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FUNCTIONAL RESULTS AND PATIENT SATISFACTION WITH SACRAL NERVE STIMULATION FOR IDIOPATHIC FAECAL INCONTINENCE

Hypothesis / aims of study
Sacral Nerve Stimulation (SNS) is a minimal invasive procedure which has become an established treatment option for faecal incontinence when conservative treatment has failed to restore continence to a satisfactory extent. Treatment efficacy has mainly been evaluated by using bowel habit diary's and incontinence scores. With these evaluations tools SNS has revealed excellent results in the short-term, and evidence is accumulating on the long-term outcome of the procedure. The aims of the present international two-center study were, firstly, to investigate treatment satisfaction in patients, with idiopathic faecal incontinence (IFI), treated with SNS-therapy. Secondly, to evaluate the relationship between patient satisfaction and clinical outcome assessed by bowel habit diaries and symptom scores.

Study design, materials and methods
The present study is an international two-center, retrospective analysis of prospectively collected data performed in patients with IFI treated with SNS-therapy in the period April 2000 to May 2009. At most recent follow-up 127 (80%) of the 158 primarily implanted IFI patients were identified as having active SNS-therapy. A 49-item questionnaire and a 3-week bowel habit diary were mailed to these patients. Wexner incontinence score, St. Mark's score and Rockwood Fecal Incontinence Quality of Life Scale (FIQLS) were included in the questionnaire. Additionally, patients were asked to indicate (yes/no) if they were satisfied with their current treatment result.

Results
The primarily implanted IFI patients had a median age at permanent implantation of 60.9 years (range 30-83). The duration of faecal incontinence before IPG implantation was median 5 years (range 0.7-41.4). A total of 108 (85%) patient returned the mailed questionnaire among the responders 99 patients had the pacemaker active after a median of 46 (range: 11-122) months follow-up. A total of 75 out of the 99 patients with active SNS-therapy were satisfied with current treatment result at latest follow-up. The follow-up group was subdivided into patients who reported being satisfied with current treatment result and those who were not. Statistically significant better scores in Wexner incontinence score, St. Mark's score and all parts of FIQLS at most recent follow-up, were seen in the satisfied patient group (Table 1). Patients who reported being satisfied with current treatment result had a statistically significant reduction in incontinence episodes and in total number of bowel movements per three weeks compared to the dissatisfied group (Table 1). Bowel habit diaries at baseline and at most recent follow-up were available in 91 out of 99 patients with active SNS-therapy at follow-up. Patient satisfaction was clearly related to reduction in incontinence episodes. The satisfied group had a statistically significantly higher median reduction in incontinence episodes than the dissatisfied patients (Table 1).
Patients experiencing full continence were all satisfied, satisfaction rate dropped as FI episodes increased. But still forty-six percent of the patients with more FI episodes at follow-up than baseline were satisfied (Table 1). In total 74.7% of the patients with active SNS-therapy had ≥50% reduction in FI episodes, 10.3% of who were dissatisfied after median 46 months follow-up.
Intention-to-treat(ITT) analysis evaluating all patients offered a test operation at one of the centers shoved on an ITT basis that 35% of the patients initially offered a test operation were satisfied with the SNS-therapy after median 39 months follow-up.
Per-protocol-analysis evaluating all patients implanted in the two-centers resulted in a self reported satisfaction rate of 57.7% after median 46 months follow-up.

Interpretation of results
Patient satisfaction was clearly related to the achieved reduction in incontinence episodes. The satisfaction rate dropped as the number of incontinence episodes increased. An unexpected finding was that 46% of the patients with more incontinence episodes at follow-up than baseline were satisfied. These patients explained that they had obtained a more active social life after the SNS-therapy. This aspect of social behavior is not addressed in the bowel habit diary, and traditional evaluation would consider these patients as failures even though the patients were satisfied. In this study 74.7% of the patients with active SNS-therapy had a reduction of ≥50% in faecal incontinence episodes which is comparable to reports from other centers [1-2]. However, among these patients 10.3% were dissatisfied with their functional result at latest follow-up.

Concluding message
Patient satisfaction was reached in 57.7% of the patients initially offered SNS-therapy. This figure is lower than the results reported based on bowel habit diaries and incontinences scores with a cutoff point of ≥50% improvement.
There is a clear relation between patient satisfaction and improved continence – However, 46% of the patients with more incontinence episodes at latest follow-up than baseline were satisfied. Therefore, in the future we should focus on patient satisfaction and quality of life, in combination with bowel scores and diaries to get a more accurate measure of SNS-therapy efficacy for faecal incontinence.

Table 1

		Total n=99	Satisfied with current functional result n=75	Dissatisfied with current functional result n=24	P-value♦
Follow-up	Follow-up months		52.4(11-122)	40.3 (11-96.9)	NS

Wexner inc.		8(0-20)	13(5-20)	<0.0001
St. Marks Score		11(0-24)	16.5(9-22)	<0.0001
Reduction in incontinence episodes	n=91	96(-250 -100)% n=72	25(-350 - 98)% n=19	<0.0001
Reduction in bowel openings (baseline-latest follow-up)	n=91	32(-106 - 70) percent n=72	0(-108- 70) percent n=19	0.0053
Patients with increased number of incontinence episodes		6 (46%)	7	
FIQLS				
– Lifestyle		3.4(1-4)	2.6(1-3.6)	0.0006
– Coping/behavior		2.4(1-4)	1.6(1-2.9)	<0.0001
– Depression/Self perception		3(1.7-3.9)	2.3(1.2-3.4)	0.0001
– Embarrassment		2.7(1-4)	2(1-3.7)	0.0006

Values are medians (range). ♦Unpaired t-test.
NS: Non-significantly

References

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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 ethics committee approval because	**According to Danish and Dutch law, this study did not require approval from the local ethics committee, because the study was performed as a quality assessment of an established treatment.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**