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Original Article

A 7-year follow-up of sacral anterior root stimulation for bladder control in patients with a spinal cord injury: quality of life and users' experiences

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Study design: Cross-sectional descriptive study.
Objectives: To assess long-term effects and quality of life (QoL) of using sacral anterior root stimulation (SARS) in spinal cord injured patients.
Setting: Neurosurgical and Urological Departments of a large teaching hospital and a large rehabilitation centre in the Netherlands.
Methods: In all, 42 patients with complete spinal cord injury (SCI) implanted between 1987 and 2000 were included. A questionnaire was constructed to determine complications, technical failures and personal experiences of the patients. The Qualiveen questionnaire was used and the outcome was compared with data obtained from a reference group of 400 SCI patients with neurogenic bladder problems not using the bladder controller. The Qualiveen questionnaire measures disease-specific aspects in four domains with respect to limitations, constraints, fears and feelings and general QoL aspects, suitable for use in SCI patients with urinary disorders.
Results: The results of 37 patients are presented. Our results with the bladder controller with respect to medical and technical complications and infection rates are similar to the results presented by others. From users' experiences, the most important advantages reported were a decreased infection rate (68%), improved social life (54%) and continence (54%). Comparison of the obtained results of our patient group with the Qualiveen questionnaire with a reference group not using the bladder controller indicates that the specific impact of urinary disorders in the four domains on QoL is reduced and that general QoL is improved.
Conclusion: SARS is effective and safe for neurogenic bladder management in patients with complete SCI. Users' experiences are positive. Furthermore, this therapy seems to reduce the effects of urinary-disorder-specific QoL aspects, and to increase the QoL in general.
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Keywords: spinal cord injury; sacral anterior root stimulation; neurogenic bladder; quality of life

Introduction/background

In the last 30 years considerable progress has been made in the urological rehabilitation of patients with neurogenic bladder disorders as a result of a spinal cord injury (SCI). Nevertheless, these patients frequently develop complications such as urinary tract infections, stones of the upper and the lower urinary tract and deterioration of the bladder. Furthermore, upper urinary tract problems can be caused because of reflux and/or obstruction, increasing the risk of deterioration of kidney function. Incontinence remains another important problem for these patients.[1]

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The management of neurogenic bladder dysfunction after SCI in general consists of increasing bladder capacity, maintaining low-pressure storage of urine with preservation of the upper urinary tract and preventing incontinence. In addition, bladder management aims at full evacuation of urine to reduce the incidence of urinary tract infections. In patients with complete SCI at a level that leaves the sacral segments intact, detrusor hyper-reflexia generally develops after a phase of spinal shock. This type of bladder dysfunction can cause important morbidity. Anticholinergic therapy is the usual treatment but is often insufficient.[1–3]

In the 1970s, Brindley developed the sacral anterior root stimulator (SARS) for complete SCI patients with severe neurogenic bladder disorders. The device was implanted in the first patient in 1976.[4,5] Nowadays SARS is usually combined with posterior sacral root

rhizotomy, eliminating all reflex activity of the detrusor and thereby increasing bladder capacity and controlling reservoir function of the bladder. Stimulation of the efferent nerves (anterior roots) produces a contraction of both the detrusor and the sphincter muscle. Voiding is possible upon intermittent stimulation because the striated muscle of the sphincter contracts and relaxes more rapidly than the smooth muscle of the detrusor.[2]

In the literature, remarkable results of SARS for management of both urinary and faecal incontinence in SCI patients are reported. Short-term results have shown that 85–97% of the patients use their implants regularly for micturition and 55–70% to assist defaecation. Complete continence is reported in 68–91%. In male patients 41–71% reported full implant-driven erections, sufficient for coitus in 26–55%.[2,6–11] A substantial decrease in symptomatic urinary tract infection has been reported by many groups (65–71% have had no urinary tract infection in the previous year after implantation[6,9]). Side effects, for example, pain, increased spasms, loss of reflex erection or occasionally autonomic dysreflexia on stimulation, are rare.[6–14] Implant failures of the internal equipment are reported in 14.4% of users.[15]

Few studies have reported on the experiences of the users and effects of the bladder controller on the quality of life (QoL). Kachourbos and Creasey[16] showed an improvement in QoL using a self-made structured questionnaire. Wielink *et al*[14] used the Nottingham Health Profile, a generic measure covering the dimensions of physical mobility, pain, energy, sleep, emotional reaction and social isolation, but did not show significant improvement after implantation of the bladder stimulation. The subscales 'pain' and 'physical mobility' appeared to be inapplicable in SCI patients, as several items relate to difficulties experienced in walking and standing. The Karnofsky Performance Index to quantify 'objective' QoL aspects in cancer research did not show significant improvement either. The fact that drainage of the bladder is just one of the many problems that patients with a SCI experience, may explain these small effects on QoL. However, overall well being as assessed with the Affect Balance Scale, did improve significantly with SARS. Wielink *et al*[14] used a self-constructed questionnaire to assess the degrees of experienced bothersomeness caused by bladder problems, urinary incontinence and micturition problems (on performing household work, shopping, odd jobs about the house, sports and going out) on QoL, this showed significant improvement using SARS.

A limitation reported in all studies is the measured QoL for these SCI patients, because validated disease-specific instruments available for this purpose alone were lacking. The majority of existing questionnaires is generic and not responsive to detect changes in QoL in SCI patients. In addition, the impact on QoL of urinary disorders in these patients remained unknown. In order to address this need, the Qualiveen questionnaire was developed for use in SCI patients with urinary disorders.[17]

The objective of this study is to determine the long-term results of the implanted bladder controller in SCI patients with respect to effectiveness, side effects, complications and advantages. Furthermore, this study intends to determine the users' experiences, and to gain experience with the newly developed Qualiveen questionnaire for measuring QoL.

Methods

A cross-sectional descriptive study was conducted. The study was approved by the local Medical Ethics Committee. All patients gave their informed consent. In all, 42 patients were recruited from a database at the Rehabilitation Centre Het Roessingh. All patients were implanted at the Neurosurgical Department of Hospital Medical Spectrum Twente (Enschede, The Netherlands) between 1987 and 2000. Most of our patients have been included in the study of the Dutch Study Group on SARS published in 1997, and therefore the selection criteria for implantation were equal with those mentioned in other publications.[3] Four patients had died of unrelated causes. One patient did not respond on our request. The patient characteristics are described in Table 1.

A questionnaire was constructed to determine the complications, technical failures and personal experiences of the patients with the bladder controller. The items addressed were related to expectations, advantages and disadvantages, recommendation to future patients and willingness to undergo the implant procedure again with their present knowledge. Patients' medical records were used to complete the data.

A bladder disease-specific questionnaire, that is, the Qualiveen questionnaire of Coloplast (Laboratoires Coloplast, Cedex, France), was used. We used the official Dutch version which was cross-translated by Coloplast. This questionnaire is composed of two parts. The first part measures the specific impact of urinary problems (SIUP) in four scales, that is, limitations (eg are you bothered by urine leaks during the day?), constraints (eg can you go out without planning in

Table 1 Characteristics of the population

Gender	32 male and five female
Age at questionnaires (years)	43 (23–63)[a]
Time postinjury (months)	73 (46–498)[a]
Time between injury and implantation (months)	87 (11–471)[a]
Follow-up (months)	86 (16–159)[a]
Level of injury	14 tetraplegic 23 paraplegic
Actual use	89%

[a]Means (range)

advance?), fears (eg do you worry about smelling of urine?) and feelings (eg do you feel embarrassed because of your bladder problems?). The scores of the four scales range between 0 and 4 (not at all, slightly, moderately, quite a bit or extremely) meaning urinary disorders do have low (0) or high (4) impact. The mean of these four scales is calculated and results in the mean SIUP.

The second part of the questionnaire measures the QoL of SCI patients using nine questions starting with the statement 'You feel things are going…'. In order to obtain a disease-specific questionnaire, questions on standing and walking are no elements of the questionnaire. The answers range from very badly to very well (−2 to +2). The mean score is calculated resulting in the QoL index; low scores indicate poor QoL and high scores indicate better QoL.

To compare our results as best as possible, we compared our scores with the scores of a group of 400 French SCI patients with neurogenic bladder problems reported in the manual of the Qualiveen questionnaire. None of these patients use SARS. We tried to obtain the crude data of this group to be able to match our patients with these reference data. However, after several requests we did not receive a respond and decided to use the data from the manual.[18]

Statistical analysis

A nonparametric test, the Mann–Whitney *U*-test, was used to analyse the differences of the median scores of the SIUP in the four scales, the overall index and the QoL index between the study group and the reference group.

Results

The. characteristics of 37 patients are presented in Table 1. The mean age was 43 years. The mean follow-up was 7 years with a range from 1 to 13 years. Table 2 describes the different methods of bladder management the patients used before the implant of the bladder controller; most patients used percussion and about one-third intermittent self-catheterisation.

Of the 37 patients, 32 (87%) still use the bladder controller for urinary control with a mean micturition frequency of four times a day. In all, 22 (60%) patients present a clear benefit in the evacuation of stools. Of the 32 male patients, 20 (65%) were able to achieve a stimulation-driven erection, but none of them have used it for coitus. The erection is considered particularly useful when attaching a condom for urine drainage.

Complete urinary continence was achieved in 57% of the patients during the day and 70% at night. An overall improvement in urinary continence was found in 73%, while some patients (16%) only experienced mild stress incontinence.

Figure 1 shows the incidence of urinary tract infections requiring treatment with antibiotics before implantation and after long-term use. The results show that the infection rate decreased dramatically with the use of the bladder stimulator. About 87% of the patients experienced a reduction in urinary tract infections with SARS. In 16 (41%) patients, urinary tract infections were not seen again after implantation.

Table 2 Bladder management before the implant of the bladder controller ($n=36$)

	%
Percussion	67
Intermittent self-catheterisation	31
Intermittent catheterisation by others	8
Indwelling catheter	8
Other	3

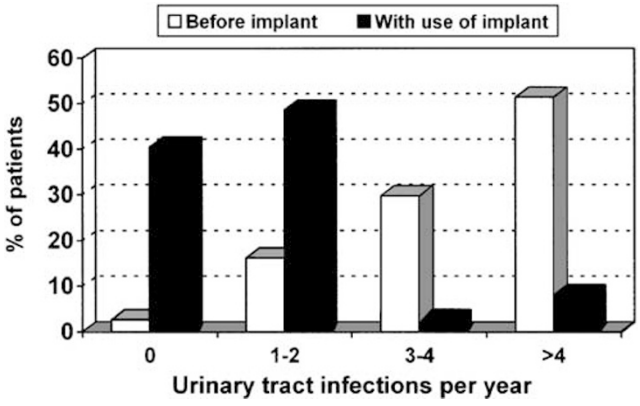

Figure 1 Urinary tract infection rates prior to implantation and after long-term use of the bladder controller

Table 3 Expectations before implantation ($n=37$)

	%
Decrease of urinary tract infections	84
Continence	76
Less time for defecation	35
Independence	32
Erection	27
Less time for micturition	19
Other	11

Patients' experiences and expectations

Before implantation, the majority of the patients expected to achieve complete continence and expected a decrease in urinary tract infections.. Table 3 presents the patients expectations about the bladder controller before implantation. With respect to micturition these expectations were met in 62% and partially met in 32%, and for defaecation in 38% (partial in 30%). The male patients' expectations about the possibility to have stimulated erections were met in 47%.

Table 4 Experienced advantages and disadvantages ($n=37$)

Advantages	*%*	*Disadvantages*	*%*
Decreased infection rate	68	Other	32
Improved social life	54	None	30
Continence	54	Loss of erection	19
Less incontinence devices	41	Difficulties in using the device	11
Improved bowel function	35	Depending on others	11
Other	19	Deteriorated bowel function	11
Improved erection	19	Complications	5

Table 4 presents the experiences with respect to advantages and disadvantages of the bladder controller. The main advantages mentioned are a decrease in urinary tract infections, an improvement in social life and achieved continence. About one-third did not experience disadvantages because of the implant, another third mentioned several different disadvantages like loss of ejaculation (two), a dependency on a technical device (two) and appearance of spasm while stimulating (one).

In 92%, the implanted bladder controller has had positive influence on several aspects in life. Almost 90% of patients would chose again for surgery and nearly the same amount would recommend the bladder controller to other patients with neurogenic bladder dysfunction.

Complications and technical failures

In three patients the bladder controller never functioned, in two of these patients because of fibrosis around the sacral roots and in one patient probably by S3 and S4 root failure. However, the latter patient did reach complete continence because of deafferentation.

Postoperative leakage of cerebro-spinal fluid (CSF) and neuropraxia both occurred once. Detrusor weakness occurred in four patients (11%). All problems occurred immediately after surgery and recovered completely within several weeks postoperative. During the use of SARS two patients experienced outflow problems, which were treated using medication and a change in the controller parameters. Two patients suffered from detrusor weakness caused by distension of the bladder. In one patient progressive sphincter weakness causes increased incontinence and in one patient a strong motor response on stimulation was reported. Technical failures with the external equipment were cable breaks (16) and transmitter defects (seven), that is, once per 17 and 38 user-years, respectively. Technical failures with the internal equipment occurred four times (11%), that is, once per 66 user-years. The defects occurred after 43–120 months of controller use. In three of the four cases, the receivers were replaced successfully.

Table 5 Median scores of SIUP on QoL in four scales, overall index and QoL index comparing patients groups with and without using a bladder controller

	Study group		*Reference group*
	Medians	*10–90th percentiles*	*Medians*
Limitations	0.62	0.00–1.99	1.28
Constraints	1.38	0.42–2.73	1.75
Fears	0.63	0.00–2.00	1.60
Feelings	0.80	0.40–1.76	0.91
SIUP index	0.84	0.31–2.00	1.49
QoL index	0.89	−0.50–1.63	0.23

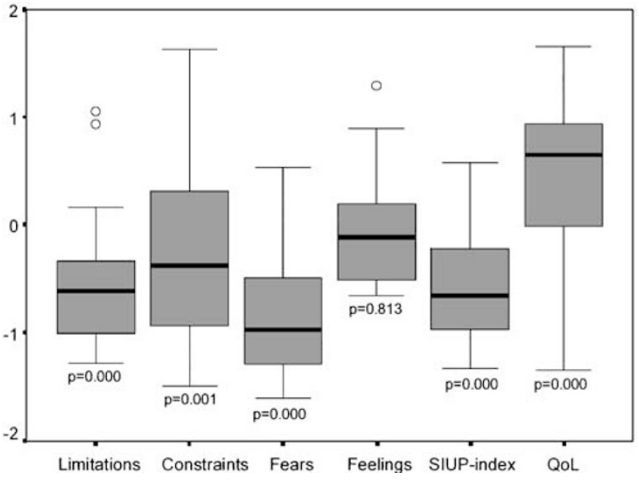

Figure 2 Box plots of differences in median scores comparing patients groups with and without using a bladder controller (specific impact of urinary problems (SIUP) subscales, overall SIUP index and quality of life (QoL) index)

Quality of life

In Table 5, the median scores with 10–90th percentiles of the SIUP for each scale, the SIUP- and QoL index are presented. The median SIUP index in the study group is 0.84 and in the reference group 1.49 indicating that the SIUP on the QoL is smaller with the Finetech–Brindley bladder controller. The median QoL indices for the study group and the reference group are respectively 0.89 and 0.23, indicating that the overall QoL is rated higher in the study group.

In Figure 2, the boxplots of the differences of these median scores between the study group (all patients still using the bladder controller (32)) and reference group are presented. As shown, the differences between the two groups are significant, except for the scale feelings.

Discussion

The objectives of this study were to investigate the long-term effectiveness of the implanted bladder controller in SCI patients and in particular the users' experiences and the impact of urinary disorders and QoL.

Our long-term results with the bladder controller with respect to medical and technical complications and infection rates are similar to the short-term results presented by others.[2,4,6–8] The achieved complete urinary continence, however, was less than in other groups. If stress incontinence is included in this definition, our results are similar to other groups.

The novelty of this study is that together with the medical benefits the users' personal experiences and QoL have been investigated. The main benefits of SARS experienced by the patients were a decreased infection rate, improved social life and continence.

The first experiences with the Qualiveen questionnaire are promising; however, some remarks have to be made. The questionnaire is easy to complete, none of the patients did mention any difficulty by completing the questionnaire. While we described retrospective data responsiveness of the questionnaire remains ambiguous.

The results of the Qualiveen questionnaire indicated that with the bladder controller, the specific impact of urinary disorders on QoL aspects were reduced, and the overall QoL improved. The reference group and our study group are equal with respect to gender, age, time since lesion and social situation. The major difference between the two groups is determined by the different methods used for micturition. The patients in the reference group used self-catheterisation (41%) or percussion (28%), the bladder controller was not used. Another difference between the two groups is that in our group all patients have complete lesions, whereas in the reference group about half of the patients had a complete lesion. This difference could have influenced the results. Assuming that patients with a complete SCI in general have a more severe neurogenic bladder dysfunction, the difference between groups may have been even more striking when the reference group was composed of complete SCI patients only. Unfortunately, we were not able to match our patients with the reference group by lacking crude data of these reference group of 400 French SCI patients. However, we did analyse the differences between the median scores on the Qualiveen items, and they were significant, except for the subscale feelings.

The Qualiveen questionnaire was developed to measure disease-specific aspects with respect to limitations, constraints, fears and feelings and general QoL aspects, suitable for use in SCI patients with urinary disorders. It is questionable whether this questionnaire considers all aspects of QoL as defined by the World Health Organization: 'QoL is a broad-ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their environment'.[19] Nevertheless most existing questionnaires about QoL, as mentioned before, are generic and not responsive to detect changes in QoL in SCI patients. In addition, the impact on QoL of urinary disorders in these patients remains unknown. Therefore, the Qualiveen questionnaire could be supportive in studies investigating effects of treatment of urological disorders in SCI patients, but further research on responsiveness is recommended.

Conclusions

Our results confirm that the bladder controller for SARS is an adequate technique for bladder management in patients with a complete SCI over long-term use. It decreases incontinence and infections, and increases QoL. These findings support the idea that the bladder controller is the preferred method of neurogenic bladder management in a well selected group of SCI patients.

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