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Contr. Gynec. Obstet., vol. 16, pp. 150–155 (Karger, Basel 1987)

High-Dose Medroxyprogesterone Acetate and Danazol in the Treatment of Endometriosis

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Studies on cytosol endometrial estrogen and progestin receptor concentrations and 17β-hydroxysteroid dehydrogenase activity have shown that the effects of danazol and medroxyprogesterone acetate (MPA) are similar. Therefore we conducted a placebo-controlled study to compare danazol (600 mg/day) and MPA (100 mg/day) in the hormonal treatment of mild-moderate endometriosis. The duration of treatment was 6 months. Laparoscopy was performed before the trial and 6 months after the treatment. Sixteen patients receiving MPA, 18 patients receiving danazol and 17 receiving placebo completed the study.

The resolution of the peritoneal endometriosis implants was similar in the MPA (63%) and danazol (60%) groups, results differing significantly from the placebo effect (18%). MPA and danazol significantly alleviated endometriosis-associated pelvic pain, lower back pain and defecation pain and they did not differ from each other. In comparison with placebo, MPA appeared to be less androgenic than danazaol, while anabolic side effects were similar.

High-dose MPA is thus a useful alternative in the hormonal treatment of endometriosis.

The Impact of Gestrinone upon the Natural History of Endometriosis

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There is no placebo-controlled trial of any treatment of endometriosis and therefore there is no description of the natural history of the disease or complete validation of the efficacy of drug therapy. There is, therefore, debate about the need for treatment especially in asymptomatic mild and moderate disease.

Forty patients with asymptomatic endometriosis were recruited to a randomised, double-blind controlled trial of gestrinone (Roussel-UCLAF) 2.5 mg orally twice weekly. The endometriosis was diagnosed at laparoscopy and scored using the American Fertility Society System (1979). The range of scores was 1–6 (median = 2). After 24 weeks a repeat

laparoscopy was performed. Cure was defined as no visible endometriosis, improvement as a decrease in and deterioration as an increase in the score.

There were 18 evaluable patients randomised to gestrinone and 17 to placebo. In the placebo group cure was seen in 4, improvement in 5 and deterioration in 8 patients. In the treatment group cure was seen in 11 and improvement in 15 patients. No patient showed deterioration. The difference in rates of improvement ($p < 0.001$) of the disease in the treatment group and of deterioration ($p < 0.001$) in the placebo group was statistically significant.

This study has shown a natural history of deterioration of the disease in nearly 50% of patients with asymptomatic endometriosis which does not occur on treatment. This cannot be predicted for any individual and therefore it is recommended that medical therapy is prescribed in all. Gestrinone is an effective treatment of endometriosis.

Metabolic Effects of Hormonal Treatment for Endometriosis: Danazol versus LHRH-Agonist (Buserelin) Therapy

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Between 1979 and 1986 102 patients were treated for endometriosis. Diagnosis was made by laparoscopy or laparotomy and histological examination of suspect specimens. After confirmation of the diagnosis 'endometriosis', we started a 6-month treatment course with either 600 mg/day danazol (62 patients) or 900 µg/day buserelin intranasally (40 patients). Before and under therapy we checked the complete blood count, clotting parameters, electrolytes and renal function as well as liver enzymes and lipid metabolism. After treatment, the success of therapy was assessed by control laparoscopy.

Complete blood count, serum electrolytes as well as renal function were unaffected by treatment of both drugs. In contrast, danazol led to a disturbance in liver function. After 6 months of therapy glutamic pyruvic transaminase (GPT) significantly rose up to 18.4 ± 5.6 U/l. Some patients presented with an even more pronounced increase of GPT as well as glutamic oxaloacetic transaminase levels, so that cessation of therapy had to be discussed. While total cholesterol, low-density lipoprotein-cholesterol and triglycerides stayed within the normal range, high-density lipoprotein (HDL)-cholesterol levels decreased significantly to 26 ± 11.3 mg/100 ml after 2 months of danazol, resulting in an increased atherogenic index. In contrast to this, buserelin caused increasing HDL-cholesterol levels. There was no effect of buserelin on clotting parameters. Danazol lowered fibrinogen concentrations to 164 mg/100 ml after 3 months and 151 mg/100 ml after 6 months, respectively. This effect was outweighed by increased plasminogen concentrations (15.9 mg/100 ml after 6 months of danazol). Consequently there were no bleeding complications during control laparoscopy.

We conclude that liver and lipid metabolism should be observed carefully during danazol treatment. In case of severe disturbance of these parameters an alternative in