Ability of women to read and interpret home ovulation tests

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Introduction

Determining pregnancy is often not as straightforward as couples expect. Indeed, using natural fertility awareness alone, two in three couples fail to conceive in their first cycle, one in five fail to conceive within their first six cycles, and six in ten fail to conceive within their first 12 cycles. For successful natural fertility contraception, intercourse must occur within a window that spans five days prior to ovulation and coincides with the estimated ovulation window with peak fertility being the day before, and the day of ovulation.

Menstrual cycle length varies considerably both between and within women, with the majority of this variation being attributable to the follicular phase. Therefore, reliance on the luteal assumption that ovulation occurs on day 14 will result in many couples trying to conceive at the wrong stage of the menstrual cycle (see ASCO 2011 paper by Johnson et al., Fertil Steril). Accuracy of perception of ovulation day in women trying to conceive has been shown to affect sex with more awareness of its most fertile time has an increased chance of conception.

1 Ovulation occurs 24–36 hours after the onset of the LH surge, which is measured on auri progesterone (LH surge) as detection of the LH surge provides a means by preconceptionally identify the time of peak fertility. Home ovulation tests provide a simple way for women to appropriately time intercourse in order to maximize their chance of conception. However, as most products differ in terms of their peak test window and the way their results are displayed to the consumer, the ability of the user to obtain the correct result may vary between products. For example, current ovulation tests rely on the user interpreting the intensity of a colored line in a result window against a similarly colored line in a reference window. This interpretation can cause problems as it is clearly subjective, and as a result, the Classic Digital Ovulation Test was developed. This device automatically compares the intensity of the two lines and presents the result as a single digital reading. The objective of this study was to compare the results of the Classic Digital Ovulation Test with those commonly used ovulation tests. Methods

Complete menstrual cycles comprising daily urine samples in advance from 25 volunteers (aged 16–45) were tested using four different home ovulation tests: (A) CBT-Dot Digital Ovulation Test (CBT-Dot), (B) Classic Digital Ovulation Test (CDOT), (C) Clearblue® Advance Ovulation Test (Clearblue®), and (D) Ovulation Signs (16-9). Testing was performed according to manufacturer’s instructions, including the determination of the day that leading should start (based on the volunteers reported menstrual cycle length). A total of 42 cycles were recorded.

The test results were read and interpreted by both female volunteers (72 volunteers, aged 16–45) external to the study staff and trained study technicians. The order of each such test was presented to the volunteers was randomized across the different menstrual cycles, and both volunteers and technicians were blocked to the menstrual cycle they were reading. Volunteer and technician testing was performed and recorded independently, with neither party being able to observe the other’s results. Agreement was achieved after the second reading from the technician and volunteer were identical for all samples tested throughout a single cycle.

A secondary endpoint of the study was to examine volunteers’ experience when using the tests. Therefore, volunteers were also asked to rate each product using a seven-point Likert scale (1=not at all; 7=very much) for the hierarchy ranking and 1 being the lowest ranking and 7 being the highest ranking, according to the following questions:

- How CERTAIN were you of the test result?
- How CLEAR did you think the test results were?
- How likely did you think the test results were to be?
- How much do you TRUST the results of this test?
- How ACCURATE do you believe this test to be?
- How LACKLY do you think you would be to recommend this test to a friend who wanted to use an Ovulation Test?

Volunteers were then asked to rate each of the tests using the following criteria:

- Overall, this is the Ovulation Test I most prefer
- This test is the best test I have ever used
- This test gives me the most accurate results
- This test is the most important
- This test is the ‘hardest’ or ‘most intelligent’ test
- This test gives me absolute confidence in the result
- I would choose this test over all others.

Results

Agreement analysis (i.e., the technician and volunteer agreeing on the results of all samples in a particular cycle) showed that CBT-Dot was associated with a significantly higher percentage agreement (97.3%) after CBT-Dot (93.9%), Ovulation Signs (93.9%), and Ovulation Tests (75.7%) (see Figure 1).

For the secondary endpoint of assessing the certainty with which volunteers read CBT-Dot results when compared to the three other tests, CBT-Dot was found to have significantly superior (better) Likert scores than CBT-Dot, CBT-Dot, and Ovulation Signs for all seven attributes. (Figure 1). This shows the percentage of women assigning a Likert score of 5 of the seven attributes and indicates that CBT-Dot is much more likely to be ranked highest for all attributes tested.

Conclusion

This study showed that in a group of women measured live tests. When compared to live tests, users read significantly and accurately, and with significantly more certainty.


discussion

To be able to be a dif ferent time for couples, especially when conception does not occur as quickly as expected. Therefore, it is important that products designed to increase the chance of conception are accurate, easy to interpret, and understandable. The subjective comparison of the intensity of a result and reference line can make it very difficult to interpret the result, especially if LH concentration at the time of the surge is low or there are high baseline levels of LH. Our study hypothesized that the removal of the subjective interpretation of the color of the test and associated digital display would both eliminate this uncertainty and produce more accurate results.

As expected, agreement between the volunteers/technician results was considerably higher for CBT-Dot than for any of the live tests, thereby demonstrating the ease with which an untrained volunteer could easily interpret the CBT-Dot results. In contrast, approximately one in three users incorrectly interpreted the first Response test, and approximately one in three users incorrectly interpreted the Answer test. Volunteers also reported that the digital test was easy to read and understand, and that they preferred it to visual tests.

For a couple seeking to conceive, the use (and correct interpretation) of a reliable ovulation test can increase their chance of timing intercourse to coincide with the woman’s peak fertility period. This, in turn, can help the woman become pregnant sooner. This is particularly important in today’s society, where women are becoming pregnant later in life, and fertility is more often affected by a combination of lifestyle work and family commitments. In addition, for apparently healthy fertile couples, a continued failure to conceive can adversely affect their social and emotional well-being.