THINKING AND METHODS

The Role of Acupuncture Treatment in Obstructed Defecation Syndrome

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ABSTRACT Background: Obstructed defecation syndrome (ODS) is a group of symptoms that are mainly caused by pelvic floor dysfunction concerning bowel symptoms. It is challenging in clinical practice. Acupuncture has advantages in the treatment of complex symptoms because of its multi-target and bi-directional regulation of the human body. Since 2500 years ago, acupuncture has been applied empirically to the treatment of constipation. Does acupuncture have any effect on ODS? Objectives: By showing the clinical thoughts, methods, and achievements of acupuncture series in ODS in recent ten years by the author's team, and two scientific papers published in English on acupuncture treatment of chronic intractable constipation and stress urinary incontinence, it is proved that the core scheme of acupuncture treatment of defecation disorder syndrome (ODS) is flexible. In order to raise awareness of the therapeutic effect of acupuncture in ODS, it can be integrated into existing practice to get opportunities for multidisciplinary cooperation and further research and development. Materials and Methods: By summarizing the diagnosis and treatment of ODS, the first-line selection of pelvic floor rehabilitation and the minimally invasive sacral neuromodulation were reviewed, and it was pointed out that there was a gap between the high demand of patients and the expectation of cost-effectiveness. Then, on the basis of modern eastern and western medical achievements, the holistic concept was introduced into the treatment of pelvic floor dysfunction, and an acupuncture scheme suitable for ODS was proposed. Results: Acupuncture is based on the idea of improving the patients' central nervous system, autonomic nervous system and intestinal nervous system, and is effective in treating ODS. The acupoints were set two groups when patient in supine position, which includes ST 25 (Tianshu), SP 15 (Daheng), SP 14 (Fujie), CV 6 (Qihai), CV 4 (Guanyuan), ST 36 (Zusanli), ST 37 (Shangjuxu); When patient is in prone position, it includes BL 20 (Pishu), BL 23 (Shenshu), BL 25 (Dachangshu), BL 33 (Zhongliao), BL 34 (Xialiao), and GV 20 (Baihui). The key was the technique of deep needling of the ST 25 (Tianshu) and deep needling of the BL 33 (Zhongliao) & BL 34 (Xialiao). It needs 2-15 Hz sparse-dense wave electrical stimulation, 30 minutes each time, a total of 20 times, which was a scheme that could achieve satisfactory short-term and long-term effects. Conclusion: At present, clinical and basic experimental studies have proved that acupuncture plays a role in treating ODS in a multi-target way. This is a very promising research direction of pelvic floor integrated medicine. In the future, further study on optimizing the protocol and meeting the patient's gap individually and cost-effectively.

KEYWORDS Acupuncture; Obstructive Defecation Syndrome; Pelvic floor symptoms; Constipation; Protocol; Electronic stimulation; Sacral nerve modulation; Pelvic floor rehabilitation

INTRODUCTION

Obstructed Defecation Syndrome (ODS) is a type of constipation, which is a kind of pelvic floor

dysfunction disease mainly complains of bowel symptoms, which is characterized by fragmented stools, over straining at defecation, sense of incomplete evacuation, tenesmus, urgency, pelvic heaviness and self-digitation[1].

Pelvic floor is a functional unit connecting bladder, uterus, rectum and other organs through muscles and ligaments, which is controlled by the same nervous system at different levels. The functions of any organs in pelvic floor are balanced with each other, rather than exist alone. In addition to the above-mentioned defecation symptoms, patients may also have overlapping existing urination, pelvic floor relaxation and sexual symptoms.

Patients usually can't get satisfactory results from general lifestyle changes, fiber diet, exercise and laxatives. Some patients may even become addicted to taking laxatives, suppository or rectal irrigation. It greatly affected patients' quality of life physically and mentally.

Western medicine doctors may recommend patients to physiotherapists for pelvic floor biofeedback therapy, which is the first choice recognized by gastroenterology^[2] and colorectal^[3]. However, patients may easily quit from the frustrated specialist behavioral training for some reasons.

Some selected patients may benefit from the sacral neuromodulation (SNM), a minimally invasive surgical technique, with a total success rate of 73%. It is promising but still not well accepted worldwide mainly due to the cost-effectiveness and complications from the device and operation itself^[4].

In 2008, the author^[5] published the preliminary research results of acupuncture treatment in obstructive defecation syndrome (ODS) in China, and conducted a series of studies later^[6,7], which showed that acupuncture in ODS had advantages combining with the abovementioned methods^[8].

It is hoped that through further multidisciplinary cooperation and multi-center research, acupuncture will be applied and popularized effectively in pelvic floor disorders.

OBSTRUCTED DEFECATION SYNDROME (ODS)

Symptoms and Pathophysiology

Obstructed defecation syndrome (ODS) is a type of constipation, which is a kind of pelvic floor dysfunction disease mainly complains of bowel symptoms, which is characterized by fragmented stools, over straining at defecation, sense of incomplete evacuation, tenesmus, urgency, pelvic heaviness and self-digitation^[1].

ODS is frequently encountered in colonrectal, gastroenterology or gynecology clinic. According to Rome II Criteria of functional gastrointestinal disorders, the incidence of chronic functional constipatio is 6.07% to 11.5% in China general population, double incidence in aged female patients. Almost over 60% of the constipation patients contributes obstructed defecation syndrome (ODS)^[8].

Based on the pelvic floor integral theory from Petros and Ulmsten put forward for the first time in 1990s, pelvic floor is regarded as a functional unit connecting bladder, uterus, rectum and other organs through muscles and ligaments, which is controlled by the same nervous system at different levels. The functions of any organs in pelvic floor are balanced with each other, rather than exist alone^[9]. So in addition to the above-mentioned defecation symptoms, ODS patients may also have existing overlapping urination, pelvic floor organ prolapse and sexual symptoms.

Other related pathophysiological factors also involved the pelvic floor dysfunction, including the muscle system (puborectalis muscle and/ or the internal anal sphincter can't relax during defecation), peripheral nervous system (sacral parasympathetic nerve and/or pudendal nerve neuropathy)^[10,11], central nervous system (Parkinson's disease^[12]), and psychological or behavioral issues^[13] etc.

Diagnosis and Evaluation

ODS is a challenging disease, a well-trained multidisciplinary team is needed in the pelvic floor

center. The diagnosis of ODS is based on a careful evaluation of the clinical history of patients. The severity of symptoms may be objectively evaluated using a validated score^[14]. After testing, ODS is defined as three major subtypes of constipation, which are usually identified as normal colonic transit, slow transit and functional defecation or not. Digital rectal examination is a useful bedside tool for evaluating functional defecation, which is used to identify dyssynergia and rectocele, and is convenient to select patients for further confirmatory physiology testing^[15], including anorectal manometry, transanal or transperineal dynamic ultrasound[16], magnetic resonance imaging defecography[17], and psychological evaluation which may offer the morphological and functional abnormal evidence of the patients[18].

Then ODS can have subsets like dyssynergic defecation, pelvic floor relaxation and mixed. Dyssynergic defecation is most often associated with an inability to coordinate abdominal, rectoanal, and pelvic floor muscles during defecation. The condition often represents an acquired behavioral disorder. On rectal examination, the patient may have a high resting pressure, and on bear down descent may be poor or paradoxical. Pelvic floor relaxation patients may have a normal or lower resting tone, and on bear down perineum descent great, may manifest rectocele, intussusception even pelvic organ prolapse of rectum, enterssueption, uterus, or bladder.

Suffered from severe chronic defecation symptoms, patients may have psychological issue. In our a 90 cases research on chronic functional constipation, 35 (38.9%) cases have the problem, of which 14 cases are mild to moderate depression while 21 cases are severe depression and anxiety, almost all the patients have sleeping dysfunction. Additionally note fatigue weak and some of female patients may have menstruation shortage or weight loss due to endocrine or nutrition dysfunction^[8]. Although not directly life threaten, this psychosomatic disease adversely affects a patient's social and personal life as 4"D" as abbreviation of discomfort, depression, dollar costs and drug toxicity.

Pelvic Floor Rehabilitation

In view of the complexity of etiology, pathology and overlapping symptoms, a multidisciplinary approach seems to be the key^[1], which requires a holistic method to fix the functional balance, namely pelvic floor rehabilitation.

Basically, the ODS patients can not get satisfactory results from the management for constipation, such as changing life style, fiber diet, exercise, laxatives, etc., And some patients may even take more laxatives, suppository, or rectal irrigation for temporary relief. It greatly affects patients' quality of life physically and mentally.

Being safe and none invasive, pelvic floor biofeedback therapy has been considered as the first choice on ODS for rehabilitation in western medicine. Recommended by international guidelines on gastroenterology^[2] and colorectal^[3]. This kind of retraining from maladaptive behavior can improve the defecation effect by learning, and help patients to cultivate a better understanding of pelvic floor muscle self-control and brain-gut reflex reconstruction.

A successful biofeedback therapy requires proper cognitive preparation, guidance and instruction before using the instrument. The success of biofeedback depends on appropriate patient selection, the well trained therapist and treatment compliance. Biofeedback effectively relieves symptoms of defecatory disorders in 69% of affected adults^[19]. Therefore, if patients have mental disability or have severe anxiety and depression, they may have no ability or motivation to fulfill the repeated trial and error training, or if they can't get the encouragement from a well-trained therapist, they may easily quit from the frustrated behavioral treatment^[20].

Sacral Nerve Modulation

If the patients are dissatisfied with non-surgical treatment, some selected patients may benefit from the sacral nerve modulation (SNM), it has shown great potential in treating pelvic floor dysfunction in recent decades^[21]. The minimum invasive procedure includes two stages. Initially, an electrode

was implanted into the posterior sacral foramen (mostly the right S3) to stimulate the sacral nerve roots, a temporary electrode lead is connected to a portable battery unit outside the body. After 2-3 weeks testing, if symptoms are improved more than 50%, the second stage operation is feasible, this is replaced by the implanted battery for permanent stimulation.

A systematic review^[21] assessed the therapeutic effects of chronic constipation. There are 13 studies using SNM in chronic constipation all over the world, and the success rate in the first stage is 42% -100%. then 87% patients improved after the permanent implantation, and the average follow-up time was 28 months. Another systematic review showed that the total "success rate 'of patients who received permanent implantation was 73%, and the removal rate of instruments was about 12%^[4]. The balance of risk versus benefit must be fully understood by patients and clinicians, and realistic expectations set out before treatment^[4].

It is promising but still not well accepted worldwide mainly due to the cost-effectiveness and complications from the device and operation itself as well.

On the basis of ODS clinical research and management update, the multidisciplinary pelvic floor team of Nanjing University of Traditional Chinese Medicine and National Center of Integrated Colorectal Surgery started to carry out acupuncture research in the "sacral nerve modulation era" in 2005.

Most of the original works were published in Chinese. This is the first original paper on teamwork and achievement published in English since then. The authors will exhibit a set of acupuncture protocols based on clinical trials and research evidence or animal studies finding, combining with the authors' expertise to meet the gap of patients' needs cost-effectively.

ACUPUNCTURE FOR ODS

Acupuncture based on traditional Chinese medicine treats patients as a whole. The first record

for constipation was from "Inner Canon of Yellow Emperor (Huangdi Neijing)" around 4700 years ago. It has been empirically practiced in China for several millennia, and the technique treating constipation is now being increasingly accepted by practitioners and patients worldwide, including United States^[22-23].

Acupuncture has bidirectional holistic and physiologic limit modulation effect in treatment. Bidirectional modulation, namely, an unbalanced (hyperactive or hypoactive) pathophysiological state can be normalized by acupuncture based on patient physique individually, it is not a purely excitatory or suppression process. Holistic modulation means acupuncture has multi-target and multi-system effect through meridians by adjusting the Yin and Yang^[24]. It is an option of complex pathological mechanism diseases like chronic constipation.

The goal of acupuncture program is to regulate the whole pelvic floor muscle and nerve function from the philosophy of Chinese medicine and Western medicine.

Acupoints Selection^[25]

The nervous system is composed of central nervous system (CNS), autonomic nervous system (sympathetic nervous system and parasympathetic nervous systems) and enteric nervous system (ENS). The selection of acupoints in the sacrum, lower abdomen, back and head is based on this design concept.

The first group set when patient in supine position, which includes ST 25 (Tianshu), SP 15 (Daheng), SP 14 (Fujie), CV 6 (Qihai), CV 4 (Guanyuan), ST 36 (Zusanli), ST 37 (Shangjuxu); The second group set when patient in prone position, which includes BL 20 (Pishu), BL 23 (Shenshu), BL 25 (Dachangshu), BL 33 (Zhongliao), BL 34 (Xialiao) and GV 20 (Baihui).

The most important acupoints are ST 25 (Tianshu), BL 33 (Zhongliao) & BL 34 (Xialiao) and GV 20 (Baihui) which respectively represent the regulation of ENS, ANS, and CNS.

Acupoint ST 25 Deep Needling Technique^[26]

Patients take the supine position, the acupoints ST 25 (Tianshu) is located two inches (50 mm) away from the navel, use needle (size 75 mm \times 0.30 mm) slowly penetrate 40-50 mm vertically in depth, according to the thickness of the patient abdominal wall until the needle tip reaches the peritoneal layer.

During the process of needle insertion, the operator feels heavy and a little resistance, and continues to deepen the needle. When there is an obvious breakthrough under the needle tip, the patient may feel pulled and then stop.

Compared with the shallow needle (the needle tip only enters the fascia layer, and did not penetrate the peritoneum), the deep needling has faster reaction.

Acupoints BL 33 & BL 34 Deep Needling Technique^[27]

Patient take the prone position, the acupoint BL 34 (Xialiao) and BL 33 (Zhongliao) are located in the 4th and 3rd sacral foramen, use needle (size $75\text{mm} \times 0.30\text{mm}/0.40\text{mm}$ or $100\text{mm} \times 0.30\text{mm}/0.40\text{mm}$) slowly penetrate 75-100mm into the anterior sacral foramen at 90° and 70° angles respectively.

Figure 1 shows the appearance of needles penetration. Figure 2 shows the needle position confirmed into the anterior sacral foramen in 3D-CT image, sagittal view).

When the needle is inserted deeply, the operator feels neat first and cross-section and sagittal view then sticky, but without resistance. At the same time, the patient may feel sore or heavy radiating to the anus or perineum. No severe pain, When the needle is inserted deeply, the operator may feel slippery at first, and then a little sticky, but without resistance. which is considered an important part of success. This technique is similar to implanting electrodes into the sacral foramen of the sacral neuromodulation procedure.

Appropriate Electronic Stimulation Parameter^[28]

Electroacupuncture was combined on BL 33







Abdominal Points for ENS

Back Points for ANS

Head Points for CNS

Figure 1. Shows the Appearance of Needles Penetration









Figure 2. Shows the Needle Position Confirmed into the Anterior Sacral Foramen in 3D-CT Image, Sagittal View

(Zhongliao) and BL 34 (Xialiao) when in prone position, while on ST 25 (Tianshu) and SP 14 (Daheng) when in supine position. Electroacupuncture apparatus (Han's, LH 202 H) was connected on the needle-handles by disperse-dense wave, 2/15 Hz and suitable intensity based on patients' tolerance, preferably with the skin around the acupoints shivering mildly without pain.

The parameters of electrical stimulation were set from a single center randomized controlled clinical trial. 2 Hz, 15 Hz, and 100 Hz were applied in ODS patients to investigate their difference. It was observed that symptom relief was better at 2 Hz and 15 Hz than at 100 Hz, and then sparse-dense wave of 2/15 Hz was determined^[29]. It is different from other parameters of patients with stress urinary incontinence (continuous wave of 50 Hz and a current intensity of 1 to 5 mA^[30]).

Course and Follow up

Routinely, the two sets of acupoints were used alternately, one set /day, with 20 sessions being a therapeutic course. Every session retain for 30 min once daily. After a 4-week acupuncture treatment, dyssynergic defecation usually responds better than

pelvic floor relaxation but if prolonged the treatment to 8 weeks, result reverse from our observation. So some patients maybe need prolong treatment course if acupuncture respond slow.

Resistance response may happen after good response during the treatment which is a period of poor reaction for whatever treatment use. After 1 or 2 weeks terminated interval, it will release and return to the effect or be better.

Patients were given follow up telephone calls at one and three months after conclusion treatment as scheduled by a research fellow. The follow up data requested including Wexner Constipation Scoring System^[31], stool consistence, awareness to defecate and PAC-QOL^[32] in the research. Other overlapping symptoms response may use other questionnaire accordingly.

Follow-up time is important and prolongs the treatment session intervals after the regular sessions, since function after acupuncture may deteriorate with time. Prolong the treatment interval to cease gradually is a way to obtain a long term efficacy. If symptoms return, acupuncture still works.

SUPPORTING EVIDENCE FOR ACUPUNCTURE PROTOCAL IN ODS

Clinical Evidence: ST 25 and ST 36 and Deep Needling for Severe Constipation^[33]

The author made a comprehensive exposition of the core acupoints in the above-mentioned ODS treatment, with emphasis on the functions and deep needling techniques of acupoints ST 25 and ST 36. This important result has been confirmed by a large paper entitled "Acupuncture Treatment of Chronic Severe Functional Constipation: Randomized Trial" published in the Western mainstream core journal "Annals of Internal Medicine" in the US.

This multicenter trial has 1075 participants from 13 hospitals, which shows that during the 8-week treatment period, electronic acupuncture can alleviate the symptoms of patients with chronic severe constipation and improve their quality of life; These effects persisted throughout the 12-week follow up.

Experimental Evidence: ST 25 and ST 36 Repair the ENS^[34]

In the experimental scientific research, by comparing the expression of protein markers in normal group, ENS neuropathy group, ENS neuropathy sham treatment group and ENS neuropathy acupuncture group, the author confirmed that acupoints ST 25 and ST 36 were beneficial to the recovery of intestinal function in enteric nervous system neuropathy model rats^[33]. Shown in Figure 3.

The expression of PGP 9.5 was a characteristic marker to evaluate the function of intestinal ganglion, shown by histopathological sections staining.

Clinical Evidence: Sacral Nerve Modulation by Acupuncture for Pelvic Floor Dysfunction^[30]

The author made a comprehensive exposition of the core acupoints in the above-mentioned ODS treatment, with emphasis on the functions and deep needling techniques of acupoints BL 33 & BL 34. This important result has been confirmed by a large paper entitled "Effect of Electroacupuncture on Urinary Leakage Among Women With Stress Urinary Incontinence A Randomized Clinical Trial" published in the Western mainstream core journal "JAMA(Impact factor 45.54 in 2019)" in the US.

This multicenter randomized clinical trial conducted at 12 hospitals in China and enrolling 504 women participants, participants were received 18 sessions (over 6 weeks), needles (size 0.30×75 mm,

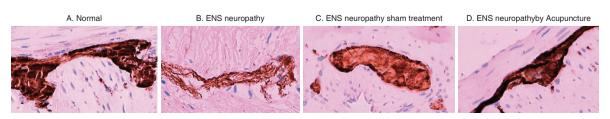


Figure 3. PGP9.5 Positive Expression in Rat Intestinal Myenteric Plexus (×400)

bilateral BL 33, located in the S3 foramen for 30 minutes.

Potential Pathophysiological Mechanisms

Acupuncture treatment for ODS is explained by two theories, the traditional meridian theory and the modern nerve-electrophysiology theory.

From the neuroanatomy point of view, human defecation function is dominated by central nerve system (CNS), autonomic nervous system (ANS) and enteric nervous system (ENS). ANS innervation comes from C6 to T2 and S2 to S4 segments of the spinal cord and controls the gastrointestinal function. It has been suggested that acupuncture could influence the visceral sensory system by stimulating the somatic sensory system. A series of investigations undertaken on somatoautonomic reflexes have provided good evidence of the importance of cutaneous input in autonomic control of GI motility[22]. The ENS takes its input from the intestine's myenteric plexus and Cajal cells, while CNS from the braingut axis. Stimulation of the corresponding points on the head (GV 20) and back (BL 23, BL 25, and BL 31-34, from the 1st to 4th sacral foramen respectively) and abdomen(ST 25, SP 14, SP 15, CV4 and CV6) will modulate the intestinal function.

It has been proven that stimulation of the sacral nerve can promote the colonic motility, and improve pelvic floor sensation^[4,21]. These neurophysiological findings^[35,36] influenced our selection of acupoints for clinical study. In our a 90 cases research on chronic functional constipation, over 90% patients have sleeping dysfunction. We found that the acupoint GV 20 can improve insomnia quickly, and has effect on bowel movement.

SUMMARY

Acupuncture has no requirements for ODS candidates, and it will react quickly compared to the pelvic floor biofeedback therapy. This is a minimally invasive, cost-effective, and flexible method compared to the sacral nerve modulation implantation procedure.

Acupuncture is a multi-target holistic therapy,

but it still has limitations for pelvic floor dysfunction. For different individuals, it is always necessary to optimize the treatment scheme or integrate other modalities.

In addition, acupuncture is not only a physical stimulus to the body but also a face-to-face communication process between doctors and patients in the daily treatment, which plays the role of psychological counseling. Besides, acupuncture itself can improve mental and sleeping disorders through neural regulation.

Acupuncture has important potential for treatment and to be integrated into Western Medicine. It is an evidence-based contribution to the treatment of patients, and it is a combination of systematic "Tao" and individualized "technique".

Enthusiasm for research is growing, and the cooperation of multidisciplinary teams will speed up the process of integrating acupuncture into conventional western medicine.

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