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ORIGINAL REPORT

EFFICACY OF FUNCTIONAL MAGNETIC STIMULATION IN NEUROGENIC BOWEL DYSFUNCTION AFTER SPINAL CORD INJURY

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Objective: **The aims of this study were to assess the usefulness of functional magnetic stimulation in controlling neurogenic bowel dysfunction in spinal cord injured patients with supraconal and conal/caudal lesions, and to investigate the efficacy of this regimen with a 3-month follow-up.**

Design: **A longitudinal, prospective before-after trial.**

Subjects: **A total of 22 patients with chronic spinal cord injured and intractable neurogenic bowel dysfunction. They were divided into group 1 (supraconal lesion) and group 2 (conal/caudal lesion).**

Methods: **The colonic transit time assessment and Knowles-Eccersley-Scott Symptom Questionnaire were carried out for each patient before they received a 3-week functional magnetic stimulation protocol and on the day following the treatment.**

Results and conclusion: **Following functional magnetic stimulation, the mean colonic transit time for all patients decreased from 62.6 to 50.4 h ($p<0.001$). The patients' Knowles-Eccersley-Scott Symptom scores decreased from 24.5 to 19.2 points ($p<0.001$). The colonic transit time decrement in both group 1 ($p=0.003$) and group 2 ($p=0.043$) showed significant differences, as did the Knowles-Eccersley-Scott Symptom score in both groups following stimulation and in the 3-month follow-up results ($p<0.01$). The improvements in bowel function indicate that functional magnetic stimulation, featuring broad-spectrum application, can be incorporated successfully into other therapies as an optimal adjuvant treatment for neurogenic bowel dysfunction resulting from spinal cord injury.**

Key words: constipation, functional magnetic stimulation, neurogenic bowel dysfunction, spinal cord injury.

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INTRODUCTION

Neurogenic bowel dysfunction (NBD) is recognized as a major physical difficulty, especially among patients with chronic spinal cord injury (SCI). NBD impairments include difficulty with evacuation, abdominal distension, faecal impaction and faecal incontinence. These symptoms are highly prevalent in patients with SCI, affecting 41–86% of patients (1, 2). Even when undergoing extensive medical treatment (1, 3–6), combined with digital stimulation or manual evacuation, most patients with SCI still experience refractory constipation. As many as 41% of patients spend more than 1 h every day on bowel care and patients with SCI have rated this problem as a moderate to severe life-limiting disability (4, 5). These observations imply that the current medical methods available to reduce the functional impact of NBD on daily life have only a limited effect.

Recent advances in rehabilitation and surgical interventions have offered patients alternative bowel care programmes. Electrical stimulation to the sacral roots or sacral dermatomes has had some success in bowel elimination, but also has considerable disadvantages (7–9). Implanting a neuroprosthesis requires surgery and has the risks of abolishing reflex erection and reflex ejaculation (after dorsal rhizotomy). In one study with a 12-month observation, 80% of patients who had undergone neuroprosthesis implantation were still relying on manual evacuation to remove remaining stool. Research on surface electrical stimulation of sacral dermatomes to facilitate the somatovisceral reflex has found that stimulation does not seem to result in actual bowel emptying, despite an increase in the number of colonic spike waves (10).

Functional magnetic stimulation (FMS), on the other hand, is capable of directing stimulation of the spinal nerves and contraction of deep muscles to facilitate bowl elimination without surgical procedures or unnecessary tissue damage. This technique has been developed to aid expiratory functions, micturition and bowel elimination in a non-invasive manner (11–15). In one study that assessed the effect of FMS on 6 patients with SCI, notable increases in rectal pressure and suppression of hyperactive rectal contractions were found to have taken place (16). In another study, 4 patients with SCI experienced improvement in their bowel routines after 3 weeks of FMS conditioning, with evidence of shortened colonic transit time (CTT) (17). However, it is still not known whether this repeated magnetic pulsation produces a cumulative effect

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on the nervous system. More research needs to be carried out with larger numbers of patients with SCI with NBD to verify whether FMS produces consistent results. Given both the potential of FMS for treating patients with SCI with NBD, and considering the ambivalence that still exists over how it affects the nervous system, the present study was firstly designed to recruit larger patient groups with a longer follow-up period.

SCI lesions are traditionally classified into supraconal or conal/caudal lesions, according to pathophysiological and clinical implications (18–21, 22). Apart from evidence suggesting that FMS can induce physiological changes in supraconal SCI, it has not been established whether it influences conal/caudal lesions as well. Nevertheless, these patients manifest a different type of NBD, which has so far yielded very disappointing treatment results, and is certainly worthy of further investigation.

We included both supraconal and conal/caudal patients with SCI in this study to test the effectiveness of FMS on each of these pathologies and to compare their responses to FMS treatment. We also included these patients in order to identify patient characteristics that predict a good response to treatment; and to assess the usefulness of this regimen in patients with SCI with a 3-month follow-up.

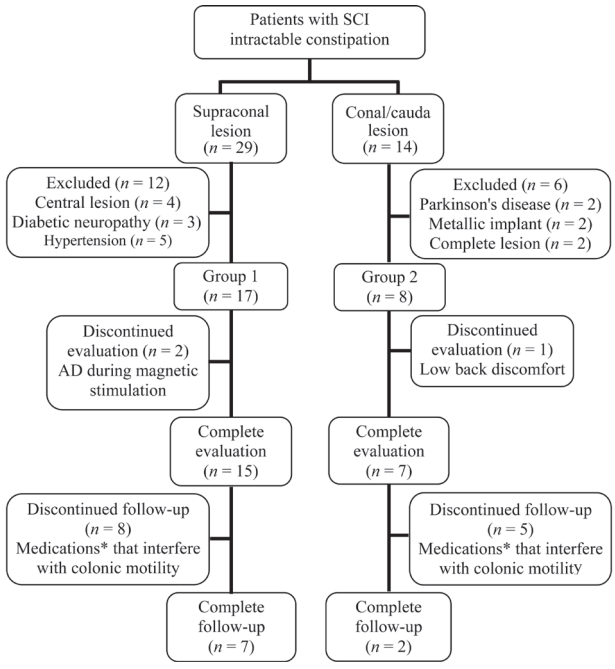

Fig. 1. Consort flow-chart diagram outlining the progress of participants. Patients who completed the evaluations were included in the statistical analyses. Those who continued the follow-up evaluations were included in the analyses for long-term effect. SCI: spinal cord injury; AD: autonomic dysreflexia; Medications* = anticholinergic agents, tricyclic antidepressants, anti-hyperlipidaemia agents, and compounds containing codeine, calcium and caffeine.

METHODS

Participants

Patients with traumatic SCI and intractable constipation were recruited prospectively to this study from the SCI centre of Taipei Veterans General Hospital between January 2005 and December 2006. Spinal cord or roots lesions had been confirmed in previous electrophysiological studies and magnetic resonance imaging surveys; and most of the patients had already undergone surgical decompression and neural repair. We followed the modified Rome criteria for the definition of constipation: "2 or fewer bowel movements a week, the use of laxatives or enema more than once a week or digital evacuation of faeces on all occasions" (1). None of the patients was satisfied with their existing bowel routine. During this time, 43 patients with SCI for over 6 months and fully recovering from spinal shock were eligible for inclusion.

Full physical and history examinations, including motor function, sensory function, and spinal sacral reflex testing, were carried out to determine the neurological condition of our patients. We used the American Spinal Injury Association (ASIA) Impairment Scale to assess the extent of each patient's injury.

Eighteen of the original 43 patients were eventually excluded from this study for the following reasons: patients with SCI with complete conal/caudal spinal cord lesions ($n=2$), since in previous testing patients with this condition have not responded with rectal pressure or pressure change following magnetic stimulation (17). The patients who were characterized by severe faecal incontinence will be investigated in further studies. Patients with diseases or conditions that are capable of complicating neurogenic bowel problems, such as Parkinson's disease ($n=2$), stroke sufferers ($n=3$), traumatic brain injury ($n=1$) or patients with a history of peripheral neuropathy such as diabetics or metabolic neuropathy patients ($n=3$), were excluded from the study. Also, in the exclusion criteria were patients with cardiac pacemakers or other metallic devices ($n=2$) that risk being damaged or displaced; as well as patients with a history of uncontrolled high blood pressure ($n=5$) or major abdominal surgery, which may cause adverse side-effects during treatment. (Fig. 1)

The impairment of colonic function was found to be associated with several neurological characteristics. These characteristics include patients' neurological levels (3), the patterns of their SCI and their degree of mobility (23). Patients with a higher neurological SCI level, who suffer from complete lesions and are non-ambulatory, tend to be more dependent on assistance with bowel hygiene (23). Using these tendencies as a guide, we divided our patients into the following groups: (*i*) group 1: patients with supraconal lesions; and group 2: patients with incomplete conal/caudal lesions; (*ii*) group A: patients with complete spinal cord lesions; and group NA: patients with incomplete spinal cord lesions; (*iii*) group S: patients who were capable of standing; and group NS: patients who were incapable of standing. Grouping patients according to these characteristics was a key step in isolating the factors that enable patients with SCI to respond to FMS, both in this and possible future studies.

All of the group 2 subjects had preserved anal superficial sensation and spinal sacral reflexes (bulbocavernosus reflexes), which ensured nerve continuity in the circumstance of receiving magnetic stimulation. Group A corresponded with grade "A" in the ASIA impairment scale (patients with complete spinal cord lesions), and group NA corresponded with groups "B", "C", or "D" in the ASIA Impairment Scale (incomplete lesions). The group S patients were ambulatory or could stand with pelvic belt support for more than 1 h per day, and the group NS patients were bedridden or wheelchair bound. This study adhered to the Occupational Health and Safety Administration regulations, and was approved by the local institutional review board. Informed consent was obtained from all patients.

Stimulation protocol

A Medtronic MagPro R30 Magnetic Stimulator (Medtronic A/S, Skovlunde, Denmark) was used for this conditioning protocol. This stimulator can generate a maximal field strength of 2.2 tesla at the centre of the coil. This protocol was developed as part of a pioneering experiment by Lin et al. (17) after the most effective parameter setting with respect to the rise in rectal pressure was determined. We adopted the protocol

for this study, and followed its general principles for administrating our own research. During hospitalization, each patient underwent a 3-week stimulation period, consisting of 20-min stimulation sessions twice a day. Each session contained 10 min of thoracic nerve stimulation with the centre of the coil placed at the T9 spinal process, and another 10 min of lumbosacral nerve stimulation with the coil at the L3 spinal process. The patients underwent stimulation from a sitting position. The stimulation intensities were set at 50% on the first day, 60% on the second day, and then stabilized at 70% for the remaining days. The stimulation frequency, burst length, and interburst intervals were fixed at 20 Hz, 2 sec, and 28 sec, respectively.

Evaluation methods

We adopted a simplified version of the CTT assessment protocol (24) for this study because it involves less radiation exposure. CTT utilizes 3 distinct marker types (Sitzmark radiopaque capsule (Konsyl Pharmaceuticals, Inc. Easton, USA)) that the patient ingests 1 by 1 on 3 consecutive days, followed by a single abdominal radiograph to visually record the numbers of each kind of marker. We carried out the CTT assessment for each patient before they received FMS treatment and on the day following the treatment. During CTT testing, all of the patients followed a normal hospital diet, but each had to suspend laxative medication, enema usage or digital manoeuvring for 3 days to avoid any disturbance of colonic motility. CTT was calculated by applying the following equation:

$CTT = N_1 + N_2 + N_3$

where "N_1" means the total number of the first type of marker present in a given film, N_2 = number of the second type of marker present, and N_3 =number of the third type of marker present. Localization of markers on abdominal films relied on the identification of bony landmarks and gaseous outlines as described by Arhan and colleagues (25). Retention of all 72 markers on day 4 following treatment yielded an estimated transit of 72 h, a value of the upper limit by this method.

The Knowles-Eccersley-Scott Symptom (KESS) questionnaire was performed before the FMS intervention, and on the day finishing the protocol. Between 2 weeks and 3 months after the intervention, it was also followed up by telephone at 2-week intervals. Table I lists the details of the questionnaire. Items include the frequency of bowel movement using existing therapy, difficulty of evacuation, laxative use, and time taken in the lavatory for bowel evacuation attempts. Since the duration of constipation in our before-and-after trial remained consistent, our version of the KESS questionnaire omitted the original question about the duration of constipation (26).

Data analysis

The values obtained on the CTT test and from the KESS for all the patients were compared from baseline to post-FMS with the Wilcoxon signed-rank test. Meanwhile, the non-parametric Mann-Whitney *U* test was used for inter-group comparisons (group 1 vs 2, group A vs NA, and group S vs NS). To account for the repeated measurements' dependency, we used the generalized estimating equations (GEE) method (27) to examine the improvements in the series of KESS scores in comparison with the baseline values, representing the patients' clinical progression during 3 months of follow-up. Statistical tests were declared statistically significant if $p < 0.05$.

RESULTS

Patient demographics

Twenty-two patients met the aforementioned inclusion criteria. Their relevant characteristics, including neurological levels and bowel management methods, are listed in Table II. There were 19 men and 3 women, age range 22–65 years, with a mean age of 46.7 years. The mean duration of the injury was 38.6 months. Among these patients, 15 had supraconal lesions,

Table I. *Distribution (%) among the Knowles-Eccersley-Scott Symptom (KESS) questionnaire items at baseline and post- functional magnetic stimulation (FMS) intervention for 22 patients with spinal cord injury*

Symptoms	Scale	Base-line	Post-FMS	*p*
Laxative use				
None	1	27	55	0.023*
Occasionally or short duration usage	2	23	13	
Regular or long duration usage	3	50	32	
Long duration, ineffective	4	0	0	
Frequency of bowel movement (using current therapy)				1.00
1–2 times per 1–2 days	1	86	86	
2 or less times per week	2	14	14	
Less than once per week	3	0	0	
Less than once per 2 weeks	4	0	0	
Unsuccessful evacuation				
Never/rarely	1	9	27	0.016*
Occasionally	2	27	36	
Usually	3	23	14	
Always (manual evacuation)	4	41	23	
Feeling of incomplete evacuation				
Never	1	14	32	0.017*
Rarely	2	14	18	
Occasionally	3	18	18	
Usually	4	23	14	
Always	5	32	18	
Abdominal pain				
Never	1	68	68	0.25
Rarely	2	5	14	
Occasionally	3	18	14	
Usually	4	4.5	0	
Always	5	4.5	4	
Bloating				
Never	1	41	50	0.12
Perceived by patient only	2	32	41	
Visible to others	3	18	4.5	
Severe, causing nausea	4	9	4.5	
Severe, with vomiting	5	0	0	
Enema/digitations				
None	1	0	0	0.08
Occasional enema/suppository usage	2	18	32	
Regular enema/suppositories usage	3	27	23	
Occasional manual evacuation	4	50	45	
Manual evacuation always	5	5	0	
Time taken (minutes at each evacuation /evacuation attempt)	1	0	9	<0.001*
<5	2	18	59	
5–10	3	59	27	
10–30	4	23	5	
>30				
Difficult evacuation causing painful effort				
Never	1	14	45	0.001*
Rarely	2	0	5	
Occasionally	3	9	9	
Usually	4	27	23	
Always	5	50	18	
Stool consistency				
Soft/ loose/ normal	1	59	86	0.02*
Occasionally hard	2	23	14	
Always hard	3	14	0	
Always hard, usually pellet-like	4	4	0	

*Wilcoxon signed-rank test showed significant differences at $p < 0.05$.
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Rarely = <25%; occasionally = 25–50%; usually = >50% of the time.

Table II. *Clinical characteristics of 22 patients with spinal cord injury (SCI)*

Patient	Neurological level	ASIA class	Age, years	Months post-injury	Bowel care	Standing	Colonic transit time, h	Score
Group 1								
1	C4	A	30	54	Lax + Ene	No	71	29
2	C6	D	53	144	Ene	Yes	69	30
3	C6	A	22	47	Lax + Ene	No	71	32
4	C5	C	26	15	Lax + Ene	Yes	72	25
5	C7	B	62	18	Lax + Ene	No	53	16
6	T6	A	36	22	Lax + Ene	Yes	36	28
7	C4	C	52	13	Ene	No	55	22
8	C3	B	34	21	Lax + Ene	No	72	26
9	C5	A	56	18	Lax + Ene	No	72	19
10	T6	A	27	36	Lax + Ene	Yes	72	22
11	T3	B	35	9	Lax	Yes	72	24
12	C4	A	55	35	Lax	No		24
13	C8	B	25	7	Lax + Ene	No	58	20
14	C4	D	42	31	Ene	Yes	72	32
15	T6	C	42	24	Ene	Yes		25
Group 2								
1	L2	D	76	74	Dig	yes	36	21
2	T12	C	46	120	Lax + Dig	yes	40	25
3	T12	C	76	18	Lax + Dig	yes	67	29
4	L4	C	79	120	Ene	yes		26
5	T11	B	62	7	Lax + Ene	yes		25
6	L3	B	24	7	Dig	yes	72	17
7	T12	B	65	9	Lax	yes	67	23

C: cervical level; T: thoracic level; L: lumbar level; ASIA: American Spinal Injury Association classification; Lax: laxatives; Ene: enema; Dig: digital evacuation.

and constituted group 1; the remaining 7 had incomplete conal/caudal lesions and comprised group 2. The patient numbers of groups A, NA, S, and NS were 6, 16, 14 and 8, respectively.

Colonic transit time

The individual and mean CTT are shown in Tables II and III, respectively. Seven cases manifested marked prolonged CTT of over 72 h, an upper-limit value according to the CTT method. For ethical reasons, we processed the CTT data with this value without prolonging the observation period, since all our patients were prohibited from using laxatives and enemas during the CTT testing. The mean colonic transit time for all patients decreased from the baseline value of 62.6 h to 50.4 h after FMS stimulation, with a p-value of < 0.001. Significant improvements were also found in CTT for group 1 ($p = 0.003$), group 2 ($p = 0.043$) and the other groups (Table III). There was no baseline difference for the inter-group comparisons. The inter-group comparisons of CTT differences, including groups 1 and 2 ($p = 0.49$), groups A and NA ($p = 0.48$), and groups S and NS ($p = 0.26$), did not achieve statistical significance.

Knowles-Eccersley-Scott Symptom questionnaire

Table I describes the details of our patients' pre- and post-FMS bowel functions. Among them, the scores for frequency of laxative use, unsuccessful evacuation attempts, feeling of incomplete defecation, difficulty with evacuation, and time taken showed significant decreases ($p < 0.02$).

The total score of the questionnaire for all patients showed a significant decrease when compared with baseline data (24.5 to 19.2, $p < 0.001$). In group 1, the mean score on baseline evalua-

Table III. *Data summary of the colonic transit time (hours) and score of Knowles-Eccersley-Scott Symptom (KESS) questionnaire at baseline and after functional magnetic stimulation (FMS) conditioning*

	Colon transit time, mean (SD)			Total questionnaire score, mean (SD)		
	Baseline	Post-FMS	p	Baseline	Post-FMS	p
Group 1	65.0, 11.2	53.6, 16.5	0.003	24.9, 4.7	19.1, 4.7	0.001
Group 2	56.4, 17.0	42.0, 16.1	0.043	23.7, 3.9	19.4, 4.5	0.026
Group A	65.9, 13.3	54.6, 16.0	0.04	24.2, 5.1	19.0, 5.7	0.017
Group NA	60.5, 13.3	47.7, 17.5	0.002	24.7, 4.1	19.4, 4.0	0.001
Group S	61.4, 15.6	51.7, 18.0	0.017	25.1, 3.9	20.0, 4.0	0.007
Group NS	64.6, 8.8	48.3, 15.6	0.007	23.5, 5.3	17.9, 5.4	0.003
All subjects	62.6, 13.1	50.4, 16.7	<0.001	24.5, 4.4	19.2, 4.6	<0.001

SD: standard deviation; Group 1: patients with supraconal lesions; Group 2: patients with incomplete conal/caudal lesions; Group A: patients with complete spinal cord lesions; Group NA: patients with incomplete spinal cord lesions; Group S: patients who were capable of standing; Group NS: patients who were incapable of standing.

Table IV. *Points and differences of follow-up questionnaires compared with baseline data in 9 patients*

	Baseline	Post FMS	2nd week	4th week	6th week	8th week	10th week	12th week
Mean (SD)	23.8 (4.2)	15.7 (3.5)	18.1 (4.8)	20 (4.8)	19.9 (5.6)	19.6 (4.6)	20.3 (5.4)	20 (4.4)
Difference		8.1	5.7	3.8	3.9	4.2	3.4	3.8
p-value[a]		<0.001	<0.001	0.001	0.004	<0.001	0.007	<0.001

[a]*p*-values obtained from generalized estimating equations (GEE) method.
FMS: functional magnetic stimulation; SD: standard deviation..

tion was 24.9, then decreased to 19.1 after FMS stimulation ($p = 0.001$). In group 2, the mean baseline score was 23.7, and improved to 19.4 after intervention ($p < 0.05$). Table III lists the results for the other groups. There was no baseline difference for the inter-group comparisons. In an analysis of groups 1 and 2 ($p = 0.43$), groups A and NA ($p = 0.61$), and groups S and NS ($p = 0.61$), the magnitude of change in the scores did not reach statistical significance.

Therapeutic effect follow-up

The results of the questionnaires carried out 12 weeks following intervention are illustrated in Table IV. Among the 22 participants, 9 persons (7 from group 1, 2 from group 2) completed the full 12 weeks of telephone evaluations. We excluded the other 13 patients from this part of the experiment because they took additional medication such as anticholinergic agents, tricyclic antidepressants, anti-hyperlipidaemia agents, or compounds containing codeine, calcium, and caffeine, which can interfere with colonic motility.

Using the GEE method, we found significant improvement in scores from the second to the eighth evaluation, lasting for the whole 12-week observation with the *p*-value varying from < 0.001 to 0.007. Compared with the baseline score, the greatest improvement of 8.1 points occurred just after FMS administration. The effect was maintained overall, with a slight drop (3.4 to 5.6 points difference) over the follow-up period.

DISCUSSION

This study demonstrated the efficacy of FMS in controlling NBD in patients with SCI with both supraconal and incomplete conal/caudal lesions. The effect of FMS was not influenced by variables such as lesion completeness and degree of mobility. The present study is the first to date that has shown that FMS produces a consistent and broad effect on patients with varying manifestations of SCI with NBD.

Although the storage and propulsion of stool acts mainly through the intrinsic nervous system in an enteric reflex manner, the loss of autonomic spinal reflexes does indeed disturb colorectal motility and coordinated external sphincter relaxation during defecation (27). A supraconal lesion manifests a spastic hyperactive colon, combined with a tight dyssynergic pelvic floor. In contrast, a conal/caudal lesion manifests a flaccid hypoactive rectum and a suppressed rectoanal inhibitory reflex (3, 19). A supraconal lesion results in generalized prolonged colonic transit throughout the colon, whereas conal/caudal injuries result in prolonged rectosigmoid transit and severely compromised emptying at defecation (19, 20). The present study particularly addresses the usefulness of FMS in cases of both supraconal and conal/caudal SCI, for generating significant improvement on severe constipation, as documented in improved CTT and KESS questionnaire score.

The exact mechanisms through which FMS ameliorates NBD in patients with SCI remain inconclusive. There are several reasonable speculations as to the possible pathways. Firstly, the process of neuromodulation may be generated at the injured spinal level and pass through the descending serotonergic sprouting to the caudal segments, following the process of spinal plasticity (28, 29). The polysynaptic sacral reflex can be reorganized through repetitive FMS, with the result of reducing sacral reflex latency (13). The second possible mechanism is through enteric and pre-vertebral ganglia, releasing appropriate neurotransmitters in sequence. The direct modulation of the myenteric plexus, ganglia and interneuron connections may facilitate colon motility not only in supraconal patients with SCI, but also patients with partial and complete conal/caudal lesions. The third possible mechanism is through abdominal muscle contraction. When the magnetic coil is placed at T9, the spinal nerves between T6 and T12, with the corresponding innervated abdominal muscles, may all be activated, resulting in massive abdominal contraction. The massage-like exercise may thus trigger enteric nervous system activity via pressure-sensitive nerves, make further transmissions to the central nervous system through the autonomic ganglia (27), and release excitatory neurotransmitters at the enteric neurons (30). Abdominal massage, adjuvant to traditional bowel programmes for patients with SCI, has already been proven to facilitate total CTT (31).

Among the items of the KESS questionnaire, patient satisfaction was greatest in "time taken for each evacuation" and "difficult evacuation" ($p < 0.01$). These variables were found to be closely related to the disordered defecation in constipation (25). Based on these findings, FMS can improve constipation complicated by the issue of difficulty with evacuation. If, as we speculated, FMS prompts the polysynaptic sacral reflex and consequently shortens the time of response to enemas or digitations, the lessening of difficulty with evacuation among our patients might be explained by the activation of this mechanism by FMS. From this viewpoint, complete evacuation seems to be achievable with our protocol and results in less effort, more successful evacuation attempts ($p = 0.01$), and less feeling of incomplete evacuation ($p = 0.016$).

The other anticipated finding in this study was the decrease in laxative use ($p = 0.02$), which was found to be closely related to the improvement in CTT (25). The therapeutic benefit of FMS

was not reflected in the domains of bowel frequency and enema use, because in situations of such serious constipation, as with the patients in this study, enema or digitation still needs to be performed every day or every other day, as part of the general discipline of rehabilitation programmes.

Abdominal pain and bloating were often experienced by patients with SCI, even those with complete lesions. It has been hypothesized that this sensation, arising from the rectum, is able to bypass the injured spinal cord and ascend through sympathetic afferents and the cervical or thoracic interganglionic fibres to the supraspinal connection. The properties of such pain have been suggested to be part of the central pain of the injury or to be associated with psychological distress or somatic pain syndrome (32). The other possibility is that abdominal pain or bloating occurs as a result of the discomplete lesion, in which a clinically complete SCI is accompanied by neurophysiological evidence of a residual neural connection to the brain (33). Given that such sophisticated generators lead to these syndromes, it is not surprising that the scores of these 2 items did not show significant change after our intervention.

We divided all patients into groups of complete and incomplete injuries according to the ASIA Impairment Scale, and assumed that a complete lesion is less receptive than an incomplete lesion to modulation by FMS. However, our investigation disproved this hypothesis. Our data with the CTT and questionnaire score indicated that a complete lesion had no more preferential effect than an incomplete lesion on an SCI patient's ability to respond to FMS. The same pattern was found between the standing and non-standing groups. The standing (S) group comprised either grade C to D tetraplegics or grade A to D paraplegics (Table II), and represented stronger abdominal and back control for maintaining upright position, in contrast with those in the incapable-of-standing (NS) group, who were bedridden or wheelchair-bound. The group S patients were supposed to have enough gravity stimulation for defecation, and therefore have a better a prognosis for FMS treatment. But the result obtained in this study contradicted this assumption. The characteristic of standing ability did not improve the efficacy of FMS. Our findings emphasized that the effect of neuromodulation for successful bowel functioning takes place through the enteric nervous system and autonomic pathways or through spinal reorganization, rather than being influenced by the above hypothesized factors.

This study has several limitations. Firstly, we did not design a randomized, double-blind controlled model. On the other hand, the intractable constipation of most of the chronic patients with SCI was refractory to various medical treatments they had already tried during a considerable time-span. The severity of their NBD had reached a stable condition, which would not simply improve with time. Therefore, in our opinion, the before-after nature of this trial was valid, and its results were reliable. The fact that 13 patients had to be excluded from the 12-week follow-up period had consequences for the reliability of the long-term results. To better confirm the reliability the results achieved in this study, more research needs to be carried out with larger numbers of follow-up patients. Overall, this was a preliminary study that followed the guidelines of the pioneering research on FMS in patients with SCI by Lin et al. (17), and continued to explore the usefulness of FMS in varied patient populations.

Secondly, the KESS questionnaire was designed to assess and diagnose functional constipation, and was not validated for doing the same for NBD. By the initiation of our study in January 2005, no known validated scoring system existed for NBD. The "Neurogenic bowel dysfunction score" (34), published in 2006, comprised questions for both the constipation and incontinence symptoms that were often experienced in NBD patients. However, the KESS score comprised various questions that distinguishing the subgroups of constipation, and was therefore also feasible for monitoring the efficacy of treatment for constipation. It was the most appropriate scoring system to use when we initiated the study, and, taking these factors into account, it has proved a reliable scoring system to use.

Despite all the patients stopped laxatives 2 days before the CTT examination, we found that 6 out of the 22 patients had relatively shorter baseline CTT (< 60 h) in comparison with previous research (17, 20). The differences in CTT may be due to variations in diet between Taiwan and western countries. Possible explanations will be investigated in a future study.

In conclusion, this is the first study to date which has demonstrated the wide-spectrum effect of FMS in patients with SCI with NBD characterized by severe constipation. The outcomes of our study have demonstrated that further investigation should take place on the optimal parameters setting of magnetic stimulation for other bowel problems, such as neuropathic pain syndrome or faecal incontinence in complete conal/caudal SCI. We have successfully demonstrated the consistent and broad effects of FMS on a general SCI population. At the same time, strategies for establishing more practical and appropriate research settings for investigating FMS use with SCI NBD patients are in continual development. FMS should be available as a proper alternative as a fundamental treatment in intractable NBD, and a complementary strategy to traditional therapies.

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