine cavity defects, etc.) More detailed testing will likely reveal pathologies leading to alternative diagnoses. Thus, the data on the prevalence of unexplained infertility are subjective and highly variable, as they depend on the criteria and methodologies of testing [3].

The most important clinical aspect in the treatment of unexplained infertility is the choice between a waiting strategy stimulated by intrauterine insemination or in vitro fertilization as a first-line treatment option [4].

According to the recommendations of the European Society for Human Reproduction and Embryology (ESHRE), the mandatory tests for diagnosing indeterminate infertility are ejaculate analysis, evaluation of fallopian tube patency, evaluation of the uterine cavity, evaluation of the luteal phase, and ovulation [5].

Detecting and monitoring ovulation has long been practiced by women who want to become pregnant/

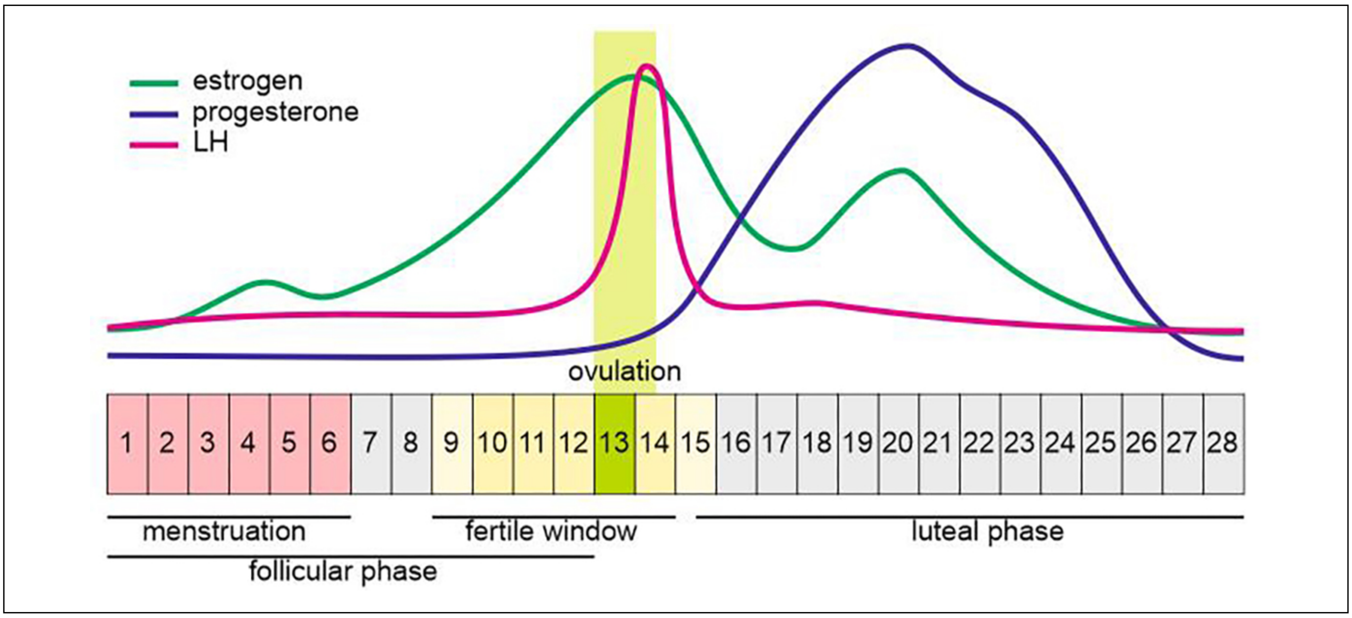

Fig. 1. Phases of the menstrual cycle by day with the corresponding hormone change charts: estrogen, progesterone and lethalizing hormone (LH)

avoid pregnancy/have fertility problems. In addition, the fertility window (Figure 1), which begins about 3-5 days (sperm life span) before ovulation and lasts about 1-2 days (oocyte life span) after ovulation, is essential. Identifying this window, not just detecting ovulation, is important for using or not using contraception. For doctors or women who want to know if their menstrual cycle is normal or to assess ovarian function, a test that retrospectively confirms ovulation may be sufficient. However, for assisted reproductive methods, the time of ovulation and the fertility window must be clearly defined [6].

Determining ovulation to increase the chances of conception has three main goals:

1) to confirm the presence or absence of ovulation (anovulation) in a reproductive cycle, 2) to confirm the day on which ovulation occurred, and 3) to use this day of ovulation in one reproductive cycle to predict the date of ovulation and the "fertility window" for the next cycle to improve the chances of natural conception or the timing of intervention [7].

Several methods for determining ovulation have advantages and disadvantages, including the calendar method, basal temperature, cervical mucus examination, urine test strips, and folliculometry. It is worth noting that the female cycle and ovulation can vary significantly from woman to woman. Different methods of ovulation detection allow for an individualized approach for each woman, contributing to the effectiveness of infertility treatment and pregnancy planning.

Research on the effectiveness of different ovulation confirmation methods is lacking, and many of the studies that support other methods are based on small samples and uncontrolled studies. Even fewer studies have included women with irregular menstruation, which is characterized by less predictable ovulation times. The following women significantly benefit from improved ovulation predictions [6].

In 56.1% of studies that required confirmation of ovulation, serum progesterone levels in the middle of the luteal phase were used for this purpose (Fig. 1). Regular menstruation was evidence of ovulation in 42.4% of studies, and 16.6% used basal body temperature measurements. The European Society for Human Reproduction and Embryology (ESHRE) guidelines for unexplained infertility support the use of urinary luteinizing hormone (LH) monitoring with accuracy and concordance with ultrasound results of 97-100%.

Evidence supports the use of transvaginal ultrasound scans as a reference standard. Evidence for the use of regular menstruation is mixed, and basal body temperature measurement is outdated and has been shown to be inaccurate. The ESHRE guidelines recommend that ovulation testing is not necessary for women with regular menstrual cycles and that if testing is required, follicular ultrasound, urinary LH, or mid-luteal progesterone is recommended. They do not support the use of basal temperature [5].

Among the evidence-based approaches that can be used at home to assess ovulation, urinary luteinizing hormone (LH) tests are common, which determine the peak of LH in the middle of the cycle, 1-2 days before ovulation. An alternative method of optimizing fertility naturally and assessing ovarian function is to monitor changes in cervical mucus during the fertility period. Both methods are tools for predicting the approach of

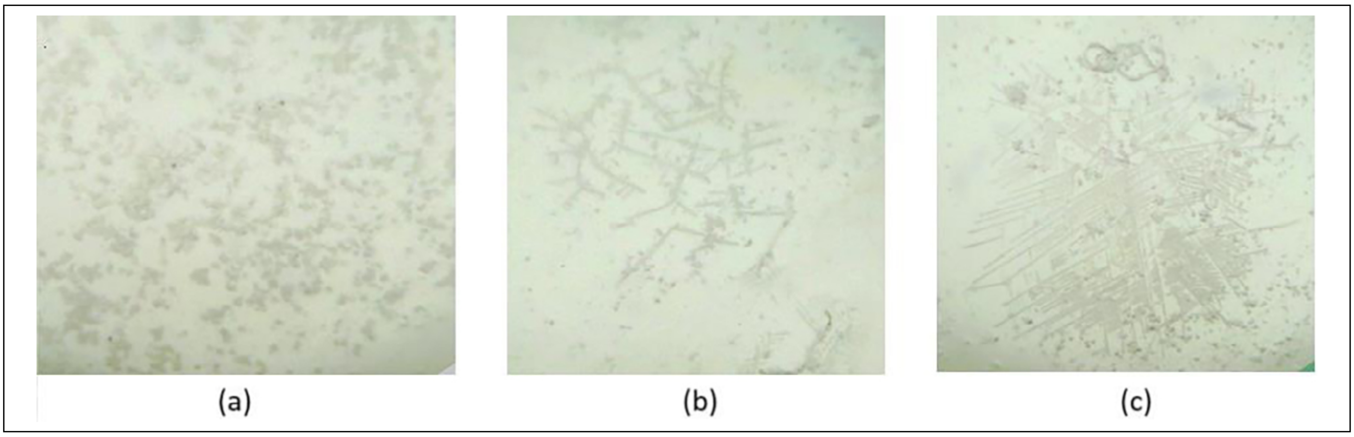

Fig. 2. Microscopic pictures of the crystallization of dried saliva. (a) - when estrogen secretion is very low; (b) - moderate estrogen secretion; (c) - ovulation period, when estrogen peak occurs

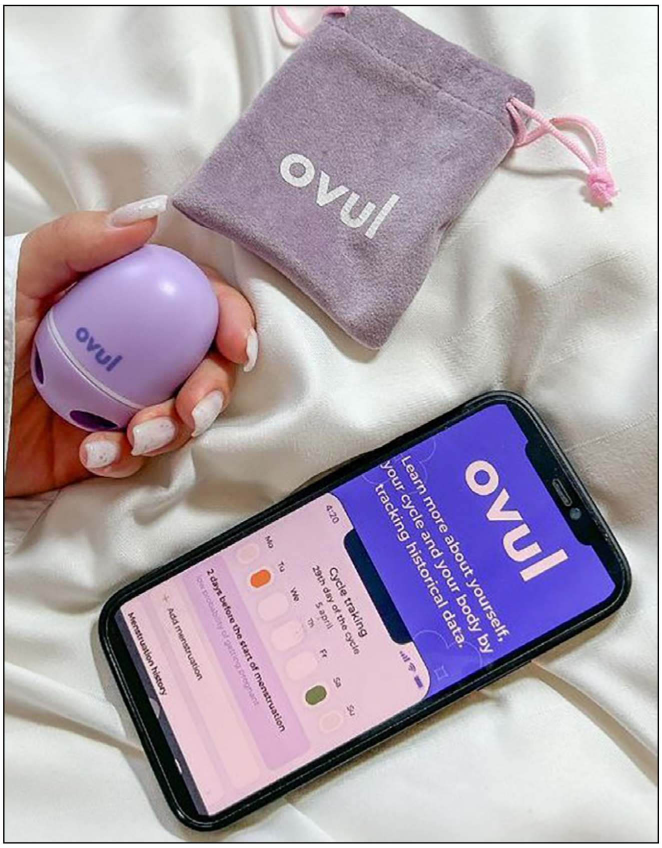

Fig. 3. The Ovul device, which is designed to track ovulation by monitoring the ferning effect in dried saliva samples

ovulation. Confirmation that ovulation has already occurred can currently be determined only by laboratory analysis of serum progesterone (with an approximate cost of $50 per test) or with serial transvaginal ultrasound (with an estimated cost of USD 300 per procedure). In addition, both tests require a visit to a doctor and specialized laboratory testing, and in the case of ultrasound, this is not always possible due to high costs and material and technical limitations [8].

For the first time, the "ferning" phenomenon was discovered in cervical mucus. The study of cervical mucus suggests using another fluid that changes during the respective cycle, i.e., saliva. Many studies have been conducted on determining the ovulation period by measuring the levels of estrogen or progesterone (Figure 1) in saliva, and it has been proven that the patterns of these two hormones in saliva reflect changes in the blood. Other studies show that saliva has many characteristics in common with cervical mucus; for example, it contains salts (especially NaCl), estrogens, and mucus, which are involved in the formation of fern patterns. Therefore, both fluids can be used to monitor ovulation.

The ferning phenomenon is influenced by estrogen and progesterone. During the follicular phase of the normal menstrual cycle, the level of estrogen in saliva increases in accordance with the increase in blood estrogen levels. The interaction of estrogen with mucus NaCl leads to the appearance of crystallization in saliva, which resembles fern patterns. The higher the level of estrogen, the more pronounced the fern patterns. Based on the fern-like structure of cervical mucus and saliva throughout the menstrual cycle, the cycle can be divided into 3 phases. The first phase (day 1 to day 7) does not show fern patterns, which corresponds to low estrogen levels; in the second phase (day 8 to day 21), estrogen levels increase and peak when ovulation is approaching, and the most distinctive fern pattern appearance is noted. In the last phase (after ovulation), the "fern" begins to disappear, and the patterns no longer resemble fern leaves.

After drying, the mucus has a characteristic fern-like pattern appearance microscopically:

1. No pronounced crystallization (when estrogen secretion is very low) (Fig. 2, a).
2. Separate, distinct crystals of rectilinear shape (moderate estrogen secretion) (Fig. 2, b).
3. Pronounced crystallization with fern patterns, long linear crystals at 90 degrees (ovulation period, when estrogen peak occurs) prevails (Fig. 2, c).

It is necessary to consider circadian rhythms that can affect the composition of saliva, including estrogen and

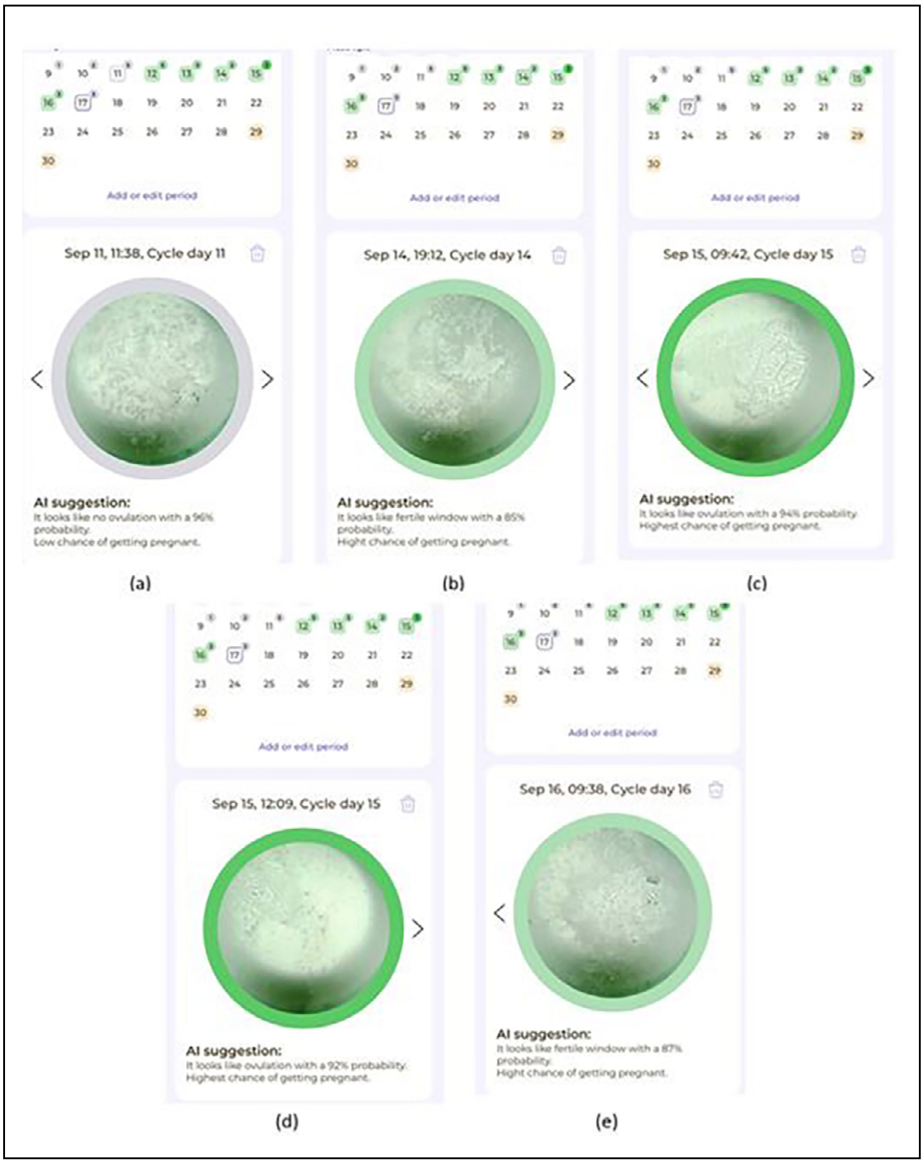

Fig. 4. An example of the display of results in the Ovul mobile application during the patient's cycle. (a) - NO – no ovulation; (b, e) - FW – fertile window; (c, d) - O – ovulation

progesterone hormones. The right time to perform a saliva test is in the morning before teeth brushing. The use of the saliva ferning test has been shown to be more effective than cervical mucus monitoring.

Changes in basal body temperature can be an indicator of ovulation, while the fern patterns have temporal specificity from day 11 to day 16. Since saliva also displays a fern pattern and is easy to collect, it can be used to assess fertility status [9]. Hence, monitoring the ferning density in dried saliva can be considered the easiest way to monitor the fertile period in women.

If the saliva ovulation test is visually assessed by the patient, the result is very subjective. A specialist's interpretation is more accurate. Artificial intelligence (AI) is gaining acceptance in medicine, and one of its main applications in healthcare is the ability to accurately interpret complex medical data with human-like precision and speed. Advances in microelectronics and machine learning have allowed current AI-based methods to work equally well on portable systems, especially smartphones. More than 4.4 billion people worldwide use smartphones, making them an excellent candidate for developing healthcare technologies [10].

Determining the moment of ovulation is important both in planning a natural pregnancy and in induced cycles when using assisted reproductive technologies; for example, determining the moment of ovulation is key to scheduling the intrauterine insemination procedure.

AIM

To evaluate the effectiveness of determining the fertile window in women with idiopathic infertility based on the results of crystallization of saliva samples obtained using the Ovul portable device with a mobile application by comparing them with the results of urine test strips and folliculometry data.

Table 1. Features of menstrual function in the examined women (M±m)

Indicator	Group	
	I, n=21	II, n=21
The age of the menarche	12.3±1.2	13.0±1.2
Cycle duration	29.5±3.2	31.5±2.5
Bleeding duration	5.0±1.1	4.8±1.1
Start of sexual activity	19.0±3.4	18.6±2.8

Note: $p>0.05$ - significance of differences between groups I and II

MATERIALS AND METHODS

The data were obtained during the examination of patients treated at the Clinic for Reproductive Technologies of the Shupyk National Healthcare University of Ukraine (CRT of the Shupyk National Healthcare University of Ukraine) for the period from August 2023 to November 2023. Forty-two women with infertility of unexplained genesis who met the inclusion criteria and signed a voluntary informed consent to participate in the study were selected. We analyzed the results of 42 menstrual cycles in women with idiopathic infertility who monitored ovulation by monitoring the results: Ovul device, urine test strips, and ultrasound diagnostics (folliculometry).

To monitor ovulation, at the end of the first phase of the cycle (day 10), after the ultrasound examination, women were given an Ovul device for home use and instructed on how to use it. They were also given disposable urine test kits to determine ovulation.

The Ovul fertility tracker (manufactured by Ovulio Corp., USA) (Fig. 3) is designed to determine ovulation by tracking the ferning effect in dried saliva samples at home. This device is a convenient, cost-effective, non-invasive, and simple way to determine ovulation. It is safe and understandable for every woman. The advantages of the device are that all data is processed automatically, and the result is sent via Wi-Fi to the mobile application, supplemented by artificial intelligence suggestions for interpretation, where it can be saved as additional information when tracking the woman's cycle.

The Ovul device (registered trademark of Ovulio Corp., USA) is a plastic product stylized as an egg, which consists of two parts that are detachable from each other (Fig. 3). The upper part of the device has a macro camera with a frontal illumination system that takes pictures of samples and color indication elements of the device's functioning. In the center of the lower part of the device is an object glass. The principle of operation of the device is based on the visual detection of crystallized salts in the form of fern patterns in dried saliva samples, which indicates that the saliva sample was taken during the fertile days of the menstrual cycle, as this well-known phenomenon is associated with an increase in the concentration of salts in saliva under the influence of their increased content during ovulation. The results are automatically processed and sent to the customer's mobile application, which looks like a women's cycle calendar with additional functions that become available due to the possibility of daily testing of saliva samples with the Ovul device. All results are supplemented by artificial intelligence suggestions for interpreting the images, which greatly simplify the user's final decision. The kit includes a charging cable, pouch, cleaning cloth, and user manual.

Each woman performed the test with the Ovul device twice a day on the 10th, 12th, 13th, 14th, and 15th/16th day of her menstrual cycle. Simultaneously with the Ovul test, a urine test for ovulation was performed. On the same days, all women came for the folliculometry to control the growth of the dominant follicle.

The results of folliculometry were presented as: DF – dominant follicle on the right/left (15-17 mm in size); SO – superovulation, two dominant follicles (16-19 mm in size); ADF – no dominant follicle (up to 15 mm in size); O – ovulation, a small amount of fluid in the ectopic space is visualized, a decrease in the size of the dominant follicle; NO – no ovulation occurred (no signs of ovulation were detected).

Results of the urine ovulation test: P – positive, N – negative.

The dominant result (within one day) according to the recommendations of the Ovul device: O – ovulation (crystal formations have predominant rectangular shapes, like fern patterns, Fig. 4 c, d); FW – fertile window – crystal formations are weakly expressed, or multidirectional patterns prevail (Fig. 4 b, e); NO – no ovulation – no clearly expressed crystal formations (Fig. 4a). If a suggestion was received regarding insufficient material, the test was repeated.

The examined patients were divided into two groups. Group I - 21 women who took drugs to induce ovulation (aromatase inhibitors or recombinant gonadotropins). Group II - 21 women who did not take drugs but had natural menstrual and ovarian cycles. The women involved in the study did not use ovulation triggers.

The analysis of anamnestic data consisted of an assessment of the menstrual cycle (age, onset of men-

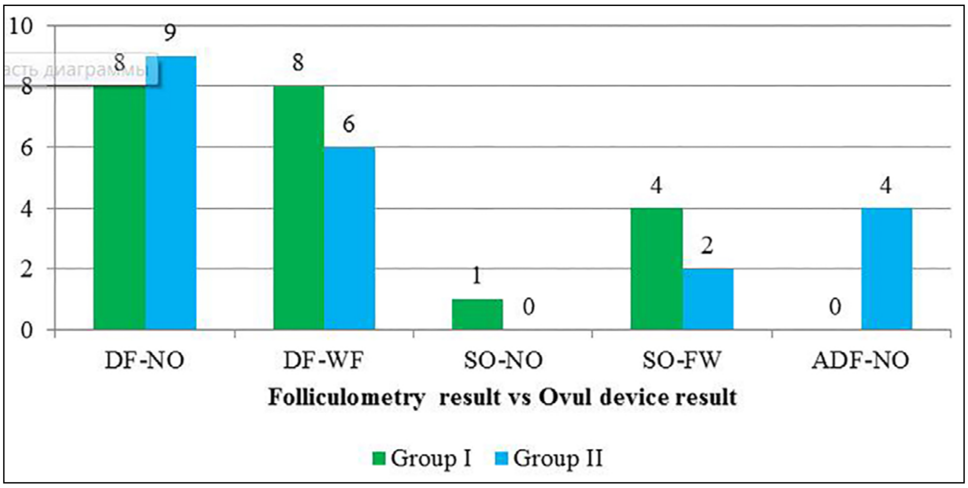

Fig. 5. Comparison of the results of folliculometry and of the Ovul device on the 10th day of the cycle, with the specified number of patients

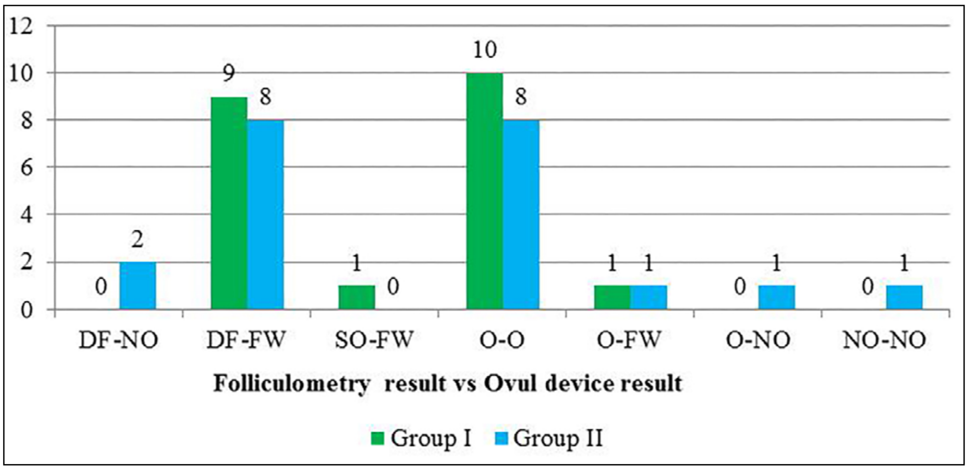

Fig. 6. Comparison of the results of folliculometry and of the Ovul device on the 12th day of the cycle, with the specified number of patients

arche, nature, duration, and regularity). A detailed analysis of past gynecological diseases and conservative and surgical treatment was carried out. Attention was paid to all possible factors that could affect ovulation: age, changes in the duration of the menstrual cycle, ovarian surgery, and past urogenital infections. A detailed assessment of extragenital diseases was carried out. All patients underwent a standard physical examination, a gynecological examination, including an examination of the external genitalia, an examination of the vagina and vaginal cervix in mirrors, and a bimanual examination.

The conduct of the study was approved by the ethics committee of the Shupyk National Healthcare University of Ukraine., the work is a fragment of the Scientific research work "Improving tactics of preconception counseling and management of early pregnancy of women with reproductive health disorders" (state registration number 0124U001616). All women gave informed consent to participate in the study.

The methods used in biomedical statistics were used to calculate the results. The data were processed using the StatSoft Statistica 8.0 software package and the statistical functions of «Microsoft Excel 2016».

RESULTS

The average age of patients was 34.4 ± 3.6 years and 32.6 ± 2.5 years in groups I and II, respectively.

The analysis of anthropometric data revealed no differences in body weight and body mass index (BMI) in the groups of women. The average body weight was 66.0 ± 12.9 kg and 64.9 ± 11.5 kg in groups I and II, respectively ($p>0.05$). Body mass index was 24.0 ± 4.5 kg/m2 and 23.0 ± 3.9 kg/m2, respectively ($p>0.05$).

Socio-economic characteristics (level of education, marital status, presence or absence of work, place of residence), as well as the presence of bad habits in patients (smoking), did not differ by group.

When assessing menstrual function (age of menarche, duration of the menstrual cycle, duration of menstrual bleeding), no statistically significant differences were found between the groups (Table 1).

A normal menstrual cycle was observed in 89.9% of patients in group I and 91.2% in group II. Menstrual irregularities in the form of oligomenorrhea were observed in 5 patients (9.1%) in group I and 4 patients (8.8%) in group II ($p>0.05$).

All women were examined for fallopian tube patency by X-ray-salpingography and sonosalpingography, and

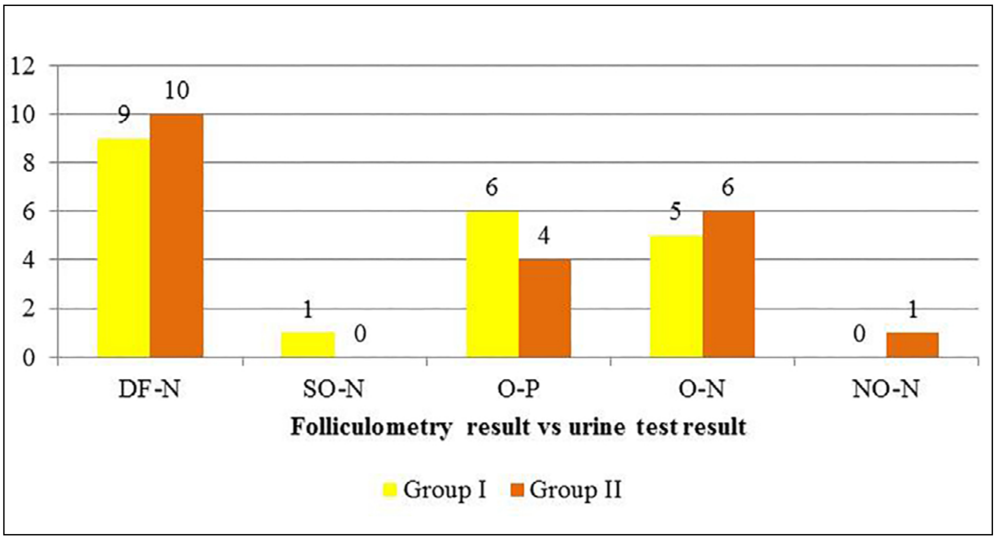

Fig. 7. Comparison of the results of folliculometry and of the urine test strips on the 12th day of the cycle, with the specified number of patients

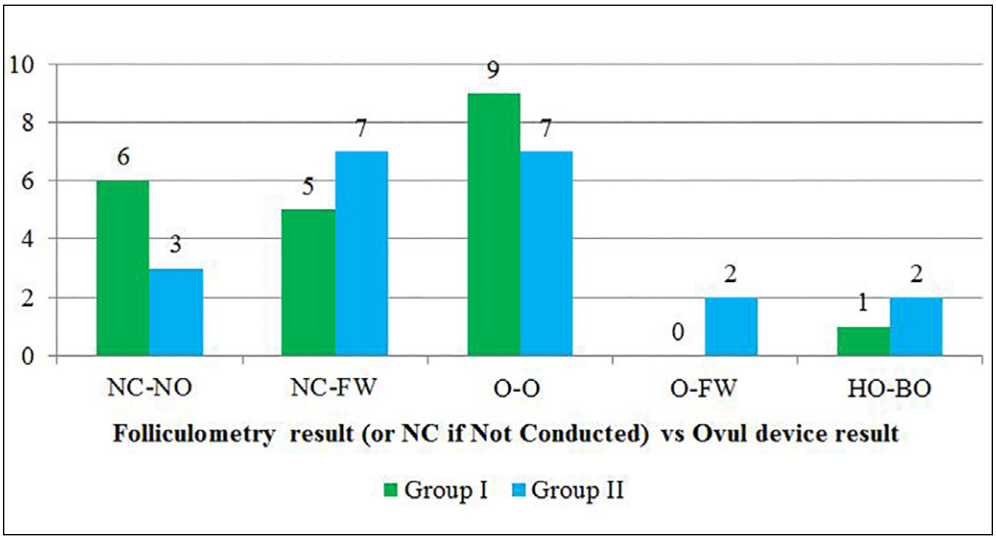

Fig. 8. Comparison of the results of folliculometry and of the Ovul device on the 14th day of the cycle, with the specified number of patients

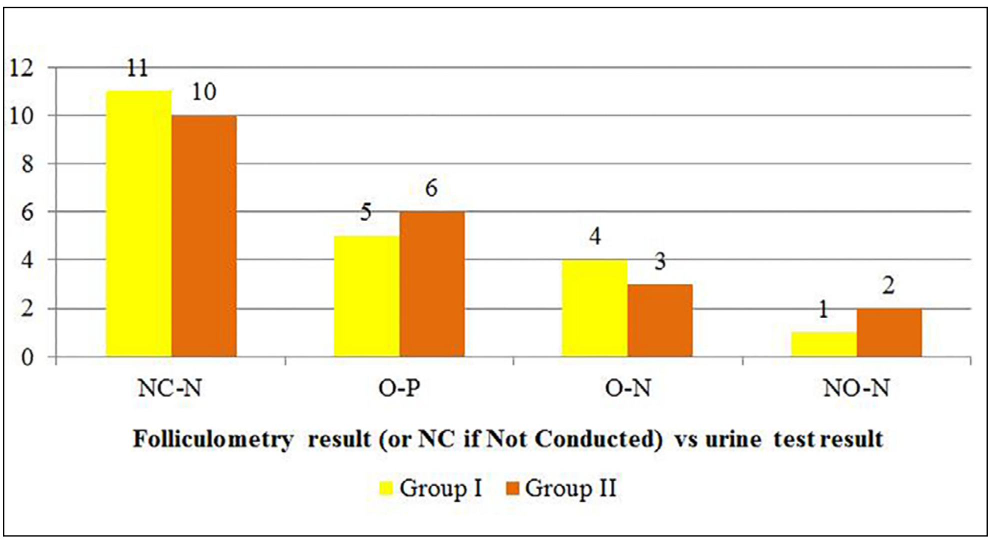

Fig. 9. Comparison of the results of folliculometry and of the urine test strips on the 14th day of the cycle, with the specified number of patients

the fallopian tubes were patent, which excludes the tubal factor in the failure to achieve pregnancy. The husbands of the women under study have normozoospermia according to the results of the spermatogram, which excludes the male factor.

Folliculometry on the 10th day of the cycle revealed (Fig. 5): that 16 women in group I and 15 in group II had one follicle in the right or left ovary measuring 15-17 mm (DF), 5 women and 2 women, respectively, had two follicles in one or both ovaries with diameters of 16-19 mm (SO),

Table 2. Calculation of ovulation test results using the Ovul device (If a positive result is considered to be folliculometry and the device O-O)

Ovul device	Folliculometry		
	O	NO	Total
O	35	0	35
NO or FW	4	3	7
Total	39	3	42

Note: Sensitivity 89.7; Specificity 100.0; Accuracy 90.5; Negative predictive values (NPV) 42.9; Positive predictive values (PPV) 100.0

Table 3. Calculation of ovulation test results using urine test strips (If a positive result is considered to be folliculometry and the test O-P, on the same day)

Urine test strips	Folliculometry		
	O	NO	Total
P	22	0	22
N	17	3	19
Total	39	3	42

Note: Sensitivity 56.4; Specificity 100.0; Accuracy 59.5; Negative predictive values (NPV) 15.0; Positive predictive values (PPV) 100.0

Table 4. Calculation of ovulation test results using the Ovul device (If a positive result is considered to be folliculometry and the device O-O or O-FW)

Ovul device	Folliculometry		
	O	NO	Total
O or FW	38	0	38
NO	1	3	4
Total	39	3	42

Note: Sensitivity 97.4; Specificity 100.0; Accuracy 97.6; Negative predictive values (NPV) 75.0; Positive predictive values (PPV) 100.0

Table 5. Calculation of ovulation test results using urine test strips (If a positive result is considered to be folliculometry and the test O-P, on the same day or within the next 72 hours)

Urine test strips	Folliculometry		
	O	NO	Total
P	37	0	37
N	2	3	3
Total	39	3	42

Note: Sensitivity 94.9; Specificity 100.0; Accuracy 95.2; Negative predictive values (NPV) 60.0; Positive predictive values (PPV) 100.0

and four women in group 2 had one follicle up to 15 mm (ADF). A saliva crystallization test on day 10 of the cycle showed no crystallization (NO) in 9 and 13 patients in groups I and II or thin complexes (FW) in 12 and 8 women, respectively, indicating the absence of ovulation. Urine test strips showed a negative result (N) in all tests.

On the 12th day of the menstrual cycle, according to folliculometry, 11 women in group I and 10 patients in group II ovulated - a small amount of fluid in the ectopic space and a decrease in the size of the dominant follicle were visualized (Fig. 6). Measurements with the Ovul device confirmed the presence of ovulation in 10 women in the group (1 woman had FW result) and in 8 patients in group 2 (1 case of FW and 1 case of NO). In 1 woman in group II, spontaneous ovulation did not occur (NO).

One-time ovulation tests showed two bright stripes (P) in only 6 of 11 women in group I with ovulation according to ultrasound (Fig. 7); in the other 4 patients bright two stripes (P) appeared after 18-24 hours, and in one patient the urine test did not show a positive result within 72 hours.

In group II, on the 12th day of the cycle, ovulation, according to ultrasound research, coincided with the results of urine strips in 4 out of 10 patients, and in the remaining six women, a positive result was obtained within 18-24 hours.

On the 14th day of the menstrual cycle, during folliculometry in patients who did not ovulate on the 12th day, it was found that nine women in each group ovulated in the next 12 hours (Fig. 8). The device showed the presence of ovulation in all 9 women of group I and 7 women of group II (in the last 2 FW, in 1 of which the device showed the result O within the next 24 hours).

One patient in group I and 2 women in group II did not ovulate on day 14 according to the results of ultrasound (folliculometry showed no signs of ovulation, no corpus luteum, and the dominant follicle regressed). The saliva crystallization test and urine test strips also showed no ovulation, although on day 15/16, the device showed a FW result in 1 woman in group II.

Urine test strips showed a positive result in 5 of 9 women with ovulation by ultrasound research in group I and in 6 of 9 in group II (Fig. 9). In 4 women of group I and 2 of group II, a positive ovulation test occurred 24 hours after the detection of ovulation by ultrasound, and in 1 woman of group II the result remained negative.

The integral calculation of the statistical indicators of the evaluated diagnostic methods (the Ovul device and urine test strips) in comparison with the "gold standard" for determining the time of ovulation - ultrasound examination (folliculometry) showed the following: if we consider the exact coincidence of the day of ovulation during folliculometry (O) and O on the device as a positive result of the device, and the negative results of O and FW, the calculation shows (Table 2) the sensitivity of the methodology is 89.7% (out of 39 positive results of the device, 35 were really positive), and the specificity is 100.0% (all negative results were really negative), the overall accuracy is 90.5% (in 38 out of 42 patients, the device readings coincided with the results of folliculometry).

As for urine test strips, if we consider the coincidence of a positive result with the day of ovulation by folliculometry, then with the same 100 percent specificity, the sensitivity was low - only 56.4 % (one third lower than that of the device), and the accuracy was also lower by one third - 59.5 % (Table 3).

If we consider the coincidence of the day of ovulation in folliculometry (O) and O or FW on the Ovul device to be a positive result (because it is important to establish the fertile window and confirm the presence of ovulation), and negative results – NO and O, we will get much better results (Table 4), the specificity of the technique remains 100%, and the sensitivity increases to 97.4%, the overall accuracy to 97.6%.

If we consider a positive result for urine test strips to be not only a coincidence with the day of ovulation according to folliculometry, but also a positive result within the next 72 hours (Table 5), then with the same 100 percent specificity, the sensitivity increases by almost a third and reaches 94.9%, and the accuracy increases to 95.2%.

DISCUSSION

Our data on the high correlation of the results of ovulation assessment using the fern pattern in saliva with the results of ultrasound folliculometry, as the "gold standard" for detecting ovulation, are consistent with the findings and results of other researchers [11], according to these authors, fern was not detected in 1 out of 30 ovulatory cycles (in our study, in 2 out of 39) and, on the contrary, there were two false positive results out of 10 anovulatory cycles, which was not observed in our study. The advantage of our study is the assessment of not only the fact of ovulation detection but also the determination of the fertile window with an estimate of the probability of the result calculated by AI algorithms, while the authors provided patients with a KNOWHEN® pocket microscope that did not have the ability to connect to a smartphone and the image was evaluated visually by the patient.

Other researchers have evaluated the frequency of fern pattern detection in saliva compared to basal body temperature measurements [9]; the authors evaluated the frequency of fern pattern detection in a saliva sample on a slide that the subjects (students and employees) by days of the cycle. The presented results were not compared with folliculometry, which made it impossible to determine the statistical indicators of the diagnostic method (sensitivity, specificity, and accuracy).

In the 2019 publication [12], the authors describe a smartphone-based device with an optical system attached to a smartphone, using tubes to collect saliva, i.e., the test is technically more complex than the device we described. The authors tested the accuracy on images with and without fern pattern (urine test strips were used as a reference); the accuracy was 99.5%, and the sensitivity and specificity of the system were 99.01% and 100%, respectively, which is similar to our results, but they did not test it on an independent sample of patients.

CONCLUSIONS

The introduction of a convenient, cost-effective, and reliable method of ovulation detection using the Ovul device with a special mobile application based on AI analysis of images of saliva crystallization with a fern effect is very important for women planning a pregnancy. Frequent visits to the doctor for ultrasound examinations can be physically and psychologically uncomfortable for women, so the ability to perform the test at home provides additional benefits.

The results of a comparative analysis of ovulation studies in women with idiopathic infertility using 3 methods (fern effect in saliva, urine test strips, and reference folliculometry) showed similar results both in ovulation induction (aromatase inhibitors or recombinant gonadotropins) and in natural menstrual and ovarian cycles.

Although ovulation detection with the device and urine test strips has 100% specificity (all negative results were really negative), the sensitivity of the device is 97.4% and accuracy is 97.6% if the positive result is ovulation or the fertile window), whereas urine test strips have a sensitivity of 94.9% and an accuracy of 95.2%, if we consider a positive result not only to be the same as the day of ovulation according to folliculometry but also a positive result within the next 72 hours (mostly 12-24). In addition, a significant advantage of using the device compared to urine strips is that it shows not only one day of ovulation but a fertile window lasting 3 to 5 days, which significantly increases the chances of a couple getting pregnant. Test strips can be used to simply detect anovulatory cycles, but their use for pregnancy planning is significantly less effective.

Thus, ovulation detection with the Ovul device is a highly accurate, 100 percent specific and highly sensitive method that can be used at home, but this technology requires further research, and its combination with other methods (such as folliculometry) will optimize diagnostics, make it more convenient and cheaper for patients who want to get pregnant or, on the contrary, who are trying to avoid pregnancy.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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