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SACRAL NERVE STIMULATION THERAPY AND ITS EFFECT ON SELF-REPORTED DEPRESSION SYMPTOMS IN PERSONS DIAGNOSED WITH VOIDING DYSFUNCTION

Aims of Study

Patients diagnosed with voiding dysfunction have had limited treatment options [1], and those that are available have met with limited success. Neuromodulation of sacral nerves through the use of an implantable device has demonstrated efficacy and safety in patients for whom alternative treatment options, including multiple surgeries, have been found unsatisfactory [2-5]. However, the effect that sacral nerve stimulation (SNS) therapy may have on depression symptoms in refractory patients has not been examined. The purpose of this analysis is to determine, in patients whose voiding symptoms were uncontrolled pharmaceutically or surgically, if treatment with an implantable SNS device leads to improvement in self-reported depression symptoms.

Methods

A multi-center, prospective, randomized clinical trial of an implantable, multiprogrammable neurostimulator (MDT-103) enrolled patients until 1999 and continues to collect follow-up data. Study candidates, documented as refractory to standard medical therapies via medical audit, were enrolled from the general urologic population, and randomized into either an implant group or a usual care (delayed implant) group. The Beck Depression Index (BDI), a widely used instrument evaluating 21 symptoms of depression, was administered to qualified patients at baseline and at 3 and 6 month intervals post enrollment or implant. Analyses were conducted between and within groups to determine if depression symptoms improved following implantation and if significant differences could be detected between the implant and delayed implant treatment groups at 3 and 6 months. Only patients enrolled in U.S. centers were included in this analysis.

Results

89 U.S. patients met study qualifications--73 (82%) were female; 28 were diagnosed primarily with urinary incontinence (UI), 12 with urinary retention (UR), and 49 with urinary frequency (UF). Average age was 38.0 (± 10.1) yrs. 56 patients were assigned to the implant group and 33 to delayed implant. At baseline 73% of patients had BDI scores indicating depressive symptoms (≥10 on the BDI using published value ranges [6]). 29 patients (32%) scored with moderate/severe or severe depression (≥19 on the BDI). By diagnosis, patients with UI and UF had higher average BDI scores and, therefore, worse symptoms (16.6 ± 11.6 and 16.8 ± 8.8 respectively), than those with UR (12.8 ± 10.1); the differences were not statistically different, however. Females had higher scores on average than males, which partially explains the differences found with diagnoses—a higher proportion of females were diagnosed with UI and UF. There were no differences between randomized groups on average BDI score at baseline. The statistical analysis from baseline to the 3- and 6-month intervals compared the 65 patients (40 implant and 20 delayed) with measures at all 3 points. The implant group reported lower (improved) scores from baseline to each interval point, the delayed implant group scores were higher (worse) over time. At 3 months, 41% of implanted and 73% of delayed group patients had scores indicating depressive symptoms. At the 3-month post-implant interval there was a significant difference ($p = 0.01$) in average BDI score between groups. At 6 months 45% of the implant group and 72% of the delayed group were depressed. Although average BDI scores at this time interval remained lower in the implant group, the difference between groups was not significant ($p = 0.07$).

	Baseline	3-month	6-month
Implant Group	17.0 ±9.5	10.3 ± 9.1	11.1 ± 9.1
Usual Care Group	16.2 ±11.3	18.0 ±13.0	17.2 ± 14.6

Conclusions

A majority of patients with refractory voiding dysfunction (UI, UR and UF) have self-reported depression symptoms using the BDI. SNS treatment is a safe and effective therapy and in this study was also associated with significant improvement in self-reported depression symptoms using the BDI.

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