

## INTERSTIM THERAPY PROGRAMMING PARAMETERS. DO THEY HAVE ANYTHING TO DO WITH POSITIVE TESTS?

### Hypothesis / aims of study

Once has been proved the safety of a prolonged timed lead test in interstim therapy (1) The aim of this study is analyzing external generator programming during S3 test and relationship between different programming parameters (frequency, pulse width and poles used) with S3 test duration in candidates to interstim therapy due to overactive bladder symptoms (OAB) or underactive detrusor (UD) in order to identify the best program parameters available in terms of response and longevity of devices. We also analyze sensitivity and specificity of S3 test duration

### Study design, materials and methods

This is a retrospective study our serie of S3 root neuromodulation test in patients with overactive bladder and underactive detrusor since 2004 to 2013. We consider S3 therapy as a second line treatment so our protocol establish, after S3 test is performed, a weekly visit in the office, until there is a subjective and objective results (patient opinion and urologist data) agreement in a positive response. We set a limit of three months for this test if no adverse events were recorded in the visits during the test time. At any time patient was able to stop the procedure. All patient gave specific informed consent During the test patients completed a weekly bladder diary and ICIQ questionnaire. External generator was checked in each visit and adverse events were recorded as well as surgical wound inspected. Every visit at the office we marked the test as positive or negative according to bladder diary data, ICIQ and patient opinion We considered positive result a decrease of more than 50% in the urge and urge incontinence episodes and postvoid residual urine under 90 cc We prolonged test time when patient referred partial results. If no results were showed in three weeks test was finished Considering it is a second line treatment we established a period of three months maximum of test and never less than two weeks even with positive respond in the first two weeks.

We analyze:

S3 test duration  $\leq$  60 days

Univariate analysis of different program variables (frequency, pulse width and poles used) and duration of S3 test ( $\leq$ 60 days).

We analyze as well specificity and sensitivity of S3 test

After a purge of the information collected it is described both upon the full sample as according to the study, and upon the test duration event  $\leq$  60 dias. Quantitative variables are summarized with stockings and typical or medium-sized deviations and percentiles 25 and 75 in the case of asymmetric distributions, and the qualitative variables with percentages. For relationships between certain qualitative predictor variables and the duration of the test  $\leq$  60 days analysis, contingency tables has been made and applied the Chi-square or the MonteCarlo not asymptotic methods and accurate test. Data analysis has been done with the Windows IBM SPSS 22.0 statistical program.

### Results

Since 2004 We have performed 19 S3 tests in overactive bladder (OAB) patients and 12 with detrusor underactivity (DU) and increased postvoid residual urine. Medium time of S3 test has been 58.77 days for positive tests and 88, days for negative. 63,6% of positive test lasted less than 60 days while only 20% of negative tests were defined less than 60 days. Frequency ranges were divided in  $<15$ , 15-34 and  $>34$  Hz. Between positives test under 60 days distribution has been as follows  $<15$  Hz, 38,1%; 15-34 Hz,33.3% and  $>34$  Hz, 28,6%. Patient with no response showed distribution as follows:  $P<15$  Hz, 60%; 15-34 Hz,0% and  $>34$  Hz, 40%. Pulse width used in positive test were 210 (86,4%) and 180 (9,1%). Sensitivity and specificity were analyzed and represented in a ROC curve as shown. Best results for specificity and sensibility was 101 days while both sensitivity and specificity in 30 days of test are really poor. We also analyzed poles distribution of charges (positive, negative or inert) getting more positive tests when poles 0,1 and 2 were used in programming the device

			Poles distribution													Total		
			++0 0123	+-0 0123	+00 0123	+0-0 0123	+00- 0123	--+0 0123	--+0 0123	--00 0123	--+0 0123	-0+0 0123	-00+ 0123	0--+ 0123	00+- 0123		00-+ 0123	
N R M O D	sí	number	0	1	5	2	3	0	1	0	1	1	2	1	1	0	2	20
		%	0,0%	5,0%	25,	10,00	15,0	0,0%	5,0%	0,0%	5,0%	5,0%	10,0	5,0%	5,0%	0,0%	10,0	100,0
	no	number	1	0	0	0	0	1	0	1	0	0	0	0	0	1	1	5
		%	20,0	0,0%	0,0%	0,0%	0,0%	20,0	0,0%	20,0	0,0%	0,0%	0,0%	0,0%	0,0%	20,0	20,0	100,0

### Interpretation of results

S3 neuromodulation is an accepted second line therapy for OAB and detrusor underactivity. Trying to get the best possible results must be a goal to achieve in these patients In our experience the rate of positive responses increases when the time of the test is prolonged.

Frequency or pulse width are main parameters used in programming devices, we found no difference between different frequencies and positives rates. We got more positive responses with higher pulse width (210 ms). Results suggest that the use of 0, 1 and 2 of the timed lead are involved in higher rate of positive tests while use of pole 3 is associated with more negative tests Short test shows less sensitivity and specificity that longer tests, 30 days tests presents really low sensitivity and specificity None of that patients showed adverse events during the test that made us to finish it promptly.

### Concluding message

Performing a long term S3 test we achieve a higher rate of positives responses without increased rate of adverse events or long

term therapy failure.

There is no relationship between positive tests and frequency and pulse width parameters while we find a positive test in more patient using 0 to 2 poles

Results suggest that Best test results are probably related to lead position and time more than programming parameters as frequency or pulse width but programming parameters results suggest as well that using lower frequencies during the test will get similar rate of positive tests and will improve IPG battery longevity

There are two main limitations in this study: it is a retrospective analysis and number of patients that made difficult to find statistical significance. Anyway we found really useful the feedback obtained to perform new tests

#### References

1. VAN KERREBROECK. Medium-term experience of sacral neuromodulation by tined lead implantation. Julio 2006

#### Disclosures

**Funding:** NO funding or grant **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** It is a retrospective study of usual second line therapy in overactive bladder and underactive bladder **Helsinki:** Yes **Informed Consent:** Yes