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Acupuncture in Treatment of Chronic Functional Constipation

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Abstract

Constipation is not only a symptom but is a predominant presenting symptom in many diseases. The prevalence is between 3 and 27% worldwide, and is especially prevalent in the elderly population. The aetiology is multifactorial. Laxative abuse or enema use are usually a norm in patients' constipation. Patients tend not to seek further medical aid after several unsuccessful therapies and this can seriously affect their quality of life.

Acupuncture based on Chinese Medicine approaches the patients holistically. While having experience and potential in treating this condition, it does meet Western Medicine's criteria for diagnosis and effectiveness, which are defined by evidence-based medicine. An integrative pelvic floor centre is a platform for offering a comprehensive diagnosis and treatment, and can further research and training. This chapter focuses on a multidisciplinary and integrated background to incorporate acupuncture as a treatment modality in chronic functional constipation with experience from a national colorectal centre in China with more than 20 years research and clinical experience in treating constipation. This includes using patient-reported outcome instruments in the evaluation of the role of acupuncture as a future treatment option.

Keywords: Chronic functional constipation, Acupuncture, Pelvic floor centre, Patient Report Outcome

1. Introduction

Constipation is not only a functional disorder, it is a major symptom in many diseases. The prevalence is between 3 and 27% worldwide, especially in the elderly population. Functional chronic constipation is defined by Rome III criteria, which comprises two or more abnormalities that must be present for at least three months during the previous year. After excluding a mechanical or secondary cause leading to constipation, these include fewer than three bowel movements per week, hard or lumpy stools, and straining at stools.

The aetiology is multifactorial. Patients do not seek medical aid usually because they lose hope, making laxative abuse or use of an enema (usually for refractory constipation) is common. Although not directly life threatening, this psychosomatic disease has four side-effects of discomfort, depression, dollar costs, and drug toxicity (4D, as an abbreviation), and these can seriously affect the patient's quality of life.

Acupuncture, based on Chinese Medicine, approaches the patient as a whole. The first record of constipation was from "Inner Canon of Yellow Emperor (Huangdi Neijing)" around 4700 years ago and other updated literature resources. While Chinese Medicine and practitioners have experience and potential in this condition, they do not exceed Western Medicine in effectiveness of diagnosis and treatment, based upon evidence-based medicine. An integrated pelvic floor centre is a platform offering comprehensive diagnosis and treatment for research and training.

This chapter focuses on a multidisciplinary and integrated background to highlight acupuncture as an adjunctive treatment option in chronic functional constipation, with data from a national colorectal centre in China with more than 20 years research in constipation, including clinical trials and research using patient-reported outcome instruments in the evaluation of acupuncture's future role.

2. Chronic functional constipation in western medicine

It is clear that constipation represents a major public health problem. The prevalence in North America is estimated between 3 and 27% [1], similar to China's 4 to 13% [2, 3], especially in the elderly population [4]. A large proportion of patients with constipation do not have a known cause and suffer from idiopathic constipation. The aetiology and pathophysiology is unclear and multifactorial[5], including diet or environmental issues, psychiatric disorders, metabolic and endocrine disorders such as hypothyroidism and diabetes, connective tissue disorders such as lupus and scleroderma, neurologic illness, and medication side-effects. Before labelling the symptoms as a functional disorder, pathologies that could cause obstruction should be excluded. Additionally, laxative abuse is a key factor associated with refractory constipation.

Two sets of formal criteria have been developed to define chronic functional constipation as a specific concept, as follows. One is the Rome III [6] diagnostic criteria, which comprises two

or more of the identified abnormalities, which must be present for at least three months during the previous year — fewer than three bowel movements per week, hard or lumpy stools, and straining more than 25% of the time. Other symptoms include a sensation of incomplete evacuation, or anorectal obstruction or blockage, or manual manoeuvres to facilitate the evacuation etc. Another criterion developed by the American College of Gastroenterology is a simpler and perhaps more clinically relevant definition. This defines unsatisfactory defecation as that characterized by infrequent bowel movements, difficult stool passage, or both. Patients can be further classified as belonging to subsets, such as slow transit constipation (motility disorders), irritable bowel syndrome (IBS), and obstructed defecation syndrome (ODS), or mixed subsets above in this chapter.

Traditional medical therapies for constipation include lifestyle changes, the intake of fibre, over the counter medication (magnesium hydroxide, lactulose, PEG 4000 bisacodyl, and senna), or phosphate enemas, among others. A recent review has shown that 15% of patients were completely satisfied and another 28% of patients were fairly satisfied, while a majority (51%) were “not particularly” or “not at all” satisfied with their medical therapy [7].

2.1. Slow-transit constipation

The main symptoms of slow-transit constipation (STC) are infrequent bowel movements fewer than three times per week, bloating, and abdominal cramping [8]. These symptoms need to be attributed to either the colon or to generalized symptoms affecting the colon as well as the stomach and small bowel. STC accounts for 16% to 40% of chronic constipation. Slow transit constipation may be due to abnormality of the myenteric plexus, associated with alteration of the interstitial cells of Cajal (ICC) and neuronal cells of the enteric nervous system [9,10]. Some research shows that it may derive partly from the anthraquinone laxative abuse [11,12].

2.2. Investigations

A diagnosis of slow transit constipation is usually done by a colonic transit study, described first by Arhan [13]. The methodology is not standardized in radiopaque marker and the abdomen plain X-ray film taken time. A positive result was defined as more than 20% of the radiopaque marker remaining on day five (120 h later), as indicative of slow transit time according to a plain X-ray film of the abdomen [14].

Other options for investigation of constipation include anorectal manometry, colonic scintigraphy, defecography, and use of a wireless motility capsule [15]. Patients are usually treated conservatively with exercise, diet modification, fibre supplementation, and laxatives or enemas. However, the success of controlling symptoms is unsatisfactory. Numerous patients choose cathartic stimulants such as phenolphthalein, rhubarb, senna, and aloe which contain anthraquinones, resulting in melanosis coli and affecting the intestinal nerves. Their side-effects make the symptoms complicated and challenging. When cathartic and other conservative measures fail, invasive treatment options are considered, including antegrade colonic enemas [16], sacral nerve stimulation [17], or subtotal colectomy to relieve the severe symptoms [18], and sometimes a stoma creation. Surgical excision of the colon can be successful in

50–75% of patients, but abdominal pain and constipation can reoccur and patients also run a risk of developing a post-operative small bowel obstruction or faecal urgency/incontinence [19]. Hence, surgery should be accepted in a very select population.

2.3. Constipation-predominant Irritable Bowel Syndrome (IBS-C)

Symptoms of IBS-C are usually associated with abdominal pain or discomfort, bloating, hard stools, fewer than three bowel movements per week, or straining, etc. The main characteristic difference from STC is discomfort that is relieved after defecation and the presence of normal-transit constipation. Some female patients have bowel symptoms that typically worsen immediately before their period and have tendencies to develop anxiety and depression.

Due to the heterogeneity of the symptoms, a single medication or treatment is usually insufficient to achieve symptom control, hence a more comprehensive strategy is required: including diet counselling, medications affecting prokinetic intestinal spasms, and treatment using mental and behavioural therapy, [20] etc. Treatment should be tailored to the patients' needs. The primary treatment of choice is fibre. Other laxatives recommended are lactulose, polyethylene glycol (PEG) 4000, etc. Some patients need a simultaneous supplement of probiotics. If the regimen fails for a time, or if patients develop tolerance to a therapy, a different agent or perhaps an additional treatment will be needed.

2.4. Obstructive Defecation Syndrome (ODS)

Obstructive Defecation Syndrome refers to a series of symptoms such as prolonged and repeated straining at bowel movements, the sensation of incomplete emptying, and the frequent need to support the perineum or the posterior vaginal wall in manual manoeuvres (digital disimpaction) [21]. ODS can have subsets such as dyssynergic defecation, pelvic floor relaxation etc. 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 behavioural disorder. On rectal examination, the patient may have a high resting pressure, and on bearing down, pelvic floor movement may be poor or paradoxical [22]. Pelvic floor relaxation patients may have a normal or lower resting tone, and on bearing down the perineum descends a great deal more and may manifest a rectocele, intussusceptions, or even pelvic organ prolapse of the rectum, uterus, or bladder [23]. Anal physiology testing – including anorectal manometry, cine defecography, anal ultrasound, and EMG findings – may uncover the morphological and functional abnormalities in order to diagnose the symptoms. Overlap between the various sub types of constipation can coexist. Relative subtleties such as rectal compliance, rectoanal inhibitory reflex, and balloon expulsion tests are perhaps less reliable, but abnormalities in these areas no doubt contribute to the overall assessment of the patient's function [24].

The spectrum of therapeutic options in obstructive defecation syndrome has developed in the last decade from nonsurgical to surgical. The first line of treatment is biofeedback therapy. Electromyography biofeedback is more popular but is not superior to pressure biofeedback. The success of biofeedback depends on appropriate patient selection, a well-trained therapist,

and treatment compliance. Biofeedback effectively relieves symptoms of defecatory disorders in 69% of affected adults [25]. It is more focused on the modulation of pelvic floor muscles and reflex dysfunction from behavioural or other secondary reasons.

Aetiologies like internal rectal prolapse (or intussusception) and rectocele are the primary or secondary pathologies of ODS, and surgical management provides some options for those patients who do not respond to more conservative treatment. These include stapled transanal rectal resection (STARR) [26,27], Transtar, laparoscopic ventral rectopexy [28], and sacral nerve stimulation [17,29], which have some benefits. However, these approaches are still associated with a significant expense and potential morbidity [30]. Their use must be tempered by the fact that benign conditions are being treated with the aim of improving quality of life. The balance of risk versus benefit must be fully understood by both patients and clinicians.

Patients and physicians have different criteria for defining and describing constipation. Accurate identification of the specific features of chronic constipation reduces the likelihood of unnecessary or inappropriate testing, and improves the chances of treatment success for currently available therapies which are not uniformly effective across all constipation subtypes [31].

Patients suffering from long-term constipation symptoms may have psychological issues. In our experience of 90 cases of chronic functional constipation, 35 (38.9%) cases have this problem, of which 14 cases are mild to moderate, while 21 cases are severe; almost all the patients have a sleeping dysfunction. Additionally we noted fatigue, weakness, and some female patients had menstruation disturbances or weight loss due to endocrine or nutritional dysfunction [32]. Although not directly life threatening, this psychosomatic disease adversely affects a patient's social and personal life as via the 4Ds: discomfort, depression, dollar costs, and drug toxicity.

3. Diagnosis and management of chronic functional constipation in Chinese herb medicine

Traditional Chinese Medicine (TCM) lists constipation as a symptom or syndrome, referring to infrequent bowel movements, a consistency that is too hard, and evacuation that is too difficult, which includes acute and chronic constipation. Chinese Medicine approaches the patient as a whole. Four methods of diagnosis are looking, listening, questioning, and feeling the pulse. Collecting data from asking the patients questions is essential, including: stools issue (sensation, consistence, interval time, colour, odour, and amount); occurrence; onset time, such as after childbirth, postpartum, menopause, or old age; the course of symptoms; how they alleviate the problem; and which accompanying symptoms such as abdominal distension, loss of appetite, fatigue, depression, insomnia, etc.

The basic aetiology and pathology of chronic constipation is abnormal not only in intestinal motility but is closely related to other whole organs and meridians, blood or body fluids, and mental or emotional functions. In diagnosis, the subsets' differentiation of constipa-

tion from Western Medicine's definition, combined with the syndrome differentiation (Zheng) from Traditional Chinese Medicine, have a unique advantage in clinical practice communication [33].

Five types of syndromes are identified as excessive heat and body fluid loss, liver and spleen disharmony of Qi stagnation, lung and spleen Qi deficiency, deficiency of liver-yin and kidney-yin, and Yang deficiency of spleen and kidney. The syndromes' processes are mainly deficiency oriented: Qi and Yin deficiency goes through and extends to yang deficiency, with pathogenic damping, heat, phlegm, and blood stasis products.

3.1. Excessive heat and body fluid loss

Patients sometimes have symptoms that are hard stools, scanty dark urine, anal burning, abdominal bloating, thirst and halitosis, red in the face and anxiety, dry and yellow coating tongue, and a fast and slippery pulse. Clear heat through bowel therapeutic principle is used, with the common herbs Gardenia jasminoides, Coptis, Scutellaria baicalensis, Citrus aurantium, and Peach kernel, etc.

3.2. Liver and spleen disharmony of Qi stagnation

Patients sometimes have symptoms that include the urge to defecate but a obstructed sensation, anal fullness, abdominal or chest distension, loss of appetite, frequent belching but incomplete flatus, pink and thin coating tongue and string pulse. Dispel melancholy and strengthen spleen Qi therapeutic principle is used. Common herbs used for treatment are Bupleurum, Radix Paeoniae Alba, Rhizoma Atractylodis Macrocephalae, Poria cocos, Chinese yam, etc.

3.3. Lung and spleen Qi deficiency

The symptoms are mainly an urge to defecate, with soft stools, but being too weak to push them out after exertion; sweating and loss of breath; fatigue; pale in the face and tongue; and a weak pulse. Invigorate Lung and Spleen Qi of the life essence therapeutic principle is used as the common herbs are Astragalus membranaceus, Codonopsis pilosula, Rhizoma alismatis, Fructus aurantii, Magnolia officinalis, Cimicifuga, Ge Gen, among others.

3.4. Liver-yin and kidney-yin deficiency

The symptoms include hard stools like chestnuts, a pale and dull appearance, delayed bowel movements about three days even one week, straining defecation, a reddish and thin coating on the tongue, and a weak pulse. Enriching body essence fluid of Liver and Kidney therapeutic principal is used as the common herbs are Figwort, Radix Rehmanniae Preparata, Ophiopogon japonicus, Cornus officinalis, Chinses Angelica, and Coptis cinnamon etc.

3.5. Yang deficiency of spleen and kidney

Symptoms include no urge to defecate or being too weak to push stools out; with sweating or lack of breath; chills; soreness and weakness of the waist and knees; use of laxatives; a pale, thick, and greasy tongue; and a deep, delayed pulse. Invigorating spleen and kidney warming Yang for relaxing the bowels is used, as the common herbs are Monkshood, Dried ginger, Epimedium, Allium macrostemon, and Pinellia, among others.

4. Perception of chronic functional constipation in acupuncture

Acupuncture based on Chinese Medicine, approaches the patients as a whole. The first record for constipation was from “Inner Canon of Yellow Emperor (Huangdi Neijing)” [34] around 4,700 years ago. He said “In case of abdominal fullness and difficulty in bowel movement, acupoints of the Kidney Meridian of Foot-Shaoyi are punctured” and “In case of occurrence of epigastric pain, abdominal distension and fullness, and constipation, Acupoints of the Spleen Meridian of Foot-Taiyin are punctured”. Other works include the Canon of Acumox-ibustion (Zhenjiu Jiayijing). Acupuncture has been practiced in China for several millennia, and the technique is now being increasingly accepted by practitioners and patients worldwide, including in the United States [35–37]. Since the side-effects of laxatives used over the long-term are not acceptable, and the outcomes after surgery are frequently unsatisfactory, alternative therapies to treat constipation are attractive to both patients and practitioners.

From Liu’s literature research [38], we know that constipation has been relevant to 229 ancient sources, with 148 acupoints involved. The most commonly used acupoints and meridians are listed in Table 1 and Table 2, as are the frequency or times of treatment. Constipation is identified as the first ranked disease spectrum in acupuncture therapy, meaning that only acupuncture can be efficacious in providing a clinical cure [39].

KI6 (Zhaohai)	SJ6 (Zhigou)	ST36 (Zusanli)	SP3 (Taibai)	LR13 (Zhangmen)	RN8 (Shenque)	BL25 (Dachangshu)
34	22	16	15	15	15	14
RN6 (Qihai)	KI3 (Taixi)	KI4 (Dazhong)	BL57 (Chenshan)	SP6 (Sanyinjiao)	BL28 (Pangguangshu)	KI1 (Yongquan)
13	11	10	9	8	8	8

Table 1. Acupoints’ frequency, using ancient literature on constipation

BL	KI	RN	SP	ST	LR	TE
93	80	65	54	39	30	25

Table 2. Acupoints’ frequency in meridians (times)

Due to its effectiveness and safety, acupuncture treatment in chronic functional constipation has gradually become accepted and is being now investigated. Before the treatment, the patient's history, symptom characteristics, severity, underlying causes, and a physical test should be reviewed by a well-trained multidisciplinary team able to offer a comprehensive protocol of acupuncture and other remedies. Based on our literature and clinical research, we are describing the research and clinical from our practice.

4.1. Acupoints' selection [32]

The acupoints used were divided in two different sets. Group Set 1 included: Bilateral ST25 (Tianshu), SP15 (Daheng), SP14 (Fujie), CV6 (Qihai), CV4 (Guanyuan), ST36 (Zusanli), and ST37 (Shangjuxu). Group Set 2 included: Bilateral BL20 (Pishu), BL23 (Shenshu), BL25 (Dachangshu), BL33 (Zhongliao), BL34 (Xialiao), and GV20 (Baihui).

4.2. Local points and direct stimulation

ST25 (Tianshu) is the Front-mu point of the large intestine and BL25 (Dachangshu) is the Back-shu point of the large intestine. The locations of the points meet the extension of the large intestine on the body's surface. They are close to the Zang-fu organ and are the most directly effective acupoints for the treatment of dysfunction of the large intestine. Concerning the distribution of nerve segments, the nerve segment of BL25 (Dachangshu) is distributed at L3 and that of ST25 (Tianshu) is at T10, which correspond to the distribution of nerve segments from T10 to L3 and the sacral plexus [40]. The pilot research of Ding et al. [15], titled "Effect of acupuncture on neurons in the intestinal nervous system in rats", verified, through the protein gene product 9.5 (PGP 9.5), that acupuncture assisted the improvement of ganglion cell function after the destruction of neurons in the intestinal nervous system.

4.3. Local points and indirect stimulation, BL33 and BL34

Miraculous Pivot: Nine Needles and Twelve Yuan Points (Lingshu: Jiuzhen Shier Yuan) stated that: "Key to needling is qi arrival". By manipulating the piercing direction and distance, the needling sensation is transmitted to the diseases sites, which maintains a satisfactory result. Constipation of dyssynergic defecation and pelvic floor relaxation is partially due to dysfunction of the pelvic floor muscles. After puncturing at BL33 (Zhongliao) and BL34 (Xialiao), the needling sensation may be conducted to the perineum. Patients may usually feel a tightening or lifting sensation in the sacrococcygeal region or around the anus and/or vagina, which becomes much more obvious with electric stimulation. BL33 (Zhongliao) and BL34 (Xialiao) are located in the sacral region, which are the nearest ones to the area (S2–S4) in which the pelvic nerve has an input in the junior defecation control system. The stimulated S4 reaction induces anus contraction and a lifting sensation of the perineum [41]. Hence, acupuncture on BL33 (Zhongliao) and BL34 (Xialiao) modulate the motion and function of pelvic floor muscle, probably by exciting the relevant nerves. Due to the variability of the human sacrum, exact positioning and punching deep in the sacral foramen still requires further research [42].

4.4. Combination of distal points and holistic regulation

From Chinese Medicine theory, constipation pathogens lie in the large intestine, lung, liver, spleen, and kidneys. Combination of distal points has two roles: firstly, indicating the disorders located on the distal of the running course of the affected meridian, like ST36 (Zusanli) and ST37 (Shangjuxu) are applied for disorder of the abdomen. BL57 (Chengshan) is divergent to the anus. Secondly, based on syndrome differentiation and holistic regulation, like KI6 (Zhaohai) communicates with the Yin Heel Vessel that dominates yin in the whole body. KI6 (Zhaohai) can nourish yin and promote bowel movement. In the “two-element holographic unit” theory, the internal malleolus corresponds to the umbilicus, and BL57 (Chengshan) is corresponds to the anus. Hence, the distal point in the lower limb can treat constipation [38]. Cao et al. [43], by applying electric stimulation at ST36 (Zusanli) on rats, discovered that colon substance P (SP) content increased significantly and that gastrointestinal motility was promoted. The effect of the combination of the nearby points and the distal points is better than that achieved by only treating the distal points.

4.5. Communicating with Du Meridian in regulating mental conditions

The incidence of abnormal mental disorders is high in cases of chronic constipation. In addition, patients with chronic functional constipation often also experienced varying degrees of psychological or emotional issues having an effect on sleep; this complicated the situation due to the prolongation of sickness. It was reported by Nehra et al. [44] that 65% of the patients with stool disturbance and constipation suffered from psychological disorders. In research into 90 cases of chronic constipation, 34 cases (38.9%) accounted for 37.8% confirmed diagnoses of depression and anxiety by psychiatric doctors, in which slow transit constipation and dyssynergic defecation patients accounted for 40% and 56.7%, respectively [32]. Slow transit constipation patients lack in confidence in the treatment of the long-term disease and respond poorly to usual medical management. This may be the reason of increased psychological issues in these patients. If patients get a good and rapid response from acupuncture, the psychological disorder will accordingly gradually get released. Anxiety or depression is common in dyssynergic defecation patients, which may increase the pelvic floor muscle tension and paradoxical contraction in defecation, boosting a psychological vicious circle. If it is combined with psychological counselling or psychiatric medication in some candidates, then efficiency and patient tolerance will be improved.

Modern research [45] has proved that the intestinal tract is controlled by the central nervous system, with the involvement of the brain-gut axis. Acupuncture was applied to GV20 (Baihui), GV14 (Dazhui), GV10 (Lingtai), and others to modulate Qi of the Du Meridian, to promote Yang in the meridian, nourish the brain, and regulate sleeping and mood. Moreover, the needling technique of qi conduction could enhance the relieving of psychological issue. Zhang et al. [46] found that acupuncture could increase the content of 5-hydroxytryptamine (5-HT) of model rats, and modulate the norepinephrine (NE) and 5-HT which two substances were related to alleviate depression.

4.6. Technique

A supine posture was required in the treatment using Group Set 1 and a prone position was required in the treatment using Group Set 2. A disposable needle of Hwato brand, 0.32 mm × 75 mm, was selected and prepared. After routine sterilization of local skin, the needles were inserted perpendicularly at ST25 (Tianshu), SP15 (Daheng), SP14 (Fujie), and BL25 (Dachangshu), 40 to 50mm in depth, and the even needling technique was applied after the arrival of Qi. Perpendicular puncturing was applied to CV6 (Qihai), CV4 (Guanyuan), and BL23 (Shenshu), 40 mm in depth, and to BL20 (Pishu), 13 to 25 mm in depth. The reinforcing technique was used after the arrival of Qi. Perpendicular puncturing was applied to ST36 (Zusanli) and ST37 (Shangjuxu), 25 to 40 mm in depth and the even needling technique was used after the arrival of Qi. The lifting, thrusting, and rotating technique was applied to GV20 (Baihui) at a low frequency and small amplitude, operated for two or three minutes. In BL33 (Zhongliao), BL34 (Xialiao), after being inserted into the posterior foramen, oblique puncture was applied, 65 mm in depth with the tip toward the medial aspect and the base of thigh. The angle of 30° was formed between the needle body and the longitudinal axle of the human body, and 60° was formed with the skin. The even needling technique was used after the arrival of Qi to ensure the needling sensation was radiating to the anus or perineum. Deep puncturing of abdominal acupoints is usually used in slow transit constipation patients to improve intestine motility. Obstructive defecation syndrome(ODS) also needs deep puncturing of BL33 (Zhongliao) and BL34 (Xialiao) in the sacral foramen. Irritable bowel syndrome needs shallow puncturing for gut hypersensitivity.

Electroacupuncture was combined on BL33 (Zhongliao), BL34 (Xialiao), ST25 (Tianshu), and ST37 (Shangjuxu). Electroacupuncture apparatus (Han's, LH 202 H) was connected to the needle-handles by disperse-dense wave, 2/15 Hz and at a suitable intensity based on patients' tolerance.

4.7. Course and follow-up

Routinely, the two sets of acupoints were used alternately, one set per day, with 20 sessions being a therapeutic course. Every session lasts for 30 minutes, once daily. Comparing a four-week acupuncture treatment period satisfaction between the dyssynergic defecation patients and pelvic floor relaxation patients, usually the former group responded better, but if the treatment period prolonged to eight weeks, the latter group would be better. It means some patients maybe need a prolonged treatment course if the efficacy displayed slow. Another phenomenon may observed in some patients of the "acupuncture resistance phenomenon", which means that at the beginning of the acupuncture treatment period patients have a good response but when acupuncture continued, symptoms recur despite other new additional treatments added. In these cases, it is beneficial to temporarily stop acupuncture for around one or two weeks interval and then continue the sessions. This results in the return of the previous good effects.

Patients were followed up with telephone calls at one and three months after the conclusion of treatment by a research fellow. The follow-up data included the Wexner Constipation Score [47], stool consistency, awareness of defecatio and PAC-QOL (Patient Assessment of Consti-

pation Quality of Life questionnaire) [48]. Follow-up time is important and prolongs the treatment session intervals after the regular sessions, since functionality after acupuncture may deteriorate with time. Prolonging the treatment interval to come to a gradual cessation is a way to obtain long-term efficacy. If symptoms recur, acupuncture is still effective.

4.8. Difference of effects

Acupuncture has bidirectional holistic and physiological limit modulation effects in treatment. Bidirectional modulation, namely, an unbalanced (hyperactive or hypoactive) pathophysiological state can be normalized by acupuncture based on the patient's individual physique; it is not a purely excitatory or suppression process [49]. Holistic modulation means acupuncture has multi-target and multi-system effects through meridians by adjusting the Yin and Yang [50]. Acupoints and meridians have specific roles to play in the human body. It is an option in treating complex pathological mechanism diseases such as chronic constipation. For example, the Stomach Meridian of Foot-Yangming and the Bladder Meridian of Foot Taiyang go through the abdomen and back, respectively; the effect will reach the meridian site in which chronic constipation pathological changes are mostly involved. Physiological limit modulation means regulation depends on the relevant organ structure's integrity and potential functional reserve. Symptoms are the patient's clinical manifestations of the disease, which generally has similar symptoms and pathology, but the same disease at different stages, or patients in different functional states, will exhibit the differences individually. Acupuncture protocol design should consider the difference may affect the treatment results, such as needle instruments; acupoints combination; treatment timing and course; reinforcement and reduction needling technique; electroacupuncture parameters; and patients' physiological, pathological, or psychological states, etc. Another concerning is how to design the control group. For acupuncture, the control method could be pseudo-acupuncture or no treatment. However, because of the nature of acupuncture, such methods are difficult to operate.

Acupuncture treatment for chronic constipation is explained by two theories, the traditional meridian theory and the modern nerve-electrophysiology theory. From the neuroanatomy point of view, human colonic function is dominated by the central nervous 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 [34]. The ENS takes its input from the intestine's myenteric plexus and Cajal cells, while CNS involves the brain-gut axis. Stimulation of the corresponding points on the head (GV20 or EX-PN1) and back (BL23, BL25, and BL31–34, from the first to the fourth sacral foramen, respectively) and abdomen (ST25, SP14, SP15, CV4, and CV6) will modulate the intestinal function. It has been proven that stimulation of the sacral nerve can promote colonic motility, and improve pelvic floor sensation [17,51]. Brain imaging studies have demonstrated two potential routes of pain modulation by acupuncture via deactivation of descending nociceptive pathways and by decreased limbic activity during acupoint

stimulation [52]. These neurophysiological findings [53,54] influenced our selection of acupoints for clinical study. In our research on 90 cases of chronic functional constipation, over 90% of patients have dysfunctional sleep. We found that the acupoint GV20 or EX-PN can improve insomnia quickly, and has an effect on bowel movement (unpublished data).

STC and IBS-C are subsets of constipation, the symptoms mainly localized in the colon. The former is due to colon motility weakness whereas the latter is due to gut hypersensitivity and spasms. Dyssynergic defecation and pelvic floor relaxation symptoms are localized in the rectum and pelvic floor. The pelvic floor is composed of muscles and ligaments that connect with three different compartments, including the bladder and urethra, vagina and uterus, and rectum and anus. All of these organs are controlled in the same central nervous system. Etiology of constipation from pelvic floor dysfunction is quite complicated, such as from behavioral or reflex loss etc. If it is not optimized by acupuncture, combination with other methods, such as moxibustion [55] and cupping [56], is recommended. Concerning the different dynamic mechanisms of constipation, the electroacupuncture parameters (frequency, waveform, and stimulation intensity) should be optioned rationally [57].

“Acupuncture resistance phenomenon” may be solved by postponing treatment sessions for one or two weeks if it occurs [58]. Related health education should be emphasized and offered as part of the treatment. When a patient has finished treatment in hospital, home training, acupoint pressure, and other remedies may prolong the short-term results. Jin’s research [32] showed short-term efficacy rank in constipation subsets was: STC, IBS-C, and either dysynergic defecation or pelvic floor relaxation by acupuncture.

Chronic constipation is challenging in clinical practice. Patients may abuse laxatives, have insomnia, anorexia, and psychological issues, among other problems, and have a poorer quality of life than healthy people [32]. Acupuncture is a potential resource and form of treatment, when integrated into Western Medicine in diagnosis, and evidence-based medical treatment and research. It is appealing for research, and can be included into standard protocols to be carried out in multidisciplinary pelvic floor centers.

5. Multidisciplinary model implement

For patients’ overlapping symptoms, as mentioned above, an effective pelvic floor multidisciplinary team (MDT) needs to be introduced for a comprehensive and efficient treatment. Our clinical experience has demonstrated the advantages of promoting acupuncture research in this context.

5.1. Organization

In a leading pelvic floor centre, a leader’s interest and training in managing this group of patients who are challenging and demanding is the first step. Besides a pelvic floor physiologist, gastroenterologist, and a specialist nurse who undertakes diagnostic evaluation of pelvic

floor abnormalities and optimizes conservative management, surgical input from the colorectal, urological, and gynaecological teams is essential. Psychologists, biofeedback rehabilitation experts, and a dedicated dietician are needed to give accurate advice to some long-term intractable patients. It is clear that those with complex issues often need a novel approach to managing the physical and psychological symptoms with appropriate experts. A well-trained acupuncturist is the key for successful treatment. The importance of the MDT cannot be overstated and it is the basis for a rigorous case presentation and discussion, consensus decision making, and mutual education. Multidisciplinary environments are places where individuals can be counselled and advised on diagnosis, treatment options, and realistic outcomes. For accurate assessment of ODS, a specialist in radiology of defecography, dynamic pelvic magnetic resonance imaging (MRI), or dynamic ultrasound for routine reporting of these studies, are also required.

Initially, the study can begin at a constipation specialist clinic, which reviews patients and refers some to the MDT, to discuss interesting or challenging cases and make decisions at a monthly meeting. Furthermore, many trainees are searching for comprehensive experience and this is rewarded by the presence of interested juniors and visitors, and is also essential for the research fellow's efforts in data collecting.

5.2. Questionnaires and database

The ability, and indeed the desire, to unearth underlying constipation pathology is dependent on carefully gathering a history, and putting simple and pertinent questions to the patient. For example, one must look deeper into why a 70-year-old woman presents with a sudden onset of constipation and haemorrhoidal symptoms. After ruling out cancer, questionnaires will unearth longstanding issues relating to bowel function that can be attributed to pelvic floor dysfunction. A systematic approach to history taking, particularly with the routine incorporation of a quality of life instrument, also lays the foundation for a system of structured prospective data collection and audit. Examples of a simple structured questionnaire are the Wexner constipation severity score. Clues to this may be found in bowel habits that have become excessive, with repeated visits to the toilet due to incomplete emptying, the requirement of assisting defecation by supporting the perineum or posterior vaginal wall, or the presence of post-defecatory soiling in the absence of significant urge incontinence. These are some key factors that suggest existing pelvic floor problems, frequently resulting from rectal intussusception or pelvic floor relaxation syndrome. Thus, a real potential cause of constipation can be found in these conditions. This relies on the standard history questionnaires being logically extended to standardized means of follow-up assessment, using quality of life instruments.

If, in the research stage, all data is collected by research fellows who do not participate in any aspect of patient care but are only responsible for data collection, then the result can be the collection of unbiased data. The data are then imported into a customized database which includes items about the patient's history, symptoms, investigations, treatment protocol, bowel diary, and follow-up data monitored by therapist and nurses. The doctor in charge is responsible for treatment protocols and management.

5.3. Efficacy evaluation methodology

There is little clinical consensus about the appropriateness of acupuncture in treating constipation. Many outcome measures were used to assess its effectiveness and there is as yet a lack of evidence as to which outcome measures are the most appropriate. Heterogeneous data-points in research are: varying signs and symptoms; lack of use of a standardized constipation severity instrument (Wexner Constipation Scoring System [47]: with this system the increasing severity of constipation correlates to increased scores); lack of accordingly technique or protocol of different constipation subsets; treatment sessions and other interventions combined; research designs; and the efficacy perceptions of the patients and doctors.

Patient requested	STC		IBS-C		Dyssynergic Defecation		Pelvic Floor Relaxation	
	Pre-	Post-	Pre-	Post-	Pre-	Post-	Pre-	Post-
<i>Days with spontaneous bowel movements</i>	√√√	*****	√√	NS	√√√	**	-	-
<i>Straining severity</i>	-	-	√√√	*****	√√	NS	√√√	**
<i>Minutes per bowel movement</i>	√√	NS	-	-	√√	NS	√√	NS
<i>Incomplete evacuation sensation</i>	√√	NS	√√	***	√√√	**	√√√	*
<i>Stool consistency</i>	√√	*****	√√√	*****	√√	NS	√√	NS
<i>Awareness of defecation</i>	√√	NS	-	-	-	-	-	-
<i>Bloating score</i>	√√	***	√√	**	√√	NS	√√	NS

*Data from Nanjing Pelvic Floor Center: a 90 cases questionnaire research in 2007. Patients received the same acupuncture protocol and the endpoint was after 20 completed sessions.

STC: Slow transit constipation. IBS-C: Constipation-predominant Irritable Bowel Syndrome.

Pre-acupuncture treatment: √√√: means patient request most to release symptom rank over 50%. √√: means patient request most to release symptom rank over 30% and less than 50%. -: means not mentioned or less than 30% patients' choice..

Post-acupuncture treatment: *****, ***, **, *, *: means rating the improved symptoms in the four subsets and itself before treatment respectively ($P < 0.001$). NS: means no significance.

Table 3. Patients' chief complaint ranking of chronic functional constipation subsets (pre- and post-acupuncture treatment)

Besides those listed above, different efficacy evaluation objectives lead to inconsistencies in various research reporting. For example, to evaluate STARR in obstructed defecation syndrome, the primary responder endpoint collection is the obstructed defecation score (ODS) reduction $\geq 50\%$ at one year, the secondary endpoint is PAC-QOL (Patient Assessment of Constipation Quality of Life questionnaire) and a continence grading scale. (The operation may result in faecal incontinence and this needs to be demonstrated [59]. The same efficacy evaluation parameters, however, are not suitable for acupuncture treatment.)

Thirdly, the Wexner Constipation Scoring System offers the total score of the main symptoms. Patients' chief complaints, however, frequently lie in the subsets, as our research has shown in Table 3. Thus different primary and secondary endpoint parameter weights vary if the Wexner CSS is used, resulting in some bias. Physiology and morphology test findings have a poor relation to the treatment results. Therefore, it is necessary to establish a symptom domain and score weight instrument for constipation subsets evaluation. This will facilitate assessing the results of the same regimen in different subsets, as well as different regimens in the same subset.

6. General effect criteria

Most of the trials reported an effective rate on a four-point scale [33], namely:

Clinical recovery, that is complete disappearance of the symptoms that the patients were most keen to resolve.

Marked improvement, where the symptoms that patients required most to be dealt with were alleviated by over two thirds as compared with the period before treatment.

General improvement, where the symptoms that patients required most to be dealt with were alleviated by one third, but less than two thirds as compared with pre-treatment.

No improvement, meaning the symptoms that patients required most to be dealt with were alleviated by less than one third as compared with pre-treatment.

Jin's clinical efficacy data on acupuncture in chronic functional constipation (n=90) showed [32], total efficacy was achieved in 61 cases (67.7%), of which three cases were a clinical recovery (3.3%), 10 cases showed marked improvement (11.1%), 48 cases showed general improvement (53.3%), and 29 cases showed no change (32.3%).

7. Patient-reported outcomes

For acupuncture, the merits are multiple factor modulations according to the patient's individual bodily constitution as defined by Chinese Medicine Theory. Evidence-based medicine requires blind, randomized controlled research data collecting, but this is controversial and inconsistent with methods in acupuncture. While patient-reported outcomes are measurements of any aspect of a patient's health status coming directly from the patient [60], such measurements may encourage clinicians to focus more on the patient as an entity rather than as an organ system [61]. For constipation patients, information collected using standardized questionnaires may facilitate detection of physical or psychological problems that might otherwise be overlooked. PRO measurement in clinical care may also be used to monitor outcomes as a strategy for quality improvement, or to reward presumed superior care [62]. Disease-specific Patient-Reported Outcomes questionnaire can be adopted for the efficacious assessment for the symptoms that patients required most to improve.

7.1. Seven specific symptoms score on constipation

Days with a spontaneous bowel movement: once every one or two days: Score = 0; once every three or four days: Score = 1; once every five or six days: Score = 2 ; once in a period longer than six days: Score = 3; inability of natural defecation without the aid of a drug, manipulation, or an enema: Score = 4. Patients recorded the bowel movements (yes/no) during the treatment period. The responses were divided into three time periods, to reflect the progress of treatment, and the days with bowel movements were calculated for each week of treatment.

Straining severity: without strain: Score = 0; defecation with a little effort: Score = 1; defecation with great effort: Score = 2; difficult defecation and need of assistance: Score = 3.

Minutes per bowel movement: 1–10 min: Score = 0; 11–20 min: Score = 1; over 20 min: Score = 2.

Incomplete evacuation sensation: no sense: Score = 0; mild sense: Score = 1; obvious sense: Score = 2; intolerable sense: Score = 3.

Stool consistency: like a sausage, smooth and soft: Score = 0; like a sausage, with cracks or soft: Score = 1; hard piece: Score = 2; separate hard lumps: Score = 3.

Symptoms	Pre-treatment	Post-treatment
<i>Days with spontaneous bowel movement</i>	2.19±1.76	0.87±1.43*
<i>Straining severity</i>	2.39±0.83	1.30±1.04*
<i>Minutes per bowel movement</i>	1.41±0.82	0.69±0.78*
<i>Incomplete evacuation sensation</i>	1.62±0.76	0.92±0.76*
<i>Stool consistency</i>	1.84±1.04	0.54±0.74*
<i>Awareness of defecation</i>	0.34±0.48	0.02±0.15*
<i>Bloating score</i>	2.15±0.39	0.87±0.32*

* Symptoms' score reduced after acupuncture treatment (All P value <0.01).

Table 4. Seven specific symptoms' scores on constipation in acupuncture (Score)

Awareness of defecation: Patients recorded an urge to defecate as either "yes" or "no" each day during the treatment period. Having the sense: Score = 0; no sense: Score = 1.

Bloating score: Patients were asked to assess the subjective degree of bloating according to the following scale: no bloating: Score = 0; mild bloating: Score = 1; moderate bloating: Score = 2; severe bloating: Score = 3. The responses were divided into three time periods, to reflect the progress of the treatment's effect, and the mean bloating score was calculated for each week of treatment.

In a 90 case study [32] of the Nanjing Pelvic Floor Center, seven symptoms' scores reduced after acupuncture, as shown in Table 4.

7.2. Patient Assessment of Constipation Quality of Life Questionnaire (PAC-QOL)

The PAC-QOL is a brief but comprehensive assessment of the burden of constipation on patients' everyday functioning and well-being. Multinational studies have demonstrated that the PAC-QOL is internally consistent, reproducible, valid, and responsive to improvements over time [63]. Its assessment includes four subcategories: worries/concerns, physical discomfort, psychosocial discomfort, and satisfaction. There are 28 items, which are classified into five grades from a mild degree to a severe one, corresponding to scores of 1–5 point, respectively. The total score is 117, and the higher the score the worse the quality of life [48]. It has also been translated into Chinese and validated by the author [64]. The questionnaires were administered before and after treatment follow-up. All of the questionnaires were completed by patients during the study period.

It is preferred at our centre, that a specific symptom questionnaire on constipation subsets efficacy assessment — which usually includes symptoms such as frequency of spontaneous bowel movements, straining severity, minutes per bowel movement, incomplete evacuation sensation, stool consistency, awareness of defecation, and quality of life — is conducted using a PAC-QOL, both before and after treatment.

Groups		Physical	Psychosocial	Worries	Satisfaction	Total
Control (n=90)		5.92±2.41	13.04±5.84	15.86±1.03	8.10±0.57	42.92±17.72
STC(n=20)	Pre-	14.36±3.0#	20.93±8.27*	39.07±3.12#	16.50±1.77#	90.86±6.70 [†]
	Post-	9.00±3.46*	13.43±3.31	24.00±8.41*	11.29±2.36	57.71±15.00*
IBS-C(n=16)	Pre-	11.88±2.90#	17.63±6.99#	28.75±3.48#	16.38±1.36 [†]	74.63±6.61 [†]
	Post-	7.67±2.42*	12.50±4.32	18.00±4.05*	11.17±5.27	49.33±8.71*
Dyssynergic Defecation (n=30)	Pre-	11.96±3.01#	18.54±5.70#	34.54±1.73#	17.13±0.95 [†]	82.17±3.57 [†]
	Post-	10.64±3.25	16.29±5.06*	29.21±10.42*	12.79±4.25*	68.93±16.96*
Pelvic Floor Relaxation (n=24)	Pre-	12.44±3.11#	15.94±2.12	32.33±3.72#	16.59±1.07 [†]	73.53±5.50 [†]
	Post-	9.20±3.67*	13.07±5.161	23.47±8.07*	12.87±3.72*	58.60±4.25*

#: Constipation four subsets PAC-QOL pre-acupuncture treatment vs. normal control (90 healthy adults matched the year and gender of the constipation subsets group), P<0.01

*: Constipation four subsets PAC-QOL pre- and post-acupuncture treatment, P<0.05.

Table 5. Chronic functional constipation PAC-QOL Score (pre- and post-treatment vs. normal control)

Although the total score showed improvement, compared with the normal control group, it was still high and it was difficult to return patients to normal functioning. GII use PGWB (the Psychological General Well-Being) and GSRS (the Gastrointestinal Symptom Rating Scale) to evaluate the QOL of 102 constipation patients (mean score: 85.5 vs. 102.9), the result of which is similar to our research [65].

7.3. Chronic Constipation PRO Rating Scale (CC-PRO)

Although PAC-QOL is a well-used patient reported outcome questionnaire in constipation efficacy evaluation, it is still insufficient in revealing the advantages and quality of life of acupuncture treatment as the Chinese cultural background difference.

Chronic Constipation PRO Rating Scale (CC-PRO) was designed by our centre's research team [66], following the PRO guideline frame from FDA [60], in order to establish a comprehensive index system combining symptoms and syndromes from Chinese Medicine theory. The implementation process included establishing a theoretical model of the questionnaire from four domains: physiological aspects (specific symptoms of chronic constipation and effectiveness index of syndrome), psychological aspects, social function aspects, and patients' satisfaction. We collected popular expressions on chronic constipation from searching the Chinese language literature; interviewing patients with different educational levels, genders, and ages; and establishing a 96 items pool of the draft questionnaire. After two rounds of screening the items from physicians and patients, the questionnaire reduced to 45 items in four domains, which included physiological aspects was 29 items, psychological aspects was 9 items, social function aspects was 3 items and patient's satisfaction aspect was 4 items accordingly. After a multicentral trial enrolling 521 chronic constipation patients and 76 healthy adults as a control, and completion of the questionnaire, its reliability, validity and responsibility were tested, and the four-level rating scale was determined as: slightly poor ($88 < \text{total score} \leq 121$), poor ($121 < \text{total score} \leq 160$), very poor ($160 < \text{total score} \leq 199$), and quite poor ($\text{total score} > 199$), which compared to the normal ($\text{total score} \leq 88$). For now, only the Chinese version is updated, and further application of acupuncture before and after treatment is on the way [67].

8. Conclusion

Laxative abuse can cause damage to the intestinal structure, damage function, and aggravate constipation, whereas acupuncture is a safe and a non-toxic choice with no side-effects. Biofeedback therapy is a form of behavioural management and is the first line of therapy for obstructive defecation syndrome patients. Candidates need much cognition and compliance to participate in a relatively long-term training programme to reset physical reflexes. Acupuncture demands little from the patients but can achieve a fairly quick response if applied appropriately. Compared to herbal medicine, acupuncture is not only a physical stimulation for the body but a face-to-face doctor-patient communication process, which involves the role of psychological counselling in daily treatment. Acupuncture itself can also improve mental and sleeping disorders through neural regulation.

Acupuncture should not be perceived as just a needling technique depending on the individual's needs; other therapies integrated in a timely fashion can also improve efficacy because the capacity of a human body to self-adjust and repair has certain limits. For those long-term and complicated patients facing a plateau in their condition, when only acupuncture has limitation in modulation, other remedies can compensate and fully arouse the body's potential regulation system.

Optimized protocols with different acupuncture techniques, integrated to accommodate different subsets of chronic constipation, to meet the patients' characters and best indications is the best practice we need. From our clinical experience, if the patient does not respond to acupuncture, then with biofeedback, electrical stimulation, herb medicine, or moxibustion

maybe still have desired effects. However, if one of the therapies is partially successful in integrating, others may shorten the working threshold time and enhance efficacy. Whether or not to integrate acupuncture for long-term efficacy is still pending further study.

Optimizing the best indication, choosing the acupoints, manipulating (needling technique, depth of insertion, electroacupuncture etc), and investigating the mechanism of action are required works later. Enthusiasm for research is growing, and collaboration in a multidisciplinary group will speed up this development. In the near future, the efficacy of modern acupuncture treatment protocols based on Patient-Reported Outcomes can treat not only chronic constipation but be extended to other functional gastrointestinal disorders, such as faecal incontinence, functional pelvic pain, and others.

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