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TITLE

TREATMENT CONTINUATION AND SATISFACTION IN WOMEN USING COMBINED ORAL CONTRACEPTION WITH NOMEGESTROL ACETATE AND ESTRADIOL: A MULTICENTER, PROSPECTIVE COHORT STUDY (BOLERO)

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ABSTRACT

Context: The real-world experience of women receiving nomegestrol acetate (NOMAC)/estradiol (E2) is not well known.

Objective: To assess treatment continuation and satisfaction of women prescribed NOMAC/E2 for contraception.

Methods: This observational, non-interventional, prospective, multicenter cohort study was conducted in 17 centers in Italy.

Patients: Eligible patients were premenopausal women 18-50 years old prescribed NOMAC/E2 (Zoely®, Teva Italia, Italy).

Intervention: Data collected at baseline, 3 months, 6 months, and 12 months.

Main Outcome Measures: The primary efficacy outcome was the number of treatment cycles completed through 12 months. Secondary outcomes included menstrual cycle-related symptoms, libido level, and treatment-related satisfaction. Adverse events (AEs) were also reported.

Results: 298 women were enrolled. The mean number of NOMAC/E2 treatment days was 303.2±110.3 (median=361 days). The probability of treatment continuation through 12 months was 81% (95% confidence interval 75.6-85.2). Women reported significant improvement in menstrual cycle-related symptoms ($P<0.0001$), libido level ($P=0.03$), and treatment-related satisfaction ($P<0.0001$) over 12 months. Menstrual cycle-related symptoms declined from a mean of 6.2±4.4 at baseline to 2.9±3.0 at 12 months ($P<0.0001$). Most women reported their libido was improved or unchanged during treatment. The majority of women (52%-59%) reported improved treatment satisfaction at each time point. Treatment-related AEs were reported by 37.9% of women. Two serious AEs were reported; 1 (lymphoma) considered unrelated to treatment and 1 pregnancy.

Conclusion: The real-world experience of women prescribed NOMAC/E2 indicates good treatment continuation and high satisfaction through 12 months. Other benefits included significantly improved menstrual cycle-related symptoms and maintained or improved libido.

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