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SACRAL NERVE MODULATION: RESULTS IN DOUBLE PELVIC FLOOR DYSFUNCTION

Hypothesis / aims of study
Sacral nerve modulation (SNM) has been shown to be effective in the treatment of both bladder and anorectal dysfunctions. We re-examined those patients who were treated with SNM for double pelvic floor dysfunction (DD).

Study design, materials and methods
In July 2006, a self-assessment questionnaire for patients treated for DD was sent to all centres which carry out SNM in the Triveneto area. The questionnaire enquired about changes in micturition and rectal symptoms using groups of questions specific to each dysfunction and to each symptom. A total of 43 patients from 6 centres were involved.

Results
Average age at implant of the Interstim (Medtronic) stimulator was 60 +/- 12 years (range 37-84). Average follow-up was 37 +/- 24 months. Indications for SNM were principally urological in 40 case - 22 urinary retention (UR) and 18 hyperactive bladder (OAB) - and mainly proctological in 3 cases - 2 fecal incontinence (FI) and 1 constipation (Co). DD was neurogenic in 12 cases. The most common DD was UR and Co (22 patients - 51.2%), followed by OAB and Co (14 patients - 32.6%) and OAB and FI (7 patients - 16.3%). When asked "After SNM, did you detect any significant and lasting change in bladder function?", 95.3% of patients responded positively, while to the same question regarding anorectal function 76.7% responded positively. Of those patients with UR and Co, 95.4% reported an improvement in UR and 71.4% of these described an improvement also regarding Co. For those patients with aOAB, 95.2% of cases improved with SNM and 85% of these (11 Co and 6 FI) also experienced a significant improvement in anorectal symptoms. See also tab 1-5 for results.

Interpretation of results
Even though there were intrinsic limits to the study - it was retrospective, it concerned a small number of patients and a totally objective analysis of the results of SNM proved difficult - DD responded well to SNM. The best results concerned urinary symptoms where improvement was detected in 95.3% of patients against 76.7% detected in anorectal symproms. The DD in which we saw the best results was OAB associated with both rectal dysfunctions, where 78.5% of patients with Co and 85.7% of patients with FI reported a significant improvement.

Concluding message
In our experience DD responded well to SNM and our data are even more significant considering that there are no alternative treatments for rectal dysfunction and that OAB and FI are severely disabling conditions.

TAB 1: Average and range for questionnaires scores (0=unchanged 200=complete resolution)

	General result	Non neurogenic patients	Neurogenic patients
VI+ST	154 (107-197)	147	168
VI+IF	152 (107-197)	151	151
RU+ST	139 (87-173)	145	130

TAB 2 Change in pads use by day in OAB and in OAB associated with IF

	OAB (21 pts)	IF+OAB (7 pts)
Improvement – No pads	9 – 43%	4 – 57%
Improvement - 1 pad/die	8 – 38%	2 – 29%
Improvement – More pads/die	2 – 10%	1 – 14%
Improvement – 1-2 pads/die	2 – 10%	0 – 0%
Unchanged (as before SNM)	0 – 0%	0 – 0%

TAB 3 Change of self-catheterisations (CIC)/die in UR (22 pts)

No more CIC	15 (68%)
Improvement - 1 CIC	1 (5%)
Improvement – less than 2 CIC	0 (0%)
Improvement – less than 3-4 CIC	5 (23%)
Unchanged (as before SNM)	1 (5%)

TAB 4 Change in laxatives use in subjects with Co

	Co (36 pts)	Co+UR (22 pts)	Co+OAB (14 pts)
Improvement – he uses nomore	16 – 44%	7 – 32%	9 – 64%
Improvement – rarely	6 – 17%	4 – 18%	2 – 14%
Improvement – sometimes	8 – 22%	7 – 32%	1 – 7%
Improvement – often	5 – 14%	4 – 18%	1 – 7%
Unchanged – used always as before SNM	1 – 3%	0 – 0%	1 – 7%

TAB 5 QoL average results (range from 1=no improvement at all to 5=complete resolution of DD)

UR-Co	3,4
OAB-FI	3,9
OAB-Co	3,8
Grand Total	3,6

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**This study is retrospective and observational without chages in clinical practice.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**