COMPARISON OF HOME PREGNANCY TEST WITH WEEKS ESTIMATOR AND ULTRASOUND CROWN RUMP MEASUREMENT TO PREDICT DELIVERY DATE

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Introduction

• Women who get a positive pregnancy test result wish to know quickly how far along they are.
• Allows a woman to plan and understand her pregnancy.
• Clinically important to ensure appropriate care.
• An improvement on LMP is long overdue.

Boundaries between weeks, as shown in figure 1 below, which has been incorrect for half of women since ovulation for women testing pregnant.

Test Background

The new test is a conventional digital pregnancy test that also estimates the number of weeks since ovulation. Results are displayed on an LCD as 1.2–2.3 and 3+ weeks categories if a “Pregnant” result is returned. The basis of the pregnancy status also estimates the number of weeks since ovulation for women testing pregnant.

Due to the exponential increase in hCG in early pregnancy, the test must be capable of measuring the low and high boundary levels of hCG with precision. A single lateral flow immunosay strip is not normally able to measure across a wide concentration range with precision, therefore, this test consists of two immunosay strips (one low and one high sensitivity) to accommodate the required range. An optical detection system and microprocessor convert the assay object into easy to understand results on an LCD screen. The internal architecture of this test is shown in figure 2.

Test Results

The demographics and menstrual cycle characteristics of the study population are summarised below:

Mean age of volunteers was 30.48 years (range 23–41, median 30.5, SD 4.1).
Highest level of education was: 26.1% High School, 50% College/Graduate School, 23.8% Post Graduate.
Mean length of time trying to conceive was 5.8 months (range 0.4–5.0, median 0.5, SD 1.0).
Shortest self-reported cycle was 17 days (range 10–26, median 22.0, SD 5.4).
Longest self-reported cycle was 39 days (range 26–60, median 34.2, SD 6.3). The mean time from ovulation to delivery based on CRL measurement was 37.4 weeks (SD 1.3), 95% Confidence Interval 37.02–37.92, range 33.07–39.91. The mean time from ovulation to delivery based on LMP was 37.4 weeks (SD 1.3), 95% Confidence Interval 36.90–37.72, range 33–41.7. The results are outlined in Table 1.

The mean from each volunteer’s majority device results (time since ovulation) to delivery was 37.4 weeks (SD 1.3, 95% Confidence Interval 37.02–37.92, range 33.07–39.91). The mean from ovulation to delivery based on LMP was 37.4 weeks (SD 1.3), 95% Confidence Interval 36.90–37.72, range 33–41.7. The results are outlined in Table 1.

Table 1. Summary of duration of pregnancy at delivery by using Clearblue Advanced pregnancy test (CAPT) with weeks estimator and ultrasound to define pregnancy duration.

Observations

- The mean duration of time from ovulation to delivery was consistent with the reported average 9 months.
- The range of delivery by LMP was considerably more than by other methods, indicating that it is an inaccurate measure.
- There was no correlation between any of the methods, with the highest level seen between CAPT and LMP, and the lowest between CAPT and LMP.
- The new pregnancy test’s “weeks estimator” provides results that much more accurate than LMP. The device results are also comparable to those of ultrasound, but are obtained earlier in pregnancy. Therefore the new device provides a woman useful and accurate information at the time of first discovering she is pregnant.

CONCLUSIONS

- Both CAPT results and LMP results provided comparable predictions of delivery date, with a slightly broader range seen using LMP measurement.
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- The range of delivery by LMP was considerably more than by other methods, indicating that it is an inaccurate measure.
- There was no correlation between any of the methods, with the highest level seen between CAPT and LMP, and the lowest between CAPT and LMP.
- The new pregnancy test’s “weeks estimator” provides results that much more accurate than LMP. The device results are also comparable to those of ultrasound, but are obtained earlier in pregnancy. Therefore the new device provides a woman useful and accurate information at the time of first discovering she is pregnant.