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Coital pain in the elderly: could a low dose estriol gel thrill the vulvar vestibule?

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ABSTRACT

Objective: The aim of this study was to evaluate the effectiveness of the application of 0.005% estriol gel to the vulvar vestibule in the management of postmenopausal dyspareunia.
Study design: Postmenopausal women with dyspareunia were enrolled in this study. Patients were instructed to use a fingertip to apply 0.25 g of vaginal gel containing 25 μg of estriol to the vulvar vestibule daily for three weeks and then twice weekly for up to 12 weeks.
Results: Assessment of symptoms (dyspareunia and cotton swab test) and signs of vestibular atrophy were performed, and changes between baseline and weeks 3 and 12 were assessed.
Adverse events were recorded. A total of 63 women were included. Of the 63, 59 (93.6%) completed the 12-week treatment period, and four dropped out for vestibular burning. Dyspareunia improved or was cured (score $\leq$1) by week 12 in 81.4% of patients. The patients also showed a statistically significant reduction in vestibular atrophy and cotton swab test at the end of treatment.
Conclusions: Application of 0.005% estriol gel to the vulvar vestibule is effective in correcting menopausal coital pain. This suggests that reduction in sensory vestibular innervation sensitivity is likely to play a pivotal role in the relief of dyspareunia. One limitation of this study is the limited follow-up, but the therapy may be continued for as long as the patients are distressed by their symptoms without estrogen intervention.

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Introduction

It is estimated that 10%–40% of postmenopausal women experience discomfort due to vulvovaginal atrophy that requires treatment, and approximately 40% of women with vaginal atrophy report dyspareunia [1]. Difficulty during sexual intercourse is very relevant; in fact, it was estimated that 52% of women 50–79 years of age have been sexually active with a partner in the past year [2]. Furthermore, a review of published literature revealed that 22% of married women 70 to 79 years of age report that they still have sexual intercourse [3].

Vulvovaginal atrophy refers to the appearance of the vulva and vagina in post menopause, but it does not describe the symptoms. Actually, it is suggested that the term, genitourinary syndrome of menopause (GSM), be used to better describe the condition [4]. It is described as a syndrome because of the array of signs and symptoms with genital and urinary elements.

GSM may include genital symptoms of dryness and burning and sexual symptoms of lack of lubrication, discomfort or pain and impaired function. We can also observe urinary symptoms of urgency, dysuria and recurrent UTIs. Women may present with some or all the signs and symptoms. The primary goals in GSM management are to alleviate symptoms and reverse atrophic changes.

The North American Menopause Society's (NAMS) position on the role of local vaginal estrogen is that non-hormonal lubricants and moisturizers in combination with regular sexual activity should be considered first-line therapies [1], but women often find these products inadequate. Estrogen therapy, administered either vaginally or systemically, is considered the therapeutic standard for moderate to severe vulvovaginal symptoms.

Current recommendations advise that treatment choices should be customized to the needs of each woman, and symptoms of vulvovaginal atrophy such as dyspareunia, should be treated with the lowest effective dose of estrogen therapy for the shortest amount of time to achieve and maintain satisfactory results [1].

The classic explanation as to why estrogen is effective in reversing vaginal menopausal symptoms is that it acts directly on vaginal tissue estrogen receptors to restore normal function.

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However, many data have suggested that although these factors are important, they are incomplete as explicative mechanisms. Autonomic and sensory neurons express estrogen receptors and are responsive to estradiol in culture, supporting the idea that estrogens can act directly on neurons [5].

It was demonstrated that vaginal innervation was reduced in women receiving estrogen replacement; moreover, topical therapy is more effective than systemic therapy [6].

In addition, very few studies on postmenopausal dyspareunia have focused on location and quality of the pain. It was reported that 95% of menopausal women with dyspareunia also had localized provoked pain in the vestibule, despite the use of hormone supplements in 31% of them [7]. This is principally related to differences in nerve density between vagina and vulvar vestibule.

A rich nerve plexus within the vaginal submucosa was identified, but it is composed only of sympathetic and parasympathetic axons with smaller contributions by sensory fibers; in the vulvar vestibule, the sensory nerve endings are dense and shallow, making this region physiologically more sensitive [8].

The aim of this study was to evaluate the effectiveness of the application of a new 0.005% estriol vaginal gel delivering 25 μg of estriol to the vulvar vestibule in the management of postmenopausal dyspareunia.

Materials and methods

Participants

Women included in the study were postmenopausal with at least one year of amenorrhea. They presented with dyspareunia and signs of vestibular and vaginal atrophy including a thinned, dry, fragile or pale mucosa. Women were excluded if they had a history of malignant lesions of the breasts or endometrium. Also excluded were women who had received any type of hormone therapy within three months before the start of the study, were allergic to the test drug or its constituents, or had any serious disease or chronic condition.

All patients included in the study have used lubricants during sexual intercourse with little or no benefit. Institutional Review Board approval for the study was obtained and all participating individuals gave written informed consent.

Gynecological examination

At the initial consultation, a careful examination of the vulva and vagina was conducted to exclude any other cause for entry dyspareunia.

The grading of dyspareunia was recorded according to the 3 grade classification of Marinoff and Turner [9]. Grade 1 is characterized by intercourse that is always painful but only occasionally prevents penetration, grade 2 is characterized by intercourse that is always painful and often prevents penetration, and grade 3 is characterized by complete apareunia.

Women found suitable for the study underwent a cotton swab test for scoring the sensitivity in seven foci around the vestibule. The cotton swab test is used to test for pain locations on the vulva. Testing starts at the thighs and moves medially to the vestibule as the face of a clock.

The vestibule is tested at the 2:00, 4:00, 6:00, 8:00 and 10:00 positions. Each time the vestibule is touched, the patient is asked to quantify the pain as none (score 0), mild (score 1), moderate (score 2) or severe (score 3). Vulvar vestibule was assessed objectively by examining epithelial integrity, surface thickness and superficial color. Grading of vestibular health was quantified using a four-point scoring system (no atrophy = 0, mild = 1, moderate = 2 and severe = 3). The gynecological examination was performed by two experienced examiners (FM, RF).

Treatment protocol

Patients were instructed to apply, with the fingertip, 0.25 g of vaginal gel containing 25 μg of estriol to the vulvar vestibule, administered daily for three weeks and then twice weekly for up to 12 weeks. An applicator was used to dose an adequate amount of drug, and patients were advised to administer the treatment preferably at night.

Women were asked to stop sexual activity until at least 15 days after starting therapy using an aqueous lubricant.

Data analysis

The primary efficacy end point was the change in dyspareunia score from baseline to week 12. The appearance of vulvar vestibule and the swab test sensitivity after 12 week of therapy were considered secondary outcomes. All the results were reported as the mean standard error of absolute values. Baseline values were compared by Student's t-test. To determine the changes in dyspareunia, appearance of vulvar vestibule and the swab test sensitivity scores at the end of treatment in comparison with baseline, Mann–Whitney U-test was performed. Treatment differences were expressed as least-squares means (standard error) and 95% confidence intervals (CIs), and the statistical significance was defined as $P < 0.05$. Statistical analysis was performed with SPSS 17.0 for Windows (IBM SPSS, Armonk, NY).

Results

Of the 63 women enrolled in the study, 59 (93.6%) completed the 12-week treatment. The baseline characteristics of the enrolled subjects are reported in Table 1.

After 12 weeks of therapy with 25 μg of estriol applied to the vulvar vestibule, there was a statistically significant decrease from baseline in the mean score of the dyspareunia (baseline score 2.85, last observation after therapy 1.23—Table 2).

This symptom improved or was cured (dyspareunia score ≤ 1) by week 12 in 81.4% of women.

At baseline the mean score for vestibular health was 2.91. After 12 weeks of 25 μg of estriol treatment, the mean vestibular health score had decreased to 1.98, and this difference was statistically significant ($P = 0.001$) compared with baseline (Fig. 1).

The patients also showed a statistically significant reduction in cotton swab test scores at the end of treatment (on a 0–3 range, 2.81 compared with 1.25 at baseline, $P = 0.02$).

Looking at the various subgroups, age did not affect the outcome of estriol treatment as we found no significant differences

Table 1
Patients demographics and baseline characteristics.

	Patients (n = 63)
Age (y)	56.4 (±5.6)
Range	49–69
Time since last menses (y)	8.2 (±5.3)
Range	1–23
Less than 2	10 (16%)
2 to less than 5	25 (39.6%)
5 or more	28 (44.4%)
Duration of dyspareunia[a] (mo)	18.7 (±14.7)

Data are presented as the mean values ± standard deviation.
[a] Scored from 0 to 3 (0 = absent, 1 = mild, 2 = strong, 3 = severe).

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