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Clinical Resource center

Endometriosis-Related Pain Reduction During Bleeding and Nonbleeding Days in Women Treated with Elagolix

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Objective

To evaluate the impact of elagolix on dysmenorrhea and nonmenstrual pelvic pain across menstrual period (bleeding days) and nonmenstrual (nonbleeding) days).

Methods

- *Data Source:* Pooled analysis from two large Phase 3 trials (Elaris EM-I and EM-II)
- *Participants:* 1,686 women with moderate-to-severe endometriosis-associated pain.
- *Intervention:* 6 months of treatment with:
  - Elagolix 150 mg once daily (QD)
  - Elagolix 200 mg twice daily (BID)
  - Placebo
- *Measurement:* Patients used a daily e-diary to record bleeding and pain severity (0=none to 3=severe).

Key results

At Month 6, elagolix significantly reduced the percentage of days with moderate-to-severe pain compared to placebo.

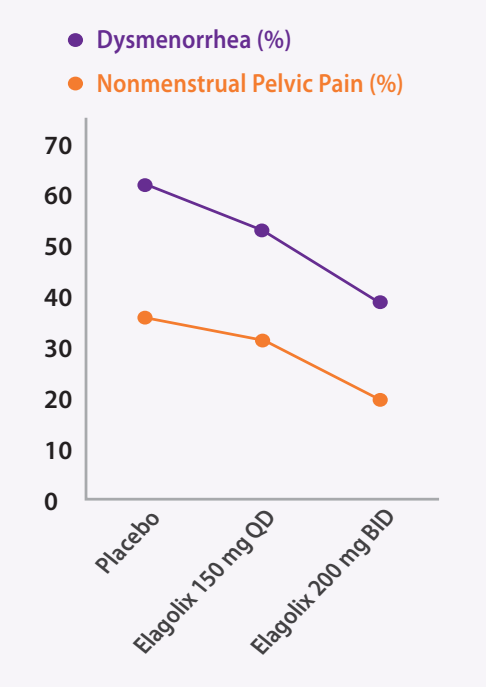
Pain type	Placebo	Elagolix 150 mg QD	Elagolix 200 mg BID
Dysmenorrhea (%)	61.3	52.4 (p=0.002)	38.5(p=<0.001)
Nonmenstrual Pelvic Pain (%)	35.6	31.1 (p=<0.001)	19.7(p=<0.001)

Conclusions

Following 6 months of elagolix treatment, women who still menstruated had a lower proportion of menstrual period days with moderate or severe dysmenorrhea compared with placebo, demonstrating pain reduction despite continued menses. Additionally, pain did not shift from dysmenorrhea to nonmenstrual pelvic pain, as the percentage of days with moderate or severe nonmenstrual pelvic pain was also reduced for elagolix-treated women compared with placebo.

Clinical implications

- Elagolix provides significant pain reduction both during menstrual bleeding and on non-bleeding days.
- Pain did not simply shift from dysmenorrhea to nonmenstrual pelvic pain. This supports the conclusion that with elagolix treatment pain relief is not dependent on achieving amenorrhea.
- The ability to reduce pain without completely suppressing bleeding with low or high doses of elagolix allows women to not require hypoestrogenism and other adverse effects. These side effects are present with the alternative treatment options that demonstrate a near complete suppression of estrogen.
- This challenges the traditional view that bleeding suppression is essential for managing endometriosis pain, offering a treatment that reduces pain without necessarily stopping periods.



Ref.: Muhammad, Juliawati et al. "Elagolix treatment in women with heavy menstrual bleeding associated with uterine fibroid: a systematic review and meta-analysis." BMC women's health vol. 22,1 14. 15 Jan. 2022, doi:10.1186/s12905-022-01596-2