LITERATURE REVIEW: NON-CLINICAL TRIALS

Author / Title / Journal / Year	Type of Study	Outcomes Studied	Patient Characteristics	Results	HCFA Comments
Bosch JL, Groen J / Neuromodulation: urodynamic effects of sacral (S3) spinal nerve stimulation in patients with detrusor instability or detrusor hyperflexia / Behavioral Brain Research / 1998	Case Series	Voiding frequency (No./24h), Average voided volume (ml), Leakage episodes (No./24h), Pads (No./24h)	70 patients initially tested for implantation. At six months follow-up, there were 24 implanted patients, with idiopathic detrusor instability (and 5 patients with neurogenic detrusor hyperreflexia), who had urodynamic data. Characteristics of the former group (20 men and 4 women): Mean age = 46 (25-65 range), Mean no. of previous operative procedures = 1.3 (0-6), Mean duration of previous drug use = 3.8 y (1-11), Mean duration of pad use = 7.5 y (1-28), and Mean duration of follow-up = 36.5 m (6-68).	Significant improvements (well below p = 0.05), at last follow-up, in voiding frequency, leakage episodes and pad use. Although mean average voided volume increased from 142 (+/- 11 SEM) to 163 (+/- 11), significance was not achieved. Of the 13 patients who had completed 3 years of follow-up, the pad use had decreased from an average of 6.8 to 1.6 per 24 h. Also, there was an incomplete correlation between symptomatic changes and urodynamic changes.	Please note that this study design does not allow for comparison with a control group. In addition, there has been an intended omission of the results for the five female patients with neurogenic disease, in order to achieve consistency with clinical trials data elsewhere presented (TEC Assessment).

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Bosch JL, Groen J / Sacral (S3) segmental nerve stimulation as a treatment for urge incontinence in patients with detrusor instability: results of chronic electrical stimulation using an implantable neural prosthesis / The Journal of Urology / 1995	Case Series	No. voiding episodes/24 h, Average voided volume (ml), No incontinence episodes/ 24 h, No. pads/24 h	31 patients tested for implantation who had urge incontinence in concert with urodynamically-proven, drug-refractory detrusor instability (either idiopathic or neurogenic). Bladder capacity of 150-500 ml, without accompanying urinary tract infection, stone disease, diabetes mellitus, psychiatric disturbances, pregnancy, stroke within previous six months, anatomic abnormalities, infection or decubitus at future operative site. 18 patients implanted: 15 F, 3M, mean age 46 (range 25-65). Mean follow-up 29 months (7-47).	Using last follow-up for a given patient, all four symptomatic outcomes showed significant improvement from baseline (all with $p<0.05$). 11/18 patients with more than 90% decrease (excellent) in pad use and/or incontinence episodes, 4/18 with 50-90% decrease (partial) and 3/18 with less than 50% decrease (failed). Only two urodynamic parameters showing significant improvement, thus showing discrepancy with symptomatic findings.	Please note that this study design does not allow for comparison with a control group. Also, there is a sub-population of patients with neurogenic bladder, which makes sampling inconsistent with clinical trials data presented elsewhere (TEC Assessment).

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Bosch LJ, Groen J / Sacral nerve modulation in the treatment of patients with refractory motor urge incontinence: long term results of a prospective longitudinal study / The Journal of Urology / 2000	Case Series	Median pads/24 h, Median leaks/24 h, Median voids/24 h, Average Voided Volume (ml). Cure defined as >90% improvement in pad use and/or incontinence episodes, with same criteria scale as Bosch & Groen 1998.	85 patients tested, with 45 implanted (39F, 6M), having a mean age 44.5 (range 16-65) and same inclusion profile as Bosch & Groen 1998. Mean follow-up 47.1 months (6-96).	All four symptomatic outcomes improved significantly ($p<0.05$), with stability in such results up to five years, except four years with respect to average voided volume. Of the 34 women with idiopathic bladder activity, 13 (38%) were cured and 7 (21%) achieved partial success, while 1 each of the 6 men achieved partial success and cure, respectively. With respect to urodynamics, of the successfully treated patients without detectable bladder instability, 72% were cured. However, only 45% of successfully treated patients, who still had unstable contractions, were cured.	Please note that this study design does not allow for comparison with a control group. Also, there is a sub-population of patients with neurogenic bladder, which makes sampling inconsistent with clinical trials data presented elsewhere (TEC Assessment); however, some of the results could be separated from those in the idiopathic group.
Das AK, White MD, Longhurst PA / Sacral nerve stimulation for the management of voiding dysfunction / Reviews in Urology / 2000	Review article			Discussed the history and mechanism of action of SNS, along with its indications. After presenting the details of the preliminary test procedure, along with follow-up implantation, efficacy results from several articles (elsewhere listed in HCFA package) were reviewed. Finally, complications and future directions of SNS were discussed.	Review article without primary data.

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Elabbady AA, Hassouna MM, Elhilali MM / Neural Stimulation for Chronic Voiding Dysfunctions / The Journal of Urology / 1994	Case Series	Diary-based outcomes included: Mean voided volume, No. intermittent self-catheterizations/d, No. leaks/d, No. diapers/d. Also, a quality of life (QOL) questionnaire contained inquiries about activities inside/outside the home, and impact of voiding problem on work and emotional health.	Of 50 patients who presented for testing with unexplained dysfunctional voiding, 17 were implanted. Group 1 included 7 women and 1 man who presented mainly with chronic urinary retention (in the absence of neurological disease), and Group 2 included 6 women and 3 men who presented with other forms of voiding dysfunction, such as pain, frequency and urgency. In Group 1, mean age 28.8 +/- 3.1 yr and mean duration of symptoms 30.5 +/- 7.3 mo, and in Group 2, 39.0 +/- 4.1 yr and 65.3 +/- 12.8 mo, respectively.	In Group 1, mean voided volume increased ($p<0.05$) and intermittent self-catheterizations/d significantly decreased at six month follow-up. Even though there were marked decreases in both number of leaks/d and number of diapers/d, significance levels were not available. In Group 2, the average improvement in pain and difficulty to start voiding was 85%, frequency improved by 73%, urgency improved by 42%, and leaking episodes and numbers of diapers per day decreased by 50%. Also, several QOL indicators showed improvement. Please note that there was a discrepancy between the voided volumes recorded during urodynamic studies and those recorded in voiding diaries.	Please note that this study design does not allow for comparison with a control group. In addition, there is a wide variety of clinical presentations among the 17 implanted patients, thus not allowing specific analysis of urge incontinence, urgency-frequency, etc. patients.

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Goodwin RJ, Swinn MJ, Fowler CJ / The neurophysiologyof urinary retention in young women and its treatment by neuromodulation / World Journal of Urology / 1998	Review article			By reviewing numerous studies, the authors suggest that SNS is particularly effective for young women (between 20-30 yrs). Within 24 hours of PNE insertion (peripheral nerve evaluation) women who had been unable to void for months or years were able to do so. It is uknown why the sacral nerve stimulator is effective for both urge incontinence and retention.	Review article without primary data.
Janknegt RA, Weil EH, Eerdmans PH / Improving neuromodulation technique for refractory voiding dysfunctions: two-stage implant / Urology / 1997	Case Series	Pads/day was the primary outcome pertinent to evaluating SNS implantation; however, the focus of the article was upon using a different protocol for preliminary testing.	After an initial pool of 99 patients had been reduced to 10 after testing (8F, 2M, mean age 46, range 32-56), 8 of these patients received an implantable stimulator. Four of these patients had urge incontinence, along with available pad use data.	The average numbers of pads used in the four urge incontinence patients are as follows: 7.2 at baseline, 0.2 at 1 month, 0.3 at 3 months, and 0.4 at 6 months.	Please note that this study design does not allow for comparison with a control group, aside from its very low sample size. Data from the new testing protocol were not deemed relevant to the current assessment questions regarding permanent implantation, and, therefore, they have not been furnished.

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Shaker HS, Hassouna M / Sacral nerve root neuromodulation: an effective treatment for refractory urge incontinence / Journal of Urology / 1998	Case Series	Parameters extrapolated from the diaries were number of voids per 24 hours, voided volume per 24 hours, average voided volume, maximum voided volume, number of catherizations per 24 hours, catheter volume per 24 hours, maximum catherization volume, number of leaks per 24 hours, leak severity, average degree of urgency, percent felt empty, average severity of pelvic/bladder discomfort and average stream force. In addition, patients completed the Beck depression inventory (BDI) and the SF36 quality of life questionnaire.	18 patients received implant, who had urge incontinence refractory to all conservative measures (initial pool of patients, who were subjected to testing, was not specified). 7/18 had associated idiopathic nonobstructive chronic urinary retention. Mean patient age at presentation was 42.3 +/- 3.3 yr (range 22-67), and duration of urinary symptoms was 6.6 +/- 1.3 yr (1.2-18.8). Average follow-up was 18.8 mo (3-83).	Analyzing the voiding pattern of the 10 patients with pure urge incontinence, the frequency of voiding decreased significantly from 15.02 +/- 1.96 to 8.77 +/- 0.86 voids per 24 hours after 1 month of the implant, and stayed within that range thereafter. This decrease was associated with an increase in the average and maximum voided volume by 41% and 19%, respectively, but did not reach statistical significance. Voided volumes during uroflowmetry increased up to 2-fold when comparing baseline to the postoperative follow-up., but pressure-flow studies did not demonstrate any difference. Analysis of BDI and SF36 showed some improvement (10-40%) that was progressive in most items. All patients reported that the greatest impact of incontinence improvement was upon indoor/outdoor activities.	Please note that this study design does not allow for comparison with a control group. In addition, there has been an intention to only present the results for the patients with pure urge incontinence, in order to achieve consistency with clinical trials data presented elsewhere (TEC Assessment).

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Thon WF, Baskin LS, Jonas U, et al / Neuromodulation of voiding dysfunction and pelvic pain / World Journal of Urology / 1991	Review article			In the authors experience with over 1500 test stimulations, there were virtually no problems. No patients experienced infection or damage to the sacral nerve roots. Few patients complained of pain. The authors conclude that pelvic pain has been effectively managed in 75% of the cases treated with sacral nerve modulation over the past three years.	Review article provides no primary data.