

## IS THERE AN OPTIMAL PARAMETERS SETTING FOR SACRAL NEUROMODULATION THAT CAN IMPACT THE CLINICAL OUTCOME?

### Hypothesis / aims of study

Aim of our study was to evaluate if there are any specific programming algorithms that are associated with successful and effective InterStim Therapy in patients suffering from urinary voiding dysfunction. There is much literature available on satisfactory results of Interstim therapy, but its optimal parameter settings have never been well understood or established.

### Study design, materials and methods

From June 2002 to July 2003, 60 patients (49 female, 11 male, mean age 49+/- 15 years, range 22-78 years) underwent minimally invasive unilateral staged implant of permanent lead for sacral neuromodulation.

The procedure was performed under local anesthesia. Indications for sacral neuromodulation were: non-obstructive urinary retention (12 pts), urge incontinence (43 pts) and interstitial cystitis (5 pts). 6 pts failed screening and therefore didn't undergo second stage (IPG implant). Stimulation parameters (amplitude, pulse width, frequency, electrode configuration) and the clinical improvement were prospectively collected during each follow up that was performed at 3, 6, 12 months and then yearly. Voiding diary was required based on which the clinical improvement was measured. Continuous data were expressed as mean +/- SD, categorical variables as percentage. Statistical comparisons among groups were carried out by one-way analysis of variance (ANOVA), the statistical significance, defined as p-value < 0.05, was evaluated with the Bonferroni test. Univariate binary logistic regression analysis was utilized to evaluate the relationship between success of therapy and covariates, the statistical significance was defined as p-value < 0.2 to perform the multivariate binary logistic regression analysis. Analyses were performed with SPSS 11.5 software for Windows.

### Results

The results are shown in the table 1

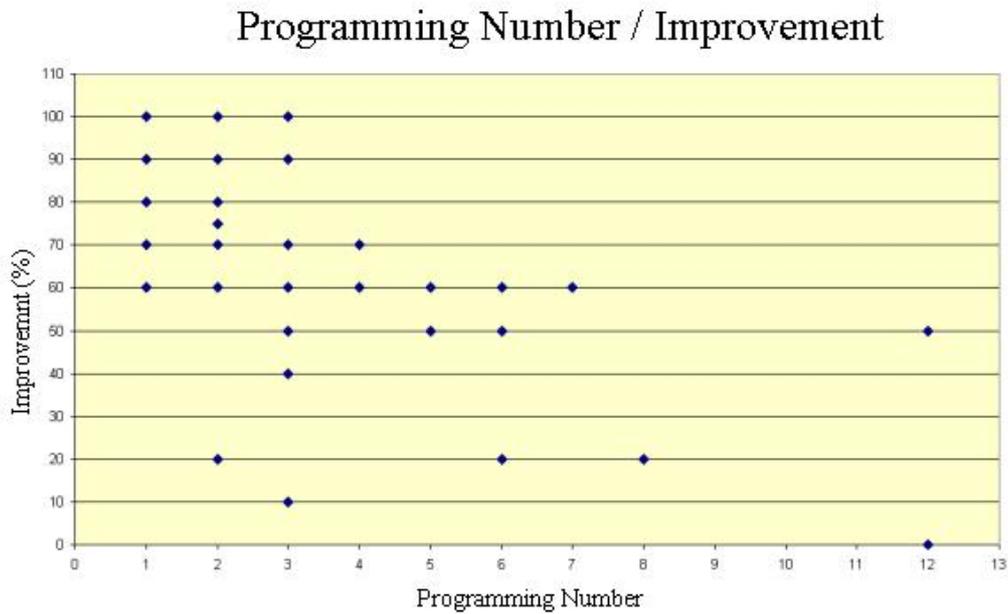
<b>Variable</b>	Urgency-frequency (39 pt)	Interstitial Cystitis (5 pt)	Retention (10 pt)
Sex (M)	17.9% (7 pz)	0.0% (0 pz)	40.0% (4 pz)
Age**	52 ± 14	42 ± 14	39 ± 10
Amplitude	1.9 ± 1.1	1.8 ± 0.9	2.0 ± 1.0
Amplitude upper limit	3.9 ± 1.6	3.4 ± 0.9	3.4 ± 1.7
Pulse width	210.0 ± 23.8	198.0 ± 16.4	216.0 ± 18.9
Unipolar configuration**	66.7% (26 pz)	60.0% (3 pz)	100.0% (10 pz)
Rate p/s	17.2 ± 8.6	15.6 ± 3.8	17.6 ± 7.3
Nr of programmings	3.0 ± 2.5	3.6 ± 2.7	2.3 ± 2.3

\* p<0,05 UF vs CI

\*\* p<0,05 UF vs R

° p<0,05 R vs CI

Table 2



#### Interpretation of results

There is a significant inverse correlation between number of reprogramming and % of clinical improvement ( $p < 0.01$ ). The higher the number of reprogramming the lower the successful rate was observed. Within the interval from 1 to 4 reprogramming, the obtained results were significant (greater than 50%) while in the group of 5 or more reprogramming the % of success was reduce to less than 50%. The other interesting observation regards the polarity. The unipolar configuration showed a better correlation with a successful treatment in all the groups of patients.

#### Concluding message

Each programming is an individual action related to a specific patient and there are not algorithms defined yet that can help standardize this in patient's follow up. However, certain parameters settings show high correlation with the clinical outcome and moreover, successfully treated patients have significantly lower number of reprogramming sessions. This also correlates to what was previously published that Interstim therapy failures would occur in the first 6 months and that reprogramming would not help in increasing the therapy efficacy.