

17th World Congress of the Academy of Human Reproduction

15–18 March 2017
Rome, Italy

TITLE

CYCLE CONTROL WITH AN EXTENDED-REGIMEN ORAL CONTRACEPTIVE COMBINING LEVONORGESTREL AND ETHINYL ESTRADIOL

AUTHOR/S

LOBO P (ES) [1], NAPPI R E (IT) [2], HSIEH J (US) [3], MICHELETTI M (FR) [4]

ABSTRACT

Context: Extended regimens (ERs) are increasing in popularity. Although women using ERs experience only 4 scheduled withdrawal bleeds per year that, on average, some women may experience even less scheduled bleeding and others unscheduled bleeding. Objective: to evaluate changes in scheduled and unscheduled bleeding over time with Seasonique®, a 91-day ER combined oral contraceptive: 30 mcg ethinylestradiol (EE)/150 mcg levonorgestrel (LNG) for 84 days and EE 10 mcg for 7 days instead of the traditional hormone free interval.

Methods: We conducted a post-hoc analysis of a multicenter, open-label, 1-year, phase 3 study of Seasonique® in sexually active, adult women aged 18 to 40 years. All women completed daily electronic diaries to record bleeding

episodes. Bleeding/spotting was considered scheduled if it occurred on Cycle Days 85 to 91 and unscheduled if it occurred on Cycle Days 1 to 84. Bleeding was defined as vaginal blood loss requiring sanitary protection; spotting did not require sanitary protection. Results: Seven hundred fifty-eight women completed at least 1 cycle. Among them, there was a 13% increase in the likelihood of reporting no scheduled bleeding for each additional cycle completed (odds ratio [OR]=1.131; 95% confidence interval [CI]: 1.025-1.249). By Cycle 4, 18% of women reported no scheduled bleeding. There was also a 63%

increase in the likelihood of reporting 0 to maximum 6 days of unscheduled bleeding per cycle (OR=1.634; 95% CI: 1.486-1.796). The most rapid

decrease in unscheduled bleeding occurred between Cycles 1 and 2.

Conclusion: The incidence and duration of bleeding decreased over time with this ER. Nearly 1 in 5 women reported no scheduled bleeding in Cycle 4. By Cycle 2, >80% of women reported no or ≤6 days of unscheduled bleeding during

each 3-month cycle. Women should be counseled that after the 1st cycle they will likely bleed less.

INSTITUTE

[1] Hospital Universitario Infanta Sofía, San Sebastián de los Reyes, Madrid, Spain, [2] Research Center for Reproductive Medicine, Gynecological Endocrinology and Menopause, Department of Obstetrics and Gynaecology, IRCCS San Matteo Foundation, University of Pavia, Pavia, Italy, [3] Teva Branded Pharmaceutical Products R&D, Inc., West Chester, PA, USA, [4] Teva Europe Women's Health Medical Affairs, Amsterdam, The Netherlands