

Vaginal core body temperature assessment identifies pre-ovulatory body temperature rise and detects ovulation in advance of ultrasound folliculometry.

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Study Questions

Is body temperature rise a post-ovulatory phenomenon and if not, could a novel vaginal temperature measurement based algorithm predict ovulation; what is the sensitivity (Se), Specificity (Sp) positive predictive value (PPV), negative predictive value (NPV) and accuracy of such an algorithm, with ultrasound folliculometry as the accepted gold standard?

Summary Answer

Body temperature starts rising pre-ovulation, in a consistent predictable fashion. A novel algorithm, utilising multiple overnight core body (vaginal) temperature measurements, predicts ovulation one day in advance, in 89% (Se) of cycles confirmed ovulatory by ultrasound; figures for Sp, PPV, NPV and accuracy, were 88%, 96%, 72% and 89% respectively.

What Is Known Already

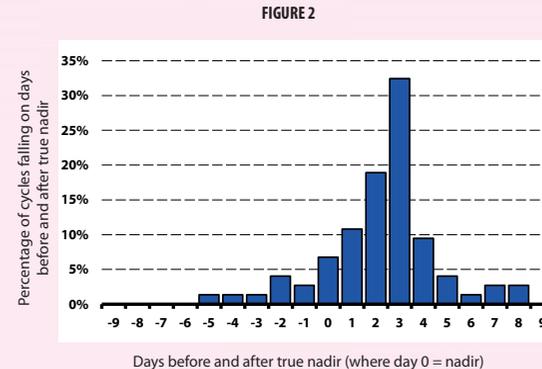
The post-ovulation progesterone rise, results in a documented rise of body temperature, due to progesterone's thermogenic effect. Skin surface temperature measurements are prone to technical error and bias, and therefore cannot describe an accurate temperature rise, representative of ovulatory activity. Prior laboratory studies have shown that assessment of core body temperature however, which is not influenced by the same inconsistencies, can predict ovulation.

Main Results & The Role of Chance

Although the average body temperature for each participant varied, the temperature curve form for all ovulatory cycles was extremely consistent in shape and slope, with a clear "onset of phase change" followed by a consistent rise over a number of days to a peak measurement. (Figure 1)



Furthermore, the date of ovulation as established by ultrasound folliculometry was found to fall on a mean of three days after the onset of phase change of the curve, and with a Gaussian distribution - thereby clearly identifying the mean as having validity and not being due to chance. (Figure 2)



Conclusion

The novel algorithm developed, correctly identified ovulation one day in advance in 9 out of 10 ovulatory cycles, with high specificity as well. The overall accuracy of the method reached 90%.

Study Design, Size, Duration

Prospective observational study, approved by the Leeds Research Ethics Committee, U.K and by the Medicines and Healthcare products Regulatory Agency, U.K. 21 participants entered the study and contributed a total of 81 cycles over one year.

Wider Implication of the Findings

Vaginal core body temperature assessment detects ovulation a day in advance through a user controlled device, with accuracy comparable to serial ultrasound, without the expense and inconvenience. It gives a much more reliable and detailed picture of peri-ovulatory temperature changes which are consistent in different subjects; temperature starts rising before ovulation. More research is needed to elucidate association of such variation to exact peri-ovulatory progesterone change, which has been associated with the possibility of fertilisation.

Participants/ Materials, Setting, Method

Vaginal temperature was measured every 5 minutes overnight with a sensor employing a thermistor with a 0.003°C resolution. Ultrasound folliculometry scans were performed in a dedicated ultrasound clinic to establish the ovulation date. The nature of the temperature curves and the mean ovulation date over the database were assessed.

Limitations, Reasons for Caution

The database used to develop the algorithm is relatively small, with 81 cycles with full comparative ultrasound folliculometry results. However, a further 17 cycles of data added since from other users of the study device; all conform to the conclusions reached by use of the novel algorithm.

Study Funding and Competing Interests

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