Accuracy of a wrist-worn medical device to identify fertile window and ovulation day

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Introduction

- More than 60% of women do not know when they can conceive during their menstrual cycle.[1] Accurately identifying the fertile window and properly timing intercourse can increase the probability for conception.
- Urine-based Luteinizing Hormone (LH) kits can routinely be used to detect the rise in LH occurring 24-36 hours prior to ovulation, identifying only the end of the fertile window.[2]
- The Ava Fertility Tracker is a wearable device measuring five physiological parameters to identify an average of 5 days in the fertile window prospectively with 90% accuracy.[3]
- **Research aim:** determine the accuracy of the Ava Fertility Tracker compared to urinary LH tests.

Methods

- This study included 205 ovulatory cycles, confirmed by LH tests, from 61 women who wore the Ava Fertility Tracker nightly for up to six cycles.
- The Ava Fertility Tracker measured pulse rate, respiratory rate, skin perfusion, heart rate variability, and skin temperature during sleep and employed two machine learning algorithms to track fertility in a smartphone application:
    1. **Retrospective algorithm** determining the fertile window after cycle end
    2. **Prospective algorithm** predicting the fertile window in real time
- Ovulation day was defined as the day following a positive LH test; the fertile window included ovulation day and the five preceding days.
- Accuracy was determined based on the number of wrongly identified ovulation days as compared to LH test results tolerating ±2 days (i.e., equivalence interval).
- Sensitivity and specificity of the algorithms were calculated by means of a mixed effects model.

Figure 1. Ava Fertility Tracker and its mobile application.

Results

- **Mean participants' age:** 26.5 ± 4.2 years
- **Mean duration of included cycles:** 29.9 ± 3.2 days

Table 1. Accuracy of the two algorithms using LH test results as reference.

Variables	Retrospective Algorithm	Prospective Algorithm
Accuracy to identify ovulation day, no. (%)		
Cycles with errors ±2 days	168 (82)	148 (72.2)
Cycles with 0 days errors	57 (27.8)	126 days (87)
Cycles with errors larger than ±2 days	37 (18)	57 (27.8)
Accuracy to label fertile/infertile days (95% confidence interval)		
Sensitivity	0.80 (0.76, 0.83)	0.77 (0.71, 0.82)
Specificity	0.95 (0.94, 0.95)	0.91 (0.90, 0.92)

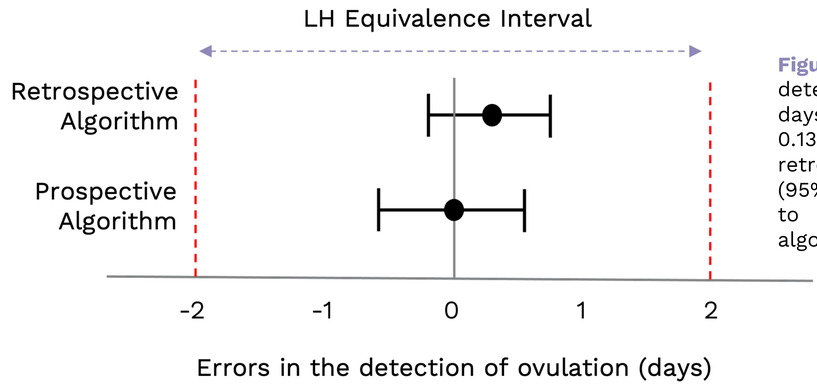

Figure 2. Mean error in detecting ovulation was 0.31 days (95% confidence interval -0.13 to 0.75) for the retrospective and -0.04 days (95% confidence interval -0.64 to 0.55) for the prospective algorithm.

Conclusion

- The Ava Fertility Tracker was as accurate in identifying ovulation day as LH tests, suggesting it could serve as a reliable marker of ovulation for real-world users as well as researchers.
- Leveraging machine learning and wearable sensor technology, the Ava Fertility Tracker also provides a larger and prospective fertile window than LH tests thereby enabling women to increase their chances of conceptive sex.[4]

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