

Progress of Biofeedback Therapy Combined with Traditional Chinese Medicine in Treatment of Functional Anorectal Pain

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Abstract: Functional anorectal pain is a kind of functional anorectal disease with various pain sensation as the main symptom. Its pathogenesis is still unclear, and simple treatment has limited efficacy. Biofeedback therapy Combined various other measures is a relatively safe and reliable way to treat the disease. Traditional Chinese medicine (TCM) plays a positive role with its characteristics of the holism conception, treatment based on syndrome differentiation, traditional Chinese medicine, acupuncture and moxibustion. This paper summarizes the efficacy of biofeedback therapy combined with TCM therapy for functional anorectal pain based on relevant literature in recent years. The conclusion provides systematic treatment ideas and reference methods for clinicians.

Functional anorectal pain (FARP) is a non-organic lesion occurring in the anorectal region. According to the diagnostic criteria of Roman IV functional bowel disease, FARP is divided into levator ani syndrome, non-specific functional anorectal pain, and spasmodic anorectal pain[1]. Table 1 shows the clinical features of different types of FARP. The disease is a series of related symptoms caused by changes in motor sensation or abnormal innervation at the anorectal site, of which anorectal pain and discomfort are the most prominent manifestations. Although it is not a common and frequently occurring disease in the clinic, it is refractory to treatment. The repeated illness and long-term pain bring bad emotional burden to patients and seriously affect their quality of life. In addition, the number of patients with FARP has been increasing in recent years. The treatment methods for this disease are various, and the specific clinical application is complicated. There is no unified standard treatment plan. As biofeedback is a non-invasive treatment that may solve potential pathophysiological problems, it is a reasonable first-line choice for patients with high resting pressure or defecation symptoms. Sacral nerve stimulation can also be selected for patients with normal resting pressure[2]. Other treatments such as warm hip bath and fiber supplementation are also recommended[3]. Some studies have suggested that biofeedback therapy plays an important role in the treatment of pelvic floor functional diseases due to its safe and

effective[4]. In recent years, there have been some explorations in the treatment of FARP with biofeedback therapy in combination with TCM therapy. This article reviews the current clinical research progress in order to expect this method to better serve the clinical practice in the future.

Table 1: The clinical features of different types of FARP

Classifications	Clinical features	
Levator ani syndrome	The puborectalis is tender when pulled back	These two kinds of pain belong to chronic anorectal pain, and are often chronic repeated vague and blunt pain, burning-like pain, or electric shock-like or tear-like, or manifested as increased rectal pressure, which worsened in the sitting and lying positions, with the pain lasting for more than 20minutes, or even lasting for several hours to several days, with relatively frequent episodes. In addition, the occurrence of pain can have a certain physiological cycle.
Non-specific functional anorectal pain	There is no tenderness when pulling back the puborectalis	
Spasmodic anorectal pain	The pain lasts for seconds to minutes is spasmodic, pressing, acupuncture-like or electrocautery-like and can relieve itself in a short time without leaving any other uncomfortable symptoms. Pain occurs irregularly at any time and at night.	

1. Overview of Biofeedback Therapy for FARP

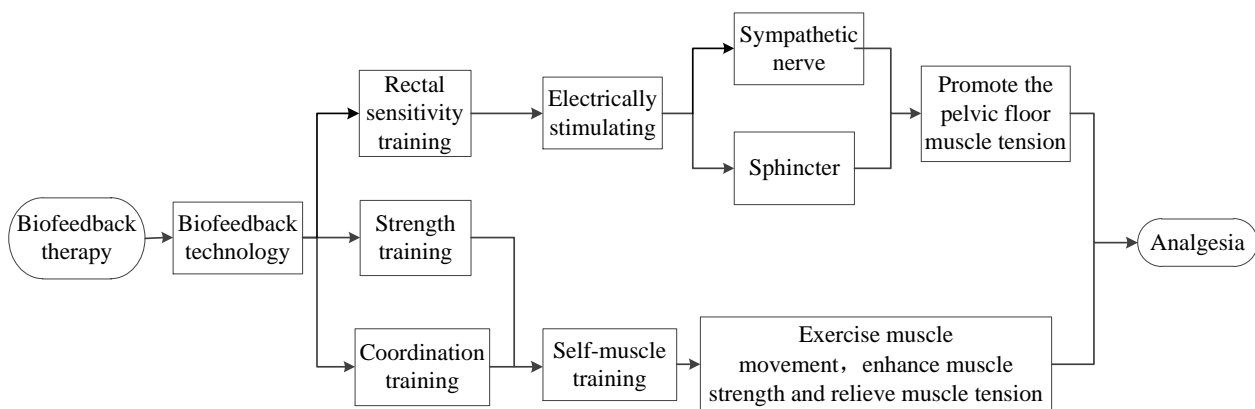


Figure 1: The principle of biofeedback therapy in the treatment of FARP.

Biofeedback therapy has been used since the 1960s and is currently considered one of the most important treatments of choice for FARP. As a behavioral therapy, biofeedback therapy can use electronic instruments and related technologies to convert physiological and pathological body functions that people are not aware of under normal circumstances into specific signals that can be heard or seen by using abstract indicators such as myoelectricity, skin temperature, blood pressure, and heart rate using biofeedback mechanism, and then use the information feed back to regulate the body. This is a treatment and training method that needs to rely on the instruments and the patients themselves to cooperate with each other for a long time. Good expectation aims to regulate the patient's body and mind to the most comfortable state and return to normal physiology, to achieve the purpose of treatment[5]. Biofeedback technology includes rectal sensitivity training, strength training, and coordination training. Generally, trained medical care personnel are required to implement the treatment in medical facilities and environments[6]. Biofeedback therapy is currently mainly applied to functional diseases related to the nervous system, which is closely related to the

pelvic floor muscles. It can promote the pelvic floor muscle tension by electrically stimulating the sympathetic nerve and sphincter. At the same time, patients should have conscious self-muscle training to exercise muscle movement, enhance muscle strength, and relieve muscle tension, to achieve the effect of analgesia[7]. The principle of biofeedback therapy in the treatment of FARP(Figure1).

As far as the current research is concerned, no systematic and effective consensus has been reached on the etiology and mechanism of FARP. At present, the tacit explanations can be divided into the following four categories in Table 2.

Table 2: The etiology and pathogenesis of FARP.

Etiology and pathogenesis	Concrete content
Social and psychological factors	The rectum itself has a very low sensitivity to pain, which can be almost ignored. Because it is regulated and controlled by the vegetative nerves, there is no contradiction between the theory and actual pain symptoms. Now many studies also classify FARP as neurosis, and it is classified as a physical and mental disease.
Abnormality of pudendal nerve	Some foreign studies have found that most patients often suffer from blunt pain in the perineum, and cords or indurations appear in the anus and rectum, resulting in imbalance of local muscle strength distribution. Once excessive traction occurs, different degrees of pain will be caused.
Sphincter and pelvic floor muscle dysfunction	It has been found in many clinical treatments that anorectal pain is related to abnormal pelvic floor muscle contraction.
Genetic factors	—

There are many treatment methods for this disease. In recent years, some clinicians continuously believe that although biofeedback therapy has many irreplaceable advantages, such as non-invasive and non-painful and no side effects, which can be repeatedly used for treatment, its treatment efficiency needs to be further improved. Some people have summarized the efficacy of clinical treatment of FARP, and the effect of using only one therapy is not as good as that of a combined comprehensive treatment[8]. However, TCM combined with biofeedback therapy has been found in clinical applications to effectively improve the efficacy and make up for the deficiencies. It plays a special role in the treatment of FARP, and its strength cannot be ignored.

2. Overview of TCM Understanding of Functional Anorectal Pain

At present, many opinions classify the names of "large intestine pain" "Gu Dao pain" and "anal pain" into FARP. However, according to the Chinese ancient literature, the contents of the mentioned anal pain basically include anorectal pain with primary disease or definite cause, such as incarceration of internal hemorrhoid, hematochezia due to hemorrhoids or constipation, diarrhea and anal fissure. They are not completely consistent with the FARP we define today(see Table3). Hence, they cannot be generalized and are far-fetched. Since the exact correspondence cannot be found in the name of the disease, we can seek a breakthrough from the perspective of TCM syndrome to seize the manifestation of pain. From the understanding of pain in Huangdi's Canon of Medicine to the development and summary of later generations of physicians, the theory of "impassability makes pain, dystrophy makes pain " in TCM for pain-related diseases has been widely recognized. It is actually the understanding of pain from both deficiency and excess. Mr. Ding Zemin[9] believes that in the clinical syndrome differentiation of this disease, the deficiency

excess should be distinguished first, and then the cold and heat, Qi and blood should be distinguished. Therefore, it is suggested that the disease should be treated with appropriate attack and reinforcement. Professor Zheng[10] also believed that the key point of syndrome differentiation of this disease lay in deficiency-excess syndrome, and further proposed that deficiency syndrome was the main pathogenesis of this disease, and deficiency-excess syndrome combined with chronic disease. Ye Tianshi , a famous doctor in Qing Dynasty, puts forward another viewpoint of "penetrating pain of the collaterals for a long time" in Guide to Clinical Medical Records. In fact, acupuncture has a long history of treating pain diseases. Some people have summarized the studies on acupuncture treatment of FARP in recent years and believe that there are still many studies on acupuncture treatment for this disease, but no consensus has been reached[11]. TCM has a consistent understanding of the theory, method, formula, and hub for diseases. The treatment also focuses on the pathogenesis, mainly focusing on the use of Chinese medicine prescriptions based on syndrome differentiation and the application of acupuncture and moxibustion, which reflects the characteristics of TCM treatment.

Table 3: Examples of comparison between anorectal pain-related disease names in ancient books and modern disease names.

Names of diseases in ancient books	Original text	The titles of the ancient books	Modern names of diseases
Large intestine pain	“Treat stool with blood, large intestine swelling, pain can not bear, swollen anus.”	Jishi Quanshu	Hemorrhoids with blood stool
	“Diarrhea and large intestine pain,the acupoints of Juxu and Shanglian main treatment.”	The ABC Classic of Acupuncture and Moxibustion	Diarrhea
Gu Dao pain	“...this recipe is specially used to treat walking crotch pain and Gu Dao pain.”	Zhu’s collection of medical prescriptions	Acute stage of hemorrhoids
	“There is a prescription for hemorrhoids and Gu Dao pain,boil the almonds into a paste andexternal application.”	Classified Materia Medica	Incarceration of internal hemorrhoids
Anal pain	“Treat fever, diarrhea, abdominal pain, even anal pain to death.”	Prescriptions for Universal Relief	Diarrhea
	“Excrete a few dry shits, the anal is painful and split.”	Treatise on seasonal diseases	Cositipation, Anal fissure

3. The Specific Efficacy of Biofeedback Therapy Combined with TCM in the Treatment of FARP

3.1. Biofeedback Therapy Combined with Oral Prescriptions in TCM

The essence of Chinese medicine oral prescription lies in the strong TCM system based on syndrome differentiation, holistic view. Generally, patients are classified according to the population or syndrome type, so they can use herbal medicine more accurately. Moreover, patients and diseases are regarded as a whole. The combination of biofeedback therapy and Chinese medicine oral prescriptions can alleviate the main pain symptoms, target the related population and patients' constitutions, and improve other related uncomfortable symptoms. Dong Ruoxi and Wang

Min et al.[12] randomly divided 60 elderly patients with FARP into an observation group using biofeedback therapy alone and the control group using biofeedback therapy in combination with Shaoyao Gancao Decoction and Ganmai Dazao Decoction. The results showed that the total effective rate, VAS score, and various indicators of anorectal pressure in the observation group were superior to those in the control group after treatment. It could be proved that the combined treatment was safe and did not increase the risk additionally, but also improved the bad mood while alleviating the pain symptoms of the patients. Li Li and Huang Shuai et al.[13] randomly grouped 38 cases of FARP by comparing the Danggui Shaoyao Powder combined with biofeedback treatment plan and the simple biofeedback treatment plan, and combining with the clinical cases, they drew the conclusion that both treatment plans could effectively reduce the pain in patients. The biofeedback therapy in this study was based on improving the blood supply and circulation of pelvic floor muscles, and combining the properties of Danggui Shaoyao Powder in promoting qi and blood circulation, which not only enhanced the pain relief effect but also significantly improved the constipation and stool traits of patients. Wu Afen and Li Ming et al.[14] divided 60 cases of FARP patients into two groups. By comparing the pelvic floor surface myoelectric value, VAS score, and total effective rate, they came to the conclusion that Xiaoyao Powder combined with biofeedback therapy had a better effect on the treatment of FARP due to liver depression and qi stagnation. Compared with biofeedback therapy alone, it had obvious advantages, and the patients' experience was more comfortable, and the operation of the treatment process was simple. Bai Yan, Wang Bo et al.[15] adopted the self-made Shengti Jieyu Decoction combined with biofeedback treatment, and selected 84 clinical cases of FARP patients for analysis. The research results showed that the total effective rate of self-made Shengti Jieyu Decoction combined with biofeedback therapy was 20% higher than that of biofeedback therapy alone. Yao Sijie[16] selected 88 eligible subjects and randomly and equally divided them into Study 1 of Zhitong Rushen Decoction and Study 2 of Zhitong Rushen Decoction combined with biofeedback treatment with a computer system. The results showed that patients in the two groups had the same incidence rate of adverse reactions of 2.27%. The total effective rate (88.64%) in Study 2 was higher than that in Study 1 (65.91%), and the recurrence rate (6.82%) at six-month follow-up was lower than that in Study 1 (22.73%). Conclusion: Zhitong Rushen Decoction combined with biofeedback therapy is safe and reliable in alleviating anorectal pain and reducing recurrence rate. Yao Jia[17] divided 60 cases of FARP patients into a study group and a control group. The results showed that Buzhong Yiqi Decoction combined with biofeedback therapy had better efficacy in the treatment of FARP patients with collapse of middle Qi, and it could effectively help to improve the pelvic floor muscle contraction function.

3.2. Biofeedback Therapy Combined with External Therapy of TCM

TCM external therapy is mainly used to treat FARP through fumigation, washing, and sitz bath. The fumigation washing is also beneficial to alleviate the anxiety and tension of patients, to improve the pain caused by local muscle spasms. The fumigation washing and sitz bath is safer through the external application of herbs than oral administration and surgical treatment. Most of the clinical prescriptions are based on the principle of activating blood and resolving stasis with be modified, mainly considering the pathogenesis of "stasis makes impassability, and impassability makes pain". Xu Shengyan[18] randomly divided 80 cases of FARP patients into one treatment group and one control group, 40 cases in each group. The control group was trained with simple biofeedback therapy. The treatment group was additionally treated with Zhitong Rushen Decoction for fumigation washing of the perianal region based on biofeedback training. In the prescription of Zhitong Rushen Decoction, the role of Taoren, Danggui, Dahuang is promoting blood circulation to

relieve pain, the effect of Qinjiao, Cangzhu, Fangfeng, Huangbai is drying dampness and relieving itching, the water detumescence efficacy is brought by Zexie and Binlang. The results of the study showed that the efficacy of the combination of the two was superior to that of biofeedback treatment alone, and there was no adverse side effects and risks. Zhong Zhifeng and Cai Cheng et al.[19] collected 100 cases of FARP patients and divided them into an observation group and a control group. They adopted biofeedback therapy in combination with Shugang Decoction, warm water sitz bath, and simple biofeedback therapy. The Shugang Decoction used in this research method is a modified version of the classical prescription of Zhitong Rushen Decoction by plused or reduced herbs. Yuanhu and Zhiqiao are added to relieve pain and inflammation, Baijiangcao and Daxueteng are augmented by clear away heat and toxic materials, the effect of Jixueteng is improving blood supply and reducing edema. Through clinical observation and comparison, the total effective rate (92.0%) of the observation group were significantly higher than that of the control group (74.0%). This study showed that the efficacy of biofeedback therapy combined with Sitz bath with Shugang Decoction in the treatment of FARP is better than that of simple biofeedback therapy.

3.3. Biological Feedback Therapy Combined with Acupuncture and Moxibustion Therapy in TCM

TCM acupuncture and moxibustion therapy of FARP mainly refers to acupuncture therapy, which includes traditional acupuncture, electroacupuncture, and acupoint injection. The selection of acupoints are concentrated on Baliao, Changqiang (GV 1), Yaoshu (GV 2), perianal local acupoints and characteristic empirical acupoints (see the figure 2 for specific acupoints).

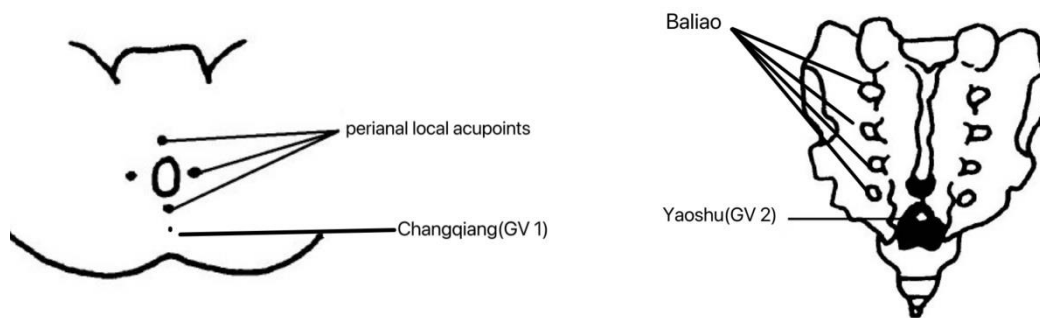


Figure 2: Related acupoints diagram.

Hui Xiaosu and Xu Yue et al.[20] selected 60 patients according to the Roman IV diagnostic criteria for FARP and divided them into the electroacupuncture at the Dongs unique extra-ordinary acupoints group, biofeedback group, and combination therapy group. The experimental results showed that there was no significant difference in VAS scores and SF-36 quality of life scale scores among the three groups before and after treatment. However, the total effective rate (80%) and SF-36 quality of life scale score in the combination treatment group were higher than those in the other two groups (40% and 50%, respectively). The results indicated that biofeedback therapy combined with electroacupuncture at the Dongs unique extra-ordinary acupoints could effectively relieve the depression and anxiety of patients, and the synergistic analgesic effect was better. In the research by Zheng Ling and Ding Shu Qing et al.[21], the data of 142 patients with FARP who have

been treated with biofeedback therapy combined with Chinese acupuncture were obtained through follow-up. The total effective rates in the short and long terms for the treatment of FARP were 85.9%(122/142) and 75.2%(76/101), and the patients' total satisfaction rates in the short and long terms were 92.3%(131/142) and 84.2%(85/101). These results indicated that biofeedback therapy combined with acupuncture had reliable efficacy in the treatment of FARP, and patients' satisfaction with the efficacy was also high. Yu Yongduo and Yin Linghui et al.[22] observed the clinical efficacy of 48 patients with FARP by dividing them into the simple biofeedback treatment group, the simple electroacupuncture treatment group, and the combination treatment group. Baliao was selected as the main electroacupuncture acupoints, and ashi points, Shenshu (BL 23), Sanjiaoshu (BL 22), Zusanli (ST 36), Sanyinjiao (SP 6), Neiguan (PC 6) and Shenmen (HT 7) were added according to the specific situation. The results of the study showed that all three groups had therapeutic effects, but the efficacy of the combined treatment regimen in the third group was significantly better than that in the former two groups. Qi Lianshan, Yang Dequn et al.[23] adopted a randomized controlled trial to study 60 patients with FARP and found that the total effective rate of patients with FARP treated through biofeedback therapy combined with compound Danggui injection injected at Changqiang acupoint and local region around the anus was 93.33%, which was much higher than 70.00% of patients treated with biofeedback therapy alone. Moreover, the combined therapy had the advantages of minimal invasion, simplicity, and low cost, and it had clinical applicability.

There are not as many moxibustion therapies for FARP as acupuncture in clinic. Xie Changying and Xiao Huirong et al.[24] adopted a randomized controlled trial to study 100 cases of FARP patients. The control group was treated with simple biofeedback therapy, and the treatment group was treated with biofeedback therapy in combination with heat-sensitive moxibustion, which utilizes its functions of activating blood and dredging collaterals, moving qi and relieving pain, warming and dredging meridians to stimulate the sensing between meridians. The acupoints were selected from the local area around Changqiang (GV 1), Yaoshu (GV 2), Ciliao (BL 32), and ashi points. The mobile moxibustion, bird-pecking moxibustion, reciprocating moxibustion, and warm moxibustion were first explored for the thermal sensitivity of the acupoints in sequence. After the acupoints became thermal sensitive, the warm moxibustion was used to continue the treatment. Observation result: the total effective rate of 92.0% in the treatment group is clearly higher than that of 70.0% in the control group, and no adverse reaction is cause. These results indicated that the biofeedback therapy combined with heat-sensitive moxibustion in TCM was effective and reliable in the treatment of FARP.

4. Discussion and Outlook

This study has shown that biofeedback therapy still plays an important role in the treatment of FARP, but the clinical efficacy of simply using biofeedback therapy is limited. Many clinical trials and studies have proved that TCM plays a good role in the comprehensive treatment of FARP in combination, which is a good precedent and demonstration of the integration of traditional Chinese medicine and western medicine in modern medicine. Since the mechanism of western medicine research on this disease is still unclear, treatment safety is an essential consideration in clinical practice. The advantages of biofeedback therapy lie in its safety and reusability. TCM has long-term experience and reliable efficacy in pain recognition. TCM and biofeedback therapy complement each other and work synergistically. However, the specific application of clinical exploration in this area is not enough and the total system size is small. In future clinical trials, efforts are expected to be made to expand the sample size and extend the trial time. The research on TCM classification and syndrome differentiation of this disease is conducive to improving the specific efficacy of

different groups of patients in clinical practice. Other symptoms related to pain, such as constipation and anxiety, should be considered in the treatment. It can be expected that more forms and deeper explorations will occur in the combination of biofeedback therapy and TCM for the treatment of FARP, to provide clinicians with a larger scope and more paradigm choices in their future treatment options. This also indicates that clinicians should attach importance to the integration of traditional Chinese medicine and western medicine, the combination of drug and non-drug treatment, the combination of physical therapy and mental psychotherapy, and should select different treatment methods to cooperate with the comprehensive treatment according to the actual situation of patients, to avoid blindly doing regular and uniform treatment.

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