

($p=0.002$) 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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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 recommend 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 follow-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.