

Poster Nr. P-196: DIENOGEST FOR PAIN SYMPTOMS CAUSED BY RECTOVAGINAL ENDOMETRIOSIS RESISTANT TO NORETHISTERONE ACETATE: PROSPECTIVE COHORT STUDY

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Study question: Is dienogest (DNG) efficacious in treating pain symptoms caused by rectovaginal endometriosis resistant to norethisterone acetate (NETA)?

Summary answer: DNG improves patient satisfaction compared with NETA. It ameliorates endometriosis-related pain symptoms and quality of life without causing significant changes in the volume of rectovaginal nodules and adverse effects.

What is known already: Progestins are valuable option for the treatment of endometriosis-related pain symptoms; however, no study compared the efficacy and safety of different progestins in the treatment of endometriosis.

Study design, size, duration: 24-week open-label prospective cohort study.

Participants/materials, setting, methods: The study included 21 women with rectovaginal endometriosis who had persistence of pain symptoms after treatment with NETA. Patients received DNG (2 mg/day) for 6 months. Patient satisfaction was the primary endpoint. Secondary endpoints were: changes in pain symptoms (measured on a 10-cm visual analogue scale), volume of the nodules (assessed by VOCAL, virtual organ computer-aided analysis), Endometriosis Health Profile-30 Questionnaire (EHP-30), Female Sexual Function Index (FSFI) and adverse effects.

Main results and the role of chance: Patient satisfaction improved at 3- ($p=0.021$) and 6-months ($p<0.001$) treatment with DNG compared with baseline treatment with NETA; in addition, patient satisfaction was higher at 6-month treatment with DNG than at 3-month treatment with DNG ($p < 0.001$; Figure 1). DNG decreased the intensity of deep dyspareunia and non-menstrual pelvic pain at 3 ($p<0.001$) and 6-month ($p<0.001$; Figure 2). By week 24, the absolute reduction in visual analogue scale was 31.3 mm for deep dyspareunia, 18.3 mm for non-menstrual pelvic pain and 19.0 for dyschezia. The volume of the endometriotic nodule did not significantly change during treatment ($p=0.378$; Figure 3). There was an improvement in three modular dimensions of the EHP-30: emotional well-being ($p=0.021$), self-image ($p=0.013$) and sexual intercourse ($p=0.039$). There was a tendency towards better total FSFI score at the end of treatment ($p=0.053$); the changes in the subdomain of the FSFI score are shown in Figure 4. The number of analgesics used significantly decreased by week 24 ($p<0.001$). There was no significant difference in the incidence of adverse effects between NETA and DNG ($p=0.295$).

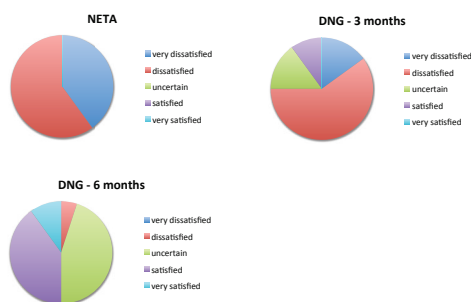


Figure 1. Patient satisfaction during treatment

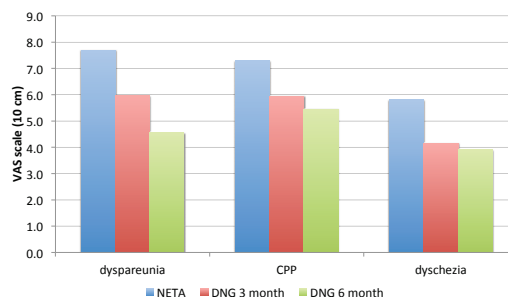


Figure 2. Changes in the intensity of pain symptoms during treatment

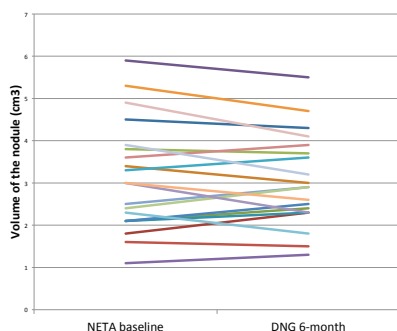


Figure 3. Changes in the volumes of the nodule during treatment

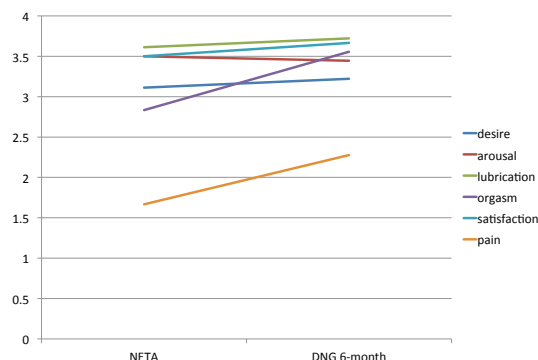


Figure 4. Changes in subdomains of the FSFI during treatment

Limitations, reasons for caution: The study was open label and treatments were not randomly allocated; the sample size was small.

Wider implications of the findings: This study confirms the efficacy of DNG in treating endometriosis-related pain symptoms and suggests for the first time that it may be more efficacious than NETA. If these finding will be confirm by randomised controlled trials with larger sample size, DNG may become the first choice progestin for the treatment of pain caused by endometriosis.

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