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

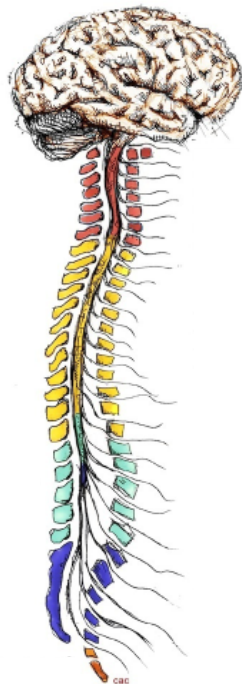
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PD36-10



Introduction: Genito-pelvic dysesthesia

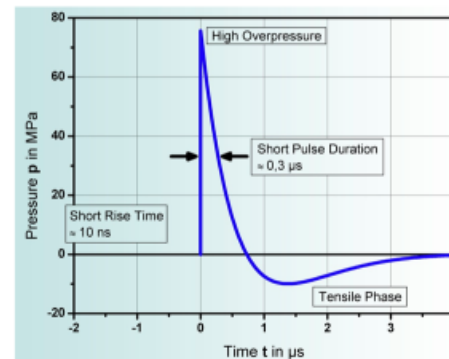
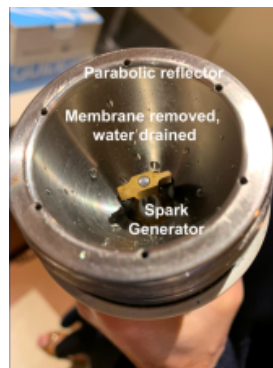
- Genito-pelvic dysesthesia, also persistent genital arousal disorder
- Suspected from inflammatory radiculopathy of sacral spinal nerve roots in the cauda equina
- Unwanted, unrelenting, unprovoked pain, arousal and/or itch symptoms that cause great distress
- Highly associated with suicidality
- Limited treatment successes in this population





Introduction: The Urogold 100™

- Low intensity shockwave therapy (LiSWT)
- Electrohydraulic shockwave device
- Unique parabolic reflector
- FDA-designated as non-significant risk in humans
- FDA-cleared to improve blood flow, ameliorate pain, and activate connective tissue





Treatment Protocol

- UroGold 100 MTS OP155 unfocused parabolic probe, Hz 3, membrane level 1
- Applied to right/left lateral sacral and lumbar area, identifying regions of discomfort (4-point scale: 0 none, 1 mild, 2 moderate, 3 severe).
- Probe was maintained over that region until discomfort diminished to zero
- Started with 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.





Aims

- This chart review represents the first US-based retrospective treatment outcome study in women with genito-pelvic dysesthesia using Urogold 100™.



Methods

- **Inclusion criteria:** Women treated between April to October 2019 with various distressing genito-pelvic dysesthesia symptoms; use of lumbo-sacral LiSWT; abnormal neuro-genital testing; abnormal lumbo-sacral MRIs exhibiting pathologies such as Tarlov cyst, herniated nucleus pulposus, annular tear, and facet cyst; and consultation with a spine surgeon.
- **Patient information collected:** Female Sexual Function Index (FSFI), Sexual Distress Scale (SDS), Patient Global Impression of Improvement (PGI-I), on a scale of 1 – 7 with clinically relevant improvement expressed by scores of 1 – 3.
- Women self-rated their genito-pelvic dysesthesia intensity prior to treatment and multiple times throughout treatment.
- Beginning with the second treatment, before the treatment, patients completed the Patient Global Impression of Improvement (PGI-I).



Results

- Five women had MISS with improvement but not full resolution of their distressing symptoms.
- All women exhibited various bothersome symptoms of genito-pelvic dysesthesia in the shockwave room during the procedure.

	n=13
<i>Mean age (range)</i>	38 years (27-49)
<i>FSFI mean scores</i>	
<i>Desire</i>	3/6
<i>Arousal</i>	2.3/6
<i>Lubrication</i>	1.9/6
<i>Orgasm</i>	2.4/6
<i>Satisfaction</i>	2.7/6
<i>Pain</i>	2.7/6
<i>Sexual distress scale</i>	21/52



Results

- 8/13 (62%) noted marked reduction in symptoms during the actual shockwave procedure.
- 4/13 (31%) also exhibited longer-term marked reduction in symptoms with reports of 1-3 on the PGI-I with follow-up of 4-6 months.
- Adverse events were limited to short-term back pain in 5 patients that fully resolved by 1 week.



Conclusion

- PGAD/GPD is a sexual health concern with significant morbidity in women.
- Currently there are limited treatment options with limited success.
- The initial results of this non-invasive, non-hormonal, non-pharmacologic shockwave energy-based strategy show positive therapeutic benefit for highly selected women with distressing GPD/PGAD secondary to suspected radiculitis of sacral spinal nerve roots.