

ATYPICAL CORE BODY TEMPERATURE PATTERNS AND THE WIDER IMPLICATIONS FOR CONDITIONS RELATED TO PREGNANCY, INFERTILITY, AND MISCARRIAGE RISK

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Objective

To determine if pregnancy complications, ovulatory abnormalities and miscarriage risk were associated with atypical Patterns of vaginal continuous Core Body Temperature (cCBT) measurements from the OvuSense (OS) system.

Study Design

Retrospective, longitudinal, comparative, observational.

Materials and Methods

Participants used OS vaginally at night to monitor Core Body Temperature (CBT) continuously when not menstruating. Three novel, atypical cCBT Patterns published previously, were confirmed in updated Total Study Population (TSP) of 20,067 ovulatory cycles from 8,177 OS users recorded between March 2016 and March 2020: (a) "Crash To Baseline" = first nightly averaged CBT falls by >0.2 degrees Celsius (°C) to lowest cycle CBT point (baseline), (b) "False Start" = rise of >0.1°C did not result in ovulation but instead a return to baseline CBT followed by ovulation two or more days later in the cycle, (c) "Crash After Ovulation" = final CBT >0.2°C lower than the post ovulatory peak CBT.

A detailed medical questionnaire was then issued to study participants and the answers from 382 respondents accounting for 1,534 of the TSP cycles were used for further assessment. TSP used to confirm prevalence of cycle Patterns (a) to (c); and questionnaire assessed per respondent for each following a historic 'Diagnosis':

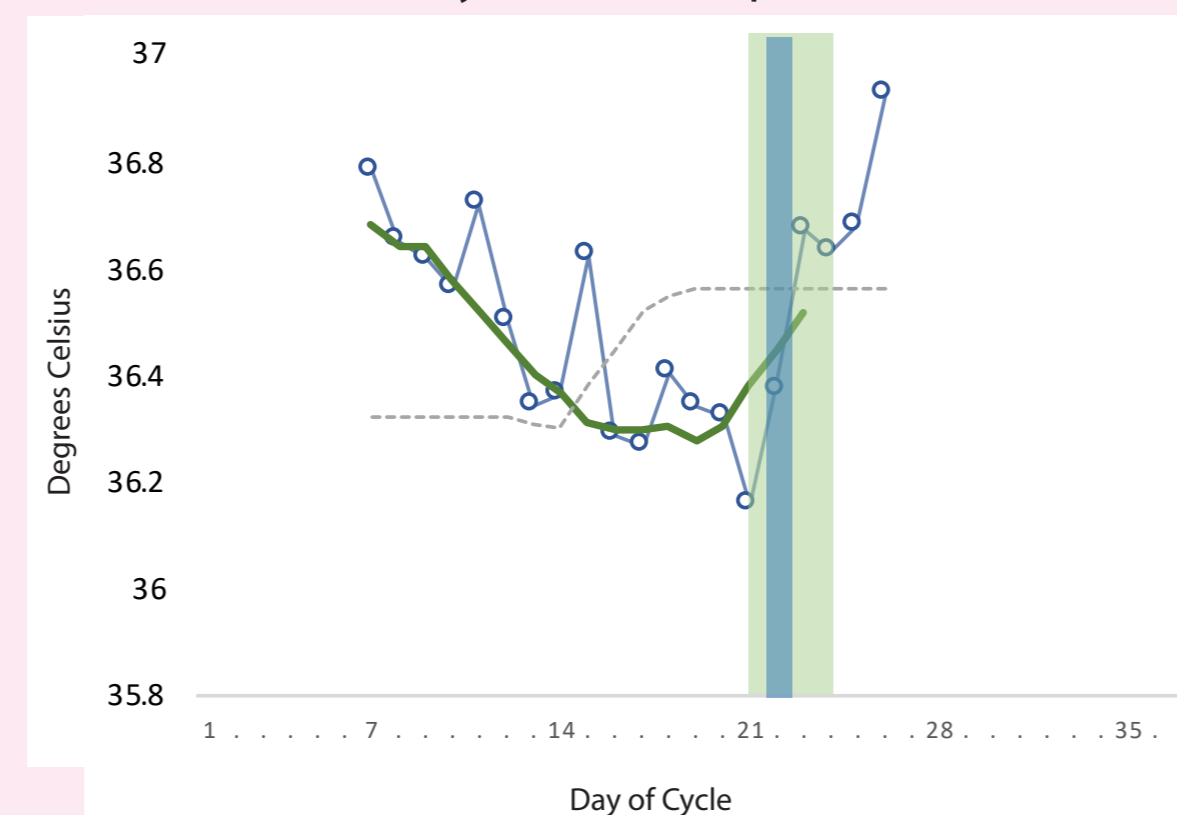
1. Any infertility related diagnosis
2. PCOS
3. PCOS and regular cycles
4. Previous miscarriage = gravida >0, # miscarriages >0.
5. Gestational Diabetes in any previous pregnancy
6. Gestational Hypertension in any previous pregnancy

Diagnostic Odds Ratio (OR) calculated as $(p/q)/(r/s)$ for each Pattern + Diagnosis combination together with their 95% confidence interval: *p*. Positive Historic Diagnosis/Condition (+D), Pattern >1 cycle for respondent (+P); *q*. No Diagnosis (-d) +P; *r*. +D No Pattern (-p); *s*. -d-p.

Results

382 out of 8,177 OS users responded to a detailed medical questionnaire, contributing 1,534 cycles.

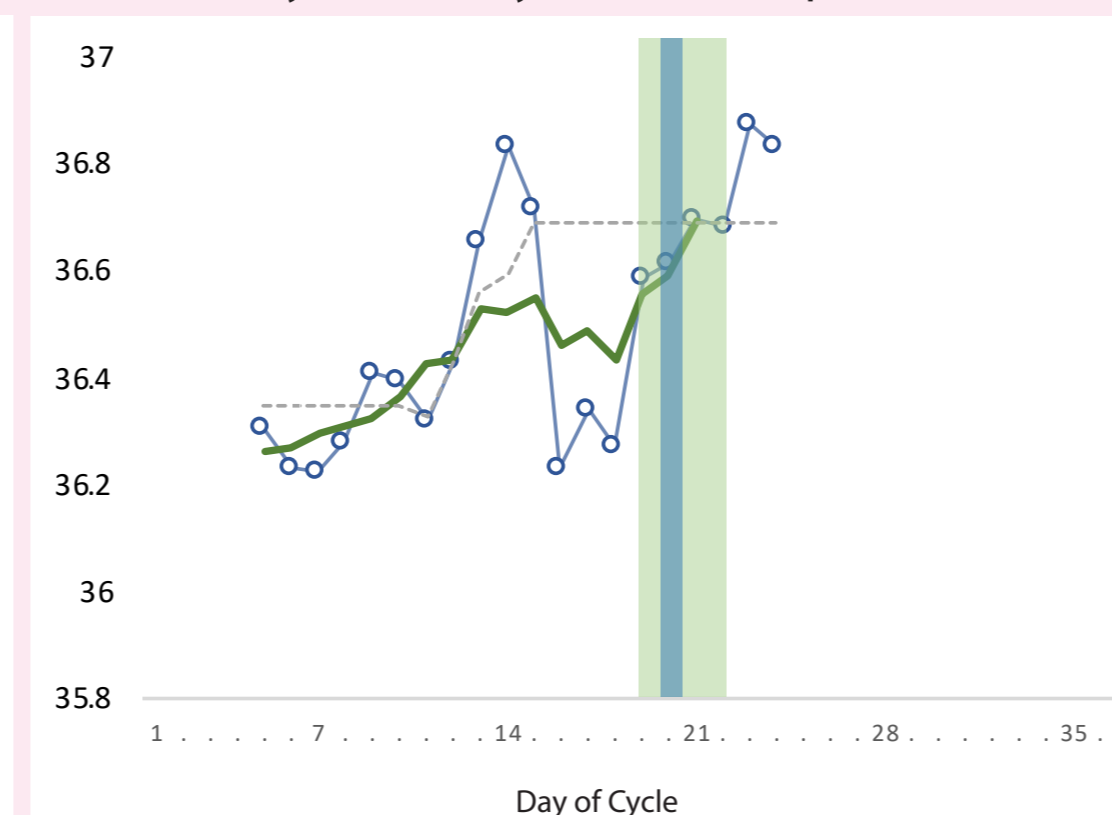
(a) "Crash To Baseline" = first nightly averaged CBT falls by >0.2 degrees Celsius (°C) to lowest averaged CBT point in cycle (baseline): 282 cycles; 172 respondents



"Crash To Baseline" example

- OS user age: 37
- Trying to conceive: 1-2 years prior to use of OS
- Cycle length for this cycle: 26 days
- OS recordings taken: from day 7 to day 26
- OS confirmed ovulation: day 22
- Similar CBT pattern for user: 3 out of 7 recorded cycles

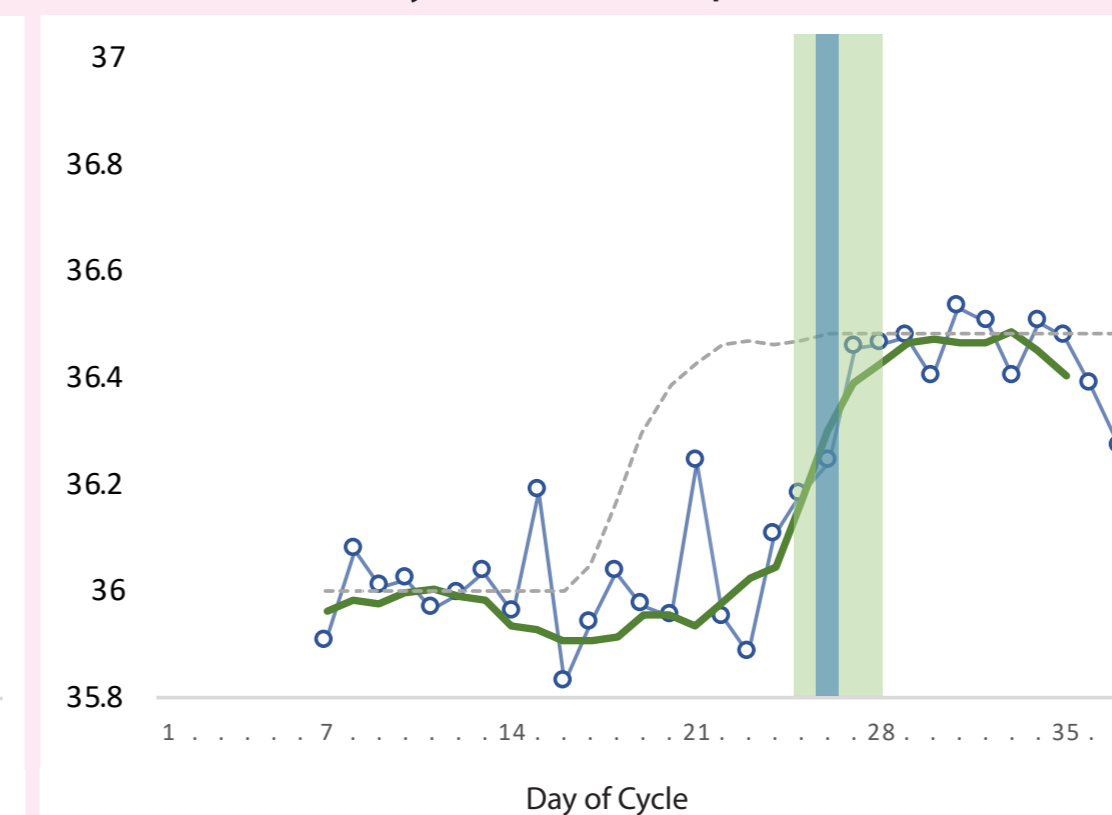
(b) "False Start" = rise of >0.1 °C did not result in ovulation but instead a return to baseline CBT followed by ovulation two or more days later in the cycle: 205 cycles; 136 respondents



"False Start" example

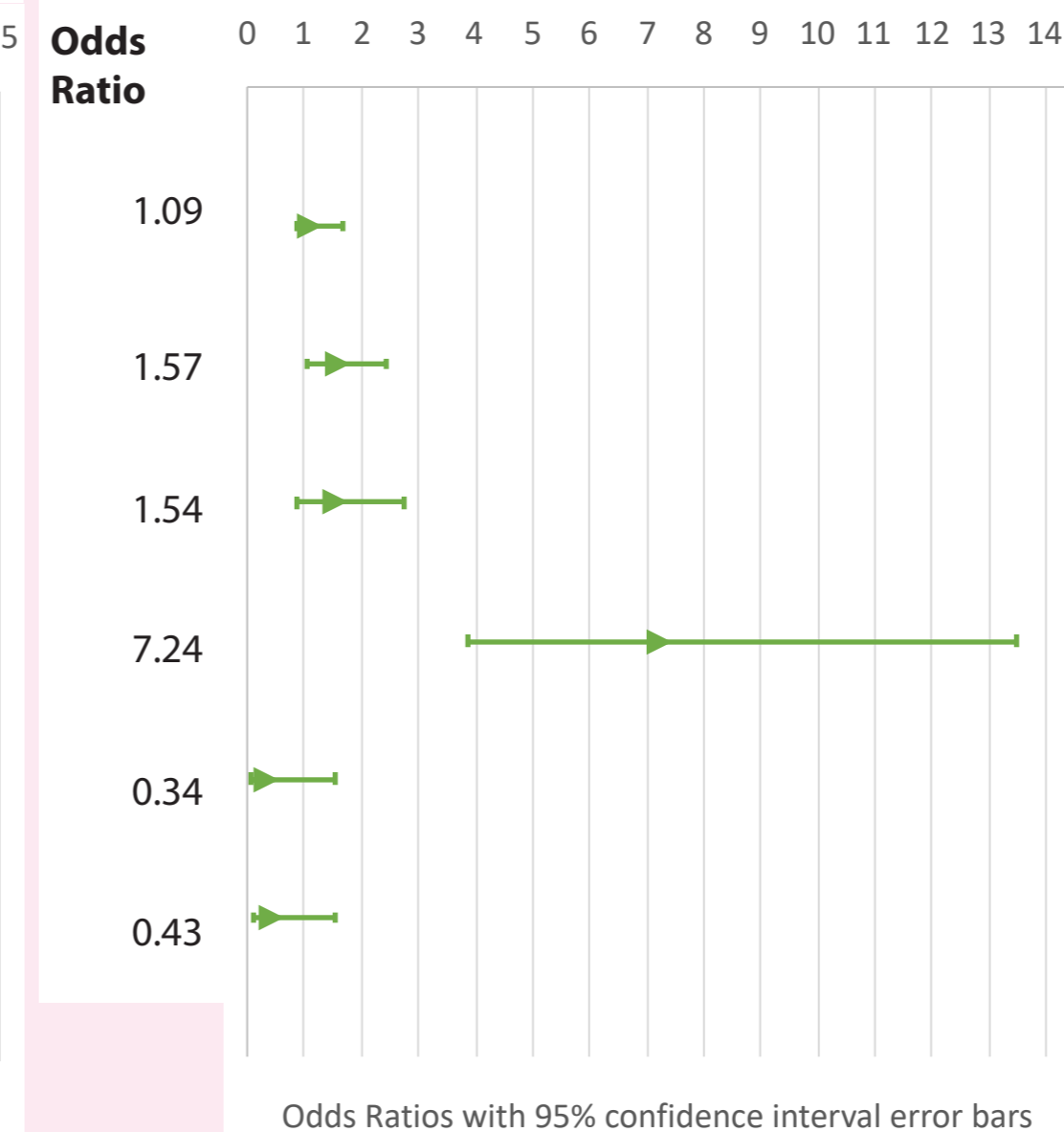
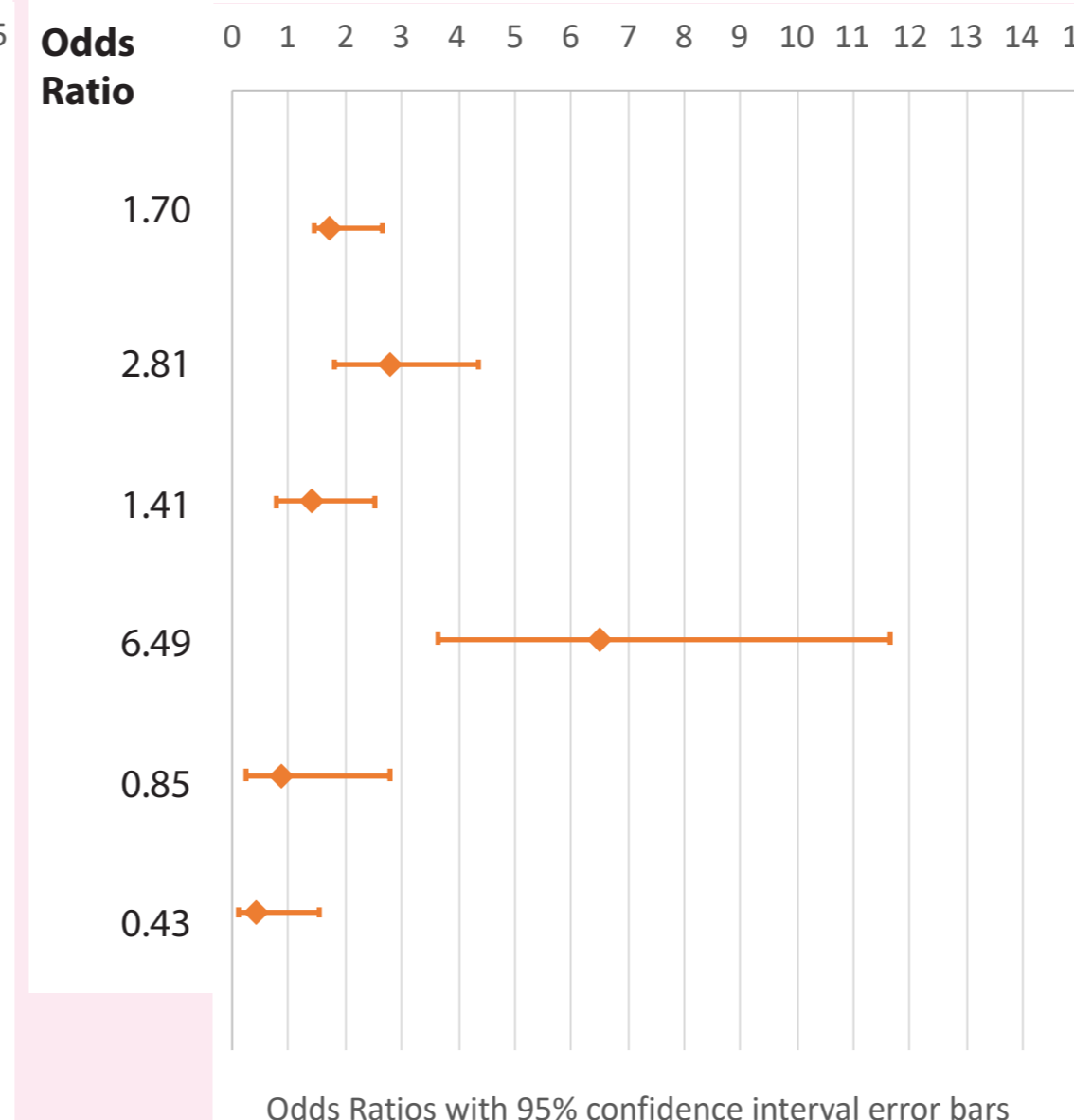
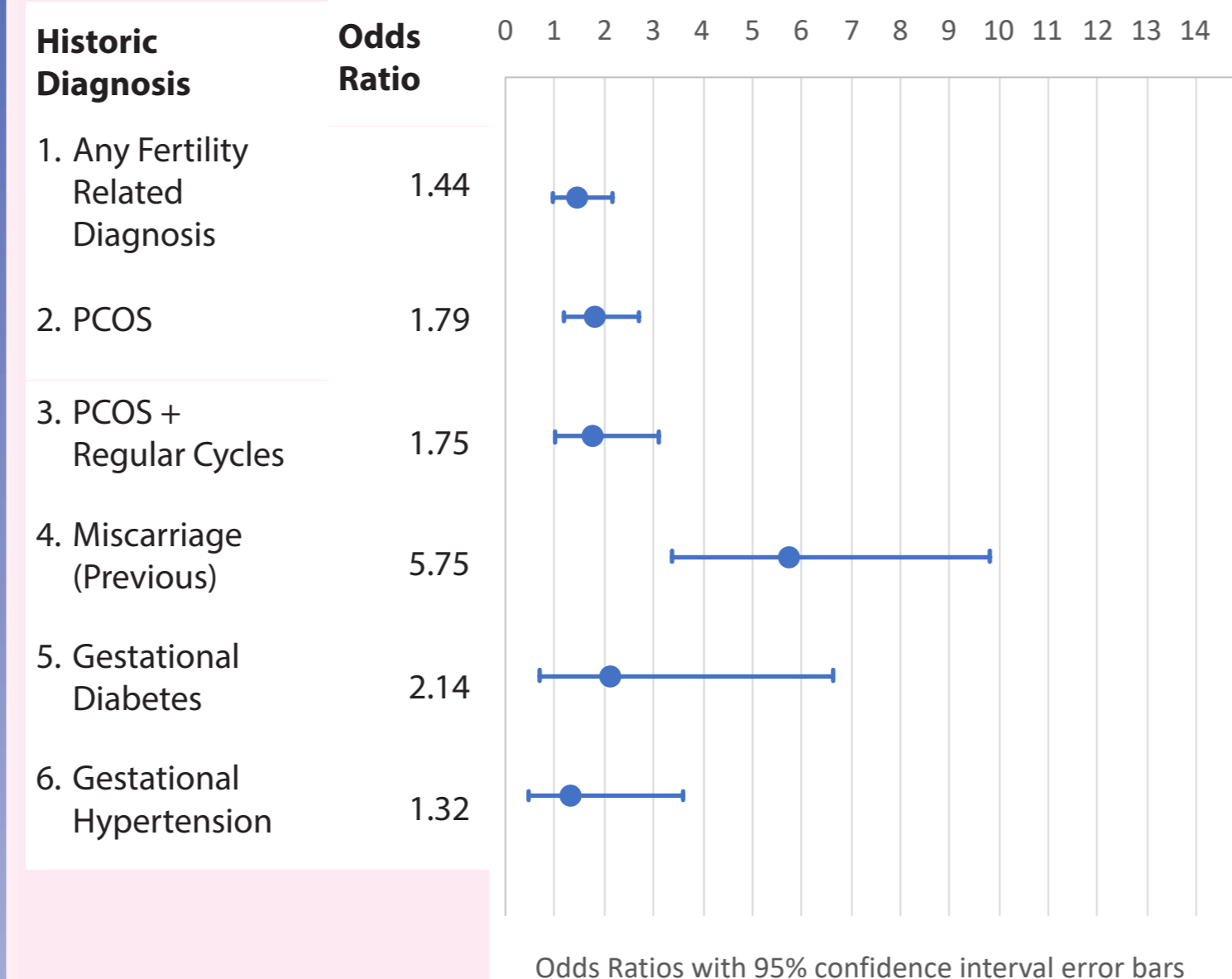
- OS user age: 30
- Trying to conceive: 0-6 months prior to use of OS
- Cycle length for this cycle: 24 days
- OS recordings taken: from day 5 to day 24
- OS confirmed ovulation: day 20
- Similar CBT pattern for user: 3 out of 7 recorded cycles

(c) "Crash After Ovulation" = final "raw" CBT >0.2 °C lower than the post ovulatory peak averaged CBT: 229 cycles ; 137 respondents



"Crash After Ovulation" example

- OS user age: 29
- Trying to conceive: No information provided
- Cycle length for this cycle: 38 days
- OS recordings taken: from day 7 to day 38
- OS confirmed ovulation: day 26
- Similar CBT pattern for user: 6 out of 10 recorded cycles



Key Representative "raw" cCBT overnight values "smooth" weighted averaged cCBT analysis "textbook" smoothed curve for this cycle Green shading is "ovulation window" from ovulation day -1 to ovulation day +2 Blue shaded line is OvuSense detected day of ovulation

Conclusions

Results confirm previous research [1] that atypical cCBT Patterns may aid diagnosis, and in particular elevated risk of miscarriage, and that pattern a. may also provide a warning for elevated risk of pregnancy issues. It should be noted that the absence of an existing Diagnosis does not necessarily render the results with positive Patterns "false", and the existence of a Pattern could anyway indicate investigation for ovulatory abnormalities.

Explanation of Charts

OS plots standard charts on a daily basis. The blue line shows the best representative "raw" CBT value produced by the OS algorithm for each set of overnight measurements taken every 5 minutes. The green "smooth" weighted average cCBT curve is used by the OS algorithm to predict ovulation up to 24 hours in advance using this current cycle's data, and then confirm ovulation. A grey "textbook" smoothed curve has been added to these charts for the purpose of this paper to show the typical pattern which might have been expected for this cycle, taking into account an expected "textbook" middle of the cycle ovulation.

References

1. Karoshi M, Hurst B (2020) Atypical Temperature Patterns as an Aid to Identify Infertility Issues and Miscarriage Risk. P-628 European Society of Human Reproduction and Embryology 36th Annual Meeting.
2. Hurst BS, Pirrie A (2019) Atypical vaginal temperature patterns may identify subtle not yet recognised causes of infertility P-345 American Society for Reproductive Medicine 75th Annual conference. Fertility and Sterility - September 2019 Volume 112, Issue 3, Supplement, Pages e244-e245
3. Papaioannou S, Delkos D, Pardey J (2014) Vaginal core body temperature assessment identifies pre-ovulatory body temperature rise and detects ovulation in advance of ultrasound folliculometry. European Society of Human Reproduction and Embryology 30th Annual Conference.

Support

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