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Title (type in CAPITAL LETTERS) AFFERENT NERVE STIMULATION FOR PELVIC FLOOR DYSFUNCTION

Aims of Study: Pelvic floor dysfunction may manifest itself as urinary urge/frequency, urge incontinence, and/or pelvic pain. Few effective treatment modalities have been available for these disabled patients, though multiple therapies have been used including medications, biofeedback, pelvic floor exercises, and efferent nerve stimulation. The purpose of this study was to document long-term follow-up data regarding minimally invasive afferent nerve stimulation for pelvic floor dysfunction.

Methods: Ninety patients were successfully screened with cystoscopy, voiding cystourethrography, baseline urodynamics, urine cultures, and voiding/pain diaries, and entered into the study. A 34-gauge stainless steel needle was inserted approximately 5 cm cephalad from the medial malleolus and just posterior to the margin of the tibia. It was advanced to the medial edge of the fibula. Electrical stimulation was applied to the needle with a low voltage, adjustable current, external pulse generator, and to the medial surface of the calcaneus. Patients were treated with one electrical stimulation per week for 20-30 minutes per session for 10 consecutive weeks. Post-treatment voiding/pain diaries were compared to baseline values.

Results: Patients have been treated with a mean follow-up of 5.1 years. They had (on average) experienced symptoms for 5.5 years, sought help from 5.7 physicians, and attempted 4 previous treatments prior to entering the protocol. A substantial number of patients had attempted suicide due to the hopeless nature of their situation prior to therapy. There were no adverse effects of therapy including infection, hemorrhage or exacerbation of symptoms. A successful outcome, defined as at least a 50% improvement of symptoms, as documented by voiding/pain diaries was seen in 81% of patients. Follow up therapy was individualized for patients with successful results, slowly increasing the interval between treatments, and instructing select patients for home administered therapy.

Conclusions: Afferent nerve stimulation is a viable treatment therapy for patients with pelvic floor dysfunction. Based on these promising long-term percutaneous results, a minimally invasive peripheral implant device is being developed.