PROSPECTIVE OBSERVATIONAL STUDY ON USE OF DIENOGEST IN WOMEN WITH ENDOMETRIOSIS

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Medical treatment of endometriosis:
- alleviation pain and other symptoms;
- reduction endometriotic lesions;
- improvement quality of life.

**What's new?**

**Dienogest in the treatment of endometriosis: systematic review.**
Andres MP, Lores LA, Baracat EC, Podgaec S.

**Abstract**
**PURPOSE:** Endometriosis is a prevalent disease that affects 5-15% of women of reproductive age. The aim of this study is to assess the effect of dienogest in the treatment of endometriosis.

**METHODS:** The search was applied to electronic databases PubMed, Cochrane, EMBASE and Liiacs until September 2014, in a public tertiary hospital. We performed a systematic literature search of randomized trials comparing dienogest to other medical therapies in the treatment of endometriosis, as well as their references list, using the keywords "dienogest" and "endometriosis" by two independent authors. The data extraction were performed by two authors using predefined data fields. Nine randomized trials were included. Dienogest 2 mg/day was superior to placebo in reducing pelvic pain (27.4 versus 15.1 mm, P < 0.0001), with similar results to buserelin, leuprolirelin, leuprolide acetate and triptorelin, in controlling symptoms associated with endometriosis. Dienogest 2 mg/day was effective in reducing endometriotic lesions (11.4 ± 1.71-3.6 ± 0.95, P < 0.001). The extended therapy with dienogest 2 mg/day also showed an improvement in pelvic pain after 24-52 weeks (22.5 ± 32.1 and -28.4 ± 29.9 mm, respectively) with tolerable side effects.

**CONCLUSION:** Dienogest should be considered as an alternative for controlling symptoms related to endometriosis. Nevertheless, in this systematic review, no studies were found comparing dienogest with first-line therapy, such as progestins and estrogen-progestogen combinations, which are proved to be effective in the treatment of endometriosis, are less expensive, and also can be used for contraception.
The aim of the study was to compare the efficacy and safety of dienogest 2 mg with estrogen-progestogen combination (ethinylestradiol 20 mcg + levonorgestrel 100 mcg) in patients with endometriosis.
Material and Methods

November 2013 - February 2015

- Prospective observational study
- Ethic committee approval
- Informed consent

44 patients with endometriosis
Enrolled randomly

22 tp with DIENOGEST

22 tp with ETHINYLESTRADIOL 20 mcg + LEVONORGESTRELE 100 mcg

Inclusion criteria:
- > 18 years old;
- Pelvic pain VAS >5;
- Clinical and instrumental diagnosis of ovarian and/or deep endometriosis.

Exclusion criteria:
- Contraindications to hormonal therapy;
- Desire of pregnancy.
## Patients

<table>
<thead>
<tr>
<th></th>
<th>22 tp with DIENOGEST</th>
<th>22 tp with EE/LNG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ovarian endometriomas</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Deep endometriosis</td>
<td>41%</td>
<td>27%</td>
</tr>
<tr>
<td>After laparoscopic surgery</td>
<td>9%</td>
<td>23%</td>
</tr>
</tbody>
</table>

44 Italian women (mean age: 34 years old)
Diagnostic evaluation:
• Medical history;
• bimanual pelvic examination;
• TV-US.

Evaluation at the enrollment (T0), after 1 month (T1), 3 months (T3), 6 months (T6):

- intensity of dysmenorrhea, dyspareunia and chronic pelvic pain, according to 10 point visual analogue scale (VAS);
- modifications ovarian endometriomas size (US);
- a questionnaire on health status (SF12)
- side effects
RESULTS

Dysmenorrhea

Progressive reduction with DIENOGEST

P = 0.038
Dyspareunia

Chronic Pelvic Pain

P = 0.38

P = 0.22
Modification in size of endometriomas

P = 0.03
Health status
Quality of life

Dienogest 2 mg

Ethinylestradiol + Levonorgestrel

% patients

T0 T3 T6

T0 T2 T6

Acceptable

Good

Very good

SF12
## Side effects

<table>
<thead>
<tr>
<th></th>
<th>DIENOGEST</th>
<th>ETHINYLESTRADIOL + LEVONORGESTREL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>•18 patients 80%</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>•8 patients 35%</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>DIENOGEST</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>T1 (1 month)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>63%</td>
<td>38%</td>
</tr>
<tr>
<td>Acne</td>
<td>37%</td>
<td>0%</td>
</tr>
<tr>
<td>Abnormal bleeding</td>
<td>58%</td>
<td>38%</td>
</tr>
<tr>
<td>Depression</td>
<td>31%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>T2 (3 months)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>58%</td>
<td>22%</td>
</tr>
<tr>
<td>Acne</td>
<td>21%</td>
<td>0%</td>
</tr>
<tr>
<td>Abnormal bleeding</td>
<td>37%</td>
<td>33%</td>
</tr>
<tr>
<td>Depression</td>
<td>26%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>T3 (6 months)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>69%</td>
<td>14%</td>
</tr>
<tr>
<td>Acne</td>
<td>12%</td>
<td>0%</td>
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<tr>
<td>Abnormal bleeding</td>
<td>44%</td>
<td>29%</td>
</tr>
<tr>
<td>Depression</td>
<td>31%</td>
<td>0%</td>
</tr>
</tbody>
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CONCLUSIONS

DIENOGEST 2 mg vs EE/LNG 20mcg/100mcg:

- Causes a progressive decrease of dysmenorrhea
- Reduces endometrioma volume;
- Improves quality of life after 6 months of therapy.

- More side effects
- More expensive
- No contraceptive
Thank you