110A

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SACRAL NERVE STIMULATION FOR REFRACTORY URGE INCONTINENCE: PATIENT OUTCOMES AND QUALITY OF LIFE

AIMS OF STUDY: Electrical stimulation of the pelvic floor has gained acceptance as a treatment for urinary incontinence. The purpose of this study was to determine the effect of sacral nerve stimulation on urinary urge incontinence outcomes and health related quality of life (HRQoL).

METHODS: A multicenter, prospective, randomized clinical investigation of 155 patients with urinary urge incontinence was conducted. After successful test stimulation, patients who qualified for implant (n=98) were randomized to treatment with surgical implantation of a sacral nerve stimulation system (n=52) or 6-month delay from implant (control) group (n=46). Primary outcomes measured were leaking episodes/24 hours; severity ranking of leaking episodes; and number of pads/diapers replaced/24 hours due to leaking. HRQoL was measured using the SF-36.

RESULTS: Baseline voiding diaries documented an average of 8.9 ± 5.9 leaking episodes per day with 90.3% of patients reported at least one moderate/heavy leaking episode. Leaking severity was 1.9 ± 0.6 on a scale of 1(drops of urine per episode) to 3 (soaking pad/diaper or outer clothing). Baseline SF-36 results indicated consistently lower scores in all areas of physical and mental function compared to US norms. At six months after implantation, the Implant Group patients demonstrated clinically and statistically significant ($p<0.0001$) reductions in all primary voiding diary parameters. Implant patients additionally demonstrated significant improvements in Physical Functioning ($p=0.001$), Vitality ($p=0.018$) and General Health ($p<0.0001$) as compared to control patients using repeated measures ANOVA at 6-months post-implant.

CONCLUSIONS: Treatment of urinary urge incontinence with sacral nerve stimulation resulted in significant reductions in symptoms and improvement in health related quality of life.

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110B

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IMPROVEMENT IN QUALITY OF LIFE: SACRAL NERVE STIMULATION FOR URINARY URGENCY-FREQUENCY

AIM OF STUDY: Sacral nerve stimulation has gained acceptance as a treatment for urinary urge incontinence. The purpose of this study was to determine the effect of sacral nerve stimulation on health related quality of life (HRQoL) for urgency-frequency patients.

METHODS: A multicenter, prospective, randomized clinical investigation of 220 patients with urgency-frequency was conducted. After successful test stimulation, patients who qualified (n=80) were randomized to implantation of a sacral nerve stimulation system (n=47) or 6-month delay from implant (control) group (n=33). 195 patients were included in the baseline analysis of HRQoL. 43 randomized patients with complete 6-month follow-up were included in the post-treatment follow-up analysis. HRQoL was measured using the SF-36.

RESULTS: Baseline SF-36 results indicated that urgency-frequency patients had significantly lower scores in all areas of physical and mental function compared to US normative values ($p<0.0001$). A 27.5 point difference was found between the norm and patients for the Physical Functioning scale. This is an impact on patients' limitations in physical activities and was found to be similar to other chronic medical conditions. In the 6-month follow-up analysis the group of implanted patients demonstrated significant improvements in the scales related to physical concepts: Physical Functioning ($p<0.001$), Role Physical ($p=0.01$), Bodily Pain ($p=0.01$) and General Health ($p=0.003$) as compared to the group of control patients using repeated measures ANOVA. Three scales related to mental health concepts also demonstrated significant improvement for the implanted group of patients: Vitality ($p=0.01$), Social Functioning

(p=0.002) and Mental Health (p=0.01). The group of implanted patients had more favorable perceptions of their general health transition compared to control patients (p<0.0001).

CONCLUSIONS: Treatment of urinary urgency-frequency with sacral nerve stimulation resulted in significant improvement in health related quality of life.

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111

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QUALITY OF LIFE IMPROVEMENT DURING CHRONIC NEUROMODULATION OF SACRAL ROOTS: A PROSPECTIVE STUDY WITH AN INCONTINENCE DOMAIN SPECIFIC INSTRUMENT (QOL-I)

Aim of Study: Treatment efficacy of urinary incontinence therapy is routinely measured as a decrease in incontinence episodes or in the number of pads used. However these outcome measurement criteria are limited in that they fail to take into account patients' perceptions of their conditions and treatment outcome. The aim of our study is to evaluate, in patients having undergone chronic sacral roots neuromodulation, both clinical outcomes and improvement in quality of life, through a validated, incontinence domain specific questionnaire .

Materials and Methods: From May 1998 to March 1999 39 pts. who failed to respond to less invasive therapy for lower urinary tract disorders underwent a permanent implant of S3 foramen electrode connected with an Interstim pulse generator. 22 out of 39 had been suffering from urge incontinence (idiopathic or neurogenic) and urgency frequency syndrome with a noticeable impairment in quality of life. We evaluated these patients in the ambit of a prospective multicentre study with the latest version of QOL-I developed by Wagner (*1*) and translated by him. This is a validated self-administered incontinence questionnaire applicable to both men and women and wich proved to be internally consistent and highly reproducible. Patients were administered the QOL-I at the baseline before the percutaneous nerve evaluation of sacral root (PNE) and after the permanent implant every 3 months during each scheduled follow-up. Moreover we asked them if as results of their experience they would undergo the same procedure again and if they would reccomend this procedure to a friend or relative. Results were gathered in a score ranging from 22 (the worst) to 110 (the best) and then normalized on a 0-100 scale.

RESULTS: To date data are available for 19 pts. (14 female, 5 male, mean age 56.6 years, range 26-70) mean follw-up 7.36 months. Mean scores improved dramatically from the baseline (30.22) to the 3 months post implant follow up (79.66, p=0.0007) and increased later on at the 6 months follow up (90.34, p=0.032) correlating strongly with the objective clinical improvement (number of pads per day, incontinence episodes, urinary frequency, bladder capacity) as shown in table 1.

TABLE 1	QOL-I score	bladder capacity	incont episodes	Urinary freq.	n. pads/day
baseline	30.22	109.23	6.10	15.28	5.80
3 months	79.66*	188.33	1.06	6.05	0.72
6 months	90.34*	225.00	1.0	6.13	0.50

*p<0.05 vs baseline

All patients answered affirmatively with regards to undergoing the same surgical procedure again and would recommend this therapy to a friend or a relative.

Conclusions: Neuromodulation dramatically improves the quality of life of patients who undergo sacral roots permanent implant for urge incontinence and urgency frequency syndrome refractory to previous medical and rehabilitative therapy.
This improvement is well correlated to clinical outcome.
QOL-I is a quality of life measurement criteria specific to urinary incontinence that could be used as an outcome criteria in clinical trials in patient care centers and particularly in neuromodulation.