

THE STAGED IMPLANT DOES INCREASE SUBJECTIVE AND OBJECTIVE IMPROVEMENT IN PATIENTS WITH VOIDING DIFFICULTIES SELECTED FOR SACRAL NERVE STIMULATION

Aims of Study

The aim was to evaluate in a prospective, randomized setting if the 2-stage implant, compared to a 1-staged implant, leads to a superior subjective or objective outcome of sacral nerve stimulation after implantation of the pulse generator in patients with voiding dysfunction.

Methods

From September 2000 till January 2003 we implanted a sacral (S3) foramen lead (model 3080) and a pulse generator (Interstim) in 23 patients with non-obstructive voiding difficulties. All patients were first evaluated for treatment by a 4-7 days (3days diary) percutaneous nerve evaluation test (PNE) and were randomized in a 1-stage or a 2-stage (1) implant if residual urine decreases with more then 50%. One patient was excluded as the 2-staged implant was performed for reasons of an inconclusive PNE. Patients were randomized according to their residual urine at baseline and age. The 2-stage implant is evaluated during 3-5 weeks (3 days diary/week). A follow-up visit was done at 3, 12 and 24 months after implantation of the pulse generator. Subjective improvement was evaluated with a visual analogue scale (VAS) for general well-being and for well-being related to bladder symptoms (scored from 0-100). Objective improvement was assessed on voiding/residual urine diaries. Residual urine measurements, if relevant, were obtained with intermittent catheterization (ambulatory patients) or ultrasound (hospitalized patients). Data are presented as mean $\pm$ -SD or median (95% range) as appropriate. Statistical analysis was done with a Wilcoxon test (paired if possible), Chi2-test and multiple regression analysis.

Table 1: Randomisation and population description of 22 patients with overactive bladder symptoms.

	1-stage implant	2-stage implant
N	11	11
Age (years)	50 $\pm$ 13	51 $\pm$ 12
Gender (n)	1 men, 10 women	3 men, 9 women
Follow-up (months)	16 $\pm$ 8	19 $\pm$ 9
Abnormal health questionnaire (n)*	5	7
3-months follow-up (n)	11	11
12-months follow-up (n)	9	10
24 months follow-up (n)	6	8
VAS score (Qol general well-being)	27 $\pm$ 18	24 $\pm$ 21
VAS score (Qol related to bladder)	14 $\pm$ 10	14 $\pm$ 13
Micturition volume (ml)	190(9-258)	155(0-290)
Residual urine (ml)	225(110-371)	267(130-394)

No significant differences were found (Wilcoxon, Chi2).

*Personality disorder: somatoform (n=8), depressive (n=7), anxiety (n=4), eating or drinking disorder (n=3).

Results

Multiple regression analysis revealed that the outcome (residual urine at 24 months) was positively related to the residual urine at baseline and with the 2-stage implant (F ratio 4.49, p=0.027). We have seen 4/23 failures (2 never functioned, 1 failed at 4 months and 1 at 1 year) and 3/4 were 1-stage implants, 1 was a 2-staged implant (Chi2 p>0.05). Three patients were put back on intermittent catheterization and 1 Bricker derivation was created.

Table 2: Subjective improvement of the quality of life related to bladder symptoms assessed with a visual analogue scale.

	1-stage implant	2-stage implant	1 vs. 2-stage
PNE	90+/-8*	88+/-11*	NS
Stage 1	-	88+/-11*	NS
3 months follow-up	75+/-27*	72+/-26*	NS
12 months follow-up	55+/-29**	79+/-13*	NS
24 months follow-up	52+/-33	78+/-25*	p<0.05

*p<0.01; **p<0.05, compared to baseline.

No significant difference between PNE and stage 1 of the 2-stage implant.

Table 3: Objective improvement of voiding dysfunction following sacral nerve stimulation.

Residual urine (ml)	1-stage implant	2-stage implant	1 vs. 2-stage
PNE	23 (1-55)*	30 (3-62)*	NS
Stage 1	-	29 (12-69)*	NS
3 months follow-up	35 (2-131)*	50 (0-101)*	NS
12 months follow-up	20 (0-262)*	38 (0-70)*	NS
24 months follow-up	215 (10-400)	15 (0-204)*	p<0.05

*p<0.05, paired Wilcoxon test compared to baseline

No significant difference between PNE and stage 1 of the 2-stage implant.

Complications are summarized as device related pain (n=5) and painful stimulation (n=2). We needed 14 revisions in order to maintain the effect.

Conclusions

The 2-stage implant is suggested useful in patients with voiding difficulties.

References

Janknegt RA, Weil EHJ, Eerdmans PH. Improving neuromodulation technique for refractory voiding dysfunction: two-stage implant. Urol 1997;78:39-46.