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Preliminary Scientific Program

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

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

Yih, J¹; Minton, J¹; Gagnon, C¹; Goldstein, I²

1: San Diego Sexual Medicine; 2: Alvarado Hospital

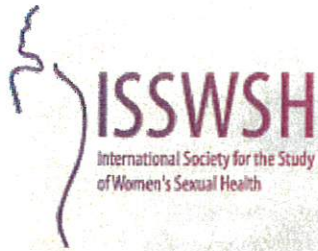
Introduction: More than one third of women report pain during sexual activity. Genital pain disorders adversely affect quality of life and place a significant financial burden on afflicted women and the healthcare system. While treatments for dyspareunia are utilized to improve quality of life and decrease pain, many are invasive, involving hormonal and non-hormonal pharmacotherapy, needling and/or surgery, and can be associated with significant morbidity. Low intensity shockwave therapy (LiSWT) is a non-invasive, non-pharmacologic, non-surgical treatment strategy with low morbidity. FDA-cleared for pain amelioration in the US as non-significant risk in humans, Urogold 100™ MTS provides unfocused electrohydraulic shockwaves with a unique parabolic reflector.

Objective: This is a retrospective chart review examining treatment outcome using Urogold 100™ MTS

in women with vestibulodynia.

Methods: Patients presenting with vestibulodynia were offered the opportunity to receive unfocused 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 test at baseline. Vulvoscopic vulvar/vestibular photographs were scored for Vulvar/Vestibular Tissue Appearance (Vul/VestTA) (0 = normal, 1 = minimal, 2 = moderate, 3 = severe) 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, 2100 shocks each (700 right/left lateral vestibule, and 700 posterior vestibule), frequency 3/sec, membrane level 1. The unfocused energy varied from 0.07 – 0.13 mJ/mm², based on patient toleration. Patients underwent vulvar-vestibular photography, perineometry and cotton-tipped swab testing prior to each LiSWT, as is routine in our practice. Before the second and subsequent treatments, patients completed the Patient Global Impression of Improvement (PGI-I), standard of care in our office for experimental therapies.

Results: To date data have been collected on 19 vestibulodynia patients, mean age 35 years (range 19 – 74). Mean baseline FSFI score was 15.2/36 and Sexual Distress Scale score was 31/52. Mean baseline cotton-tipped swab test score was 2.4, and Vul/VestTA score was 2.6. Post-treatment, 11/19 (58%) of patients reported a PGI-I of 1-3 on a scale of 1-7, indicative of clinically relevant improvement. Post-treatment cotton-tipped swab testing score was diminished to 1.9 (consistent with mild pain). Post-treatment Vul/VestTA was 1.7 and vulvar/vestibular photographs revealed reduced vestibular pallor and erythema. Of note, perineometry increased a mean of 20 cm/H₂O



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Retrospective Review of Lumbo-Sacral Shockwave Therapy Outcomes for Genito-pelvic Dysesthesia/Persistent Genital Arousal Disorder

017

Retrospective Review of Lumbo-Sacral Shockwave Therapy Outcomes for Genito-pelvic Dysesthesia/Persistent Genital Arousal Disorder

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1: San Diego Sexual Medicine; 2: Alvarado Hospital

Introduction: The first sexual medicine use of low intensity shockwave therapy (LiSWT) was reported for men with erectile dysfunction (ED) in 2010. Subsequently, LiSWT has been utilized in other sexual medicine conditions as well as other anti-inflammatory painful conditions as arthritis, tendonitis and bursitis. A literature search on Pubmed for LiSWT and pain yields over 1400 citations. Women with genito-pelvic dysesthesia suspected from inflammatory radiculopathy of sacral spinal nerve roots in the cauda equina suffer from unwanted, unrelenting, unprovoked pain, arousal and/or itch symptoms that cause great distress and are highly associated with suicidality. Treatment successes in this population have been limited.

Objective: To the best of our knowledge, this is the first report of the use of the non-invasive strategy lumbosacral LiSWT for genito-pelvic dysesthesia.

Methods: This is a retrospective chart review of 17 patients (mean age 41 years +/- 14) following use of lumbo-sacral LiSWT in women with: 1) various distressing genito-pelvic dysesthesia symptoms; 2) abnormal neuro-genital testing; 3) abnormal lumbo-sacral MRIs exhibiting pathologies such as Tarlov cyst, herniated nucleus pulposus, annular tear, and facet cyst; and 4) a consultation with a minimally invasive spine surgeon. The UroGold 100 MTS OP155 unfocused parabolic probe, Hz 3, membrane level 1, was applied to the right and left lateral sacral and lumbar area identifying regions of moderate-severe discomfort (4-point scale: 0 none, 1 mild, 2 moderate, 3 severe). The probe was maintained over that region until discomfort diminished to zero. We started with an energy flux density value of 0.07 mJ/mm², increasing energy by 0.01 mJ/mm² until a new region of moderate-severe discomfort was identified and that discomfort returned to zero, with a maximum energy flux density of 0.10 mJ/mm². 2 - 6 treatment sessions were performed with 2800 – 4900 shocks during each session, based on individual toleration. Women self-rated their genito-pelvic dysesthesia intensity prior to treatment and multiple times during treatment. Beginning with the second treatment, before the actual treatment, patients completed the Patient Global Impression of Improvement (PGI-I) on a scale of 1 – 7 with clinically relevant improvement expressed by scores of 1 – 3.

Results: We offered lumbo-sacral LiSWT to 7 patients who underwent minimally invasive spine surgery (MISS) with partial but not full resolution of symptoms, 7 patients who were not considered candidates for MISS, and 3 who chose not to undergo MISS. All women exhibited various bothersome symptoms of genito-pelvic dysesthesia in the shockwave room during the procedure, and 13/17 (76%) noted marked reduction in symptoms during the actual shockwave procedure. These patients also exhibited longer-term marked reduction in symptoms with reports of 1-3 on the PGI-I with follow-up of 2-4 months. Adverse events were limited to short-term back pain in all patients that fully resolved by 1 week.

PGAD

During the breakfast, we will discuss contemporary understanding, diagnosis and management strategies of Persistent Genital Arousal Disorder (PGAD). PGAD was first reported with five case descriptions in 2001 (19 years ago) by our first ISSWSH president, Dr Sandra Leiblum. The sexual health condition was initially called "Persistent Sexual Arousal Syndrome" (PSAS) and was associated with a woman's complaint of excessive and often unremitting arousal in the absence of conscious feelings of sexual desire. At the time there were no obvious biologic (hormonal, vascular, neurological), or psychological causes identified. Numerous case studies have been subsequently published in the peer-reviewed literature, demonstrating that this sexual medicine condition occurs both in men and women, and that the condition was not so rare; 1% of men and women have this condition. Dr. Leiblum eventually changed the name to "Persistent Genital Arousal Disorder", in part, because most patients were not sexually aroused, actually the opposite, most were extremely bothered and distressed. In 2016, the ISSWSH consensus nomenclature report became the first international society to consensus a definition of PGAD; the DSM system of the American Psychiatric Association never defined PGAD. ISSWSH defined PGAD as a sexual health condition characterized by persistent or recurrent, unwanted or intrusive, distressing feelings of genital arousal or being in the verge of orgasm (genital dysesthesia) not associated with concomitant sexual interest, thoughts or fantasies. Persistent genital arousal disorder may be associated with: i) limited resolution, no resolution, or aggravation of symptoms by sexual activity with or without aversive and/or compromised orgasm in terms of impaired orgasm frequency, intensity, timing, and/ or pleasure; ii) aggravation of genital symptoms by certain circumstances (sitting, car driving, listening to music, general anxiety, stress or nervousness; iii) despair, emotional lability, catastrophization and/or suicidality; and iv) inconsistent evidence of genital arousal on physical examination during symptoms (lubrication, swelling of clitoris or labia). ISSWSH has since developed a PGAD consensus expert panel. ISSWSH currently appreciates that multiple biopsychosocial etiological factors may be involved. ISSWSH currently appreciates that this condition is better characterized as a Genito-Pelvic Dysesthesia (GPD). ISSWSH currently appreciates that there are FIVE sites of origin of the symptoms of GPD/PGAD.