

an unchanged quality of health. There were no serious treatment-related side effects and no patient became amenorrheic. Population pharmacokinetic analyzes demonstrated danazol levels below the sensitivity range of the bioanalytical assay (2.5 ng/mL).

Conclusion

Intravaginal danazol effectively reduces pelvic pain associated with endometriosis. Most importantly there was a lack of systemic androgenic side effects and undetectable plasma levels of danazol indicating that the drug was acting locally.

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INTRAVAGINAL DANOZOL SIGNIFICANTLY REDUCES CHRONIC PELVIC PAIN IN WOMEN WITH ENDOMETRIOSIS.

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Objective

To evaluate the effect of vaginally administered danazol on chronic pelvic pain in women with a prior surgical diagnosis of endometriosis.

Methods

Twenty-four (24) women with chronic pelvic pain symptoms and a prior diagnosis of endometriosis were enrolled in an open-label, single-arm, multicenter study. Danazol 100 mg/day in a 0.2 mL volume was self-administered intravaginally using specially designed introducers daily for three menstrual cycles. In seven (7) of 23 subjects, the dose was increased to 200 mg/day for two additional cycles. The remaining 16 subjects continued on 100 mg/day for one further menstrual cycle. Pelvic pain was evaluated before, during, and after treatment using the Biberoglu and Behrman Symptoms Score (BBSS) scale, pre- and post-treatment Pain Assessment Questionnaires (PAQ), and Quality of Life (QL) questionnaires. In a subset of 12 patients, population pharmacokinetic analyzes were performed after administration of 100 and 200 mg of intravaginal danazol.

Results

There was a mean improvement in BBSS scale of greater than 50% (95% CI). PAQ indicated an average decrease from screening to end of treatment in average endometriosis pain experienced in the previous 4 weeks of 3.4 points (median decrease 3.0 points, minimum -7.0, maximum 0.0) and an average decrease in worst endometriosis pain experienced in the previous 4 weeks of 3.3 points (median decrease 3.0 points, minimum -9.0, maximum 1.0). In the QL 79% of women reported improved quality of health from screening (baseline). The remainder of the women reported