

A systematic review of clinical studies on electrical stimulation therapy for patients with neurogenic bowel dysfunction after spinal cord injury

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Abstract

Background: This study aimed to perform a systematic literature review of the clinical trial evidence on electrical stimulation for the treatment of neurogenic bowel dysfunction (NBD) after spinal cord injury (SCI).

Methods: Systematic electronic searches were carried out in the PubMed/Medline, EMBASE, Cochrane Central Register of Controlled Trials, and China National Knowledge Infrastructure databases, along with the reference lists in the include studies. Studies were eligible for inclusion if they adopted a controlled clinical design based on human population, the patients suffered from spinal cord injury, the main outcomes were the disorders of bowel function and the intervention was electrical stimulation. Also, the language was limited to English and Chinese.

Results: Eleven studies were included in this systematic review, comprising transcutaneous electrical stimulation, transrectal bowel stimulation, sacral nerve stimulation, intravesical electrical stimulation, etc. Of the 11 studies, 3 were randomized controlled trials, 8 were controlled before-and-after trials. The quality of the included studies was moderate bias risk. Most studies revealed that the electrical stimulation was beneficial for the patient with NBD after SCI.

Conclusions: Only 11 small clinical studies with 298 participants have evaluated the efficacy of electrical stimulation for NBD after SCI. Although some studies showed electrical stimulation was benefit for the patient with NBD after SCI, there was currently not enough evidence to support the use of electrical stimulation could improve the clinical symptoms of those patients. Thus, well-designed randomized controlled trials with larger patient population are warranted to establish its benefit in clinical practice in the future.

Abbreviations: CNKI = China National Knowledge Infrastructure, CSA = cross-sectional area, EPOC = Cochrane Effective Practice and Organisation of Care, NBD = neurogenic bowel dysfunction, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analysis, SCI = spinal cord injury.

Keywords: electrical stimulation, neurogenic bowel dysfunction, spinal cord injury

1. Introduction

Neurogenic bowel dysfunction (NBD) is a disease involving the loss or absence of normal bowel function due to nerve injury,

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neurological disease, or congenital defects of the nervous system.^[1,2] Fecal incontinence, difficulty with evacuation, constipation, abdominal pain, and bloating are the common clinically symptoms of NBD.^[3] Among the common causes of NBD, spinal cord injury (SCI) has been given more attention by clinical doctors. According to some reports, approximately 80% of SCI was accompanied by NBD.^[3,4] It has been revealed that people with NBD often suffer from decreased quality of life, such as loss of independence, feeling of embarrassment, mental disorder, social isolation, etc., especially in SCI patients.^[5,6]

The conservative treatments for NBD after SCI include oral laxatives, suppositories, and digital anorectal stimulation. With the increase of the research on NBD, new treatments have been found by clinicians, for example, colostomies, malone antero-grade continence enema procedure, artificial bowel sphincters, and graciloplasties.^[7] The mechanisms of those treatments are mainly through promoting intestinal fecal evacuation and strengthening the power of the anal sphincter to improve the function of bowel. Despite trying several measures, there were still numerous patients that either did not gain an acceptable level of therapeutic benefit or remained completely refractory to treatment.

Treatment was not frequently satisfactory; accordingly, other therapies should be explored. Recently, some studies have reported the use of electrical stimulation for the safe treatment of patients with NBD after SCI.^[8–10] For instance, Worsoe et al^[11]

performed a stimulation, applied with plaster electrodes using an amplitude of twice the genito-anal reflex threshold (width: 200 μ s; rate: 20 Hz), on patients with complete supraconal SCI, and found that the dorsal genital nerve stimulation led to an acute decrease of the rectal cross sectional area (CSA) and the rectal pressure CSA relation. Han et al^[12] reported that the use of intravesical electrical stimulation therapy was effective in children aged 3.9 to 13.2 years old with NBD and spina bifida. However, few studies have been conducted on the assessment of the efficacy of randomized controlled trials of electrical stimulation in the patients with NBD after SCI. Besides, the type of SCI, different intervention, variable pathophysiology of NBD could also influence the interventional safety and efficacy of electrical stimulation.

Based on these uncertainties, the current systematic review was primarily aimed to rigorously examine the clinical evidence on the efficacy of electrical stimulation in the treatment of NBD after SCI.

2. Materials and methods

This review, which systematically evaluated the safety and efficacy of electrical stimulation therapy for patients with NBD after SCI, was designed using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist. We conducted a comprehensive literature search in PubMed/Medline (1966 to Nov 2017), EMBASE (1966 to Nov 2017), the Cochrane Central Register of Controlled Trials (CENTRAL) (1999 to Nov 2017), and China National Knowledge Infrastructure (1990 to Nov 2017). The search core terms included the following: *neurogenic bowel dysfunction OR constipation OR fecal incontinence OR abdominal pain OR bloating OR colon transit time, spinal cord injury OR spinal cord trauma OR spinal cord laceration OR SCI, electrical stimulation OR electrotherapy*. Additionally, we also searched the reference lists of the identified articles to determine the relevant studies. The complete search strategies were list in Supplemental Table 1, <http://links.lww.com/MD/C548>.

In this review, all the selected studies were required to meet the following inclusion criteria: the study adopted a controlled clinical design based on human population; the subjects suffered from spinal cord injury, spina bifida, myelomeningocele, intervertebral disc, or foraminal stenosis; the intervention was electrical stimulation; the article reported the diagnostic criteria of NBD, especially described the information of colorectal and anal sphincter dysfunction; the outcomes included the colonic transit time, the stool consistency, stool frequency, anal-rectal pressure measurement, subjective satisfaction, score of neurogenic bowel function, and so on; the language was limited to English and Chinese. If a study did not meet the above-mentioned criteria, it was excluded.

The potential studies were independently selected by 2 reviewers according to the predetermined inclusion and exclusion criteria. In the process of retrieval, if divergences of opinion on the articles arose, a third reviewer evaluated the eligibility of the article in question.

In this review, a standardized form of risk of bias, which was adapted from the Cochrane Effective Practice and Organisation of Care (EPOC) Group, was used to identify the study quality.^[13] The instrument recorded 9 criteria, including “was the allocation sequence adequately generated?,” “was the allocation adequately concealed?,” “were baseline outcome measurements similar?,” “were baseline characteristics similar?,” “were incomplete

outcome data adequately addressed?,” “was knowledge of the allocated interventions adequately prevented during the study?,” “was the study adequately protected against contamination?,” “was the study free from selective outcome reporting?,” and “was the study free from other risks of bias?.” If an index was assessed “low risk,” it could have 1 score. If a study scored <4, it was considered of low quality; if a study scored 4 to 6, it was considered of moderate quality; and if a study scored >6, it was considered of high quality.

In this systematic review, ethical approval was not necessary as all the data were based on the previous published studies.

3. Results

3.1. Search results

In this systematic review, the search strategy initially identified 641 publications. For various reasons, 630 of these 641 articles were excluded. Accordingly, this process resulted in 11 articles being identified as meeting the rigid inclusion criteria. All the included studies were published between 1997 and 2015. Among the 11 articles, 3^[9,14,15] were randomized controlled trials and 8^[8,11,12,16–20] were self-controlled trials. One article^[15] was published in Chinese. The screening process is summarized in Fig. 1.

3.2. Quality assessment of included studies

In this systematic review, the checklist of risk bias with EPOC (see Table 1) indicated that 1 study achieved 3 score, 4 studies achieved 4 scores, 4 studies achieved 5 scores, 2 studies achieved 6 scores. Overall, the quality of the included studies was moderate bias risk.

3.3. Characteristics of subjects in the included studies

The subjects of 5 studies^[8,9,12,14,17] were children (see Table 2). Most of the included studies^[8,9,11,12,16,18–20] had a small sample size with <50 cases except for 3 studies.^[14,15,17] The types of SCI were mainly focused on spinal bifida, myelomeningocele, and complete suprasacral SCI, but most of the studies did not provide the severity of the SCI.

3.4. Interventional information on electrical stimulation

The basic interventional informations of electrical stimulation for patients with NBD after SCI were shown in Table 3. The types of electrical stimulation referred to transcutaneous electrical stimulation,^[9,14,16] transrectal bowel stimulation,^[17] intravesical electrical stimulation,^[12] sacral nerve stimulation,^[19,20] dorsal genital nerve electrical stimulation,^[11] percutaneous tibial nerve stimulation,^[15] threshold night-time electrical stimulation,^[8] implantable neuroprosthesis for stimulating the sacral nerves and posterior.^[18] With the different types of electrical stimulation used, the length of one session, course of intervention, frequency of the intervention, electrode area, frequency of electrode, and pulse width were variously different.

3.5. Main outcomes of the included studies

Despite disadvantages in 1 single study, on the whole, the main outcomes of electrical stimulation were safe and effective for the patients with NBD after SCI (see Table 4). However, due to the limitations regarding the sample size, study design, duration of

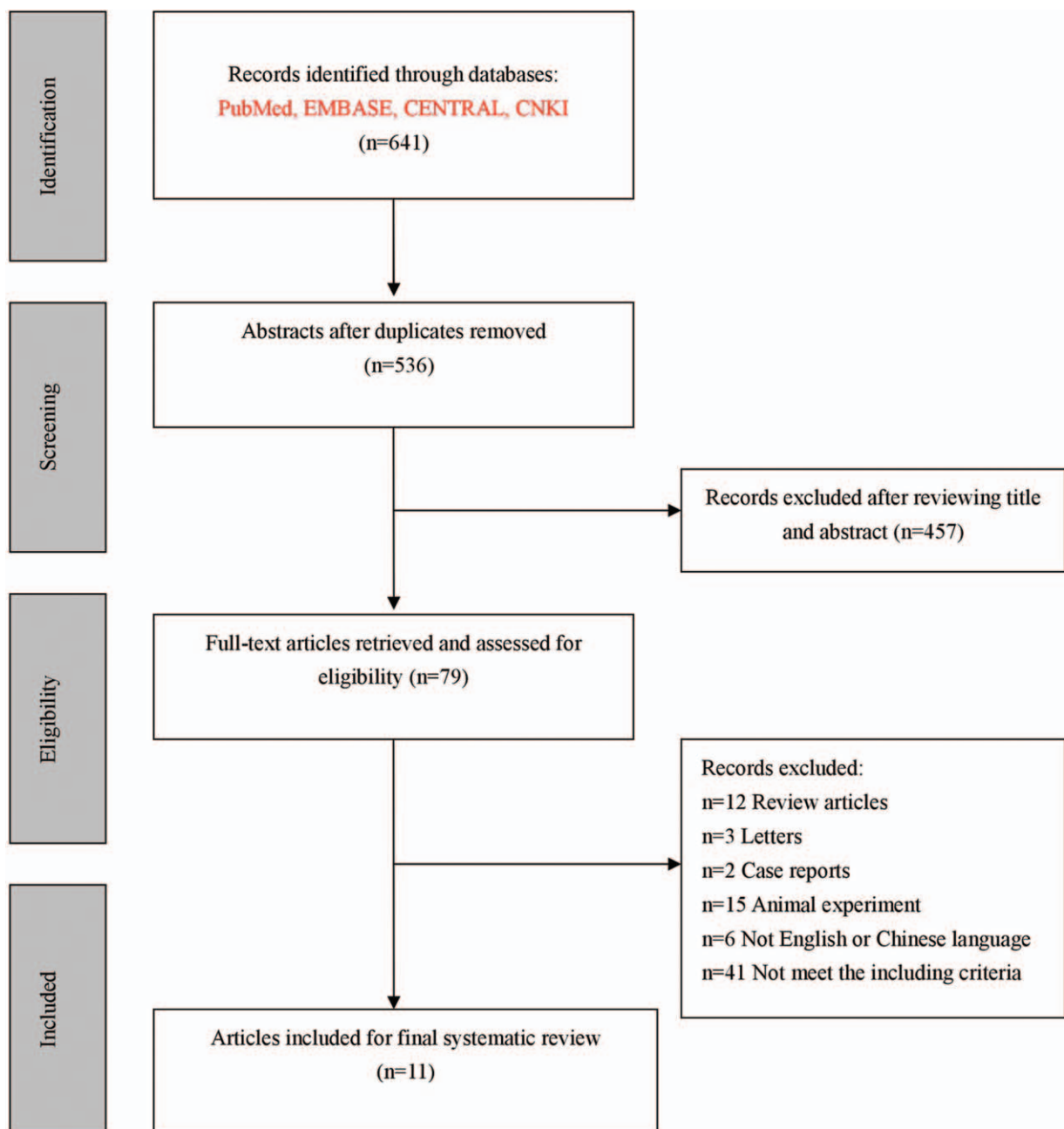


Figure 1. Flow diagram of the screening process.

intervention, etc., some studies suggested the authenticity and reliability of the electrical stimulation for NBD after SCI should be further verified in the future.

4. Discussion

To the best of our knowledge, this systematic literature review is the first paper to evaluate the efficacy and safety of electrical stimulation therapy in the current clinical use for NBD after SCI. This review includes 11 articles represented on the most comprehensive systematic analysis of electrical stimulation therapy for this indication to date. In this study, we found that there were several methods of electrical stimulation for the treatment of NBD after SCI, and they mainly involved the transcutaneous electrical

stimulation, transrectal bowel stimulation, intravesical electrical stimulation, sacral nerve stimulation, dorsal genital nerve electrical stimulation, percutaneous tibial nerve stimulation, etc. The main mechanism of the electrical stimulation therapy was the promotion of the healthy function of the intestinal function through improving blood flow, promoting protein synthesis, reinforcing muscular strength, and regulating nerve transmission.

In this review, 3 studies revealed the efficacy and safety of transcutaneous electrical stimulation for NBD after SCI. Transcutaneous electrical stimulation could stimulate sympathetic and parasympathetic nerve fibers in the bowel system and reduce the pressure of the internal and external sphincter in the anus. The outcomes of this treatment included a reduction of the difficulty of defecation and an increase of the frequency of

Table 1**Quality assessment of included studies.**

ID	Study	Year	Bias 1	Bias 2	Bias 3	Bias 4	Bias 5	Bias 6	Bias 7	Bias 8	Bias 9	Score
1	Marshall D	1997	H	H	L	L	L	H	U	L	L	5
2	Balcom A	1997	U	U	L	L	H	H	H	L	L	4
3	Palmer L	1997	H	H	L	U	H	H	U	L	L	3
4	Creasey G	2001	H	H	L	L	H	H	U	L	L	4
5	Han S	2004	H	H	L	L	L	H	U	L	L	5
6	Jarrett M	2005	H	H	L	L	H	H	U	L	L	4
7	Walker J	2011	H	H	L	L	H	H	U	L	L	4
8	Lansen-Koch S	2011	H	H	L	L	L	H	U	L	L	5
9	Kajbafzadeh A	2012	L	U	L	U	L	H	L	L	L	6
10	Worsoe J	2012	H	H	L	L	L	H	U	L	L	5
11	Yue Y	2015	L	U	L	L	U	H	L	L	L	6

H=high risk, L=low risk, U=unclear risk; Bias 1, "was the allocation sequence adequately generated?"; Bias 2, "was the allocation adequately concealed?"; Bias 3, "were baseline outcome measurements similar?"; Bias 4, "were baseline characteristics similar?"; Bias 5, "were incomplete outcome data adequately addressed?"; Bias 6, "was knowledge of the allocated interventions adequately prevented during the study?"; Bias 7, "was the study adequately protected against contamination?"; Bias 8, "was the study free from selective outcome reporting?"; Bias 9, "was the study free from other risks of bias?".

defecation in SCI patients with NBD. These studies demonstrated that transcutaneous electrical stimulation therapy was safe, non-invasive, and painless for the patient with mild or moderate constipation. The results of the 3 studies were in line with other studies despite including different population.^[21–24]

Regarding the transrectal bowel electrical stimulation, there were few study about their efficacy among patients with SCI. Palmer et al^[17] carried out a self-control study with 55 children aged 2 to 14 to assess the efficacy of transrectal bowel stimulation for NBD. They found that 68% of the patients had significantly improved bowel function. This therapy could improve the ability to control the intestinal tract, enhance the sense of the need to defecate, and reduce intestinal peristalsis, so as to reduce the rate of fecal incontinence. In addition, it was suitable for patient with myelomeningocele and NBD with several advantages, such as being well tolerated, minimal invasion, and no adverse reaction. However, we could not find the results of the application in the adults.

Intravesical electrical stimulation was frequently used to improve the bladder function not only in the humans trials^[25–27] but also in animal experiment.^[28,29] The goal of this treatment could be achieved by decreasing intravesical pressure and increasing urinary bladder capacity, or by facilitating bladder emptying.^[30] Similarly, intravesical electrical stimulation could also be used to treat the

patients with NBD after SCI. Han et al^[12] carried out a self-controlled study in 24 children with spina bifida to evaluate the efficacy of this therapy. After the intervention, the number of overall fecal incontinence episodes decreased significantly. Because of the advantages of the simple operation and excellent performance, he appraised that intravesical electrical stimulation was a viable option to control fecal incontinence in children with NBD and spina bifida.

In 1995, sacral nerve stimulation was introduced for idiopathic fecal incontinence, and then subsequently its indications had spread to include fecal incontinence of other etiologies.^[31] For sacral nerve stimulation, the electrode was often placed through a sacral foramen between S2 and S4. Among the studies in this review, Jarrett et al^[19] carried out a clinical study with 13 patients who had suffered from partial spinal injury to assess the efficacy of sacral nerve stimulation for fecal incontinence. He evaluated several indexes, such as the number of episodes of fecal incontinence per week, the number of days per week with staining or pad use, the ability to empty the bowel completely, and found that sacral nerve stimulation could benefit those patients. Javidan et al^[32] also reported the beneficial effect of sacral nerve stimulation on bowel and bladder function in patients with SCI. To date, the mechanism of sacral nerve stimulation remained ambiguous. Most clinical data tended to

Table 2**Characteristics of the subjects in the included studies.**

ID	First Author	Year	Country	Study design	Patients	Age	Number of subjects	Male/Female
1	Marshall D	1997	UK	RCT	Spinal bifida-interim	9.1 ± 3.4	50	29/21
2	Balcom A	1997	USA	SCT	Lumbar or sacral myelomeningocele	NA	11	9/2
3	Palmer L	1997	USA	SCT	Myelomeningocele	6.7 (2–14)	55	28/27
4	Creasey G	2001	USA	SCT	Complete suprasacral SCI	14–67	23	16/7
5	Han S	2004	Korea	SCT	Spina bifida	8.1 (3.9–13.2)	24	9/15
6	Jarrett M	2005	UK	SCT	Previous partial spinal injury	58.5 (39–73)	13	4/9
7	Walker J	2011	USA	SCT	Myelomeningocele	7 (4–12)	15	8/7
8	Lansen-Koch S	2011	Netherlands	SCT	Spina bifida	11.1–41	10	6/4
9	Kajbafzadeh A	2012	Iran	RCT	Myelomeningocele	6.7 ± 2.9	30	13/17
10	Worsoe J	2012	Denmark	SCT	complete suprasacral SCI	39–67	7	6/1
11	Yue Y	2015	China	RCT	SCI	Interventional group: 40.52 ± 4.51; control group: 39.44 ± 4.34	60	31/29

NA=not applicable, RCT=randomized controlled trial, SCI=spinal cord injury, SCT=self-controlled trial.

Table 3**Interventional information on the electrical stimulation.**

ID	First author	Year	Patients	Intervention	Length of one session	Course of intervention	Frequency of intervention	Electrode area	Frequency of electrode (Hz)	Pulse width
1	Marshall D	1997	Spinal bifida-interim	Cutaneous electrical field stimulation; 26 patients received electrostimulation, 24 patients received placebo units	1 hour	6 wks	Once per day	$1.2 \times 2 \text{ cm}^2$	10	200 ms
2	Balcom A	1997	Lumbar or sacral myelomeningocele	Long duration, low intensity transcutaneous therapeutic electrical stimulation	10.5 h	9 mo	Six times per week	NA	5–55 pulses per second	280 ms
3	Palmer L	1997	Myelomeningocele	Transrectal bowel stimulation	Half hour	2–3 wks	Five times per week	NA	15–20	NA
4	Creasey G	2001	Complete suprasacral SCI	Implantation of an externally controlled neuroprosthesis of stimulating the sacral nerves and posterior sacral rhizotomy	AR	1 y	AR	NA	NA	NA
5	Han S	2004	Spina bifida	Intravesical electrical stimulation	1 h	4 wks	Five times per week	NA	22	0.2 ms
6	Jarrett M	2005	Previous partial spinal injury	Sacral nerve stimulation	AR	1 y	AR	NA	15	210 μs
7	Walker J	2011	Myelomeningocele	Threshold nighttime electrical stimulation	NA	9 mo	AR	NA	35	280 ms
8	Lansen-Koch S	2011	Spina bifida	Sacral nerve modulation	AR	3 wks	AR	NA	NA	NA
9	Kajbafzadeh A	2012	Myelomeningocele	Transcutaneous interferential electrical stimulation	20 min	5 wks	Three times per week	$2.5 \times 3.5 \text{ cm}^2$	5–25	250 μs
10	Worsoe J	2012	Complete suprasacral SCI	Dorsal genital nerve electrical stimulation	96 min	AR	AR	$10 \times 20 \text{ mm}^2$	20	200 μs
11	Yue Y	2015	SCI	Percutaneous tibial nerve stimulation; 30 patients in the intervention group were treated with conventional therapy combined with percutaneous tibial nerve stimulation, 30 patients in the control group were treated with conventional therapy with placebo therapy.	Half hour	4 wks	6 times per week	NA	20	200 μs

AR=autonomic regulation, NA=not applicable, SCI=spinal cord injury.

show enhancement in striated muscular activity and neuro-modulation of sacral reflexes.^[33] However, sacral nerve stimulation, overall, was a relatively safe and effective technique for the patients with NBD and SCI despite the minimally invasive procedure.

The difference of causes and levels of SCI could also influence the effect of electrical stimulation for the NBD patients. For instance, Kim et al^[34] had classified 33 SCI patients into 2 groups according to the level of cord injury: above T9 and T9 to L2. After 4 weeks of electrical stimulation treatment, this study found that the electrical stimulation to the sacral dermatomes could significantly increase the mean squeezing pressure of rectoanal manometry on the T9 to L2 SCI patients than the group of level above T9.

In this review, although several studies achieved a positive result about the safety and efficacy of the electrical stimulation procedure for those patients with NBD after SCI, the study inevitably still had several flaws. For instance, approximately 70% of the studies were designed as a self-controlled study, which resulted in an unclear data to assess the influence of the spontaneous recovery or the electrical stimulation during the process of rehabilitation. Moreover, randomized group division and blinding method were not designed in those studies. Even the length of the treatment course, sample size, withdrawal of the subjects from the study, the severity of the SCI, etc. could also affect the accuracy of the results. Therefore, in order to accomplish an accurate assessment of the efficacy of electrical

Table 4**Main outcomes of the included studies.**

ID	First author	Year	Patients	Main outcomes	Adverse effects	Loss to follow-up	Limitation	Advantage
1	Marshall D	1997	Spinal bifida-interim	Compared with the placebo group, the active group had a 32% decrease in night-time urinary incontinence. However, no significant increases were found in the maximum or average bladder content and episodes of spontaneous normal defecation.	No	No	Heterogeneous of children were exit in the aspects of ages, degrees of bladder and bowel dysfunction, precentry treatment schedules, motivation and parental support.	Noninvasive, safe
2	Balcom A	1997	Lumbar or sacral myelomeningocele	This therapy could increase significantly bladder capacity, however, it could not change urethral pressure profile.	No	Yes	The duration of this therapy was long.	It was safe, benefit, good compliance, and ease of use.
3	Palmer L	1997	Myelomeningocele	89% of subjects had elimination of stooling accidents; 82% had increased sensation; 71% were capable of holding the bowel movement.	No	Yes	This study was not blinded, and not randomized.	It was well tolerated and minimally invasive.
4	Creasey G	2001	Complete suprasacral SCI	Of the 21 patients, 21 urinated more than 200 mL with the neuroprosthesis, 15 had postvoid volumes <50 mL. This study also found that urinarytract infection, catheter use, reflex incontinence anticholinergic drug use, and autonomic dysreflexia were substantially reduced.	Yes	Yes	The number of subjects was small.	The method was safe and effective.
5	Han S	2004	Spina bifida	The mean number of overall fecal incontinence episodes decreased significantly. However, no significant change was found in the number of daily bowel movements.	Yes	No	The major drawback of this therapy was the long duration. In addition, the effect was primarily limited to improvement in fecal incontinence.	The method was less invasive nature and benefit of freedom.
6	Jarrett M	2005	Previous partial spinal injury	The mean number of episodes of incontinence significantly decreased, as well as the number of days per week with incontinence and staining. The ability to defer defaecation significantly improved.	Yes	Yes	The number of subjects was small.	It was an effective minimally invasive surgical approach.
7	Walker J	2011	Myelomeningocele	This study found small gains in muscle strength, gait, and bowel continence, but no changes in physical function among children with myelomeningocele.	No	Yes	The number of subjects was small. The duration of this treatment was long.	No adverse effects were noted.
8	Lansen-Koch S	2011	Spina bifida	The median faecal incontinence days and episodes per 21 days decreased significantly. 30% patients had a more than 50% improvement and proceeded to a permanent sacral nerve modulation implantation. Overall, the preliminary results of this therapy look promising.	No	No	The number of subjects was small.	The method might be an alternative minimally invasive technique to treat defaecation and micturition disorder. In addition, peripheral nerve evaluation was performed before proceeding to definitive sacral nerve modulation implantation.
9	Kajbafzadeh A	2012	Myelomeningocele	To improve constipation symptoms and anorectal manometry parameters among children with myelomeningocele, it was safe, noninvasive, and effective modality.	No	No	The sample size of this study was small, and the duration of follow-up was short.	It was safe, noninvasive, painless, relatively inexpensive, could be used at home, without any waiting list for the procedure.
10	Worsoe J	2012	Complete suprasacral SCI	Dorsal genital nerve stimulation could significantly decrease rectal cross sectional area and the rectal pressure-cross sectional area.	No	No	-	It was well tolerated.
11	Yue Y	2015	SCI	This therapy could effectively improve the bowel function of patients with constipation after SCI.	No	No	The number of subjects was small. The duration of intervention was short.	This therapy had less adverse events and good safety.

SCI=spinal cord injury.

stimulation for NBD after SCI, it is necessary to perform a study in the future with larger sample size and well-designed randomized control trial.

Author contributions

Yuling Deng and Yonghai Dong designed the study, Yun Liu, Qiong Zhang, and Xihong Guan wrote the manuscript. Xiaodan Chen performed the methodology. Meng Li, Lei Xu, and Cheng Yang discussed the results.

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Formal analysis: Cheng Yang.

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Writing – original draft: Yonghai Dong, Yun Liu, Qiong Zhang.

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