Introduction

• Home ovulation tests are a convenient method for women to time intercourse in order to maximise their chances of conception
• The Clearblue Advanced Digital Ovulation Test, detects the surge in luteinising hormone (LH), and the pre-ovulatory rise in urinary estrone-3-glucuronide (E3G) that marks the onset of a woman's fertile period.1
• This identifies the additional pre-ovulatory days not detected by LH-only ovulation tests, where intercourse can lead to pregnancy, which many women find useful
• Results are digitally displayed to the user as:

| Low (basal LH/E3G): clear circle | High (E3G rise detected): flashing smiley face | Peak (LH surge detected): smiley face |

1E3G is recognised by the World Health Organization as an ideal urinary metabolite for the identification of the onset of the fertile phase.2

Objectives

• To examine the performance of the Clearblue Advanced Digital Ovulation Test compared with ultrasound-observed ovulation.

Methods

• Daily urine samples were collected from complete menstrual cycles of volunteers in the Menstrual Cycle Monitoring Study (MeMo; NCT01802060)3,4
  o N=40; all regularly menstruating with documented ovulation; aged 18–37 years, mean age 28.9 years
• Urine samples were tested, blinded and randomised, using three batches of Clearblue Advanced Digital Ovulation Test
• During one complete menstrual cycle, volunteers visited the study centre for blood sampling and transvaginal ultrasound every 2 days, or daily from follicle size >16mm until post-ovulation
• The concentration of urinary LH was measured by the AutoDELFIA analysis platform (Perkin Elmer, Waltham, MA, USA), and serum LH by AVIDA-Centaur XP Immunoassay System (Siemens, Erlangen, Germany).

Results

Timing of ovulation and LH levels

• Median day of ultrasound-observed ovulation was 14.5 (range day 8.5–26.5)
• Urinary LH surge preceded ultrasound observed ovulation by a mean of 0.81 days
• Median LH levels on the day prior to ovulation were:
  o Urine: 44.6 mIU/ml (10th–90th percentiles 6.5–101.0)
  o Serum: 38.3 mIU/ml (10th–90th percentiles 26.9–75.0).

Accuracy of Clearblue Advanced Digital Ovulation Test-estimated day of ovulation compared with ultrasound-observed ovulation

• Clearblue Advanced Digital Ovulation Test detected the LH surge in 92.5% of cycles tested (1 cycle with peak urinary LH of 15.7 mIU/ml accounted for 3% of no surge observations) (figure 1).
• For one volunteer, no peak was detected by Clearblue Advanced Digital Ovulation Test. This was a correct result as no serum of urine LH surge was present in that cycle (figure 2).

Conclusions

• The surge in urinary LH predicts ovulation, supporting the premise of home ovulation tests to provide women a means of appropriately timing intercourse
• The Clearblue Advanced Digital Ovulation Test accurately predicted ovulation and identified days of high fertility prior to ovulation
• Identifying more days for timing of intercourse is of benefit because multiple acts of intercourse across the fertile phase have been predicted to increase the chances of pregnancy.5

References


Disclosures

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