

ORIGINAL ARTICLE

Sacral anterior root stimulation improves bowel function in subjects with spinal cord injury

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Study design: Cross-sectional study.

Objective: To evaluate the long-term effect of the sacral anterior root stimulator (SARS) on neurogenic bowel dysfunction in a large, well defined spinal cord injury (SCI) cohort.

Setting: Department of Neuro-Urology, Bad Wildungen, Germany.

Methods: Subjects undergone surgery at for SARS-SDAF (sacral deafferentation) between September 1986 and July 2011 ($n=587$) answered a questionnaire. In total, 277 SARS subjects were available for the baseline (recall) and follow-up comparison.

Results: Median age was 49 years (range: 19–80), time from SCI to surgery was 10 years (range: 0–49) and from surgery to follow-up 13 (range: 1–25). Of the responders 73% used SARS for bowel emptying. On visual analog scale (VAS) ranging from 0–10 (best), satisfaction with SARS was 10. Baseline and follow-up comparison showed a decline in the median VAS score 0–10 (worst) for bowel symptoms from 6 (range: 4–8) to 4 (range: 2–6), $P<0.0001$; median neurogenic bowel dysfunction score from 17 (range: 11–2) to 11 (range: 9–15), $P<0.0001$; median St Marks score from 4 (range: 0–7) to 4 (range: 0–5), $P=0.01$; and median Cleveland constipation score from 7 (range: 6–10) to 6 (range: 4–8), $P<0.0001$. Use of suppositories, digital evacuation and mini enema and subjects totally dependent on assistance during defecation were significantly lower after SARS.

Conclusions: The SARS has the potential to be one of the few treatment methods targeting multiple organ dysfunctions following SCI. *Spinal Cord* (2015) **53**, 297–301; doi:10.1038/sc.2015.2; published online 20 January 2015

INTRODUCTION

Spinal cord injury (SCI) has profound impact on the lives of those affected. Quality of life is restricted not only by immobility but also by severe neurogenic bladder, sexual and bowel dysfunction. Since the SCI itself is not treatable yet, therapy has been targeted based on symptomatology. The primary aim of neurogenic bladder dysfunction management is lowering the bladder pressure. Standard therapy is anticholinergics combined with clean intermittent catheterization. In more complicated cases, intravesical botulinum A toxin injections, bladder augmentation and procedures enhancing bladder outlet resistance may be indicated. A different approach has been to modulate the intact neurogenic components thereby changing their effect on the target organs. Established methods for bladder dysfunction include the sacral anterior root stimulator (SARS).¹ This treatment was introduced in 1976 by Brindley and later expanded to include sacral deafferentation (SDAF).¹ The SARS procedure is almost exclusively used against neurogenic bladder dysfunction, but because of the common nerve supply from the sacral spinal roots (S2–S4), the distal colorectum and the anal sphincters are affected by stimulation and SDAF too. The clinical effects of SARS on neurogenic bowel dysfunction have been sparsely investigated. Therefore, the aim of the present study was to evaluate the long-term effects of SARS on bowel symptoms in a large, well-defined cohort of subjects with SCI.

MATERIALS AND METHODS

Sacral anterior roots stimulation

The SARS-SDAF procedure is illustrated in Figure 1 and previously described in detail.¹ Briefly, stimulation electrodes are placed on sacral anterior (ventral or motor) roots. Dorsal (posterior or sensory) roots are dissected. The stimulation electrodes are connected to a subcutaneous device controlled by an external remote creating a subject-controlled pulsative stimulation with a selective programming for bladder, bowel and sexual function.

Construction of bowel function questionnaire

A questionnaire was constructed from the International Bowel Function Basic and Extended Spinal Cord Injury Data Set^{2,3} with a few additional items. Further a visual analog scale (VAS), range 0 (worst) to 10 (best), was used to describe satisfaction with the SARS treatment and bowel dysfunction. The questionnaire items were rephrased to allow an in-person instead of an interactive completion. Afterwards, a translation was made to German by a professional translational bureau with expertise in medical translation. The questionnaire was assembled in duplicate, the first one asking about the present bowel management and the second one asking to recall the bowel management before the surgery. After translation four hospitalized SCI subjects, who had undergone the SARS procedure, filled in the questionnaire. A structured interview with each subject was performed to ensure questions and instructions were sufficiently comprehended.

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Received 17 June 2014; revised 29 December 2014; accepted 30 December 2014; published online 20 January 2015

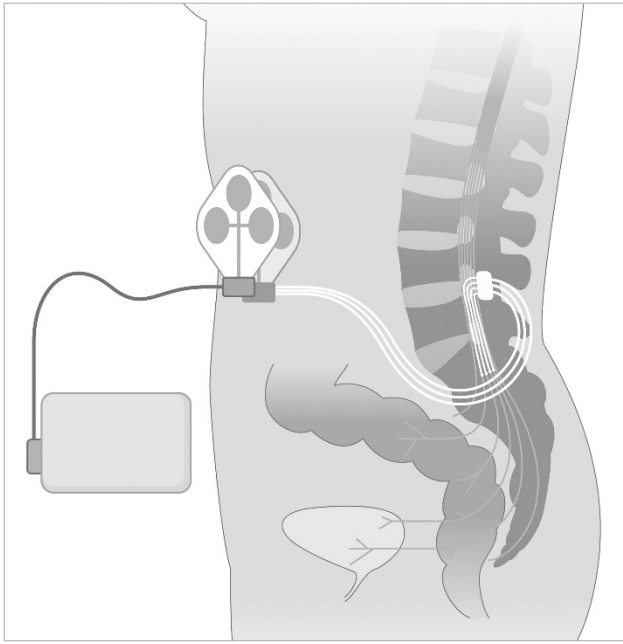


Figure 1 Schematic drawing of the sacral anterior root stimulator (SARS procedure).

Data collection

Baseline data on all subjects who had undergone the SARS procedure at the Department of Neuro-Urology, Werner-Wicker Clinic, Bad Wildungen, Germany between September 1986 and July 2011 were collected from hospital records. Then questionnaires were sent by mail to all subjects still alive and in contact with the clinic. Non-responders had another questionnaire re-mailed encouraging them to participate. Based on the questionnaire, the following bowel function scores were computed: the neurogenic bowel dysfunction score (0–6 very minor, 7–9 minor, 10–13 moderate, 14+ severe bowel dysfunction);⁴ the St Marks fecal incontinence score (0=perfect continence, 24=totally incontinence);⁵ and the Cleveland constipation score (0=minimal, 30=worst constipation).⁶ In order to perform test–retest analysis, an identical questionnaire was re-mailed to 40 randomly chosen responders after a mean of 2½ months.

Statistical analysis

Data were analyzed by using the Wilcoxon signed rank test or Stuarts *t*-test whenever appropriate. Mean and 95% confidence interval are given for Gaussian and median with 25 and 75% quartiles for non-Gaussian data. $P < 0.05$ was considered as statistically significant. Test–retest analysis was performed comparing an agreement between the returned questionnaires.

Ethical considerations

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

RESULTS

The SARS procedure had been performed for neurogenic bladder dysfunction in 587 subjects. Excluding deceased subjects ($n = 63$) and other no longer in hospital follow-up ($n = 60$), the questionnaire was sent to 464 of whom 333 (72%) responded. Ten responders had an ostomy and another 46 no longer used the stimulator. This left a total of 277 subjects available for an analysis of bowel function (Figure 2). Comparing subjects responding with those not, there were no significant differences in gender, age at follow-up, time since injury,

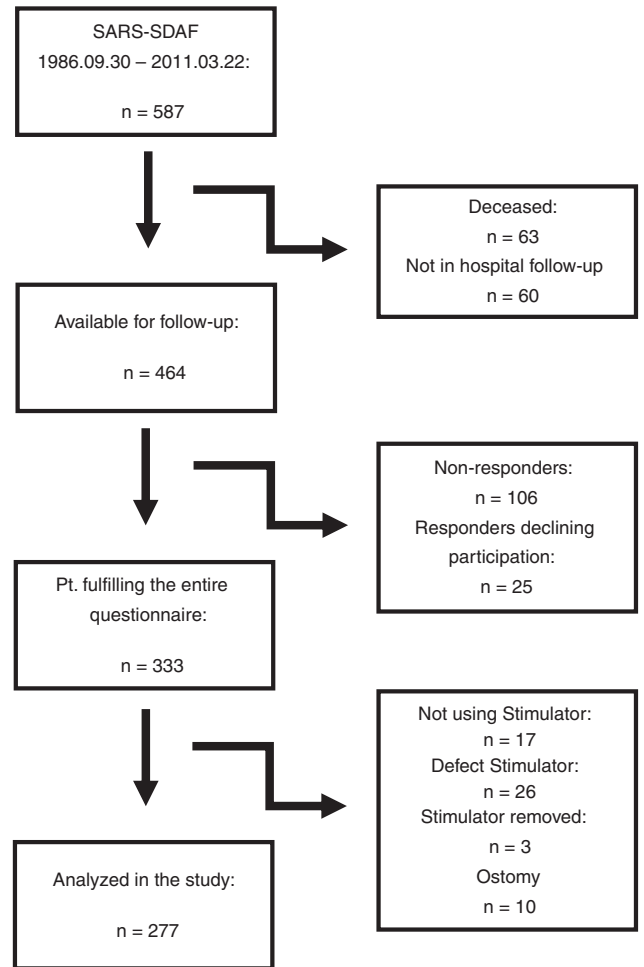


Figure 2 Subject inclusion.

time since surgery, time from SCI to surgery, AIS grade (American Spinal Injury Association Impairment Scale),⁷ lesion level or SCI etiology (Table 1).

Median age was 49 years (range: 19–80), median time from SCI to SARS surgery was 10 years (range: 0–49), and median time from SARS surgery to follow-up was 13 years (range: 1–25). The majority of subjects were AIS A ($n = 234$, 84%), followed by AIS B ($n = 38$, 14%) and AIS C ($n = 5$, 2%). The injury level was cervical ($n = 131$, 47%), thoracic ($n = 143$, 52%) or lumbar ($n = 3$, 1%). Subject demographics are described in detail in Table 1.

Among the 333 responders, SARS was routinely used as the primary bowel emptying procedure in 223 (67%). Including supplementary use reported in 19 subjects, a total of 242 (73%) used SARS as part of their bowel routine (Table 2). In the 277 subjects still using SARS, the median VAS score for overall satisfaction with treatment was 10 (range: 0–10) and median VAS score for overall severity of bowel symptoms was 4 (range: 2–6). The median neurogenic bowel dysfunction score was 11 (range: 9–15) which corresponds to a moderate neurogenic bowel dysfunction. Median St Marks incontinence score was 4 (range: 0–5) and median Cleveland constipation score was 6 (range: 4–8).

An analysis was performed comparing recall data of the bowel function prior to SARS and the current situation (follow-up). The median VAS score for overall severity of bowel symptoms was 6

Table 1 Patients demographics

	Patients analyzed: n = 277	Range: (min-max)	Not analyzed: n = 310	Range: (min-max)
Age at follow-up (median, years)	49	(19–80)	50	(22–86)
Time from SCI to follow-up (median, years)	24	(4–56)	24	(4–63)
Time from SCI to surgery (median, years)	10	(0–49)	8	(1–42)
Time from surgery to follow-up (median, years)	13	(1–25)	16	(1–25)
Sex				
Male	145		187	
Female	132		123	
AIS score				
A	234		262	
B	38		38	
C	5		9	
D	0		1	
E	0		0	
Lesion level				
Cervical	131	(C1–C8)	135	(C2–C8)
Thoracic	143	(Th1–Th12)	159	(Th1–Th12)
Lumbar	3	(L1–L2)	11	(L1–L5)
Sacral	0		0	
Etiology				
Traumatic SCI	267		294	
Spinal cord neoplasm	5		6	
Inflammatory disease	4		7	
Neural tube defect	1		3	

Abbreviations: AIS, American Spinal Injury Association Impairment Scale; SCI, spinal cord injury.

Subject demographics. Left column is the analyzed group, right column is the excluded. No significant differences were found between the two groups. AIS score, ASIA impairment scale. A, complete spinal cord injury; B, sensory preserved, motor complete injury; C, less than half of key muscles preserved at grade 3 below injury level; D, more than half of key muscles preserved at grade 3; E, transient spinal cord injury with no residual symptoms at follow-up.⁷

(range: 4–8) at baseline and 4 (range: 2–6) at follow-up ($P < 0.0001$) (Table 3), median neurogenic bowel dysfunction score was 17 (range: 11–21) at baseline and 11 (range: 9–15) at follow-up ($P < 0.0001$). To explore further, the neurogenic bowel dysfunction score was partitioned into grades and compared before and after SARS (Table 4). Median St Marks fecal incontinence score was 4 (range: 0–7) at baseline and 4 (range: 0–5) at follow-up ($P = 0.01$), and median Cleveland constipation score was 7 (range: 6–10) at baseline and 6 (range: 4–8) at follow-up ($P < 0.0001$). There was less use of suppositories, digital evacuation and mini enemas after SARS and the proportion of subjects totally dependent on assistance during defecation was also lower (Table 2). No correlation was found between the change in neurogenic bowel dysfunction score and time since the surgical procedure.

Among the 40 responders who received the second questionnaire, 30 (75%) responded again and in 23 of these questionnaires were complete. In dichotome (that is, 'yes'/'no', $n = 11$) questions, 91% agreement was found between the two questionnaires. Considering questions with more variables ($n = 62$) perfect agreement was seen in

68 (59–77)%, 1 deviation in 18 (9–27)%, 2 deviations in 5 (5–9)% and more than 2 in 5 (0–14)%.

DISCUSSION

It is well known that bowel emptying at defecation is reduced in subjects with SCI.^{8,9} Reasons for this are prolonged colonic transit time¹⁰ and, in some cases, abnormal defecation and rectoanal inhibitory reflexes depending on the spinal segments S2–S4.^{5,9} Conservative treatment of neurogenic bowel dysfunction usually includes laxatives and transanal irrigation. Recently, sacral nerve stimulation has been introduced in subjects with incomplete SCI.¹¹ Antegrade colonic irrigation through an appendicostomy reduces bowel symptoms and a colostomy can help others with severe symptoms or a very-poor hand function. Alternatives to a stoma are, however, needed for some of the subjects who continue to have severe symptoms in spite of standard treatment.

The present study is the first to describe the long-term effects of SARS on bowel function in a large group of subjects with SCI. Even though introduced for bladder dysfunction management, a considerable number of subjects in our cohort used SARS as bowel emptying procedure and reported a very-high satisfaction rate. Those not using the stimulator for bowel emptying per se might also have an improved bowel function due to stimulation increased peristaltics in the distal colon and rectum. Interestingly, the effect of SARS does not seem to decrease with time as the neurogenic bowel dysfunction score was not associated with time since the surgery.

Very-few studies have focused on the effects of SARS on bowel function. The reason is probably that the stimulator was developed for bladder management.¹ It has previously been shown that SARS stimulates colonic motility,¹² reduces colonic transit time and makes defecation easier.¹³ In other studies the frequency of defecation increased,¹⁴ time spend on defecation decreased¹³ and emptying during defecation improved.¹⁵

The increased defecation frequency could indicate an increased peristaltic activity in the left colon and the rectosigmoid. It is likely that the multiple daily stimulations of bladder emptying summate to promote peristalsis of the left colon. In an animal model, SARS caused colonic contractions and rectal evacuation during stimulation.¹⁶ The SDAF as part of the SARS procedure will inevitably lead to loss of S2–S4 mediated reflexes. However, stimulation seems to outweigh this disadvantage. Another concern with stimulation of the sacral nerves is simultaneous activation of the smooth muscles in the rectal wall and the external anal sphincter. This can be avoided by correct choice of stimulation parameters or perhaps in the future with the use of selective anodal block of nerves to the external anal sphincter.¹⁷ These results from previous reports are in line with our findings adding to the existing evidence that bowel management with SARS is a feasible strategy.

The present study is the largest investigation to date examining the effects of SARS on bowel function in SCI. Of a total 587 subjects who underwent surgery, 277 could be evaluated. There is a risk of selection bias, as one could speculate that responders are the ones most satisfied with the stimulator. However, we did not find any differences in baseline information between the two groups.

To determine whether SARS improves neurogenic bowel dysfunction, we compared in this cohort the pre-surgical bowel dysfunction based on recall to the status at the time of investigation. The neurogenic bowel dysfunction score was chosen for the main assessment of symptoms since it has been specifically constructed and validated among subjects with SCI.⁴ The SARS resulted in significantly reduced neurogenic bowel dysfunction score

Table 2 Emptying details

Emptying procedure	Preoperative (n)		Follow-up (n)		P-value
	Primary	Supplementary	Primary	Supplementary	
Normal	18	2	1	0	P=0.06
Pressure on the stomach/bowel massage	28	39	11	31	P=0.27
Digital stimulation	42	32	12	28	P=0.06
Suppositories	168	22	8	14	P<0.0001
Digital evacuation	113	47	117	79	P<0.0001
Mini enema	22	26	6	5	P=0.0008
Enema	10	7	6	1	P=0.62
Ostomy	2	0	0	0	P=0.16
Other	3	3	6	4	P=0.32
Brindley	x	x	223	19	x

Need for assistance during defecation	Preoperative (n)	Follow-up (n)	P-value
	Need assistance with everything	120	
Need partial assistance, I do not clean myself	19	13	P=0.35
Need partial assistance, I do clean myself	17	21	P=0.43
Use the toilet independently, but need special aids or fixtures (e.g. railing, handles etc.)	49	51	P=0.51
Completely independent, do not need special aids or fixtures	74	84	P=0.13

On top details on individual subjects' emptying procedure (subjects can choose more than one) is outlined. Primary is a method used almost every time, supplementary is used sometimes when necessary. On the bottom is need for individual assistance during bowel emptying.

Table 3 Bowel symptomatology and emptying details

	Preoperative	Range	Follow-up	Range	Difference (baseline	P-value	
	(median)	(25–75%)	(median)	(25–75%)	- follow-up) (mean)		
Neurogenic bowel dysfunction score	17	(11–21)	11	(9–15)	4.6	(3.7–5.5)	P<0.0001
St Marks incontinence score	4	(0–7)	4	(0–5)	0.7	(0.2–1.3)	P=0.01
Cleveland constipation score	7	(6–10)	6	(4–8)	1.3	(0.8–1.7)	P<0.0001
VAS score – bowel symptoms	6	(4–8)	4	(2–6)	1.8	(1.4–2.2)	P<0.0001
VAS score – sacral anterior root stimulator	x	x	10	0–10	x	x	x

Abbreviations: CI, confidence intervals; SARS, sacral anterior root stimulator; VAS, visual analog scale.

On top data on bowel symptom scores, the neurogenic bowel dysfunction score, St Marks fecal incontinence score and Cleveland constipation score. Scores improved significantly with SARS.

Table 4 Neurogenic bowel dysfunction score at baseline and follow-up

Baseline	Follow-up				Total
	Very minor	Minor	Moderate	Severe	
Very minor	11	4	1	1	17
Minor	5	5	3	1	14
Moderate	17	18	25	7	67
Severe	17	26	69	67	179
Total	50	53	98	76	277

The neurogenic bowel dysfunction at baseline and follow-up. The majority of patients improved by one or more grades following SARS.

corresponding to a median change from severe to moderate neurogenic bowel dysfunction. The effect was on the majority of the patient cohort, which improved by one or more grades, and on a range of variables following SARS. Thus, the frequency of defecation increased, time consumption for defecation decreased as did unpleasantness during defecation. This was in accordance with significantly reduced

use of laxatives, suppositories, digital evacuation and mini enemas. Accordingly, a proportion of subjects experienced increased autonomy in bowel care. Changes in the neurogenic bowel dysfunction score were supported by an improved continence and reduced constipation when evaluated by the St Marks fecal incontinence score and the Cleveland constipation score. The reason for lesser impact on the latter two scoring systems could be that they are not specifically designed for the evaluation of neurogenic bowel function. All above mentioned parameters points toward a rapprochement of the bowel dysfunction and the defecation process to a normal individual. This is in alignment with earlier findings on the subject.

The reliability of most questions in the questionnaire used has been tested in an earlier study. Inter-rater reliability was acceptable with 58% of questions having a fair agreement or better.¹⁸ The validation was carried out internationally, however, not in German as in our study. Further, the questionnaire was modified from investigator-led to patient fill-in. The results of our test–retest, however, indicated that such use was acceptable.

Regardless of modern treatment modalities, neurogenic bowel dysfunction still causes severely reduced quality of life after SCI. This must lead to a search for treatment alternatives. SARS was invented

more than three decades ago. It has still not gained a wide spread use. Reasons for this are unknown, but probably influenced by the concerns about the irreversible SDAF including the restriction of potential future treatment options with neuromodulation. These include sacral nerve stimulation, which decrease fecal incontinence in incomplete SCI subjects,¹⁹ but not complete SCI. Pudendal nerve stimulation in cauda equina subjects was investigated in a recent study with promising results.²⁰ Other treatment modalities of interest are posterior tibial nerve stimulation, dorsal genital nerve stimulation and magnetic stimulation.¹⁹ Other aspects which may have limited the use of SARS are a long learning curve to perform the surgical procedure, subject selection, knowledge on stimulator setup, troubleshooting when errors occur and known complications to the surgical procedure (cerebrospinal fluid leakage and infection).

This study has some limitations. The present study was retrospective and thus based on recall. This design allowed us to analyze data from a large cohort of patients treated, but carries the risk of significant bias including expectation bias, recall bias and desirability bias. Patients may have overestimated the difference between their bowel function before surgery and at follow-up several years later since they expected a treatment effect. Making a memory-based fill-in of the second part of the questionnaire, the answers could be less accurate since recall could skew the true assessment. Finally, our patients are still in the care of the institution and they may have reported answers in line with expectations of the investigator and the institution. Our study design prevented assessment of such biases. However, to estimate if recall bias was significant, we plotted change in the neurogenic bowel dysfunction score against time since injury and found no statistically significant association. Non-equidistant scoring schema for several dichotomous and multiple choice items may have biased the neurogenic bowel dysfunction results despite the high rate of test-retest agreement.

Although initially invented for bladder management our results support a simultaneous positive effect on neurogenic bowel dysfunction. Thus, SARS has the potential to be one of the few treatment methods targeting multiple organ dysfunctions following SCI. We find the conclusions from this study encouraging. Thus, future prospective controlled studies should use valid end points encompassing both bladder and bowel dysfunction.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ACKNOWLEDGEMENTS

The authors thank Professor Soren Laurberg for help and support with the study. Further, we thank the Lundbeck foundation for financial support.

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