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THE STAGED IMPLANT DOES NOT INCREASE SUBJECTIVE OR OBJECTIVE IMPROVEMENT IN OVERACTIVE BLADDER SYMPTOMS IN PATIENTS 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 overactive bladder symptoms.

Methods

From October 2000 till January 2002 we implanted a sacral (S3) foramen lead (model 3080) and a pulse generator (Interstim) in 22 women with overactive bladder symptoms. 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 a more then 50% improvement in incontinence (pad weight - urge incontinence) or functional bladder capacity (urgency/frequency) is seen compared to baseline. Patients were randomized according to their symptoms (urgency/frequency or urge incontinence) and age. The 2-stage implant is evaluated during 3-5 weeks (3 days diary/week). A follow-up visit was done at 3 and 12 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. Objective improvement was assessed on voiding/incontinence/residual urine diaries. Residual urine measurements, if relevant, were obtained with intermittent catheterization (ambulatory patients) or ultrasound (hospitalized patients). Data are presented as mean+/-SD or median (quartile range) as appropriate. Statistical analysis was done with a Student t-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)	47+/-13	49+/-18
Urge incontinence (n)	6	6
Frequency (n)	5	5
Abnormal health questionnaire*	4	6
Psychiatric history**	5	6
3-months follow-up (n)	6	5
12-months follow-up (n)	5	6
VAS score (Qol general well-being)	43+/-27	28+/-23
VAS score (Qol related to bladder)	11+/-9	16+/-15
Daily voided volume (ml)	1252+/-416	1382+/-788
Functional bladder capacity (ml)	162+/-83	122+/-84
Frequency (n/day)	10+/-4	9+/-3
Leakage episodes (n/day)	3+/-2	3+/-2
Pad weight (g)	17(0-115)	88(0-128)
Residual urine (ml)	0(0-108)	0(0-44)

No significantly differences were found

*Personality disorder: somatoform (n=4), depressive (n=8), anxiety (n=3), eating disorder (n=1)

**Psychiatric history: depression (n=5), hysteria (n=4), other (n=2)

Results

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
Baseline	11+/-9	16+/-15
PNE	81+/-13*	72+/-16*
Stage 2	-	70+/-12*
3 months follow-up	72+/-21*	62+/-30*
12 months follow-up	79+/-19*	70+/-12*

*p<0.0001, compared to baseline
No significant differences were found between 1-stage or 2-stage procedures. Considering all 22 patients a significant lower subjective improvement was seen at 3 months compared to the PNE or the 12 months follow-up (p=0.048). At 12 months the subjective improvement was not significantly better (p=0.079).

Multiple regression analysis revealed that subjective improvement is only significantly related to functional bladder capacity; R-adjusted 0.36, F-ratio=3.67, p=0.004. At 3 months follow-up, 4 patients had less then 50% subjective improvement (1 was 1-staged, 3 were 2-staged, Chi2:NS). In 2 patients this subjective failure was not related to objective failure or complications. At 12 months all 11 patients had a more then 50% subjective improvement.

Table 3: Objective improvement (diaries) of overactive bladder symptoms following sacral nerve stimulation

		n	Functional bladder capacity (ml)	Frequency (n/day)	Leakage episodes (n/day)	Pad weight (g)
Baseline	1-stage	11	162+/-83	10+/-5	2(0-5)	17(0-15)
	2-stage	11	122+/-84	9+/-4	2(0-5)	88(0-128)
PNE	1-stage	11	238+/-58*	6+/-1**	0(0-0)*	0(0-0)*
	2-stage	11	192+/-76**	9+/-5	1(0-3)*	1(0-103)
Stage 2	1-stage	0	-	-	-	-
	2-stage	11	223+/-106**	7+/-2	0(0-1)*	0(0-14)
3 months follow-up	1-stage	11	254+/-114*	6+/-1*	0(0-1)	0(0-1)*
	2-stage	11	194+/-101**	7+/-2*	0(0-1)	0(0-95)
12 months follow-up	1-stage	5	249+/-147	7+/-5	0(0-0)	0(0-0)
	2-stage	6	294+/-110**	6+/-2**	0(0-0)	0(0-0)

**p<0.01, paired t-test compared to baseline
*p<0.05, paired t-test compared to baseline
No significant differences were found between a 1-stage or a 2-stage procedure.
At 3 months, lack in objective improvement of more then 50% was seen in 3/12 urge incontinent patients and in 3/10 urgency-frequency patients. At 12 months this was respectively 1/5 and 2/6 patients. There was no significant difference in objective improvement at 3 months compared to the PNE results.
During the 2-stage implant only 1 patient failed to improve her incontinence with 50% but the incontinence decreased gradually during the 2-stage evaluation (> 50% improved in the end).

Conclusions

In patients with overactive bladder symptoms, both approaches have a similar outcome. A 2-stage implant did not improve the outcome after the implantation of the pulse generator. If therapy fails this is seen later then during the 3-5 weeks evaluation of the staged implant.

References

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