

Intravaginal Danazol Is Efficacious With Limited Side-Effect Profile in the Treatment of Endometriosis

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OBJECTIVE OF THE STUDY: To evaluate the safety and efficacy of intravaginal danazol in women with endometriosis and chronic pelvic pain symptoms.

METHODS: A cohort of 22 women with laparoscopically diagnosed endometriosis were enrolled in an open-label, single-arm, multicenter study. Danazol 100 mg/d was administered intravaginally for 3 menstrual cycles. At the start of the fourth menstrual cycle, at the discretion of the Investigator, the dose could be increased to 200 mg/d for 2 additional cycles. Efficacy was assessed using the Biberoglu and Behrman Symptom Score (BBSS) Scale. In a subset of 12 patients, pharmacokinetic studies were performed after administration of 100 and 200 mg of intravaginal danazol.

RESULTS: All patients completed the study; approximately 30% of patients were increased to 200 mg/d at the fourth menstrual cycle. The mean improvement in BBSS was 4.5 points with a 95% CI of 3.3 to 5.8. There were no serious treatment-related adverse events. One subject developed mild facial acne, considered possibly drug-related; there were no other systemic androgenic side effects. No patient became amenorrheic. Pharmacokinetic studies demonstrated danazol levels to be below the sensitivity range of the assay (2.5 ng/mL).

CONCLUSION: Intravaginal danazol appears to be both safe and effective for the management of chronic pelvic pain secondary to pelvic endometriosis. It was well tolerated and demonstrated a favorable side effect profile with a paucity of systemic androgen-like effects. Peripheral levels of danazol were undetectable, indicating that the drug was effective locally.

Outcomes After Deinfibulation

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OBJECTIVE: The outcomes of deinfibulation, a surgical procedure to recreate the genital anatomy after female circumcision/female genital cutting, are largely unknown. The purpose of this study is to evaluate health outcomes and patient satisfaction after deinfibulation.

METHODS: All patients who underwent deinfibulation through the African Women's Health Center at Brigham and

Women's Hospital and at Massachusetts General Hospital between 1995 and 2003 were identified. Chart review and telephone interviews were conducted to assess surgical outcomes, complications, resolution of symptoms, obstetrical outcomes, patient satisfaction, and cultural acceptance.

RESULTS: Twenty-nine of 37 patients (78%) were successfully interviewed. Ninety-five percent of the patients were Somalian, 65% were married, and more than 50% were between the ages of 19 and 25 years. Indications for the procedure included pregnancy (32%), dysmenorrhea (30%), difficulty voiding (26%), apareunia (19%), and dyspareunia (14%). There were no surgical or postoperative complications, and 50% of patients had an intact clitoris present under the scar tissue. Ninety percent reported complete resolution of symptoms, and 10% had ongoing dyspareunia. Of the 12 women who had subsequent pregnancies, 6 (50%) had cesarean delivery, and 3 (33%) had third-degree lacerations. There were no fourth-degree lacerations. All interviewed patients and their husbands were satisfied with the results. Twenty-eight of the women (97%) reported that they would recommend this procedure to other women; however, 13 (45%) did not discuss the procedure with others.

CONCLUSION: Deinfibulation appears to be a safe, highly effective procedure to treat the long-term complications of female circumcision/female genital cutting. Minimal complications are coupled with very high satisfaction ratings. Benefits were shown for both reproductive and emotional health.

Endometriosis of Adolescents With Incapacitating Chronic Pelvic Pain

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OBJECTIVE: Evaluate the incidence of endometriosis among adolescents with chronic pelvic pain.

METHODS: Retrospective review of 37 cases of adolescents with incapacitating chronic pelvic pain in a tertiary referral center.

RESULTS: Thirty-one adolescents (84%) underwent laparoscopy. Six (16%) were treated medically. The average age was 17.4 years. The average age for the patients with diagnoses of endometriosis was 18.9 years. Therapy included laparoscopic surgery and medical treatment. Medical therapy included hormonal suppressive therapy and/or nonsteroidal anti-inflammatory agents (NSAIDs). All surgeries were preformed in an ambulatory care setting. Twenty-seven adolescents (73%) had obvious pelvic pathology. Nineteen (70%) had histologic confirmation of endometriosis. Of the 31 patients who had sur-

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