# RANDOMIZED MULTICENTER SHAM CONTROLLED TRIAL OF TRANSLUMBOSACRAL NEUROMODULATION THERAPY FOR FECAL INCONTINENCE

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**Abstract Body**

**Background:** Fecal incontinence (FI) is a multifactorial disorder with few effective treatments and little impact on key dysfunctions such as anorectal neuropathy. Our aim was to investigate the efficacy and safety of translumbosacral neuromodulation therapy (TNT), a novel non-invasive treatment targeting neuropathy, in a randomized sham controlled multicenter trial. **Methods:** FI patients (> 1 episode/wk) were randomized to receive either active TNT (2400 or 3600 stimulations) or sham (2400 stimulations) repetitive magnetic stimulations (Magstim Rapid 2), at 4 lumbosacral sites with 1Hz, and weekly for six weeks. Daily FI episodes and bowel symptoms were assessed with prospective stool diaries. Outcomes included a ≥ 50% decrease in weekly FI episodes (primary), FI severity index (FISI), subject's global assessment (SGA), FI-QOL, anorectal sensorimotor function and neurophysiology. **Results:** Of 109 randomized patients, 90% in each group completed the study. There were no demographic differences between the groups. Responder rates were significantly higher in the 2400 ($p<0.001$) and 3600 ($p<0.001$) stimulation groups compared to sham, with no differences between the active treatment groups (Fig). Weekly FI episodes decreased significantly in all groups (2400 and 3600 ($p<0.001$; sham, $p=0.001$), but reductions were significantly greater in active groups ($p=0.008$) (Table). FISI scores improved in the active groups compared to sham ($p=0.02$). All 4 FI-QOL domains improved in 2400 ($p=0.003$) and 3600 ($p=0.003$) but not in sham group ($p=0.061$). Maximum and sustained anal squeeze pressures increased significantly with active treatments ($p <0.05$). Lumbo-anal and Sacro-anal nerve conduction significantly improved ($p<0.02$) with active treatments compared to sham. One patient had transient numbness/tingling and 3 patients had unrelated SAEs.

**Conclusions:** TNT significantly reduced FI episodes, improved FI severity, QOL, anal sphincter function and anorectal neuropathy compared to sham therapy. Safe, well tolerated and non-invasive, TNT represents an effective and useful treatment option for FI. Acknowledgement: This study was supported by NIH – R01-DK057100-05.

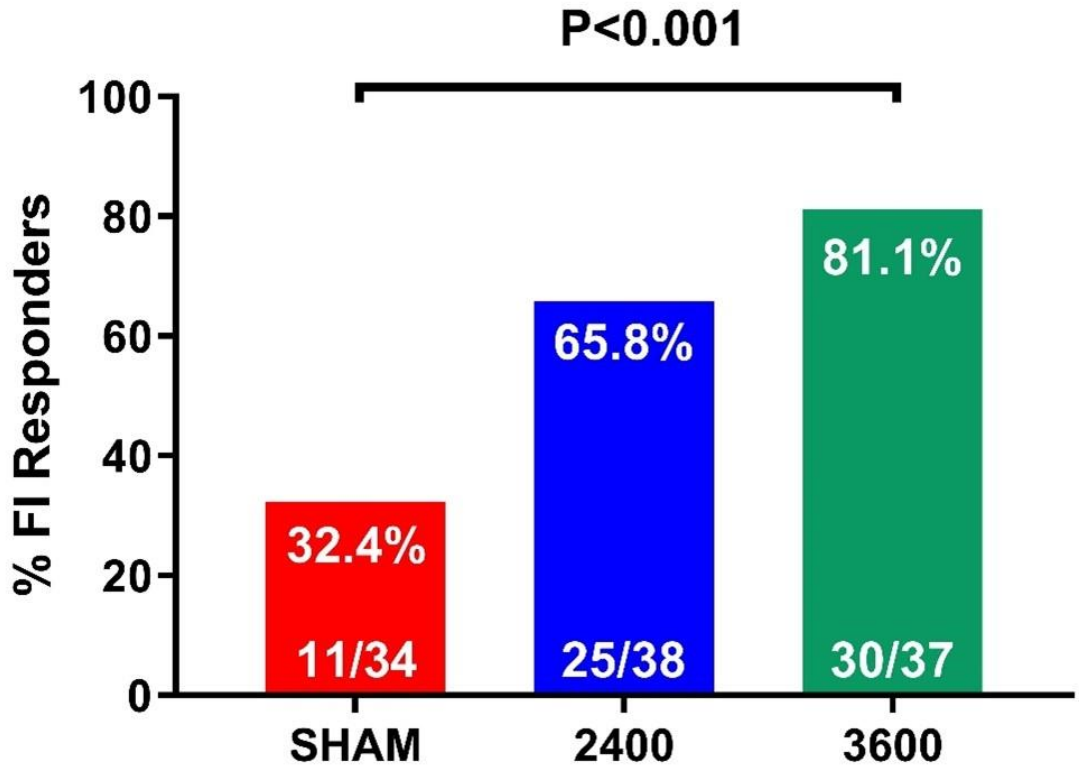


Table: Effects of TNT treatment on FI symptoms, FI severity, QOL and anorectal physiology. **Bold = p<0.05 vs baseline and sham**

| | 2400 Baseline | 2400 Post-Treat | 3600 Baseline | 3600 Post-Treat | Sham Baseline | Sham Post-Treat | ANOVA |
|---|---|---|---|---|---|---|---|
| FI episodes/wk | 8.3±5.0 | **3.5±4.6** | 7.7±5.8 | **2.8±3.9** | 6.6±6.5 | **4.6±4.8** | **0.0086** |
| FISI | 38.5±8.6 | **29.9±11.7** | 37.2±10.1 | **31.7±14.9** | 35.2±9.7 | 33.7±9.8 | **0.0195** |
| SGA | 65.8±15.5 | **40.7±25.2** | 64.6±19.3 | **47.0±25.1** | 57.7±17.6 | **47.4±17.4** | **0.0279** |
| Max Squeeze pr (mmHg) | 127.7±46.4 | **161.9±62.8** | 133.0±68.6 | **148.1±80.4** | 134.9±68.5 | 134.9±66.2 | **0.0051** |
| Sustained Squeeze pr (mmHg) | 65.4±21.9 | **88.7±25.5** | 75.6±41.9 | **89.2±41.7** | 60.8±30.2 | 70.1±28.3 | **0.0453** |
| Lt Lumbo-anal (ms) | 4.8±1.8 | **4.0±1.6** | 5.3±2.1 | **3.9±1.6** | 5.0±1.6 | 5.1±1.9 | **0.0274** |
| Lt Sacro-anal (ms) | 5.5±2.1 | **4.1±1.2** | 5.2±1.6 | **4.3±1.5** | 5.1±2.0 | 5.0±1.6 | **0.0067** |
| Rt Lumbo-anal (ms) | 5.5±2.2 | **4.4±1.7** | 5.3±2.3 | **4.0±1.3** | 5.1±1.8 | 5.0±1.9 | 0.0805 |
| Rt Sacro-anal (ms) | 5.2±2.8 | **4.2±1.5** | 5.2±1.6 | **4.1±1.3** | 4.5±1.8 | 5.4±1.8 | **0.0023** |
| QOL-Lifestyle | 2.3±0.9 | **2.6±0.9** | 2.4±1.0 | **2.6±1.0** | 2.6±0.9 | **2.8±0.9** | 0.7312 |
| QOL-Coping | 1.8±0.7 | **2.1±0.8** | 1.8±0.7 | **2.1±0.8** | 2.0±0.8 | 2.1±0.7 | 0.4001 |
| QOL-Depression | 2.6±0.8 | **2.9±0.9** | 2.8±0.8 | **3.0±0.8** | 2.8±0.8 | **2.9±0.7** | 0.6213 |
| QOL-Embarrassment | 2.0±0.7 | **2.4±0.8** | 1.9±0.8 | **2.3±0.9** | 2.0±0.9 | 2.2±0.8 | 0.2767 |