Conclusions

a) Smooth

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 cCBT falls by >0.2 degrees Celsius (C) to lowest CBT point in cycle (baseline): 282 cycles; 172 respondents

(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

(c) “Crash After Ovulation” = final “raw” CBT two or more lower than the post-ovulatory peak CBT: 229 cycles; 137 respondents

Results

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

(a) “Crash To Baseline” – firstly averaged cCBT falls by >0.2 degrees Celsius (C) to lowest averaged CBT point in cycle (baseline): 282 cycles; 172 respondents.

(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

(c) “Crash After Ovulation” – final “raw” CBT two or more lower than the post-ovulatory peak averaged CBT: 229 cycles; 137 respondents

36.1 36.5 36.6 36.8

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


Support

The study was financially supported by Fertility Focus Ltd.