Objectives: To examine efficacy and safety of a combined oral contraceptive pill containing the estetrol (E4) and drospirenone (DRSP) in a 24/4-day oral regimen.

Methods: Two parallel, multicentre, open-label, phase-3 trials (United States/Canada and Europe/Russia) enrolled healthy participants 16–50 years to use estetrol 15 mg/drospirenone 3 mg (E4/DRSP) for up to 13 cycles. Data of participants 16–35 years at screening were pooled to assess the Pearl Index (PI) in at-risk cycles (confirmed intercourse and no other contraceptive use). In addition, PI was stratified by previous hormonal contraceptive use and body mass index (BMI). Groups were compared using chi-square testing. Adverse events (AEs) were evaluated for all participants.

Results: 3417 participants were enrolled (3027 of whom were 16–35 years), and treated with E4/DRSP. Reported treatment compliance was ≥99%., The PI among participants age 16–35 years was 1.52 (95% CI 1.04–2.16). For starters (n = 1368) and switchers (n = 1469), PI was 1.88 (95% CI 1.09–3.00) and 1.24 (95% CI 0.68–2.08), respectively ($P = 0.25$). For BMI <25.0 kg/m^2 (n = 1771), 25–30 kg/m^2 (n = 656) and ≥30 kg/m^2 (n = 410), PIs were 1.14 (95% CI 0.64–1.88), 2.19 (95% CI 1.05–4.03) and 2.27 (95% CI 0.83–4.94), respectively ($P = 0.17$). There were no on-treatment pregnancies reported among 147 Canadian participants. Most frequently reported treatment-related adverse events were metrorrhagia (4.7%), acne (3.3%) and headache (3.2%). Three treatment-related AEs (0.1%) were considered serious: worsening depression (continued treatment), ectopic pregnancy (discontinued) and venous thromboembolism (discontinued).

Conclusions: Overall, and in subgroups stratified by contraceptive history and BMI, E4/DRSP demonstrated contraceptive efficacy and adverse events occurred at low rates.

Keywords: estetrol; drospirenone; oral contraceptive

■ O-GYN-EDU-MD-173

Hands-on Training in a Virtual World: Novel Simulation-based Virtual Training for Subdermal Contraceptive Implant Placement and Removal

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Objectives: The COVID-19 pandemic necessitated a shift from traditional face-to-face instruction for new technical skills to virtual delivery of medical education training. Our objectives were to develop and validate a virtual simulation training program for Canadian healthcare professionals (HCPs) on the insertion, localization, and removal of the etonogestrel subdermal contraceptive implant.

Methods: A scientific committee of Canadian family planning experts developed a two-part virtual training program during the COVID-19 pandemic. In Part 1, core educational content was provided in an asynchronous, self-directed, on-line format. Part 2 consisted of synchronous, simulation-based training using web conferencing. HCPs were provided with model arms and training placebo applicators, trainers demonstrated implant insertion/removal techniques, and trainees received individual feedback on technical performance. All trainees were asked to complete an on-line evaluation upon program completion.

Results: Between March 2020 and June 30, 2021, 2130 Canadian HCPs had completed Parts 1 and 2 of the training program and 1275 participants completed the program evaluation (response rate 60%). Participants reported high levels of satisfaction with virtual simulation-based training. Ninety-seven percent (1229/1275) of participants agreed the virtual format was effective. Four percent (51/1275) requested additional training prior to inserting the implant in clinical practice.

Conclusions: Virtual simulation-based learning provides effective education and technique training for etonogestrel implant insertion and removal. Online delivery of implant training can be scaled to use as needed to reach professionals in remote or underserved locations and for training provision of other technical or surgical procedures.

Keywords: simulation-based training; contraceptives; virtual learning

■ O-GYN-MD-046

Bleeding Patterns with Use of an Oral Contraceptive Containing Estetrol and Drospirenone: Pooled Analysis of Phase-3 Clinical Trials

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Objectives: To evaluate bleeding patterns with use of a 24/4-day novel combined oral contraceptive regimen containing estetrol, a natural estrogen, and drospirenone.

Methods: Bleeding data from two parallel, multicentre, open-label, phase-3 trials (United States/Canada and Europe/Russia) were pooled. Healthy participants aged 16–50 years with body mass index of ≤35.0 kg/m^2 used estetrol 15 mg/drospirenone 3 mg for up to 13 cycles. Participants reported vaginal bleeding (blood loss requiring use of sanitary protection) or spotting (minimal blood loss, requiring no new use of sanitary protection) on daily diaries. Bleeding outcomes were evaluated in participants that started treatment and had at least 1 evaluable cycle. Mean frequency of scheduled and unscheduled bleeding and/or spotting and median duration of bleeding and/or spotting episodes were calculated.

Results: Of 3417 participants starting treatment, 3265 were included in the bleeding analysis. Mean reported treatment compliance was ≥99%. Across cycles, 87.2–90.4% of participants reported scheduled bleeding/spotting, with a median duration of 4–5 days/cycle. Unscheduled bleeding/spotting frequency decreased from 27.1% in Cycle 1 to <17.5% from Cycle 5 onwards, with a median duration of 3–4 days/cycle and most episodes (62.7%) were spotting-only. Of 2234 women completing 13 cycles, 754 (34%) reported unscheduled bleeding/spotting in only 1 or 2 cycles and 911 (41%) did not report any unscheduled bleeding/spotting. The most common bleeding adverse events (AEs) considered treatment-related were 'metrorrhagia' (159 [4.7%]) and 'vaginal hemorrhage' (101 [3.0%]). One hundred four (3.0%) participants discontinued for a bleeding-related AE.

Conclusions: Most users of estetrol/drospirenone oral contraceptive experienced a predictable bleeding pattern and limited unscheduled bleeding.

Keywords: estetrol; oral contraceptive; bleeding profile; drospirenone

■ O-GYN-MD-024

Impact of a 10-Minute Educational Video Prior to Initial Consultation in a Mature Women's Health and Menopause Clinic

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