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Stimwave for Pudendal Neuralgia

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Table 1. Comparison between "Very Satisfied" participants and all others

	"Very" Satisfied (Likert Scale 7) **N= 85**	"Moderately", "Slightly" or "Un"- Satisfied (Likert Scale 1-6) **N= 39**	p-value
"Responder" at 1 month (N=110)	72%	28%	--
"Responder" at 1 year N (%)	75%	25%	--
Prior 3rd line therapy N (%)	19 (22)	16 (41)	0.05
History of Anxiety/Depression N (%)	32 (37)	15 (38)	0.84
Mean Age ±SD	59±11	58±16	0.75
Baseline Voids ±SD	10.5±2.5	10.5±3.4	0.91
Baseline Leaks ±SD	5.9±3.6	5.4±3.0	0.09
Baseline Urgent Leaks ±SD	5.6±3.6	5.3±3.0	0.14
Baseline Leaks w/ Amount Large ±SD	1.0±1.8	1.1±1.6	0.69
Delta Voids ±SD	-2.6±3.4	-1.0±3.1	0.01*
Delta Leaks ±SD	-4.8±3.4	-3.2±2.4	0.004*
Delta Urgent Leaks ±SD	-4.7±3.4	-3.1±2.3	0.04*
Delta Voids w/Desperate Urgency ±SD	-0.6±1.3	0.2±2.1	0.03*
Delta Leaks w/ Amount Large	-0.9±1.7	-0.7±1.2	0.56

Funding: None

#M69 | TRANSVERTEBRAL MAGNETHIC NEUROMODULATION FOR TREATMENT OF OVERACTIVE BLADDER: 6 MONTHS OF OBSERVATION

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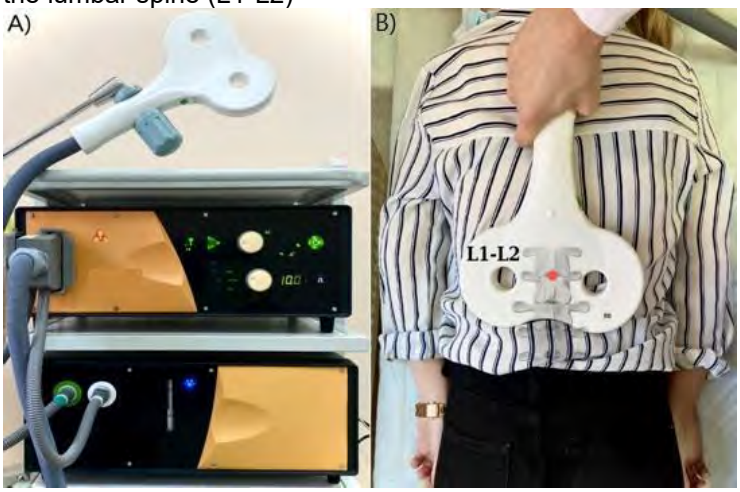
Presented By: Gleb Kovalev, MD

Introduction: The most common type of lower urinary tract dysfunction is an overactive bladder (OAB). Today there is a need to search for new effective methods of treating this disease.
Purpose. To evaluate the effectiveness of transvertebral magnetic neuromodulation (TMN) of the lumbar spine in patients with OAB.
Methods: 26 patients were enrolled in the clinical study. The treatment course consisted of 15 procedures (3 times a week for 5 weeks). Before and after treatment at 1, 3 and 6 months, complaints were assessed using the ICIQ-SF and OAB-q SF questionnaires. Objective parameters were assessed by urodynamic tests before and 6 months after treatment.
Results: We observed a significant improvement in patients subjective clinical status at all points of assessment. Transvertebral magnetic neuromodulation had the greatest influence on such urodynamic parameters as: the first sensation, the first desire, strong desire, maximum cystometric capacity. Patterns of phase hyperactivity were absent in 60.8% of patients after treatment and terminal hyperactivity - in 41.7% of patients.
Conclusion: This small study observed a significant therapeutic effect of TMN in patients with OAB. Further large, placebo-controlled trials are needed to develop universal effective protocols for lower urinary tract dysfunction treatment.
Fig1.Installing the "figure eight" stimulating coil on the lumbar spine (L1-L2)



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#M70 | STIMWAVE® FOR PUDENDAL NEURALGIA

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Presented By: Ly Hoang Roberts, MD

Introduction: Pudendal neuralgia is a chronic and debilitating condition with 10- 25% of patients refractory to traditional therapies including sacral neuromodulation. Prior studies have shown chronic pudendal nerve stimulation with Interstim® (Medtronic, Inc., Minneapolis, MN) is effective for this patient population. This study reports on a wireless system to power an implanted lead at the pudendal nerve, StimWave®, to treat pudendal neuralgia.
Methods: Retrospective chart review identified patients with pudendal neuralgia who had a lead placed at the pudendal nerve and powered

wirelessly according to patient need. Clinical outcomes were assessed at post-operative visits as well as phone calls. Non-validated follow-up questionnaire were administered including the GRA, percentage of pain improvement, satisfaction with the device, the initial settings of the device at implantation, and the current settings (number of hours/day of stimulation).
Results: Thirteen patients with pudendal neuralgia had the StimWave® lead placed at the pudendal nerve, 12 (92%) female and 1 (7.6%) male. Mean age was 50 years (range: 20-58) with average BMI of 25.3 kg/m2. Failed prior therapies include medical therapy (100%), pelvic floor physical therapy (PFPT) (92%), pudendal nerve blocks (85%), pelvic floor muscle trigger point injections (69%), neuromodulation (30.7%), or surgeries for urogenital pain (23.1%). After the trial period, 10/13 (76.9%) had > 50% improvement in pain with 6/13 (46.1%) reporting 100% pain improvement. Nine went on to undergo permanent lead placement. At last post-operative follow-up (range 6-83 d), 4/9 patients reported 50% or greater pain improvement. Seven patients were reached for follow-up (8-734 d), reporting their symptoms to be “markedly improved” (n=2; 28.6%), “moderately improved” (n =4; 57.1%,), or “slightly improved” (n=1; 14.3%). Over half (5/7) reported post-operative complications including lead migration (n=2), broken wire (n=1) or non-functioning antenna (n=2).
Discussion: Complex patients with pudendal neuralgia refractory to traditional therapies may benefit from pudendal nerve stimulation via StimWave® neuromodulation.
Funding: N/A

#M71 | WEARABLE NEUROMODULATION SYSTEM FOR OVERACTIVE BLADDER (OAB): A PREFERRED TREATMENT OPTION

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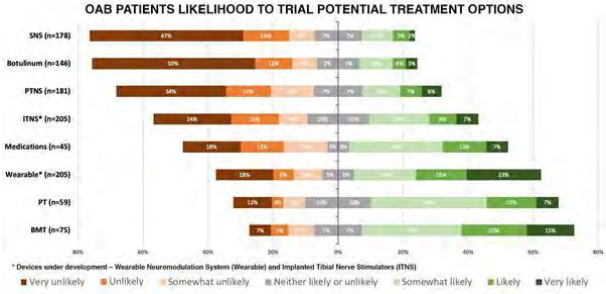
Presented By: Monica L. Tarver

Introduction: Neuromodulation therapies are proven to produce therapeutic benefits for patients suffering from OAB. However, these therapies have poor adoption rates due to low awareness, surgical risk, cost, and inconvenience. We investigated patient awareness and trial likelihoods associated with OAB therapies to determine strength of interest in a new wearable neuromodulation system for use in the home.
Methods: Subjects diagnosed with OAB completed an online survey on their awareness of specific OAB therapies. If they were aware of a particular therapy, they were asked whether they had tried it. If they were not aware of a particular therapy, we provided a brief description and asked them to rate their interest in trying it.
Results: Data from 205 respondents was analyzed. Awareness and trial rates were significantly lower for neuromodulation therapies compared to other treatments. Only 12% (n=24) were aware of PTNS with 3.9% (n=8) having tried it. This was similar for SNS, 13% (n=27) awareness with 4.8% (n=10) having tried. The highest awareness was for PT at 71% (n=146) with 36% having tried it (n=74).
Figure 1 shows likelihood that an OAB patient would try a therapy of which they were previously unaware. 58% of the respondents were likely to trial a wearable neuromodulation system, 59% physical therapy and 66% behavioral modification. The likelihood of trial of more invasive 3rd- line therapies ranked significantly lower than the wearable neuromodulation system (PTNS 25%, botulinum toxin injection 17%, SNS 17%, emerging implanted tibial nerve stimulation 34%).
Conclusion: Adoption for neuromodulation therapies for OAB remains low which can be attributed to low awareness, surgical risk, cost and inconvenience. Among patients naive to the availability of specific therapies, likelihood of trial remains lowest for more invasive therapies such as SNS, PTNS, botulinum toxin and emerging implanted tibial nerve stimulators. A non-surgical wearable neuromodulation system demonstrated higher likelihood of trial versus all other neuromodulation therapies, including emerging implanted tibial nerve stimulators, and represents an opportunity to increase the number of patients able to be treated with neuromodulation Additional research is required to understand the efficacy and feasibility of a wearable neuromodulation system for use in the home and its placement in the OAB treatment algorithm.



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