Clinical Trial: Transcutaneous Interferential Electrical Stimulation in Individuals with Irritable Bowel Syndrome – A Prospective Double-Blind Randomized Study

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Key Words
Interferential current therapy · Irritable bowel syndrome · Gastrointestinal tract

Abstract
Background: The exact etiology of irritable bowel syndrome (IBS) remains unclear. Curative treatment is not available and current treatment modalities are mainly directed against the predominant symptoms. There are a few studies reporting the beneficial effects of transcutaneous electrical stimulation in patients with chronic constipation, gastroparesis, and functional dyspepsia. Aim: To investigate whether transcutaneous electrical stimulation is an effective procedure in IBS patients. Methods: IBS patients were randomly placed in vacuum interferential current (IFC) and placebo groups. Both treatments consisted of 12 sessions administered over 4 weeks. Symptoms due to IBS were documented via questionnaires, including the IBS Global Assessment of Improvement Scale, numeric rating scales, visual analogue scale, and IBS Quality of Life Scale at the beginning of, end of, and 1 month after the treatment. Results: Patients in the therapy (29 cases) and placebo (29 cases) groups were homogeneous with respect to demographic data and gastrointestinal system symptoms. When compared to the beginning scores, severity of abdominal discomfort, bloating, and abdominal distension and rumbling improved significantly in either interference or placebo groups at both the end of treatment and 1 month after treatment. In the IFC group, severity of symptoms continued to decrease significantly at 1 month after treatment when compared to scores at just the end of treatment, whereas in the placebo group severity of these symptoms did not change significantly on numeric severity scales. Also, the visual analogue scale of the first month after treatment continued to decrease significantly when compared to the level at the end of treatment in the IFC group. Total quality score increased significantly in the IFC group. Conclusions: Vacuum IFC therapy can significantly improve symptoms and quality of life in patients with IBS. It may represent a novel treatment modality for drug-refractory IBS patients.

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**Introduction**

Irritable bowel syndrome (IBS) is a highly common and problematic gastrointestinal disease characterized by chronic abdominal pain and altered bowel habits. Patients with IBS can present with a wide array of symptoms, which include both gastrointestinal and extraintestinal complaints for which adequate examination does not reveal a sufficient explanation through a structural or specific pathology. It is the most commonly diagnosed gastrointestinal condition [1]. The prevalence of IBS in the general population is estimated to be between 5 and 20% across countries [1]. Its management accounts for up to 25% of a gastroenterologist's workload in the outpatient clinic [2]. IBS affects men and women, young patients, and the elderly, but younger patients and women are more likely to be diagnosed with IBS. For many sufferers, it presents a lower quality of life as well as higher costs.

As the exact etiology of IBS remains unclear, curative treatment is not available and current treatment modalities are mainly directed against the predominant symptoms. Numerous treatment options have been used in the management of IBS, including dietary and lifestyle modifications, fiber, antispasmodic agents, antidepressants, anti-diarrheal agents, benzodiazepines, 5-hydroxytryptamine-3 receptor antagonists, 5-hydroxytryptamine-4 receptor agonists, lubiprostone, guanylate cyclase agonists, antibiotics, behavioral and complementary, and alternative therapies [3]. Interferential current (IFC) therapy is a form of transcutaneous electrical stimulation. Electrical stimulation at the applied site is likely to stimulate local skin nerve fibers, besides deeper stimulation activating afferent and efferent parasympathetic outflow to the gastrointestinal tract [4, 5]. In clinical practice, it is used for pain control, bladder overactivity, and chronic treatment-resistant constipation [6–8]. Furthermore, gastric electrical stimulation has been successfully tried over the last decade as a therapeutic option for a variety of gastrointestinal motility disorders, especially gastroparesis [5, 9, 10]. In the pertinent literature, there are several studies reporting the beneficial effects of transcutaneous electrical stimulation in patients with gastrointestinal tract dysfunction, including gastroparesis and chronic constipation [4, 7, 8, 11]. Also, in a recent study, we have demonstrated that vacuum interference electrical stimulation is beneficial and free of adverse effects in patients with functional dyspepsia [12]. To the best of our knowledge, transcutaneous electrical stimulation has not previously been tried in the management of IBS. In the present study, we aimed to investigate the efficacy of vacuum IFC, a non-invasive procedure for transcutaneous electrical stimulation in IBS patients.

**Materials and Methods**

Patients with IBS were recruited from the outpatient clinics at the clinics of Gastroenterology, Diskapi Yildirim Beyazit Education and Research Hospital and Ankara Education and Research Hospital in Ankara. Patients were recruited both from a pool of IBS patients at our units and from referrals from other physicians. Patients enrolled in the study were from the ‘hard to treat’ group, as they were all unresponsive to diet and lifestyle modifications, and categorized into IBS according to the Rome III criteria by the same physician (E.A.). The patients had IBS-related symptoms such as abdominal discomfort, bloating, rumbling, gas and incomplete relief after defecation for a long time, from 1 to 20 years at the baseline. They were all not newly diagnosed and nobody was under medication before we started the study. The subjects were randomized consecutively.

Subjects with concomitant functional dyspepsia symptoms and who refused to participate in the treatment sessions were excluded. Patients with a history of gastrointestinal surgery, gastrointestinal cancer, and inflammatory bowel disease were also eliminated. Participants were prohibited from using laxatives, antidepressants, anxiolytics, antispasmodics, antibiotics and any dietary modifications until the end of the study. The utility of IFC alone was investigated for IBS patients.

An ethics committee approval was provided before beginning the study. After informed consent was obtained, patients were consulted for physical treatment and randomly assigned to the treatment and control groups according to a basic random sampling method. Patients in the treatment and control groups were unaware of their treatment allocation. In each session, 15 min of vacuum IFC or sham IFC therapy was applied to the patients. IFC was applied three times a week for a total of 12 sessions in 4 weeks.

IFC was supplied by an Ito EU-940 device (Germany). The skin of the abdominal and dorsal paravertebral area was cleaned with alcohol and the electrodes were applied in a quadripolar manner to this area for an intersecting electrical current to the projection of the colon (fig. 1). In both IFC and placebo groups, electrodes were placed on the skin by suction cups using vacuum. In the IFC group, interferential stimulators delivered IFC using four electrodes, with a carrier frequency of 4 kHz, an adjustable intensity and a beat frequency sweep covering 80–150 Hz. The intensity of the stimulator was increased gradually until the patient reported that a further rise would cause discomfort. The intensity of the stimulator was increased in the course of the therapy because of the tolerance to IFC. According to this protocol, in the IFC group the IFC intensity was carried out between 15 and 25 mA. The placebo group had no current from the vacuumed suction cups as they did not feel any electrical sensation but did feel a vacuum sensation. Both the IFC and placebo groups received 12 × 15 min sessions of real or placebo IFC, respectively. All vacuum IFC and placebo treatment sessions were applied by the same physicians (S.E. and M.A.U.).

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The procedure was explained before therapy to all patients. The questionnaires were translated and validated for patients before IFC application. Patients completed standard questionnaires just before beginning the therapy sessions, and after the treatment sessions. The questionnaire was given to the patients by the gastroenterologist (E.A.) and completed before the treatment. The physician was unaware of the treatment methods.

**Questionnaires**

The questionnaires at baseline, just at the end of therapy, and 1 month after treatment included the following: (1) the IBS Global Assessment of Improvement Scale (IBS-GAI), (2) numeric rating scales, (3) visual analogue scale (VAS), and (4) IBS Quality of Life Scale (IBS-QOL).

The IBS-GAI asks participants: 'Compared to the way you felt before you entered the study, have your IBS symptoms over the past 7 days been: (1) 'substantially worse', (2) 'moderately worse', (3) 'slightly worse', (4) 'no change', (5) 'slightly improved', (6) 'moderately improved' or (7) 'substantially improved'.

For numeric rating scale the main outcome was patient-assessed 'overall severity of gastrointestinal symptoms', as measured on a 0–10 scale (10 = most severe).

Study outcomes included improvement in abdominal discomfort as measured by a 100-point VAS.

The IBS-QOL is a 34-item measure assessing the degree to which IBS interferes with patient quality of life. Each item is rated on a 5-point Likert scale, thus yielding a total score that has a theoretical range of 34–170, with higher scores indicating worse quality of life.

**Definition of a Responder**

For this analysis we identified those who responded to the intervention according to the four main outcomes described above. As such, four different responder definitions were compared: (1) IBS-GAI, where a responder was defined as a patient who responded that compared to 4 weeks ago, their symptoms were either 'moderately improved' or 'substantially improved'; (2) change in IBS-QOL from enrollment to 3 weeks' follow-up, where a responder was defined as a clinically meaningful change of ≥10 points in this measure; (3) change in total numeric points score from enrollment to 4 weeks' follow-up, where a responder was defined as a patient whose overall symptom severity on the numeric points score changed ≥50 points, and (4) improvement of abdominal pain more than 50% in VAS.

**Statistics**

Data analyses were performed using SPSS 15.0 (IBM, Chicago, Ill., USA) for Windows. The continuous variables are presented as mean ± SD or median (min–max), whereas categorical variables are presented as percentage. Student’s t tests were used to determine if there were any significant differences between groups. χ² was used for categorical comparisons. A paired sample t test was used to evaluate response rates of IBS symptoms. The detected power of this study was 83.8%. We assessed the efficacy of IFC by an intention-to-treat analysis. p < 0.05 was accepted as statistically significant for the results.

**Results**

**Patient Characteristics**

Sixty-seven patients were randomized into IFC (n = 33) and placebo (n = 34) groups. Four and five patients dropped out of the study because of non-medical reasons just after beginning the treatment sessions in IFC and placebo groups respectively. There were 58 patients who completed the therapy sessions (fig. 2). As IBS subgroups, 41.8% had constipation-dominant IBS, 36.4% diarrhea-dominant IBS and 21.8% had mixed-type IBS. The number of patients regarding IBS subgroups was comparable in both groups. Demographic characteristics of either group, including age, gender, body mass index, smoking and alcohol habits, occupation, education level, marital status, duration of the IBS symptoms and number of admissions to a physician with IBS in the last year were comparable (table 1).

In the interference group, bloating or abdominal distension, rumbling, gas and incomplete relief after defeca-
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Effects of Baseline Severity on Response to Treatment

Primary Outcomes

For the numeric severity scale, a more than 50% improvement of the symptoms was accepted as treatment response. At the end of treatment in the interference group, rates of treatment responses were 42.9, 11.1, 30.4, 22.7 and 33.3% for abdominal discomfort, bloating or abdominal distension, rumbling, gas and incomplete relief after defecation, respectively. For the placebo group, rates were 37.0, 34.6, 39.1, 30.4 and 35.3% for abdominal discomfort, bloating or abdominal distension, rumbling, gas and incomplete relief after defecation, respectively. p values were 0.659, 0.038, 0.535, 0.558 and 0.903, respectively.

Rates of response in the interference group were as follows at the first month after treatment: 67.9% for abdominal discomfort, 48.1% for bloating or abdominal distension, 56.5% for rumbling, 36.4% for gas, and 44.4% for incomplete relief after defecation. For the placebo group, rates were 44.4, 46.2, 56.5, 47.6 and 41.2% for abdominal discomfort, bloating or abdominal distension, rumbling, gas and incomplete relief after defecation, respectively (p values were 0.079, 0.884, 0.487, 0.454 and 0.478, respectively).

Similarly, a more than 50% improvement of the abdominal discomfort was accepted as treatment response for VAS. At the end of the treatment, frequencies of the responses were 48.3 and 51.7% in interference and placebo groups respectively (p = 0.414). At the first month after treatment, interference and placebo groups were comparable with respect to VAS response rates (72.3% for interference and 69.0% for placebo groups).

Table 1. Demographic data of the patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>Placebo (n = 29)</th>
<th>IFC (n = 29)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>40.5 ± 9.1</td>
<td>43.1 ± 11.1</td>
<td>0.122</td>
</tr>
<tr>
<td>Female, %</td>
<td>82</td>
<td>65</td>
<td>0.131</td>
</tr>
<tr>
<td>Body mass index</td>
<td>28.7 ± 6.1</td>
<td>28.6 ± 4.0</td>
<td>0.784</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>11</td>
<td>12.2</td>
<td>0.211</td>
</tr>
<tr>
<td>Alcohol</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Married, %</td>
<td>85</td>
<td>89</td>
<td>0.624</td>
</tr>
<tr>
<td>Housewife, %</td>
<td>79.3</td>
<td>70.9</td>
<td>0.877</td>
</tr>
<tr>
<td>Education level, %</td>
<td></td>
<td></td>
<td>0.166</td>
</tr>
<tr>
<td>Elementary school</td>
<td>86</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>High school</td>
<td>14</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>Duration of symptoms, years</td>
<td>3 (1–15)</td>
<td>3 (1–20)</td>
<td>0.300</td>
</tr>
<tr>
<td>Attending a physician¹</td>
<td>4 (1–10)</td>
<td>3 (1–10)</td>
<td>0.409</td>
</tr>
</tbody>
</table>

¹ In the last year with the complaint of IBS.
Treatment response was defined as a more than 10% change in IBS-QOL at the end of the first month after treatment. In the interference group response rates for dysphoria, interference with activity, body image, health worry, food avoidance, social reaction, sexual, relationship and total quality scores were 60.7, 48.1, 48.1, 61.5, 50, 38.4, 38.5 and 61.5%, respectively. Rates were 53.6, 36, 32, 44, 36, 32 and 56.0% in the placebo group. p values were 0.589, 0.0375, 0.234, 0.209, 0.312, 0.227, 0.629, 0.163 and 0.688, respectively.

According to IBS-GAI, response rates were 40.7, 25.9, 33.3, 14.8 and 14.8% for abdominal discomfort, bloating or abdominal distension, rumbling, gas and incomplete relief after defecation at the end of treatment in the interference group, respectively. For the placebo group, rates were 50.0, 46.4, 42.9, 42.9 and 21.4%, respectively. p values were 0.490, 0.112, 0.467, 0.126 and 0.524, respectively.

IBS-GAI showed comparable rates for the first month after treatment responses. Response rates for abdominal discomfort, bloating or abdominal distension, rumbling, gas and incomplete relief after defecation were 55.6, 44.4, 37.0, 25.9 and 29.6% in the interference group and 46.4, 39.3, 42.9, 42.9 and 28.6% in the placebo group, respectively. p values were 0.498, 0.698, 0.659, 0.185 and 0.931, respectively.

**Secondary Outcomes**

**Numeric Severity Scales**

According to the numeric severity scale, symptoms including abdominal discomfort, bloating or abdominal distension, rumbling, gas and incomplete relief after defecation were measured on a 0–10 scale and participants were asked at the beginning, the end of treatment and the first month after treatment. When compared to the beginning scores, the severity of abdominal discomfort, bloating or abdominal distension and rumbling improved significantly in either the interference or placebo groups at both the end of treatment and the first month after treatment.

Severity of abdominal discomfort, bloating or abdominal distension and rumbling, continued to decrease significantly in the interference group at the first month of treatment when compared to scores just at the end of treatment (p = 0.02 for abdominal discomfort, p = 0.002 for bloating or abdominal distension, and p = 0.007 for rumbling), whereas the end of treatment and the first month after treatment scores were comparable in the placebo group (p = 0.760 for abdominal discomfort, p = 0.768 for bloating or abdominal distension, and p = 0.768 for rumbling).

Severity of gas and incomplete relief after defecation decreased significantly in either the interference or placebo group at both the end of treatment and the first month after treatment when compared to beginning scores. However, there was no difference between scores of the end of treatment and the first month after treatment in either group (table 2).

A multivariate analysis was performed by stepwise logistic regression analysis for all variables including age, gender, body mass index, occupation and education level that can be related to symptoms in both the placebo group and IFC group. There was no an independent factor related to symptom improvement (p values were 0.552, 0.964, 0.629, 0.863, 0.171 in the placebo group and 0.691, 0.605, 0.904, 0.599, 0.152 in the IFC group, respectively).

**Visual Analogue Scale**

VAS was also measured three times to evaluate abdominal discomfort or pain. VAS at the beginning, end of treatment and first month after treatment were 56.0 ± 8

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**Table 2.** Numeric severity scale scores before and after both real and placebo IFC

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>IFC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pretreatment</td>
<td>end of</td>
</tr>
<tr>
<td>Abdominal discomfort</td>
<td>7.6 ± 2.4</td>
<td>5.0 ± 2.7</td>
</tr>
<tr>
<td>Bloating, abdominal distension</td>
<td>7.8 ± 3.0</td>
<td>5.5 ± 3.0</td>
</tr>
<tr>
<td>Rumbling</td>
<td>5.0 ± 3.4</td>
<td>3.3 ± 3.3</td>
</tr>
<tr>
<td>Gas</td>
<td>5.5 ± 3.5</td>
<td>4.3 ± 3.4</td>
</tr>
<tr>
<td>Incomplete relief after defecation</td>
<td>4.8 ± 4.3</td>
<td>3.2 ± 3.8</td>
</tr>
</tbody>
</table>

* p = 0.02, ** p = 0.002, *** p = 0.007 for end of treatment vs. post-treatment first month.
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Table 3. Quality of life scores before and after both real and placebo IFC

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th></th>
<th>IFC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pre-treatment</td>
<td>post-treatment first month</td>
<td>p value</td>
<td>pre-treatment</td>
</tr>
<tr>
<td>Dysphoria</td>
<td>27.1 ± 7.8</td>
<td>24.4 ± 9.5</td>
<td>0.04</td>
<td>21.8 ± 8.0</td>
</tr>
<tr>
<td>Interference with activity</td>
<td>24.1 ± 6.7</td>
<td>22.7 ± 7.0</td>
<td>0.252</td>
<td>19.6 ± 5.5</td>
</tr>
<tr>
<td>Body image</td>
<td>13.0 ± 4.2</td>
<td>12.1 ± 4.5</td>
<td>0.303</td>
<td>11.4 ± 3.4</td>
</tr>
<tr>
<td>Health worry</td>
<td>11.4 ± 2.4</td>
<td>10.5 ± 3.5</td>
<td>0.089</td>
<td>9.1 ± 2.5</td>
</tr>
<tr>
<td>Food avoidance</td>
<td>10.7 ± 3.1</td>
<td>10.7 ± 2.9</td>
<td>0.695</td>
<td>9.6 ± 4.0</td>
</tr>
<tr>
<td>Social reaction</td>
<td>12.3 ± 4.4</td>
<td>11.6 ± 5.3</td>
<td>0.215</td>
<td>9.5 ± 4.0</td>
</tr>
<tr>
<td>Sexual</td>
<td>6.0 ± 3.9</td>
<td>6.0 ± 2.9</td>
<td>0.179</td>
<td>4.1 ± 2.3</td>
</tr>
<tr>
<td>Relationship</td>
<td>9.0 ± 4.2</td>
<td>8.9 ± 4.1</td>
<td>1</td>
<td>8.0 ± 4.6</td>
</tr>
<tr>
<td>Total IBS score</td>
<td>109.5 ± 29.5</td>
<td>103.1 ± 32.9</td>
<td>0.211</td>
<td>93.0 ± 25.5</td>
</tr>
</tbody>
</table>

Fig. 3. VAS scores before and after both real and placebo IFC.

Among subtypes, dysphoria, health worry and food avoidance also improved significantly (p values were 0.014, 0.018, 0.024 respectively). In the placebo group, dysphoria was the only significantly improved parameter (p = 0.02) (table 3). There were no adverse events due to either vacuum IFC or placebo.

Discussion

The present study is the first report on the beneficial application of vacuum IFC in IBS patients. Both placebo and vacuum IFC were effective in the treatment of patients with IBS, however vacuum IFC was more effective and longer lasting with respect to improving symptoms of IBS and their self-perceived quality of life as compared to placebo.

IBS is characterized by chronic abdominal pain and altered bowel habits in the absence of any organic cause that may explain the symptoms. Patients with IBS have a diminished health-related quality of life. It is also difficult for doctors in many cases to treat and expensive for society [13]. The etiology of IBS remains uncertain. Hereditary and environmental factors are likely to have a role. Several pathophysiological mechanisms, including abnormal gastrointestinal motility, visceral hypersensitivity, microscopic inflammation, postinfectious IBS, alteration in fecal microflora, psychological dysfunction, and emotional stress have been implicated in patients with IBS [14]. Despite intensive investigations, the results have often been conflicting and no physiologic or psychological abnormality has been found to be specific for this disorder.
As the exact pathophysiological mechanisms causing symptoms in an individual patient cannot be depicted, there is no standard treatment modality for patients with IBS. Therefore, a wide variety of treatment options have been described, including dietary and lifestyle modifications, various pharmacological agents, and complementary and alternative treatments [3]. However, there is no curable therapy that consistently provides relief to the majority of IBS patients, supporting the heterogeneity of IBS. Thus, it is difficult to generalize the same therapeutic approach for these patients and to predict the degree of response.

Interferential therapy is a form of non-invasive transcutaneous electrical stimulation. It produces sinusoidal currents that cross within the body. Treatment with IFC is painless and relatively inexpensive. Although it requires trained physiotherapists, home-use, portable units have recently become available. There are only a few contraindications to treatment with IFC, such as skin damage and cardiac pacemaker in situ [7]. It has been applied to the treatment of several disorders, including muscle strengthening, soft tissue mobilizing, detrusor instability and slow transit constipation [6–8]. Also, in a few studies, it has been reported that gastric electrical stimulation improved symptoms in gastroparesis [15, 16]. When interferential therapy has been used clinically to treat urinary incontinence due to gallbladder overactivity, diarrhea occurred as a side effect of IFC, and temporary or permanent improvement of constipation in almost all of the patients with gastroparesis has been noted, suggesting an increase in bowel motility [6, 8]. Subsequently, IFC has been tested in patients with chronic constipation. Chase et al. [4] suggested that transcutaneous electrical stimulation has a beneficial effect for children with chronic treatment-resistant constipation. Subsequently, Clarke et al. [7, 8] reported that IFC therapy can significantly speed up colonic transit in children with slow transit constipation and improves their self-perceived quality of life. Recently, we have demonstrated in a preliminary study that vacuum IFC is an effective treatment in patients with functional dyspepsia as a novel treatment modality [12].

The current study examined the potential application of a novel non-invasive form of transcutaneous electrical stimulation in patients with IBS. To our knowledge, interferential therapy has not previously been applied to patients with IBS. We have demonstrated that treatment with IFC is effective in patients with IBS and no participant experienced any side effects with treatment. It has been well tolerated. The study found that after only a short treatment period (12 sessions for 4 weeks) of IFC, there was a significant improvement in symptoms, including abdominal discomfort, bloating or abdominal distension and rumbling at 1 month after the treatment, as well as VAS scores and self-perceived quality of life when compared to placebo. As in the present study, other studies have no reported side effects of IFC. It is non-invasive, painless and relatively inexpensive.

Actually the mechanism of IFC therapy is not known, but electrical stimulation at the applied site is likely to stimulate local skin nerve fibers, vagal sympathetic and parasympathetic outflow to the gastrointestinal tract, and nerves within the gut [4]. Improvement of constipation in previous reports and symptoms of IBS in the present study may be due to neuromodulation where there is a balance between excitatory and inhibitory neural control being altered by a supraspinal or a spinal pathway [4, 8].

In the current study, patients were homogeneous with respect to age, gender, occupation, and educational status. Most of the patients suffering from IBS are women and housewives, and with a low educational status. More research is needed not only to test these results but also to extend the range of participants, for instance to male patients and those with different occupations. High response rates for placebo in the present study support the psychological aspect of IBS. Actually, patients enrolled in the study were from the ‘hard to treat’ group, as they were all unresponsive to pharmacological treatment. A limitation of the study was a lower number of patients than we had planned.

In conclusion, this preliminary study suggests that vacuum interference electrical stimulation is a promising alternative therapy for IBS. It seems beneficial, has no side effects and may be applied at least when the symptoms of IBS are aggravated or are unresponsive to medical treatment. Further studies involving a larger number of homogeneous patients or more patients including all subtypes of IBS are needed to confirm this benefit and to determine the ideal stimulation parameters.

Disclosure Statement
The authors have no conflicts of interest to disclose.
References


