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Clinical Effects of Implantable Sacral Neuromodulation Combined with Floating Needle Reperfusion in the Treatment of Patients with Functional Defecation Disorders

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Abstract: *Objective:* To investigate the clinical effect of implantable sacral neuromodulation combined with floating needle reperfusion in treating patients with functional defecation disorder. *Methods:* 40 eligible constipated patients with defecation disorder were screened according to the criteria of Rome IV for chronic constipation, and were divided into 20 cases each in the control group and the study group according to the random number table method. The control group was given oral lactulose combined with mosapride treatment, and the study group was given implantation of sacral nerve stimulation electrodes and floating needle reperfusion treatment. The clinical symptoms, visual analog scale (VAS) score, Wexner score for constipation, quality of life score, anorectal manometry, adverse reactions, and complications were observed in both groups. *Results:* After treatment, the median number of voluntary feces per week and the median number of days of voluntary feces per week in the study group were higher than those in the control group, and the median duration of defecation was lower than that in the control group ($P < 0.05$); the median VAS score of the study group was significantly higher than that of the control group ($P < 0.05$); the constipation Wexner score of the study group was significantly lower than that of the control group ($P < 0.001$); the quality of life scores of the study group were overall better than those of the control group ($P < 0.05$); the anal resting pressure, anal residual pressure, and rectal propulsion of the study group were significantly better than those of the control group ($P < 0.05$); liquefaction of the incision occurred in only one patient during treatment in the study group, which was healed after changing the medication and did not have any serious complications, and two patients in the control group had abdominal pain, and there was no significant difference between the two groups ($P > 0.05$). *Conclusion:* In the treatment of patients with functional defecation disorder, implantable sacral neuromodulation combined with floating needle reperfusion therapy can effectively improve the clinical symptoms and quality of life of patients.

Keywords: Sacral neuromodulation; Floating needle reperfusion; Functional defecation disorder; Clinical effects

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1. Introduction

Functional defecation disorder is a common digestive disease, which seriously affects the quality of life of patients. Although traditional treatment methods can relieve patients' symptoms to a certain extent, the long-term effect is not ideal and there are certain side effects [1]. In recent years, with the continuous progress of medical technology, new therapeutic methods such as implantable sacral neuromodulation and floating needle reperfusion have gradually gained attention, providing new ideas for the treatment of functional defecation disorders. Implantable sacral neuromodulation is a method to improve intestinal motility by regulating the function of sacral nerves, which has been proven to be effective for some patients with functional defecation disorders [2]. Floating needle reperfusion, on the other hand, promotes blood circulation and qi regulation by stimulating specific acupoints, thus achieving the purpose of treating the disease. The combined application of the two methods can further improve the therapeutic effect, therefore, this study aims to investigate the clinical effect of implantable sacral neuromodulation combined with floating needle reperfusion in the treatment of patients with functional defecation disorders with a view to providing a more effective therapeutic solution.

2. General information and methods

2.1. General information

According to the criteria of chronic constipation Rome IV, 40 eligible constipated patients with defecation disorder were screened and divided into 20 cases each of the control group and the study group according to the method of the random number table, and there was no statistical significance in the general information of the two groups ($P > 0.05$).

Inclusion criteria: (1) patients diagnosed with functional defecation disorder; (2) patients who have not received other similar treatments or treatment failure; (3) patients who agreed to participate in the study and signed the informed consent.

Exclusion criteria: (1) patients with other serious diseases or complications that may affect the results of the study; (2) pregnant or breastfeeding women; (3) patients with allergies or contraindications to the medications or treatments used in the study; (4) patients who are unable to cooperate with the requirements of the study or unable to complete the follow-up visits.

2.2. Methods

Patients in the control group were given oral lactulose combined with mosapride treatment. The initial dose of mosapride was 5 mg three times a day, and 30 ml of lactulose was taken once in the morning. The maximum dose of mosapride was the same as the initial dose, and 30 ml of lactulose was given twice a day.

The study group was given implantation of sacral nerve stimulation electrodes and floating needle reperfusion treatment.

(1) Implantation of sacral nerve stimulation electrodes: Before the operation, the patients took oral laxatives and enema and took the prone position, after local anesthesia, the S3 sacral foramen was positioned by X-ray fluoroscopy under the cross-positioning method or ultrasonic localization method. After the positioning was completed, skin expansion was carried out, and then the stimulating electrodes were placed, and the third section was positioned at the S3 nerve foramen into the pelvic cavity under the C-arm machine, and the stimulation test was carried out on four electrodes. After the effect was satisfied, an incision of about 4–5 cm was made above the puncture point, connecting the external connector of the implantable regulator with the external power cord and embedding it under the skin, testing the electrode again to see if they were functioning, and observing for 14–21 days, and

implanting the permanent regulator after the symptoms had improved by more than 50%.

(2) Implantation of the permanent regulator: After disinfecting and spreading the towel, the original incision on the buttocks was extended, the external connector of the implantable electrode was disconnected from the external power supply, and the external power supply cable was taken out. Appropriate subcutaneous space was freed to place the sacral neuromodulator, the implanted electrode and the sacral neuromodulator were connected, the regulator was completely embedded under the skin, and the incision was closed.

(3) Needle reperfusion therapy: The patient took the supine position, bent the leg, and the routine disinfection was performed. A single-use floating needle (Nanjing Paifu Medical Technology Co., Ltd.) was taken, and, at a distance of 15 cm from the affected area, a specialized floating needle inserter was used to quickly insert the needle into the subcutaneous tissue at a 20° angle to the skin. The inserter was then removed, the needle was laid flat, and the floating needle was slowly inserted along the subcutaneous tissue. The needle handle was rotated and retracted to return the floating needle tip back into the needle tube and secured. The floating needle technique was used to perform local sweeping for 2 minutes, about 200 times. At the same time, the patient was instructed to perform reperfusion actions such as abdominal expansion and leg lifting. This was continued until the local nodules, cords, and tension improved or disappeared. After the procedure, the needle core was removed, leaving the needle tube in place for 6 hours, and it was covered with a dressing. The procedure was performed once every other day, three times a week, for a total of 12 sessions over 4 weeks.

2.3. Observation indicators

(1) Clinical symptoms: The median number of voluntary defecations per week, the median number of days of voluntary defecation per week, and the median duration of defecation.

(2) Visual analog scale (VAS) score: VAS was used to assess patients' feelings during and after defecation.

(3) Constipation Wexner score: The constipation Wexner scale was used to assess the frequency of defecation, pain, incomplete sensation, abdominal pain, duration of each defecation, type of assistance, number of unsuccessful attempts to defecate per 24 hours and duration of constipation.

(4) Quality of life score: The SF-36 quality of life questionnaire was used to assess the patients' quality of life in eight areas, including physical function, somatic pain, vitality, emotional function, physiological function, general health, social function, and mental health.

(5) Anorectal manometry: Three-dimensional solid-state high-resolution anorectal manometry was used to detect anorectal dynamics indicators, including anal resting pressure, anal residual pressure, and rectal propulsion.

(6) The occurrence of adverse reactions and complications.

2.4. Statistical methods

SPSS26.0 statistical software was used for data analysis. Measured data that obeyed normal distribution were expressed as mean ± standard deviation (SD), paired *t*-test was used for comparison before and after treatment within the group, and two independent samples *t*-test was used for comparison between groups; measured data that did not obey normal distribution were expressed as mean (P25~P75), and Wilcoxon test was used for comparison between groups. The count data were expressed as frequency, and the comparison between groups was made by χ^2 test. $P < 0.05$ was regarded as a statistically significant difference.

3. Results

3.1. Comparison of clinical symptoms between the two groups of patients after treatment

After treatment, the median number of voluntary feces per week and the median number of days of voluntary feces per week in the study group were higher than that in the control group, and the median time of defecation was lower than that in the control group ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of clinical symptoms between the two groups

Groups	Median number of voluntary feces per week (times)	Median number of days of voluntary feces per week (day)	Median time of voluntary fecal evacuation (min)
Study group ($n = 20$)	8.2 (0 ～ 11)*	5.3 (0 ～ 7)	3.8 (3 ～ 30)
Control group ($n = 20$)	5.7 (0 ～ 8)	3.6 (0 ～ 7)	6.5 (4 ～ 35)

*$P < 0.05$ compared with the control group

3.2. Comparison of VAS scores between the two groups of patients

After treatment, the median VAS score of patients in the study group was significantly higher than that of the control group ($P < 0.05$), as displayed in **Table 2**.

Table 2. Comparison of VAS scores between the two groups of patients

Groups	Before treatment	After treatment
Study group ($n = 20$)	9.0 (7 ～ 40)	85.0 (20 ～ 95)**$^{\triangle}$
Control group ($n = 20$)	9.1 (7 ～ 42)	68.0 (15 ～ 85)$^{\triangle}$

*$P < 0.05$, **$P < 0.01$ compared with the control group; $^{\triangle}P < 0.05$ compared with the pre-treatment

3.3. Comparison of constipation Wexner scores between the two groups of patients before and after treatment

After treatment, the constipation Wexner score of patients in the study group was significantly lower than that of the control group ($P < 0.001$), as presented in **Table 3**.

Table 3. Comparison of Wexner score of constipation before and after treatment in two groups of patients

Groups	Before treatment	After treatment
Study group ($n = 20$)	21.38 ± 4.12	13.27 ± 1.64
Control group ($n = 20$)	20.97 ± 4.07	16.53 ± 2.18
t	0.317	5.344
P	0.753	0.000

$P < 0.05$ compared with the control group; $P < 0.05$ compared with the pre-treatment

3.4. Comparison of the quality of life of patients in the two groups before and after treatment

After treatment, the quality of life scores of patients in the study group were overall better than those of the control group ($P < 0.05$), as shown in **Table 4**.

Table 4. Comparison of the quality of life scores of patients in the two groups

Groups	Indicators	Before treatment	After treatment	*t*	*P*
Study group ($n = 20$)	Physical function	83.58 ± 12.08	85.93 ± 12.36	0.608	0.547
	Somatic pain	88.46 ± 9.53	89.02 ± 8.62	0.195	0.847
	Vitality	81.25 ± 7.14	89.76 ± 7.83	3.592	0.001
	Emotional function	82.15 ± 11.46	92.57 ± 6.69	3.512	0.001
	Physiological function	71.24 ± 10.93	73.85 ± 12.06	0.717	0.478
	General health	80.17 ± 9.28	90.01 ± 8.84	3.434	0.002
	Social function	83.24 ± 9.57	92.36 ± 6.18	3.580	0.001
	Mental health	82.54 ± 8.29	93.12 ± 6.07	4.605	0.000
Control group ($n = 20$)	Physical function	83.42 ± 11.93	84.65 ± 12.27	0.321	0.750
	Somatic pain	88.02 ± 8.43	88.93 ± 6.04	0.392	0.697
	Vitality	80.86 ± 7.26	88.36 ± 5.39	3.709	0.001
	Emotional function	81.84 ± 8.03	88.13 ± 7.52	2.557	0.015
	Physiological function	71.38 ± 9.52	72.16 ± 12.38	0.223	0.825
	General health	79.68 ± 8.31	87.25 ± 6.07	3.290	0.002
	Social function	81.93 ± 9.05	86.84 ± 8.29	1.789	0.082
	Mental health	81.54 ± 8.29	88.09 ± 6.72	2.745	0.010

*$P < 0.05$ compared with the control group; $^{\triangle}P < 0.05$ compared with the pre-treatment

3.5. Comparison of anorectal manometry between the two groups of patients before and after treatment

After treatment, the anal resting pressure, anal residual pressure, and rectal propulsion of patients in the study group were better than that of the control group, and the difference was statistically significant ($P < 0.05$), as presented in **Table 5**.

Table 5. Comparison of anorectal manometry between the two groups of patients before and after treatment

Groups	Time	Anal resting pressure (mmHg)	Anal residual pressure (mmHg)	Rectal propulsion (mmHg)
Study group ($n = 20$)	Before treatment	118.09 ± 18.26	124.86 ± 16.59	17.12 ± 2.26
	After treatment	76.13 ± 10.54*$^{\triangle}$	70.26 ± 9.84*$^{\triangle}$	32.74 ± 6.87*$^{\triangle}$
Control group ($n = 20$)	Before treatment	119.13 ± 17.93	125.17 ± 16.38	17.25 ± 2.08
	After treatment	85.27 ± 11.25$^{\triangle}$	81.29 ± 10.16$^{\triangle}$	20.03 ± 6.39$^{\triangle}$

*$P < 0.05$ compared with the control group; $^{\triangle}P < 0.05$ compared with the pre-treatment

3.6. The occurrence of adverse reactions and complications after treatment in the two groups of patients

Only one patient in the study group experienced liquefaction of the incision during treatment, which healed after dressing change without serious complications, and two patients in the control group experienced abdominal pain, with no significant difference between the two groups ($P > 0.05$), as displayed in **Table 6**.

Table 6. The occurrence of adverse reactions and complications after treatment in the two groups of patients

Groups	Incision liquefaction	Abdominal pain	Total incidence
Study group (n = 20)	1 (5%)	0	1 (5%)
Control group (n = 20)	0	2 (10%)	2 (10%)
χ^2	-	-	0.000
P	-	-	1.000

4. Discussion

Functional defecation disorder is a state in which defecation is not smooth and stool cannot be passed smoothly [3,4]. The appearance of these symptoms is associated with a variety of factors, such as anal spasm and pelvic floor muscle spasm, anorectal sensory disturbances, and pelvic floor relaxation. In addition, lifestyle, dietary habits, and stress may also affect bowel function [5].

For functional defecation disorders, oral lactulose combined with mosapride treatment is indeed a common pharmacological treatment. However, this method has some limitations [6]. For example, prolonged administration of lactulose in high doses may lead to electrolyte disorders due to diarrhea, while mosapride may lead to adverse reactions such as dry mouth, diarrhea, and abdominal pain [7]. In addition, pharmacological treatments usually only provide temporary relief of symptoms without addressing the root cause of functional defecation disorders. Therefore, there is an urgent need for new methods to treat functional defecation disorders from the root. The implantable sacral neuromodulation combined with floating needle reperfusion therapy aims to improve bowel movement and defecation function by modulating sacral nerve function and stimulating specific acupoints. This treatment approach may be more effective in improving defecation disorders by acting more directly on bowel function than oral medication.

This paper found that, after treatment, the median number of voluntary defecations per week and the median number of days of voluntary defecation per week in the study group were higher than those in the control group, and the median duration of defecation was lower than that in the control group ($P < 0.05$); the median VAS score of the patients in the study group was significantly higher than that of the control group; the Wexner score of constipation of the patients in the study group was lower than that of the control group ($P < 0.001$); and, after treatment, the study group had a higher anal resting pressure, anal residual pressure, and rectal propulsion than the control group, and the difference was statistically significant ($P < 0.05$), all of which indicate that implantable sacral neuromodulation combined with floating needle reperfusion therapy can effectively improve the clinical symptoms of the patients in the treatment of patients with defecation disorders. This is mainly due to that implantable sacral neuromodulation can directly regulate the nerve reflexes related to defecation. By stimulating the sacral nerve through the implanted device, the nerve reflex activities of the bladder, sphincter, and pelvic floor related to urination and defecation can be adjusted, so that the abnormal nerve reflexes can be rebalanced [8]. This treatment, which acts directly on the nervous system, can more effectively improve bowel movement and defecation function, thus relieving the symptoms of defecation disorders. On the other hand, floating needle reperfusion therapy can promote blood circulation and qi and blood harmonization by stimulating specific acupoints. This treatment can improve the microcirculation of the intestinal tract and increase the peristalsis of the intestinal tract, which can help to relieve constipation and defecation difficulty [9,10].

This study also found that after treatment, the quality of life scores in the study group were overall better than those of the control group ($P < 0.05$), indicating that implantable sacral neuromodulation combined with floating

needle reperfusion therapy has certain advantages in enhancing the quality of life of patients with functional defecation disorder, and by comprehensively improving the clinical symptoms of the patients, it can alleviate patients' mental stress and anxiety, improve their mental health, and significantly enhance their quality of life.

5. Conclusion

In conclusion, implantable sacral neuromodulation combined with floating needle reperfusion therapy can effectively improve the clinical symptoms and quality of life of patients with functional defecation disorders.

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Disclosure statement

The authors declare no conflict of interest.

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