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https://www.smsna.org/V1/meetings/past-sms-meeting/20th-annual-fall-scientific-meeting-of-smsna/program/scientific-program

- Saturday, October 26, 2019, 04:00 p.m. - 05:30 p.m., Location: Broadway Ballroom C-D
  Female Sexual Dysfunction - Moderated Posters

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Retrospective Chart Review of Treatment Outcome Following Low-Intensity Shockwave Therapy for the Treatment of Vestibulodynia with Urogold 100™

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Introduction: Genital pain disorders have devastating effects on a woman's quality of life, including social isolation. These disorders occur with high prevalence; more than 1/3 of women report pain during sexual activity, placing a significant financial burden on women and the healthcare system. Multiple medical treatments for dyspareunia are available to improve quality of life and decrease pain, however many are invasive, involving pharmacotherapy/hormone therapy/needle insertion/surgery, and are associated with significant morbidity. Low intensity shockwave therapy (LiSWT) is a non-invasive, non-pharmacologic, non-hormonal, non-surgical, low morbidity treatment strategy. FDA-cleared for pain amelioration in the US as non-significant risk in humans, Urogold 100™ is an electrohydraulic shockwave device that generates energy levels such as 0.10-0.12 mJ/mm^2 with a unique parabolic reflector.

Objective: This chart review represents the first US-based treatment outcome study in women with vestibulodynia using Urogold 100™.

Methods: Patients presenting with vestibulodynia were offered the opportunity to receive LiSWT as a potential treatment for their genital pain disorder. As standard of care in our practice, patients completed the Female Sexual Function Index (FSFI), Sexual Distress Scale (SDS), vulvoscopy with photography, and cotton-tipped swab (Q-tip®) test at baseline. Vulvoscopic vulvar/vestibular photographs were scored for Vulvar/Vestibular Tissue Appearance (Vul/VestTA) (0 = normal appearance, 1 = minimal, 2 = moderate, 3 = severe concerns) for the vulva, vestibule and urethral meatus, with low scores associated with healthier tissue appearance. Cotton-tipped swab testing rated pain at the 1:00, 3:00, 5:00, 6:00, 7:00, 9:00 and 11:00 positions (0 = no pain, 1 = minimal, 2 = moderate, 3 = severe). The LiSWT protocol involved 6 treatment sessions, 3000 shocks each (1000 right/left lateral vestibule, and 1000 posterior vestibule), frequency 4/sec, membrane level 1. The energy varied from 0.10 – 0.12 mJ/mm^2, based on patient toleration. Patients underwent vulvoscopy with photography and cotton-tipped swab testing prior to each LiSWT, as is routine in our practice. At the end of treatment, patients recorded their treatment response by Patient Global Impression of Improvement (PGI-I), a scale of 1 – 7 with clinically relevant improvement expressed by scores of 1 – 3.

Results: To date data have been collected on 14 vestibulodynia patients, mean age 37 years (range 21 – 74). Mean baseline FSFI domain scores for desire, arousal, lubrication, orgasm, satisfaction and pain were: 2.6/6, 3.1/6, 3.4/6, 2.2/6, 2.6/6, and 1.6/6, respectively. Mean baseline Sexual Distress Scale score was 35.7/52, cotton-tipped swab test score was 2.6, and Vul/VestTA score was 2.5. Post-treatment, 9/14 (64%) of patients reported a PGI-I of 1 - 3. Post-treatment cotton-tipped swab testing score was diminished to 1.4 (consistent with mild pain). Post-treatment Vul/VestTA was 1.3 and vulvar/vestibular photographs revealed reduced vestibular pallor and erythema. No treatment-related side effects were reported. No patient experienced worsening of symptoms.

Conclusions: Vestibulodynia is a significant sexual health concern in women. Efforts to improve non-invasive, non-pharmacologic, non-hormonal, non-surgical, low morbidity treatment strategies should be encouraged. This chart review of LiSWT using Urogold 100™ is supporting the development of a prospective, sham-controlled clinical trial of LiSWT in women with vestibulodynia.

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