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Effectiveness of a Digital Fertility Awareness-Based App for Contraception in the United States [4M]

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INTRODUCTION: There is an unmet need for effective, non-hormonal methods of contraception. Natural Cycles is a digital fertility awareness-based method of contraception delivered in the form of a mobile app. The aim of this study was to assess the effectiveness of the app in a cohort of women from the United States (US).

METHODS: Data from 18,304 users registered between August 2014 and November 2017 were included in the analysis. Participants were included if they were between 18 and 45 years of age and had at least 20 daily data entries. Questions addressing key characteristics (age, body mass index (BMI) and previous hormonal contraception) were mandatory for onboarding into the app. Other demographics were assessed through in-app messaging. Contraceptive effectiveness during typical use was calculated as both a 13-cycle cumulative probability of pregnancy from a life-table analysis and as a one-year Pearl Index (PI) (EPN, Stockholm, diary number 2017/563-31).

RESULTS: The mean age of users of the application was 29 years and mean BMI was 22. The majority of the cohort had a university degree or higher (74.8%) and reported being in a stable relationship (85.7%). The 13-cycle failure rate was $6.2\% \pm 0.5$ and the one-year PI was 5.9 ± 0.2 .

CONCLUSION: In this real-world observational study, this digital fertility awareness-based method of contraception had a 13-cycle failure rate of 6.2% in a cohort of users from the US. This is in-line with the typical-use failure rates of Natural Cycles users globally.

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Endometrial Safety With a 1-Year Segesterone Acetate/Ethinyl Estradiol Contraceptive Vaginal System [5M]

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INTRODUCTION: A new contraceptive vaginal system (CVS) for 13 cycles of use has been developed that releases a daily mean of segesterone acetate (SA) 0.15 mg and ethinyl estradiol (EE) 0.013 mg. We evaluated endometrial safety during use of the SA/EE CVS for up to 13 cycles.

METHODS: In this multicenter, open-label, phase 3 study, 2308 women used the SA/EE CVS on a 21-day in/7-day out regimen for up to 13 cycles. Women could choose to participate in an endometrial safety sub-study at 5 study sites. Three blinded pathologists histologically examined endometrial biopsies at screening, at cycle 6 in the first 25 women reaching 6 cycles, and at the end of study (cycle 12/13) or early study termination in the remainder. Women with endometrial hyperplasia or cancer at baseline were excluded. We evaluated histologic changes in women with both screening and follow-up biopsies.

RESULTS: Of the 156 women who participated, 83 had follow-up biopsies. Pathologists identified no cases of endometrial hyperplasia or carcinoma at cycle 6 (n=24), cycles 12/13 (n=30) or other end of therapy times (n=29). The most frequent histologic diagnoses were atrophic/inactive or secretory: atrophic/inactive (29%, 27% and 28%,

respectively), secretory (29%, 37%, and 45%, respectively), proliferative (17%, 7%, and 21%, respectively), mixed (17%, 10% and 3%, respectively), menstrual (4%, 7%, and 0%, respectively), or insufficient/no tissue (0%, 10%, and 3%, respectively).

CONCLUSION: Use of the SA/EE CVS for up to 13 cycles did not result in any unexpected endometrial safety effects based on endometrial histology.

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Fertility Knowledge of Women in the United States [6M]

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INTRODUCTION: The demographics of women seeking to conceive has changed, with many women now seeking pregnancy when older. This can lead to disappointment, with the sentiment “I wish I had known more about fertility”. This study sought to assess US women basic understanding of fertility.

METHODS: On behalf of SPD, Ipsos Suisse SA interviewed a representative sample of 1,000 US women aged from 20 to 45 years old who are able to have children (with quotas set upon age and region). Interviews were conducted online (computer assisted web interview) via online Panel.

RESULTS: When asked “what would you say is the most accurate description, for you personally, of a menstrual cycle?”, only 14% selected the right answer from the five options presented, with 16% selecting “the days on which there is bleeding”. Only 20% knew there were fertile 3-6 days during a menstrual cycle, with 25% thinking pregnancy was possible following intercourse on any day of the cycle; for the 20-24 age group 38% thought pregnancy possible on any day. Only 27% of women could correctly state when the fertile days were in a cycle.

CONCLUSION: This survey found a basic gap in fertility knowledge for many US women. Especially worrying was the proportion of these women who believed that pregnancy was possible following intercourse on any day of the cycle, as this could hinder conception chances.

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