

Takagi award - winning paper

## Effect of Acupuncture and Moxibustion in Patients with Irritable Bowel Syndrome -A series of single case study-

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### Abstract

**[Objective]** Irritable bowel syndrome (IBS) is one of the most common gastrointestinal disorders. Many cases with IBS often resist conventional treatment and seek alternative therapies to manage the condition. This study investigates the clinical effects of acupuncture and moxibustion treatment in patients with IBS through a series of single-case study design..

**[Subjects & Methods]** Four patients who had suffered from IBS for more than four years and had been medicated for more than half a year without sufficient recovery were treated with acupuncture and moxibustion according to the theory of Traditional Chinese Medicine. Ten or twenty sessions of acupuncture and moxibustion therapies were performed during a treatment period ("period B"), and alternated with a non-treatment period ("period A") (ABAB design). To evaluate bowel movement disturbance, intensity of abdominal pain or bloating, frequency of defecation and condition of the stool were recorded in bowel diaries. Their psychological state and quality of life (QOL) were also evaluated.

**[Results & Discussion]** During period B, three of four patients showed a significant improvement in abdominal pain, bloating and QOL, and doses of medication were decreased in two patients, while their psychological state showed inconsistent changes.

The results of this study with periods of treatment or non-treatment indicated that acupuncture and moxibustion may be effective in improving the condition of patients with IBS, such as abdominal pain and QOL.

**Key words:** Irritable bowel syndrome, Abdominal pain, Acupuncture and moxibustion, Single case study, Reversal design

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### I . Introduction

Irritable bowel syndrome (IBS) shows symptoms of functional chronic bowel movement disturbance with abdominal pain and abdominal discomfort<sup>1-3)</sup>. Its mor-

bidity prevalence rate in advanced countries is about 10-15% of general populations and is the highest in gastrointestinal diseases. Declining quality of life (QOL) in patients with IBS is significant<sup>4-6)</sup>, which is sometimes reported to be lower than that of dialysis patients<sup>6)</sup>. So-

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cial issues such as high medical cost for the treatment or economic loss caused by sick leave are also profound so that patients with IBS are considered to have the most important therapeutic objectives in gastrointestinal diseases in the future<sup>1-3</sup>).

There are various reports regarding the therapeutic effects of acupuncture treatment to digestive systems<sup>7,8</sup>) and a few reports indicated that acupuncture and moxibustion treatment is clinically effective in patients with IBS<sup>9,10</sup>).

In this study, we performed acupuncture and moxibustion treatment on four patients with IBS and evaluated the clinical effects of the treatment on abdominal symptoms, psychological state and their QOL using the method of reversal design<sup>11</sup>).

## II. Subjects and Methods

### 1. Subjects

Subjects were patients in the outpatient department of

Table 1. Characteristics of the patients

Case	Age /sex	Disease condition	Disease duration (yr)	Abdominal symptoms	Frequency of defecation (mean/day)	Condition of stool	Medication	
							Contents	Period (month)
1	38/F	IBS	4	Abdominal pain Bloating	7	Loose to liquid stool	Meperzolate bromide Lactobacillus preparation Scopolamine butylbromide	8 8 as needed
2	44/F	IBS	4	Abdominal pain Bloating	1.6	Loose to liquid stool	Polycarbophil calcium	11
3	88/M	IBS	8	Abdominal pain Bloating	0.6	Loose to liquid stool	Trimebutine maleate Magnesium oxide Sennoside Metoclopramide	15 96 14 8
4	45/M	IBS	4	Abdominal pain Bloating	9.4	Loose stool	Polycarbophil calcium Loperamide hydrochloride	12 36

Table 2. TCM diagnosis, acupoints used and number of sessions in each treatment period

Case	TCM diagnosis	Acupoints used	Sessions/period
1	Disharmony between liver and spleen, Yang deficiency of spleen and kidney, Yin deficiency	Zusanli ST36, Ganshu BL18, Pishu BL20, Zhaohai KI6, Feishu BL13, Guanyuan CV4 (moxibustion)	20
2	Yang deficiency of spleen and kidney, Qi stagnation	Zusanli ST36, Pishu BL20, Shenshu BL23, Ganshu BL18, Baihui GV20, Guanyuan CV4 (moxibustion)	10
3	Yang deficiency of spleen and kidney	Zusanli ST36, Pishu BL20, Guanyuan CV4 (moxibustion), Taixi KI3 (moxibustion)	10
4	Disharmony between liver and spleen, Yang deficiency	Zusanli ST36, Ganshu BL18, Pishu BL20, Dachangshu BL25, Ciliao BL32, Sishencong Ex-HN1 (4 points that are spaced respectively 1 sun (3.03 cm) apart from each of the four sides of Baihui), Guanyuan CV4 (moxibustion)	20

internal medicine in the hospital of Meiji University of Oriental Medicine who were suffered from IBS for more than one year and had been treated with conventional medication for more than half a year without any clear improvement of their symptoms. Diagnosis of IBS was given according to Rome II<sup>1,2)</sup> criteria, excluding detectable organic diseases based on the findings of colonic endoscopy and blood chemistry data.

Four patients were investigated. Two of them were males and two were females. Mean ( $\pm$ SD) age of the subjects was  $53\pm 23$  years old. The characteristics of the four patients are shown in Table 1. In terms of disease duration, three patients had suffered for four years and one had suffered for eight years. Prior to enrollment, the purpose and procedure of the investigation were explained to all the subjects, and they were informed that they should take part in or leave this investigation on their own volition. Informed consent was obtained in writing form from all the patients. The protocol of the present study was approved from the Ethics Committee of Meiji University of Oriental Medicine.

## 2. Acupuncture and moxibustion therapy

In acupuncture and moxibustion treatment, each patient was diagnosed according to the TCM theory<sup>33)</sup> and acupoints were selected with consideration to the nature of the points. Treatment points and times of treatment session per intervention period are shown in Table 2. Needles used for acupuncture were 40 mm #16 (0.16mm in diameter) disposable stainless steel needles. Needles were retained for 10 minutes after deqi (dull or numb sensation around the needle) was obtained. No further stimulating technique such as twisting or tapping was given. Moxibustion was performed in the presence of yang deficiency to the meridian points which have an effect of warming yang on spleen or kidney function<sup>33)</sup> and also in which flaccidness and coldness were felt by palpation. In the moxibustion procedure, rice-grain sized moxa cones were lit and removed before they were burnt out (about 70% of the way burning) in order to avoid burn injury and they were applied in a row to treatment points until patients felt warm on the points. Approximately 10-20 moxa cones were applied at each point.

## 3. Study protocol

Reversal design<sup>11)</sup> in which observation period (period A) and intervention (acupuncture) period (period B) were alternatively repeated was employed in the present

study (ABAB design). Frequency of acupuncture and moxibustion treatment was set at once or twice a week and twenty therapies were used, in principle. For patients who had some difficulty visiting the hospital often, ten therapies were set for one period. The non-treatment period between two treatment periods was basically longer than that of treatment periods. However, if a patient requested starting treatment because of aggravation of symptoms during the non-treatment period, the treatment period was started at this point. During the non-treatment period, at least once in two weeks, patients were given a check such as interview and palpation without acupuncture and moxibustion treatment. The conditions for two periods would be almost the same except for acupuncture and moxibustion treatment. During the observation period the patients were examined by their physicians in the same way as that before participation in this study, once in two weeks to one month. A drug medication regimen for bowel movement disturbance was to be constant during the observation period. However, if the symptoms of patients were reduced or exacerbated remarkably, the physicians could change the medication. In both the acupuncture clinic and the internal medicine clinic, patients were not provided with any guidance about daily life matters such as diet on an outpatient basis.

## 4. Endpoint

### (1) Bowel Diary

Patients had to record their bowel conditions. Those are abdominal pain, bloating, frequency of defecation and condition of the stool every day in our original bowel diaries. Intensity of abdominal pain was expressed in five levels of 0 to 4 (0: no pain, 1: slight, 2: medium, 3: considerable but endurable pain, 4: very strong and unbearable pain) and degree of bloating was expressed in three levels of 0 to 2 (0: no bloating, 1: light, 2: strong). Condition of the stool was expressed in five levels of liquid stool, loose stool, normal stool, hard and heavy stool and scybalum, and was reported after each bowel movement on the bowel diaries.

Patients were also encouraged to write down special events, if any, such as their accompanying symptoms, remarkable changes in their diet, serious events in their daily lives and so on.

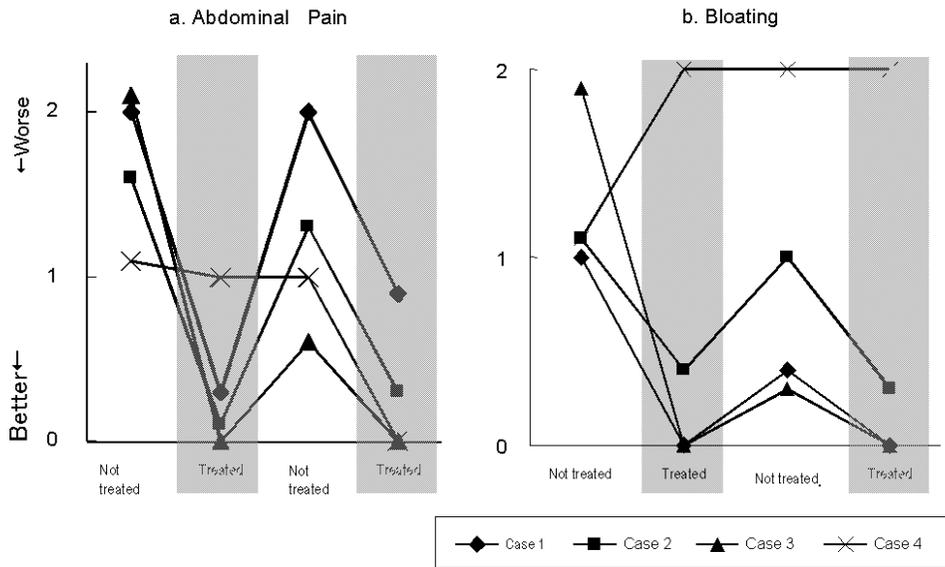


Figure 1. Changes in abdominal symptoms

Changes in abdominal pain (a) and bloating (b) are shown for all periods. The vertical axis shows the mean values of records in the bowel diary. The horizontal axis is a time axis, in which periods with or without acupuncture and moxibustion treatment are shown as Treated or Not treated, respectively.

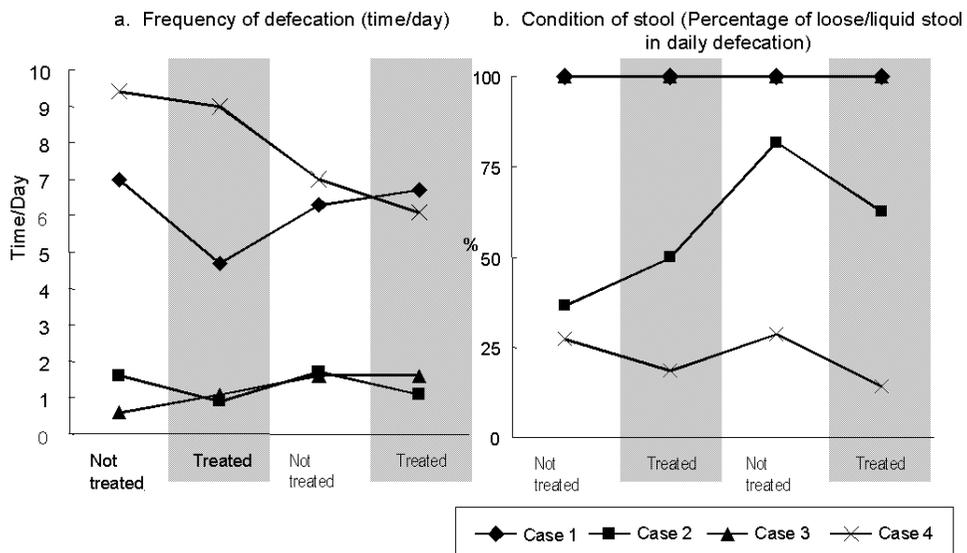


Figure 2. Changes in stool frequency and condition

Changes in frequency of defecation (a) and condition of the stool; loose to liquid stool (b) are shown for all periods. Frequency of defecation (a) and percentage (%) of liquid/loose stool in daily defecation (b) are shown on the vertical axis. The horizontal axis is a time axis, in which periods with or without acupuncture and moxibustion treatment are shown as Treated or Not treated, respectively.

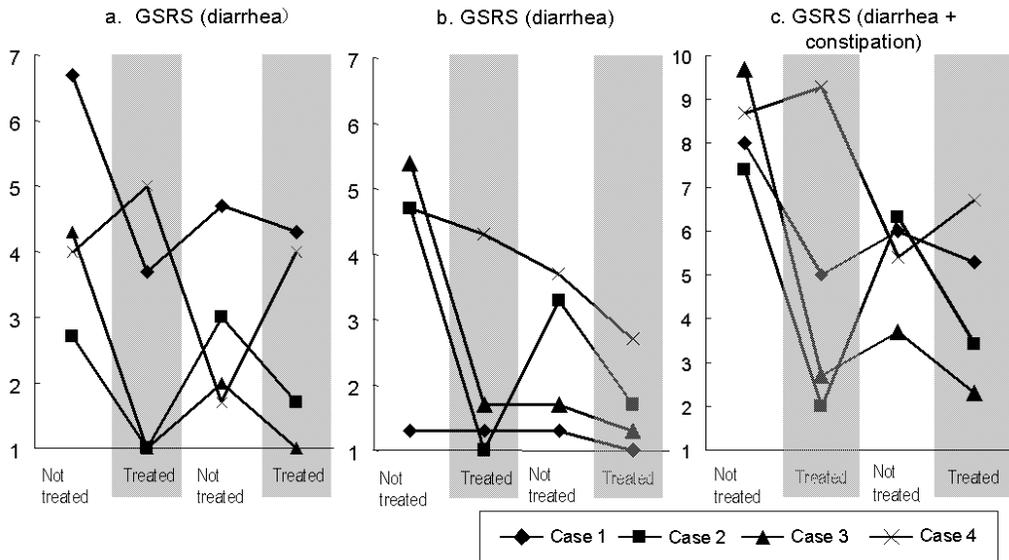


Figure 3. Changes in QOL

Changes in GRSRS on diarrhea (a), constipation (b) and sum of both scales are shown. The vertical axis of the graph is the GRSRS score, the horizontal axis is time, and acupuncture and moxibustion treatment period and non-treatment period are shown as “Treated” and “Not treated”, respectively. Score 1 of GRSRS indicates no influence on each digestive symptom on the daily life of patients, and score 7 indicates intolerable adverse effects on the daily life of patients.

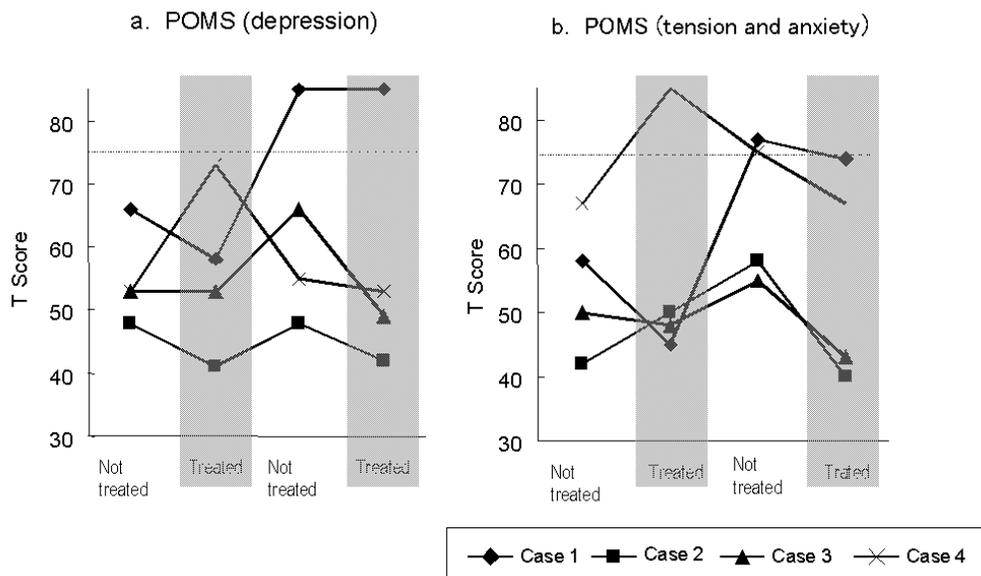


Figure 4. Changes in psychological state

Changes in POMS on depression (a) and anxiety/tension (b) are shown. The vertical axis on the graph is the T score of POMS, the horizontal axis is time, and the acupuncture and moxibustion treatment period and non-treatment period are shown as “Treated” and “Not treated”, respectively. A full T score is 85 points, and a T score of 75 points or higher indicates a psychological state in which patients need to consider visiting a specialist.

## (2) QOL

QOL of the patients was evaluated using the Gastrointestinal Symptoms Rating Scale (GSRS)<sup>12</sup> designed to evaluate digestive symptoms. GSRS is a questionnaire on the influence (adverse effect) of digestive symptoms on 15 items of a patient's daily life in the past week, by which QOL of patients can be evaluated in five subscales of reflux, (upper) abdominal pain, digestive disturbance, diarrhea and constipation. In this study, scales of diarrhea and constipation were selected and evaluated as subscales associated with bowel movement disturbance. The scale of diarrhea is the average of three sub-subscales, loose stool, frequent bowel movement (diarrhea) and urgent desire of defecation, while the scale of constipation is the average of three sub-subscales, constipation, hard stool and feeling of unsatisfied defecation. Scores of GSRS are made up of score 1 to score 7. Score 1 indicates that digestive symptoms have no effect on the patient's daily life and score 7 indicates that digestive symptoms have intolerable adverse effect on it.

## (3) Psychological state

Two kinds of scales, depression/dejection and anxiety/tension were selected out of five scales in the Japanese version of Profile of Mood States (POMS)<sup>13</sup>.

## 5. Evaluation of the effect

The patients recorded data on abdominal pain, bloating, frequency of defecation, and condition of the stool every day, and the mean values of those scores in a day were calculated from the data for a week and compared with those of the last week. As for GSRS and POMS, their conditions on the last week were compared with those of the past week at the start and end of the treatment period. For two periods of acupuncture and moxibustion treatment, if the values of each evaluation item decreased, even if not much, and the values for each item were lower than those of the first visit with two treatment periods, it was considered that the condition of the item was improved by the acupuncture and moxibustion treatment and that they had effect on the symptoms.

## III. Results

Changes in all treatment and non-treatment periods of all four cases are shown below.

### 1. Abdominal pain and bloating

In cases 1, 2 and 3, abdominal pain and bloating were decreased during all treatment periods, and those in every non-treatment period were increased (Figs. 1a, 1b).

### 2. Bowel conditions (frequency of defecation, defecation days and condition of the stool)

Changes in frequency of defecation, defecation days and condition of the stool are shown in Fig. 3. In case 2, the mean frequency of defecation in two periods of treatment decreased from 1.6 times a day to 0.9 times a day and from 1.7 times a day to 1.1 times a day and that in the non-treatment period was increased, but a pattern that was common to two periods of treatment was not found in cases 1 and 3 (Fig. 2a). As for the condition of the stool, the ratio of total frequency of loose stool and liquid stool to overall frequency in one day did not change, remaining at 100% for cases 1 and 3 (Fig. 2b).

### 3. QOL

In a scale of GSRS for diarrhea, which consists of liquid/loose stool, frequency of defecation and urgent desire of defecation, values for cases 1 to 4 in the non-treatment period before the treatment period were 6.7, 2.7, 4.3 and 4.0, respectively. However, in cases 1, 2, and 3, the values decreased for each treatment period and increased for each non-treatment period (Fig. 3a). The values for these three cases also changed to 4.3, 1.7, and 1.0, respectively after two periods of treatment, which were lower than those at the patient's first visit. Values for cases 1 to 4 in the constipation scale were 1.3, 4.7, 5.3 and 4.7, respectively during the non-treatment period before acupuncture and moxibustion treatment. Cases 2 and 3 decreased for each treatment period and in case 2 increased for each non-treatment period. In cases 1, 2 and 3, they were 1.0, 1.7, 1.3 and 2.7, respectively, which were lower than those at the patient's first visit with two periods of treatment (Fig. 3b). In cases 1, 2 and 3, the sum of scales of diarrhea and constipation decreased for each treatment period and increased for each non-treatment period, showing lower values with two treatment periods than those of the first visit (Fig. 3c). The diarrhea scale and sum of scales of diarrhea and constipation scores in case 4 became worse during the first treatment period and improved during the non-treatment period after a dose of medication was increased.

Table 3. Changes in medication regimen for each patient before and after the observation period

Case	Medication	Before observation	After observation
1	Meperzolate bromide (mg/day)	45	45
	Lactobacillus preparation (g/day)	3	3
	Scopolamine butylbromide (mg/week)	80 (as needed)	Not needed
	Loperamide hydrochloride (mg/week)	2-3 (as needed)*	Not needed
2	Polycarbophil (mg/day)	3000	3000
3	Trimebutine maleate (mg/day)	600	300
	Magnesium oxide (mg/day)	2	Not needed
	Senoside (mg/week)	48 (as needed)	Not needed
	Metoclopramide (mg/day)	15	Not needed
4	Polycarbophil (mg/day)	2500	3000
	Loperamide hydrochloride (mg/week)	2-4 (as needed)	14
	Trimebutine maleate (mg/day)	300*	300
	Etizolam (mg/day)	3*	3
	Fluvoxamine maleate (mg/day)	0*	50
	Nirjinto (g/day)	7.5*	Not needed

\* Added before starting the 2nd treatment period.

#### 4. Psychological state

During the two periods of treatment, depression, or anxiety/tension of POMS was decreased in some patients and it was increased or stayed the same in other patients (Fig. 4). There was no common tendency during two periods of treatment. In terms of POMS, patients with more than and equal to a T score of 75 points, where the maximum is 85 points, need to see a doctor<sup>13)</sup>. Depression in case 1 during the second treatment and non-treatment periods and anxiety/tension in case 4 during the first treatment period showed 85 points, respectively.

#### 5. Changes in medication regimen

After two periods of treatment, the medication dose was reduced or medication was withdrawn in cases 1 and 3, whereas those in case 4 was increased. (Table 3)

#### 6. Remarks column

Each of case 1, during non-treatment period after the first treatment period and during the second treatment period, and case 4, during the first treatment period, had an unfortunate incident such as a traffic accident and hospitalization of a family member, which caused considerable distress including a sense of uneasiness and a sense of irritation. Furthermore, case 4 often complained of discomfort in the anal region that accompanied the

urge to defecate, along with abdominal pain and bloating. There was no remarkable change in their eating habits.

#### IV. Discussion

According to Rome II criteria, IBS is defined to be diagnosed based on at least 12 weeks or more, which need not be consecutive, in the previous 12 months where there was abdominal pain and abdominal discomfort that had two out of three of these features: (a) Relieved with defecation; and/or (b) Onset associated with a change in frequency of stool; and/or (c) Onset associated with a change in form of stool<sup>3)</sup>. IBS is considered a biopsychosocial disorder resulting from a combination of 3 interacting mechanisms: pshychosocial factors, altered motility and transit, and increased sensitivity of the intestine or colon<sup>1,3,14)</sup>. In a common treatment for IBS, an anticholinergic agent, regulator of gastrointestinal motility, laxative, antifatulent, antidepressant or antianxiety agent is given and if a patient does not respond to the medication, psychotherapy is sometimes practiced<sup>1,3)</sup>. Recently, new drugs as polycarbophil calcium have been used for IBS<sup>3)</sup>, but the treatment has not been established. This study was performed in order to investigate the efficacy of acupuncture and moxibustion on IBS patients.

## 1. Research design

Many kinds of studies on treatment methods for IBS show that the placebo response is very variable and high, ranking between 40 and 70%<sup>15,16</sup>. The placebo effect was characterized by rapid reaction, sharp change and gradual decreasing of efficacy throughout the administration. Therefore, it is necessary to conduct randomized, double-blind placebo-controlled trial with minimum length of 8-12 weeks, to set up a run-in period and to set up a period for follow-up, in order to minimizing the placebo effect in IBS patients<sup>15,16</sup>.

In this study, we found it difficult to have a control group for the patients or to adopt a double-blinded trial for our study because there are not many cases of IBS in our institution. It is difficult to perform placebo-acupuncture or a double-blinded trial because of the characteristic features of acupuncture and moxibustion treatment, therefore, we investigated every efficacy of acupuncture and moxibustion treatment on each case with a single-case reversal design<sup>11</sup>. Patients who had suffered from IBS for a long time and had been treated with conventional medicine for more than half a year without any improvement were selected, and they were treated for two periods of acupuncture and moxibustion treatment with a non-treatment period intervening between the two periods. The observation period lasted for 6 months to 13 months (average was 8.2 months.)

## 2. Effects of acupuncture and moxibustion on IBS patients in this study

### (1) Abdominal symptoms and bowel movement

The presence of abdominal pain or abdominal discomfort is a precondition of IBS as described above, which means improving these symptoms is important in the treatment. Many new drugs have been recently developed based on the pathological condition of IBS<sup>3</sup>. In the present study, abdominal pain and bloating were improved in three out of four cases during the first treatment period, which deteriorated with the suspension of treatment and then improved again during another treatment period. It was suggested that acupuncture and moxibustion treatment was effective in improving abdominal pain and bloating. There was no common tendency in frequency of defecation during two periods of treatment.

### (2) QOL

It was reported that perceived severity is defined by the limitations the disease imposes, rather than by the symptoms in IBS patients<sup>5</sup>. Furthermore, digestive symptoms have various affects on common health conditions and social life, and health-related QOL of IBS patients sometimes is worse than that of patient with diabetes mellitus and end-stage renal disease. Therefore, it is considered as significant to evaluate efficacy of IBS treatment on QOL improvement of IBS patients<sup>4,6</sup>.

In this study, we selected diarrhea subscale and constipation subscale of GSRS, which can measure QOL related to digestive symptoms. According to an investigation which was performed for healthy adults in Sweden, it was reported that in the GSRS diarrhea subscale, the mean value (95% confidence interval) was 1.38 (1.35-1.41) and there was no significant difference between ages or sex. In a similar way it was reported that in the GSRS constipation scale, the mean value (95% confidence interval) was 1.55 (1.51-1.58) with a slight difference between ages or sex<sup>24</sup>.

Before starting acupuncture and moxibustion treatment, all four of our cases showed higher than mean values in the diarrhea scale and cases 2, 3 and 4 showed a higher value in the constipation scale. There seemed to be deterioration of QOL by bowel movement disorders in all cases. The scores of the diarrhea scale in cases 1, 2 and 3 were decreased in all treatment periods, and it decreased to 1.0 which was the minimum value at the end of the last treatment in case 3 and decreased to 1.7 which was close to the mean value of healthy people in case 2. Even in case 1, it decreased to 4.3, which was still higher, but lower compared to that of the first examination. The constipation scale score decreased in cases 2 and 3 during all treatment periods and the score for case 1 was 1.3 which was lower than the mean value of healthy people at the beginning of the treatment and remained unchanged during the first treatment period, but decreased to 1.0 during the second treatment period. In IBS, because diarrhea alternates with constipation or diarrhea occurs at almost the same time as constipation, it is sometimes difficult to distinguish diarrhea-predominant from constipation-predominant. That is, it is considered to be important to evaluate both values as an overall value of bowel movement disorders in order to assess QOL of IBS patients, and therefore, we evaluated changes in the total scores of diarrhea and constipation scales. As a result, total scores of the diarrhea and

constipation subscales decreased in cases 1, 2 and 3 in all treatment periods, and further decreased to a lower value than that of the first visit at the end of the second treatment period. For this reason, in this study, it was suggested that acupuncture and moxibustion treatment is effective in improving QOL of IBS patients.

In cases 1 and 3, in terms of stool condition, the ratio of loose/liquid stool was not changed, remaining at 100% during the observation period, but in terms of GSRS diarrhea scores constituted by frequency of loose/liquid, stool/defecation and an urgent desire to defecate decreased during the treatment period. Because the GSRS scores consist of items in order to obtain information about disorders on daily life caused by each item, they are associated with frequency and degree of symptoms but not necessarily the same frequency or degree<sup>12)</sup>. In cases 1 and 3, GSRS scores changed with improvement of (lower) abdominal pain and bloating described in the bowel diaries. In these cases, there was a possibility that improvement in abdominal pain and bloating bring about decreased disorders in patients' daily life in stool condition or frequency of defecation that patients themselves were aware of and contribute to improvement of their QOL. However, this is not clear because there is no endpoint for lower abdominal pain in items in GSRS. Even if there was no significant change in stool condition, acupuncture and moxibustion treatment was considered to be effective treatment for IBS because of an improvement of QOL, which is important in the treatment of IBS.

As for case 4, although the scores of the constipation subscale were seen to decrease during all treatment periods, the scores of the diarrhea subscale or the total scores of diarrhea and constipation scales as an endpoint for overall disorders of bowel movement was decreased during the non-treatment period and increased during the treatment period. For this reason, there is a possibility of the influences of additional medication administered during the non treatment period, an aggravated psychological state described later, aggravated abdominal bloating, or a sense of discomfort in the anal region which was not estimated in this study. There was not, however, a clear explanation for this progress.

### (3) Relationships between psychological state and symptoms of IBS

The gastrointestinal system is easily affected by stress and emotions and the axis of stress, brain, and digestive

apparatus is called brain-gut interaction. This is considered to be important in the pathological condition of IBS<sup>1,3,14)</sup>. There is experience on a daily basis for digestive symptoms of IBS to be increased along with exacerbation of a psychological state represented by depression and can be decreased along with an improvement of psychological state<sup>14,28)</sup>. The development or exacerbation of abdominal pain or bowel movement disorder caused by psychosocial stimulation (stress) is considered one of the typical distinctive symptoms of IBS<sup>14,29,30)</sup>. Recent studies reported excess reaction on gastrointestinal caused by psychological stress in IBS patients<sup>14)</sup>. It was reported that IBS patients under mental stress have exaggerated response of duodenum and colonic motility related to abdominal pain<sup>31)</sup>. It was also reported IBS patients showed excess secretion of adrenocorticotrophic hormone (ACTH), and aggravation or abnormality of motility along with abdominal pain by intravenous administration of corticotrophin-releasing hormone (CRH)<sup>32)</sup>, which is a common mediator for stress reaction<sup>14)</sup>. Many IBS patients show depression or anxiety neurosis, which are psychological tendencies<sup>14)</sup>. Accordingly, changes in psychological state were evaluated using scales of depression/dejection and of tension/anxiety of POMS.

Some of the POMS values in this study decreased during treatment periods, and others did not change or increased. There was no common tendency during two periods of treatment.

It is not necessarily appropriate to discuss changes in psychological state, because it may not be a cause of bowel movement disorders but may be caused by bowel movement disorders. In cases 1 and 4, however, the patient or a family member had a traffic accident or disease during the period, while their psychological state was not good, and they complained about their psychological problems caused by the affairs in their bowel diaries. It was considered that deterioration of POMS might be caused by those unhappy affairs rather than the bowel movement disorder itself.

In case 1, during the first acupuncture and moxibustion treatment period when both degrees of depression and tension/anxiety were decreased, abdominal symptoms were greatly improved. After, however, both degrees of depression and tension/anxiety increased during the non-treatment period and the scores of the depression scale remained at 85 points which was highest during the second treatment period. Furthermore,

before and after the second period there was not as great an improvement in abdominal pain or GSRS scores as those of the first period. In case 4, during the first treatment period, both degrees of depression and tension/anxiety became worse and the scores greatly increased to 85 points, well over the 75 points at which patients need to see a specialist. Although there was no improvement seen in abdominal pain or frequency of defecation and GSRS scores became worse during this period, the values were improved by medication with an antidepressant and anti-anxiety agent after the first treatment period. Finally, before and after the second acupuncture and moxibustion treatment, POMS scores with tension or anxiety improved to be the value of the first examination accompanied by decreased frequency of defecation, abdominal pain, etc. In the cases of this study, these psychological problems may possibly be associated with factors which cause resistance to acupuncture treatment.

#### (4) Therapeutic mechanism of acupuncture and moxibustion treatment

The main pathological mechanism of IBS is thought to be a vicious circle of brain-gut axis that is formed by a gastrointestinal motility disorder not only of the large intestine but also of the small intestine, an impaired perception threshold of the intestine or colon, and psychological disturbance<sup>14</sup>.

The effects of acupuncture and moxibustion treatment on intestinal movement have been reported in which the influence of acupuncture treatment or acupuncture electrical stimulation was studied by using human intestinal sounds or rat intestinal motility as indicators<sup>9, 17-20</sup>. There have been reports which used the colon transport time of radiopaque markers or opioid activity in the plasma as indicators<sup>21,22</sup>. The studies were on the effects and mechanisms in patients with chronic constipation after undergoing acupuncture electrical stimulation or acupuncture treatment for several weeks<sup>21,22</sup>. However, mechanisms of a long-term effect of acupuncture and moxibustion treatment has not been thoroughly clarified in these studies.

With the influences on the perception threshold of the intestine, there are a few reports studying the mechanisms using animal experiments<sup>7</sup>, one of which showed suppression of visceral pain by acupuncture stimulation with rotating needle technique on the face of anesthetized rats. It is said that no change is induced by the mild

stimulation such as retained needle as used in this study. The therapeutic mechanism of acupuncture was not definitive in the studies of Chan et al<sup>9</sup>, and Fireman et al<sup>10</sup>, regarding the therapeutic effects of acupuncture on IBS, and no other studies have shown any clear-cut long term effects and mechanisms on chronic visceral pain of the intestine. Xiang et al<sup>24</sup>, showed that the rectal perception threshold was increased by percutaneous electrical stimulation to acupuncture points (TEAS), and not modulated by changes in rectal biomechanics. Xiao et al<sup>25</sup>, also reported that percutaneous electrical stimulation to acupuncture points (acupoint TENS) increased, in a short term effect, the rectal perception threshold of IBS patients with diarrhea-dominant symptoms. Moreover, the patients showed a significant increase of the rectal perception threshold and a significant decrease of frequency of defecation and intensity of abdominal pain in a long term effect after acupoint TENS treatment for two months. Although a similar mechanism may be involved in the acupoint stimulation with acupuncture and moxibustion, it is not thoroughly clarified. Cases 1 and 3 showed improvement in abdominal pain and bloating, whereas they showed no change in stool condition known to reflect intestinal transport time<sup>26</sup> and exhibited no clear-cut psychologically common response in two periods of treatment. Accordingly, it is suggested that improvement of abdominal pain and bloating in these cases was induced by increasing the rectal perception threshold. Further investigation is necessary to understand the therapeutic mechanism of acupuncture treatment, because it could not be clarified by the methods and results of this study.

As described above, we made comparative examinations at all evaluation points between periods with or without acupuncture and moxibustion treatment. Three cases with IBS showed improvement in abdominal pain, bloating and QOL that are important for treatment of IBS, during all periods of acupuncture and moxibustion treatment.

There were lower values of these score after completion of two periods of treatment as compared with that before treatment. These findings suggested therapeutic efficacy of acupuncture and moxibustion treatment. Although more elaborate study is required, acupuncture treatment is suggested to be an effective therapy for IBS patients.

## V. Conclusion

- 1) On the basis of single-case reversal design, acupuncture and moxibustion treatment was performed on four IBS patients who did not show a favorable response to medical pharmacologic therapy.
- 2) Improvement in abdominal pain, bloating and QOL was seen in three of four patients in all acupuncture and moxibustion treatment periods without dose escalation, and these symptoms became worse after ceasing acupuncture and moxibustion treatment.
- 3) In two patients, the dose requirement of medication was decreased after two periods of acupuncture and moxibustion treatment.
- 4) A possibility is suggested that acupuncture and moxibustion treatment can be a useful method of therapy to improve abdominal pain, bloating and QOL of IBS patients.

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