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The effect of spinal magnetic stimulation on the management of functional constipation in adults

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Abstract

Background Functional constipation is a type of functional bowel disorder characterized by difficult defecation with a sense of incomplete evacuation. It is a common disorder with an increasing prevalence, and the underlying cause is poorly identified. Nonpharmacological management of functional constipation includes lifestyle and dietary modification, regular physical activity, advice about toileting posture, and behavioral therapy. Biofeedback training as part of the behavioral training showed great efficacy with long-term results. Spinal magnetic stimulation is the application of extracorporeal magnetic stimuli to the spinal nerves and deep pelvic muscles to enhance bowel evacuation without surgical drawbacks. This study was designed to enhance bowel elimination in functional constipation patients through the dual effect of biofeedback and spinal magnetic stimulation. This work aimed to study the efficacy of spinal magnetic stimulation and biofeedback training versus biofeedback alone in the management of functional constipation.

Results There was a statistically significant difference between before and after the intervention in both studied groups regarding the mean weekly spontaneous bowel movement, a Numerical Rating Scale for pain assessment, and the Patient Assessment of Constipation Quality of Life questionnaire. When comparing the two groups after the intervention, the spinal magnetic stimulation showed superiority in the mean weekly spontaneous bowel movement and manometric anal pressure at rest.

Conclusions Spinal magnetic stimulation in addition to biofeedback pelvic floor muscle training could increase the mean weekly complete spontaneous bowel movements and manometric anal pressure at rest in patients with functional constipation. It did not show any additive benefits in improving pain during defecation or patient quality of life.

Trial registration ClinicalTrials.gov, 0305398. https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S000BQ0H&selectaction=Edit&uid=U0004JW0&ts=2&cx=-xmnims

Keywords Functional constipation, Spinal magnetic stimulation, Biofeedback, Pelvic floor

Background

Functional constipation (FC) is a type of functional bowel disorder characterized by difficult defecation with a sense of incomplete evacuation [1–3]. The underlying cause is poorly identified [1]. According to the Rome IV criteria to diagnose FC, the patient must have two or more of the following for the last 3 to 6 months of symptom onset before diagnosis: excessive straining, hard stool, sense of incomplete evacuation, sense of anorectal blockage, digital

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facilitation in evacuation, less than three bowel movements in a week, loose stools only with the use of laxatives, and the insufficient criteria to diagnose irritable bowel syndrome [3, 4]. FC is a common disorder with an increasing prevalence, associated with a reduced health-related quality of life, increased economic burden, and decreased productivity [1]. The elderly are thought to be more vulnerable to FC [5], due to different factors, including inadequate exercise, insufficient fiber and water intake, and autonomic nervous system imbalance [6]. But recent studies showed the involvement of younger age groups and children [7]. Females are more commonly affected [6].

The pathophysiology of FC is multifactorial including genetic factors; however, no specific genes have been identified, making some researchers suggest that lifestyle and environmental factors in some families are the real cause of the positive familial history among FC patients [8]. Lifestyle factors including lack of adequate fibers and fluid in diet and food allergy have been accused as an etiology [9]; eating disorders such as anorexia nervosa or bulimia must be ruled out during investigating FC [10]. Diminished level of physical activity is another important lifestyle risk factor [10]. The role of the gut microbiota has an impact on gastrointestinal mobility [11]. Colonic manometry studies reported high-amplitude propagating contraction causing colonic contents mass movement in an anterograde direction [10]. Impaired anorectal function or structure is another underlying factor [12].

The clinical diagnosis of FC is made using the Rome IV criteria mentioned above. A thorough medical history and clinical examination are crucial for accurate diagnosis and not missing an organic etiology of constipation [10].

The first steps in FC management include lifestyle and dietary modification, regular physical activity, advice about toileting posture, and behavioral therapy [10].

The pharmacological management of FC includes fecal dis-impaction via high-dose oral polyethylene glycol, enemas, or suppositories, followed by maintenance therapy to avoid fecal re-accumulation osmotic laxatives, lubricants, and stimulant laxatives, and they are the most commonly used maintenance medication. The commonest side effects of these drugs are abdominal pain or distension and diarrhea. Prosecretory and serotonergic agents have been used off-label. Follow-up studies showed that about 50% of FC patients are unsatisfied with the available medication due to the lack of efficacy and side effects [13, 14].

Anorectal biofeedback (BF) training showed effective long-term results as compared to drugs [15]. About 70% of patients had satisfactory results [16]. It is a training technique to teach the patient how to relax their pelvic floor muscles during straining [17]. BF re-training was recommended by the American and European Neurogastroenterology and Motility Societies [16].

Electrical therapy has been introduced to treat FC, sacral nerve stimulation (SNS), and colonic electrical stimulation. In SNS stimulators and electrodes inserted on the sacral nerves, 2–4 provide continuous nerve stimulation. Indeed, it is considered a safe and effective method, but the high cost and adverse effects are of concern in clinical practice [18].

Spinal magnetic stimulation (SMS) is the application of extracorporeal magnetic stimuli to the spinal nerves and deep pelvic muscles to enhance bowel evacuation without surgical drawbacks [19]. We designed this work to enhance bowel elimination in FC patients through the dual effect of BF and SMS. This work aimed to study the efficacy of SMS and BF training versus BF alone in the management of functional constipation.

Methods

The study is a prospective randomized controlled clinical trial that included 40 adult patients suffering from functional constipation. Patients were diagnosed according to the Rome IV criteria [20, 21]. The exclusion criteria were patients younger than 18 years old, patients with irritable bowel syndrome, the presence of anal hemorrhoids or bleeding, and any condition that may complicate bowel problems, such as Parkinson's disease, stroke, or traumatic brain injury. Also, patients with any contraindication for SMS, such as metal implants in the lumbar region, implanted devices (such as spinal cord stimulator), and pregnancy, were excluded from the study. The study protocol was approved by the local ethical committee of the faculty of medicine. Written informed consent was obtained from all subjects before the study.

The baseline assessment of all patients included questionnaires to identify the severity of the problem and its impact on life: mean weekly complete spontaneous bowel movements (CSBMs), the Bristol Stool Scale was used to assess stool consistency [22], Numerical Rating Scale for pain assessment, Patient Assessment of Constipation Quality of Life questionnaire (PAC-QOL score), anal reflex in response to perianal touch [23], and digital rectal examination to evaluate the anal sphincter tone at rest and on voluntary contraction using Modified Oxford Muscle Grading System (MOS) [22]. A manometric pressure assessment was done to evaluate the anal resting pressure, maximal squeezing pressure, and assessment of anismus [24].

Re-evaluation was repeated for all patients with the abovementioned tools after completing the designed rehabilitation program (after 1 month).

The designed rehabilitation program included biofeedback pelvic floor muscle training for the 40 patients

for a total of 12 sessions. The session lasted for 30 min of trans-rectal pressure BF relaxation technique. Auditory and visual feedback were provided in addition to positive verbal reinforcement [25]. The recruited patients were divided into 2 groups randomly by a computer program: group 1 in which patients received 12 sessions of BF-assisted pelvic floor muscle relaxation plus Sham repetitive spinal magnetic stimulation (3 sessions/week); group 2—patients received 12 sessions of BF-assisted pelvic floor muscle relaxation followed by real spinal magnetic stimulation (3 sessions/week). The repetitive spinal magnetic stimulation (rSMS) was done using Neurosoft equipment (Neuro-MS/D Variant-2 therapeutic Neurosoft, Russia). A circular coil was used for lumbo-sacral spinal nerve root stimulation; the mid-point of the upper margin of the magnetic coil was placed at the S1 vertebral spine. The magnetic coil was placed in a plane parallel to the lumbosacral spine, with the handle pointing towards the feet and the knob kept on the left side to maintain a single coil orientation. This coil position is for stimulating spinal nerve roots. The coil generated a magnetic field of up to 2.2 T at the periphery of the coil. The intensity was fixed at 50% of maximal output, and the frequency was fixed at 20 Hz. The work period in a train is equal to 5 s, and inter-train interval is equal to 25 s. The total number of pulses per session is 4000. The session lasts for 20 min. Both groups received health education, dietary modification, and a home exercise program.

Statistical analysis was performed using SPSS Statistics Version 25. Qualitative data were described using numbers and percentages. The data was tested for normality using skewness and normality curve. The data had a normal distribution, and parametric tests were used. Qualitative data were described using numbers and percentages. Quantitative data were described using the mean and standard deviation. Comparison between the two groups regarding the categorical variables was tested using the chi-square or Fisher exact test. Comparison between the two groups was tested using an independent sample *t*-test. Comparison between the same groups before and after the intervention was tested using paired *t*-test. Significant test results are quoted as two-tailed probabilities. The significance of the obtained results was judged at the 5% level.

Results

The study was conducted on 40 patients (20 patients in each group). Group 1 included 5 female patients and 15 male patients; their mean age in years was 51.7 ± 13.7. The mean disease duration was 10.15 ± 12.8. Group 2 included 9 female patients and 11 male patients, with a mean age of 50.7 ± 17.7. The mean value of disease duration (in years) was 9.7 ± 10.3. There was no statistical significant difference between the two groups regarding the demographic data, anthropometric measures, and clinical characteristics.

Regarding the mean weekly CSBMs, there was no statistically significant difference between the two groups at baseline assessment. The mean for group 1 was 1.3 ± 0.6, and for group 2, it was 1.4 ± 0.6 (P value $= 0.9$).

The Bristol Stool Scale was used to assess stool consistency, eight patients in group 1 (40%) and eleven patients in group 2 (55%), chose type 3 (sausage with cracks on its surface), which represents stool like a sausage but with cracks on its surface.

The Numerical Rating Scale for pain assessment during defecation was used for all patients. It revealed that 6 patients in group 1 (30%) suffered from pain during defecation, with a mean of 2.5 ± 4, and 11 patients in group 2 (55%) had pain during defecation with a mean of 4.2 ± 4.4.

Patient Assessment of Constipation Quality of Life Questionnaire (PAC-QOL score) was applied to all patients at the baseline assessment. The mean of dissatisfactory component was 70.6 ± 14.4 in group 1 and 69.3 ± 20 in group 2. The mean of the satisfactory component was 3.6 ± 3.1 in group 1, and 2.2 ± 3.3 in group 2. There was no statistically significant difference between the two groups at baseline for the dissatisfactory and satisfactory components (P value $= 0.07$ and 0.52, respectively).

Table 1 shows the comparison in group 1 at baseline and after the end of the designed rehabilitation program regarding the selected assessment tools. A statistically significant improvement was found in all the selected parameters. The manometric pressure assessment at rest and at maximum contraction did not show a significant change in group 1 at the end of the rehabilitation program. Table 2 demonstrates the comparison of group 2 at baseline and at the end of the rehabilitation program. As in group 1, a statistically significant improvement was found in all the selected parameters. A significant increase in manometric pressure assessment, including resting pressure and maximum squeezing pressure was found in group 2 patients.

To fulfill the aim of this study to discover the additional benefit of rSMS in treating FC, a comparison between the two groups at the end of the rehabilitation program was done. The only detected difference in the assessment parameters was in the CSBMs. Group 2 patients showed a significantly higher number of the mean weekly CSBMs in comparison with group 1. Regarding manometric pressure measurements, group 2 showed a higher value at rest, which reflects the pelvic floor muscle-strengthening effect.

Table 1 Comparison of the outcome measures before and after the rehabilitation program in group 1 patients

	Baseline	After 1 month	Test of significance	*P*-value
Mean weekly CSBMs	1.3 ± 0.6	2.3 ± 0.97	3.9	0.001*
Numerical Rating Scale for pain assessment	2.5 ± 4	1.1 ± 3	2.17	0.042*
PAC-QOL (dissatisfactory component)	69.5 ± 12.7	50.9 ± 25.3	3.93	0.001*
PAC-QOL (satisfactory component)	3.6 ± 3.15	6 ± 5.3	3.94	0.001*
PAC-QOL questionnaire (total)	73.1 ± 13.39	56.9 ± 21.6	3.84	0.001*
Manometric pressure assessment (hPa)				
At rest	14 ± 5.7	14 ± 5.7	1.00	0.330
Maximum contraction	67.7 ± 43	68 ± 42.9	1.00	0.330

hPa hectopascal (it is the unit of pressure, and it is equal to 100 Pa), *CSBMs* Complete spontaneous bowel movements, *PAC-QOL* Patient Assessment of Constipation Quality of Life questionnaire

Significant $P \leq 0.05$

* *P*-value of the paired *t*-test

Table 2 Comparison of the outcome measures before and after the rehabilitation program in group 2 patients

	Baseline	After 1 month	Test of significance	*P*-value
Mean weekly CSBMs	1.4 ± 0.6	4.1 ± 2.3	5.06	0.0001*
A Numerical Rating Scale for pain assessment	4.2 ± 4.4	1.3 ± 2	3.92	0.001*
PAC-QOL (dissatisfactory component)	69.3 ± 20	43 ± 24.7	5.17	0.0001*
PAC-QOL (satisfactory component)	2.2 ± 3.3	8.1 ± 3.4	3.56	0.0001*
PAC-QOL questionnaire (total)	71.50 ± 19.8	51.15 ± 23.5	4.91	0.0001*
Manometric pressure assessment (hPa)				
At rest	20.8 ± 8	23.2 ± 6.7	3.74	0.001*
Maximum contraction	74.3 ± 47.4	78.5 ± 46.4	2.33	0.031*

hPa hectopascal (it is the unit of pressure, and it is equal to 100 Pa), *CSBMs* Complete spontaneous bowel movements, *PAC-QOL* Patient Assessment of Constipation Quality of Life questionnaire

Significant $P \leq 0.05$

* *P*-value of the paired *t*-test

An important observation was that two patients in group 2 reported improvement in mechanical low back pain due to lumbar spondylosis after receiving three sessions. No side effects were reported in the two groups.

Discussion

Biofeedback-assisted pelvic floor muscle training is a highly effective and safe tool in the management of functional constipation for more than fifty years [26, 27]. BF is a behavioral training technique to teach the patient how to relax the pelvic floor muscles and increase intraabdominal pressure at the same time during defecation [28]. It could be practiced in outpatient clinics or at home [29]. In the current study, all patients received 12 BF-assisted pelvic floor muscle training sessions at the outpatient clinic. Group 1 received sham rSMS, and group 2 received real rSMS following each BF session.

In group 1 patients, a significant improvement in all selected outcome measures was detected, including CBMs, Numerical Rating Scale for pain during defecation, and in the total PAC-QOL score with its satisfactory and dissatisfactory components. These results further support the beneficial value of BF in treating FC [26, 27]. FC protocol in this study was closely similar to the modified BF training suggested by Xu et al. It entails a tailored BF protocol according to the abilities of each patient [27]. This protocol was more convenient to us and to the patients than using fixed BF values. The manometric pressure assessment did not show a significant change at rest or at maximum contraction at the end of the rehabilitation program. Biofeedback pelvic training does not affect the strength of pelvic floor musculature because it depends on the behavioral training to relax rather than stimulating the pelvic floor muscles [30]. Indeed, it is logical that BF relaxation training does not affect the pressure manometry values.

Adding rSMS to BF in group 2 showed some benefits, and patients showed significant improvement in all assessed outcome measures after completion of their rehabilitation program (Table 3). The number of weekly

Table 3 Comparison of the outcome measures between the two groups after the completion of the rehabilitation program

	Group 1	Group 2	Test of significance	*P*-value
Mean weekly CSBMs	2.3 ± 0.97	4.1 ± 2.3	3.2	0.003*
A Numerical Rating Scale for pain assessment	1.1 ± 3	1.3 ± 2	0.24	0.809
PAC-QOL (dissatisfactory component)	50.9 ± 25.3	43 ± 24.7	0.93	0.325
PAC-QOL (satisfactory component)	6 ± 5.3	8.1 ± 3.4	1.49	0.144
PAC-QOL (total)	56.9 ± 21.6	51.15 ± 23.5	0.81	0.423
Manometric pressure assessment (hPA)				
At rest	14 ± 5.7	23.3 ± 6.7	4.6	0.0001*
Maximum contraction	68 ± 42.9	78.5 ± 46.4	0.743	0.462

hPa: hectopascal (it is the unit of pressure, and it is equal to 100 Pa), *CSBMs* Complete spontaneous bowel movements, *PAC-QOL* Patient Assessment of Constipation Quality of Life questionnaire

Significant $P \leq 0.05$

* *P*-value of the independent *t*-test

CSBMs was increased, the numerical rating scale for pain and the dissatisfactory component of the Patient Assessment of Constipation Quality of Life questionnaire were both diminished, and the satisfactory component was improved. The technique of rSMS applied extracorporeal magnetic stimulation to the spinal nerves and pelvic floor muscles to facilitate bowel evacuation without the disadvantages of sacral electrical stimulation [19]. Previously published research proved the efficacy of rSMS in neurogenic bowel dysfunction after spinal cord injury, patients received 20 min stimulation sessions, twice daily for 3 weeks [31], and in elderly persons with chronic constipation [19] with the effect lasting up to 3 months after finishing treatment [31]; in the current study, the only additional beneficial effect offered by rSMS was the number of bowel movements per week. Mechanisms suggested for improving bowel movements by rSMS were, first, it increases the strength of the pelvic floor muscles. Muscle strengthening could be due to sacral plexus neuro-stimulation [31]. Second, it synchronizes movements of the pelvic floor muscles, to reach adequate relaxation in the puborectalis and external anal sphincter during evacuation [19].

The manometric pressure assessment among group 2 patients showed a significant increase after the end of their rehabilitation program. A possible explanation for this finding was that rSMS has a strengthening effect on the pelvic floor muscles which also could explain the increased number of bowel movements that was observed in this study. Comparing the manometric pressure at the end of the rehabilitation program in the 2 groups revealed that group 2 had a higher resting tone than group 1. This finding supports the strengthening value of rSMS.

Thirty percent of patients in group 1 and 55% of patients in group 2 suffered from pain during defecation. The pain had a significant impact on those patients regarding bowel habits and quality of life. Biofeedback was considered an additive effective tool for treating chronic pelvic pain due to various causes and in anorectal disorders [32]. rSMS has proven to have a pain-relieving effect in neuropathic pain [33]. Although there is a lack of data regarding the role of rSMS on other types of pain such as pelvic pain, phantom pain, low back pain, trigeminal neuralgia, but the observations are promising [33]. This study aimed to look for the role of rSMS as an adjuvant tool to biofeedback in pain relief. Both groups showed a significant reduction in the level of pain, with no statistically significant difference between the 2 groups after the completion of their rehabilitation program.

Population-based studies showed poorer QOL in individuals with chronic constipation [34, 35]. The Patient Assessment of Constipation QOL (PAC-QOL) questionnaire is a validated disease-specific instrument to measure the burden of constipation on everyday functions, as well as patient's satisfaction. In the current work, patients in group 1 showed a statistical significant decrease in the dissatisfactory score of their PAC-QOL (from 69.5 ± 12.7 to 50.9 ± 25.3, *P*-value = 0.001), as well as a statistical significant improvement in the satisfactory component (from 3.6 ± 3.15 to 6 ± 5.3, *P*-value = 0.001). Overall, decreasing the PAC-QOL by 1 point was validated as a relevant definition of response for the treatment group [36]. Improvement in PAC-QOL was achieved in the total score in group 1 (from 73.1 ± 13.39 to 56.9 ± 21.6) and in group 2 (from 71.50 ± 19.8 to 51.15 ± 23.5). No statistically significant difference between the two studied groups regarding QOL score was found at the end of the rehabilitation program.

The approximate session time in the current work was 45 min; patients spent 20 min in the BF training session

followed by 25 min receiving rSMS. In future research, session time could be shortened by teaching patients to do the pelvic relaxation exercise at home and receiving the rSMS at the outpatient clinic. This was proven by Go et al. that BF therapy is effective in the management of functional constipation, irrespective of whether the training was administered at home or in an office setting [37].

Limitations of the study

The study did not investigate the long-term effect of BF with or without real rSMS on the QOL.

Conclusion

From this study, we conclude that the addition of rSMS to BF could have a potential role in treating FC, by improving bowel movements and strengthening the pelvic floor muscles, which further increases the mean weekly spontaneous bowel movements.

It is recommended to conduct further studies applying rSMS only besides the standard intervention (pelvic floor exercise, dietary education, and lifestyle modifications) to discover the pain-relieving effect of rSMS in FC patients with pain during defecation.

Abbreviations

FC	Functional constipation
BF	Biofeedback
SNS	Sacral nerve stimulation
SMS	Spinal magnetic stimulation
CSBMs	Complete spontaneous bowel movements
PAC-QOL	Patient Assessment of Constipation Quality of Life questionnaire score
MOS	Modified Oxford Muscle Grading System
rSMS	Repetitive spinal magnetic stimulation

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Authors' contributions

SI: making of the study design, collection of data, analysis of the data, supervision of the writing of the paper. NM: idea of the research, collection of the data, and writing of the paper. SS: collection of the data, interpretation of the data, and writing of the paper. The authors have read and approved the final manuscript.

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Availability of data and materials

All data and materials are presented in the main paper.

Declarations

Ethics approval and consent to participate

The Ethics Committee formally approved this study of the Faculty of Medicine, Alexandria University (FWA 00018699/0201111, date:16/12/2021, serial number 0305398). The study was explained to the participants, and a written informed consent was given by each participant.

Consent for publication

A written informed consent was given by each participant regarding the publication of their information.

Competing interests

The authors declare that they have no competing interests.

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