Acupuncture for the treatment of functional constipation

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Abstract

OBJECTIVE: To assess the effectiveness of acupuncture for the treatment of functional constipation (FC).

METHODS: The literature was searched for randomized controlled trials (RCTs) comparing acupuncture with medical treatment; no medical treatment, placebo acupuncture, and sham acupuncture in patients with FC were searched. Data were extracted by two independent reviewers using standard data extraction forms. Risk of bias for each RCT was assessed using a modified Oxford 5-point quality scale. Data were pooled according to intervention and treatment course. Parameters evaluated included effectiveness/invalidity, Cleveland Clinic score (CCS), colon transit time (CTT) and adverse effects.

RESULTS: Nineteen studies involving 1679 participants were eligible for inclusion; of these studies, 16 were published in Chinese and three in English. Risks of bias were high. Acupuncture was significantly superior to medication therapy in short-term (effectiveness/invalidity, \( P = 0.0009 \); CCS, \( P = 0.02 \)) and long-term (effectiveness/invalidity, \( P = 0.004 \); CCS, \( P = 0.04 \); CCT, \( P < 0.0001 \)) effectiveness. A short treatment course of less than 15 days was sufficient. The likelihood of adverse effects was significantly lower for acupuncture than for medication therapy (\( P = 0.002 \)).

CONCLUSION: Compared with medication, acupuncture was more effective and had a lower adverse effect rate in the treatment of FC. A short treatment course of two weeks was sufficient for a good effect. However, the poor quality of the included trials indicates the need for well-designed RCTs, including adequate sample size and a reasonable placebo control, to assess the effectiveness of acupuncture for FC.

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Key words: Acupuncture; Constipation; Meta-analysis

INTRODUCTION

Functional constipation (FC), also called chronic idiopathic constipation (CIC), is a common functional gastrointestinal disorder, affecting 12%-19% of overall global populations, and with a mean annual health care cost per patient of USD 7522. In addition, a recent study of 2870 subjects reported that constipation...
had a negative impact on their health-related quality of life (QOL).\textsuperscript{3}

Causes of constipation are multi-factorial and can include dietary factors (e.g., low fiber), motility disturbances (outlet delay, slow transit time), lack of exercise, stress and eating large amounts of dairy products.\textsuperscript{4}

Thus, treatment of constipation includes lifestyle modifications such as a high fiber diet, more exercise, and increased fluid intake.\textsuperscript{4} Medications for chronic constipation can be categorized as bulking agents, stool softeners, osmotic and stimulant laxatives, lubiprostone (a chloride channel activator), 5-HT\textsubscript{4} receptor agonists and guanylate cyclase-c receptor agonists.\textsuperscript{5} Biofeedback therapy was found to play a significant role in patients with pelvic floor dysfunction.\textsuperscript{5} However, a systematic review on chronic constipation conducted by an American College of Gastroenterology (ACG) Task Force found little evidence supporting the use of many of these agents, except for the osmotic laxatives lactulose and polyethylene glycol (PEG), which were found to be effective by improving stool frequency and stool consistency.\textsuperscript{5}

Because its pathogenesis remains unclear, therapies for FC remain limited. Thus, complementary or alternative therapies, such as acupuncture, are attractive to patients. Acupuncture has been widely used for more than 3000 years. Although evidence from clinical trials has indicated the effectiveness of acupuncture in the treatment of FC,\textsuperscript{6,7} acupuncture is not widely accepted for the treatment of FC because of the small sample sizes of these trials and the lack of multicenter clinical trials. Thus, a systematic review may better reveal the efficacy and safety of acupuncture for the treatment of FC.

MATERIALS AND METHODS

Search strategy


Search strategies used for PUBMED, EMBASE, and CENTRAL were:

1# Dyschezia[mh] OR constipation[mh]) OR colonic inertia[mh];


4# 1# AND 2# AND 3#

The keywords used to search the Chinese databases had the same meaning as the English words. Manual searches were also performed to enlarge the search range and attempt to find unpublished studies. If unpublished trials were encountered (e.g. only the RCT protocol was published), the authors were contacted. One trial for which only the RCT protocol had been published had a sample size and experimental design that were both eligible and convincing,\textsuperscript{5} but that trial was still collecting participants.

Selection criteria

RCTs were included, regardless of language, if they compared acupuncture with no treatment, placebo acupuncture, sham acupuncture, and medication therapies in the treatment of FC. Patients were defined as having FC if they had chronic constipation for at least two months and were diagnosed using conventional medical criteria, such as ROME III,\textsuperscript{14} ROME II,\textsuperscript{14} or the Diagnostic Guidelines for Chronic Constipation in China.\textsuperscript{15}

Only trials that evaluated invasive traditional acupuncture or electro-acupuncture alone as intervention were included. Studies that evaluated combinations of acupuncture with other interventions, include massage and medications, were excluded; as were trials of other types of acupoint stimulation, such as moxibustion, massage, acupressure, cupping, auricular point sticking, acupoint application, transcutaneous electrical nerve stimulation (TENS), surface electrodes, and cat-gut embedded at acupoints.

Primary study outcomes included effectiveness/invalidity, based on Guidelines for Clinical Research of New Traditional Chinese Medicine,\textsuperscript{17} and the Diagnosis and Effectiveness Standard for Traditional Chinese Medicine;\textsuperscript{18} Cleveland Clinic score (CCS);\textsuperscript{19} and safety (side effects). Secondary outcomes included colon transit time (CTT).

Data extraction and risk of bias assessment

Two reviewers identified eligible articles from the searches of the databases and extracted data using pre-defined extraction forms. Disagreements were resolved by consensus. Data extracted included trial methods (e.g. randomized design, sample size), information about participants (e.g. inclusion criteria, age, sex ratio), interventions (e.g. acupoints, needle sizes, depths, electro-frequency, interventions in the control group), and study outcomes. The main characteristics of included studies are presented in Table 1. Methodological quality was assessed according to Cochrane Handbook 5.1.0.
Data synthesis and analysis
To assess the effects of acupuncture on the treatment of FC, Review Manager 5.1.1.0\textsuperscript{3} was used to calculate standard mean differences (SMD) and 95% confidence intervals (CI) for measured data and odds ratio (OR) and 95% CI for enumerated data. Heterogeneity was assessed using the Higgins $I^2$ test, Chisq test and tau\textsuperscript{2} test. Reporting bias for six or more included trials was assessed by regression tests for funnel plot asymmetry using R version 2.15.1. A fixed-effects model was used when the studies in the subgroup were sufficiently similar ($I^2 = 0$). Otherwise, a random-effects model and sensitivity analysis were used.

RESULTS

Description of included studies
A total of 1141 potentially relevant articles were identified. After screening titles and abstracts, 1092 articles were excluded, because they were nonclinical trials, case reports, lacked a comparison group, or were unrelated to acupuncture for the treatment of FC. The full texts of the remaining 49 articles were evaluated; of these, 30 were excluded because intervention sessions were unclear, methodological quality was poor, diagnosis was inappropriate, outcome data were lacking, RCTs were not performed properly or they were duplicate publications. Finally, 19 studies were included (Figure 1). As presented in Table 1, all included studies assessed difference between acupuncture and medications, including both Western medications (lactulose, PEG4000, mosapride, and bisacodyl) and traditional Chinese medicines (Maren pills, Tongbianling capsules, Folium sennae, Maziren pills, and Shuchang Runton capsule), as well as no treatment, placebo acupuncture and sham acupuncture (Table 1). Of the 13 trials with a parallel group design,\textsuperscript{25-30,32-35} six compared the effects of conventional acupuncture and medications\textsuperscript{25-30,32-35} and seven compared electro-acupuncture and medications.\textsuperscript{25-30,35} Six trials had three-armed designs, including five compared the effects of deep puncture, shallow puncture and medication\textsuperscript{20-23,35} and one comparing acupuncture, medication and their combination.\textsuperscript{24} 16\textsuperscript{20-24,26-30,32-35} were published in Chinese and the other three\textsuperscript{25,29,30} in English.

Interventions and controls
Electroacupuncture, using a Hans-100 or G-6805 (Shanghai Huayi) apparatus, was tested in 13 trials.\textsuperscript{20-23,35} The remaining trials tested traditional acupuncture. The medication intervention in five of the six three-armed trials was lactulose,\textsuperscript{20-23,35} whereas it was plantain and senna granules, both Chinese patent medicines, in the sixth trial.\textsuperscript{24} Seven of the 13 parallel trials used Chinese patent medicine or traditional Chinese herbs as a control.\textsuperscript{29,30,32-35} Of the remaining six trials, one used lactulose,\textsuperscript{5} three used PEG4000,\textsuperscript{22,23,25} one used bisacodyl,\textsuperscript{37} and one used a combination of cisapride and Maren Runchang pills.\textsuperscript{38}

Quality of the included studies
The methodological quality of the included trials was not good, because of unclear random sequence generation, lack of blinding, or inadequate concealment of allocation concealment (Figure 2, 3). The risk of bias, both performance bias and measurement bias, was high for blinding, as it was difficult to blind patients/caregivers regarding the use of acupuncture. In only

\begin{figure}[ht]
\centering
\includegraphics[width=\textwidth]{flow_diagram.png}
\caption{Flow diagram of the process of identifying eligible randomized controlled trials}
\end{figure}

CNKI: China National Knowledge Infrastructure Database; CBM: Chinese Biomedical Literature Database; VIP: China Science and Technology Journal Database; RCT: randomized controlled trial.

### Table 1 Characteristics of the included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Gender (n)</th>
<th>Age (years)</th>
<th>Duration of disease (years)</th>
<th>Intervention</th>
<th>Course of treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wang CW et al 2010&lt;sup&gt;a&lt;/sup&gt;</td>
<td>SEA</td>
<td>M: 1; F: 23</td>
<td>20-71</td>
<td>1-21</td>
<td>Tianshu (ST 25), 2/15 Hz, 30 min</td>
<td>4w</td>
<td>CTS</td>
</tr>
<tr>
<td></td>
<td>DEA</td>
<td>M: 10; F: 38</td>
<td>20-75</td>
<td>1-28</td>
<td>Tianshu (ST 25), 2/15 Hz, 30 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 4; F: 19</td>
<td>21-70</td>
<td>2-22</td>
<td>Duphalac, 20-30 mL, q.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SEA</td>
<td></td>
<td></td>
<td></td>
<td>Tianshu (ST 25), 5/10 Hz, 30 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Geng T et al 2011&lt;sup&gt;11&lt;/sup&gt;</td>
<td>DEA</td>
<td>M: 7; F: 68</td>
<td>18-26</td>
<td>1-15</td>
<td>Tianshu (ST 25), 5/10 Hz, 30 min</td>
<td>4w</td>
<td>CTS Adverse effects</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 14; F: 7</td>
<td>57</td>
<td>12.7</td>
<td>Tianshu (ST 25), 2/15 Hz, 30 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yang DL et al 2010&lt;sup&gt;20&lt;/sup&gt;</td>
<td>DEA</td>
<td>M: 30; F: 8</td>
<td>53.1</td>
<td>12.7</td>
<td>Tianshu (ST 25), 2/15 Hz, 30 min</td>
<td>4w</td>
<td>CTS</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 15; F: 4</td>
<td>50.1</td>
<td>10.6</td>
<td>Lactulose oral solution, 15 mL, q.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peng WN et al 2010&lt;sup&gt;10&lt;/sup&gt;</td>
<td>DEA</td>
<td>M: 14; F: 45</td>
<td>53.10</td>
<td>11</td>
<td>Tianshu (ST 25), 2/15 Hz, 30 min</td>
<td>4w</td>
<td>CTS</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 10; F: 11</td>
<td>59.24</td>
<td>7.8</td>
<td>Lactulose oral solution, 20-30 mL, q.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guo LK et al 2011&lt;sup&gt;11&lt;/sup&gt;</td>
<td>DEA</td>
<td>M: 62; F: 63</td>
<td>49.7±10.5</td>
<td>20.7±5.56</td>
<td>Tianshu (ST 25), Zusani (ST 36), Shangjuxu (ST 37), Dachangshu (BL 25), Zhigou (TE 6), 2/100 Hz, 15 min</td>
<td>4w</td>
<td>CTS Adverse effects Effectsivity/ invalidity</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 64; F: 61</td>
<td>51.7±10.3</td>
<td>20.67±3.41</td>
<td>Plantain and senna granules, 5 g, q.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zhang W 2005&lt;sup&gt;5&lt;/sup&gt;</td>
<td>DEA</td>
<td>M: 12; F: 18</td>
<td>65 (46-83)</td>
<td>13.4±8.62</td>
<td>Tianshu (ST 25), 20 Hz, 30 min</td>
<td>2w</td>
<td>CTS Effectsivity/ invalidity</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 15; F: 15</td>
<td>67 (39-84)</td>
<td>11.0±5.59</td>
<td>Lactulose oral solution, 10 mL, t.i.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peng JM et al 2009&lt;sup&gt;9&lt;/sup&gt;</td>
<td>SEA</td>
<td>M: 18; F: 23</td>
<td>32-73</td>
<td>4.26 (1-10)</td>
<td>Changqiang (GV 1), Ciliao (BL 32), Zhongliao (BL 33), 80 Hz, 30 min</td>
<td>2w</td>
<td>Effectsivity/ invalidity</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 19; F: 22</td>
<td>28-68</td>
<td>3.78 (1-9)</td>
<td>PEG 4000, 10 g, b.i.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gao JY et al 2010&lt;sup&gt;2&lt;/sup&gt;</td>
<td>SEA</td>
<td>M: 13; F: 17</td>
<td>33-72</td>
<td>4.46 (1-10)</td>
<td>Changqiang (GV 1), Ciliao (BL 32), Zhongliao (BL 33), 80 Hz, 30 min</td>
<td>2w</td>
<td>Effectsivity/ invalidity</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 16; F: 14</td>
<td>29-69</td>
<td>3.88 (1-9)</td>
<td>PEG 4000, 10 g, b.i.d.</td>
<td></td>
<td></td>
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<tr>
<td>Cao J 2012&lt;sup&gt;8&lt;/sup&gt;</td>
<td>SMA</td>
<td>M: 9; F: 12</td>
<td>51.2 (19-73)</td>
<td>0.5-8</td>
<td>Tianshu (ST 25), Zusani (ST 36), Hugu (LI 4), Shangjuxu (ST 37), Zhigou (SJ 6), Zhaohai (KI 6), 30 min</td>
<td>20d</td>
<td>Effectsivity/ invalidity</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 8; F: 12</td>
<td>52.4 (21-71)</td>
<td></td>
<td>Folium sennae, 3 g, b.i.d.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zhang CX et al 2010&lt;sup&gt;4&lt;/sup&gt;</td>
<td>DEA</td>
<td>M: 32; F: 28</td>
<td>51.6±10.4</td>
<td>0.5-19.4</td>
<td>Tianshu (ST 25), Shangjuxu (ST 37), Zusani (ST 36), Dachangshu (BL 25), Zhigou (TE 6), 2/200 Hz, 15 min</td>
<td>4w</td>
<td>CTS Effectsivity/ invalidity</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>M: 29; F: 31</td>
<td>49.8±10.7</td>
<td>0.5-19.7</td>
<td>Macrogol 4000, 10 g, b.i.d. Mosapride, 10 mg, t.i.d.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 1 Characteristics of the included studies (continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
<th>Gender (n)</th>
<th>Age (years)</th>
<th>Duration of disease (years)</th>
<th>Intervention</th>
<th>Course of treatment</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ji XQ et al 2005&lt;sup&gt;13&lt;/sup&gt;</td>
<td>SEA</td>
<td>M: 20; F: 14</td>
<td>44±11</td>
<td>2-16</td>
<td>Tianshu (ST 25), Zhigou (TE 6), 1 Hz, 30 min</td>
<td>4w</td>
<td>CCS</td>
</tr>
<tr>
<td>Gu H et al 2010&lt;sup&gt;13&lt;/sup&gt;</td>
<td>SEA</td>
<td>M: 1; F: 20</td>
<td>22.03±5.05</td>
<td>-</td>
<td>Tianshu (ST 25), 2/15 Hz, 30 min</td>
<td>4w</td>
<td>CCS</td>
</tr>
<tr>
<td>Zhang SQ et al 2007&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 2; F: 17</td>
<td>25.18±8.78</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Wang LS et al 2006&lt;sup&gt;13&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 14; F: 11</td>
<td>10-79</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ren YY 2011&lt;sup&gt;14&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 11; F: 24</td>
<td>42.8±11.3</td>
<td>5.6±4.2</td>
<td>Matern pills, 1 pill, t.i.d.</td>
<td>20d</td>
<td>CCS</td>
</tr>
<tr>
<td>Yang ZL 2008&lt;sup&gt;15&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 10; F: 17</td>
<td>56 (21-72)</td>
<td>1-33</td>
<td>Solution from decoction of folium sennae, t.i.d.</td>
<td>2w</td>
<td>Effectiveness/ invalidity</td>
</tr>
<tr>
<td>Xia CF et al 2006&lt;sup&gt;16&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 18; F: 24</td>
<td>66.0 (60-76)</td>
<td>0.4-11</td>
<td>Maziren pills, 1 pill, b.i.d.</td>
<td>1 w to 3 w</td>
<td>Effectiveness/ invalidity</td>
</tr>
<tr>
<td>Luo ZK 2003&lt;sup&gt;17&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 14; F: 14</td>
<td>60-88</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chen XJ et al 2007&lt;sup&gt;18&lt;/sup&gt;</td>
<td>Control</td>
<td>M: 34; F: 26</td>
<td>50 (15-60)</td>
<td>1-10</td>
<td>Maren Runchang pills, 1 pill, t.i.d.</td>
<td>2w</td>
<td>Effectiveness/ invalidity</td>
</tr>
</tbody>
</table>

Notes: M: male; F: Female; yr: years; SMA: shallow manual acupuncture; SEA: shallow electroacupuncture; DMA: deep manual acupuncture; DEA: deep electroacupuncture; CCS: cleveland clinic score; CTT: colon transit time.
found among these trials ($P = 0.05, I^2 = 46\%$). Using a random effects model, the pooled results of effectiveness/invalidity showed that acupuncture was significantly more effective than Western medications ($OR = 2.27; 95\% CI, 0.99 to 5.20, P = 0.05$). Generally, the effect of acupuncture was significantly higher than that of medications ($OR = 2.88; 95\% CI, 1.54 to 5.39, P = 0.0009$) (Figure 4A). Pooled results showed that short-term (<15 days) acupuncture treatment had significantly greater effects than medications ($OR = 3.78; 95\% CI, 1.96 to 7.31, P < 0.0001$), but long-term (≥15 days) acupuncture did not have a significantly greater effect than medications ($OR = 1.18; 95\% CI, 0.66 to 2.09, P = 0.58$) (Figure 4B). There were no significant publication biases as showed by a regression test for funnel plot asymmetry ($P = 0.13$) (Figure 5A).

Nine trials reported short-term CCS data. There was significant heterogeneity among these trials ($P < 0.0001, I^2 = 90\%$). A random effects model showed that CCS tended to be lower in patients undergoing acupuncture than in those treated with Western (SMD = −0.36; 95\% CI, −0.84 to 0.13, $P = 0.15$) and Chinese (SMD = −1.17; 95\% CI, −2.54 to 0.21, $P = 0.10$) medications. Total CCS was significantly lower in patients undergoing acupuncture than in patients treated with all types of medications (SMD = −0.53, 95\% CI, −0.98 to −0.08, $P = 0.02$) (Figure 4C). Pooled results showed that longer-term (≥15 days) acupuncture treatment had significantly greater effects than medications (SMD = −0.54; 95\% CI, −1.03 to −0.05, $P = 0.03$), whereas short-term treatment (<15 days) did not differ significantly (SMD = −0.44; 95\% CI, −0.95 to 0.07, $P = 0.09$) (Figure 4D). There were no significant publication biases, as showed by regression tests for funnel plot asymmetry ($P = 0.98$) (Figure 5B).

Five trials assessed the short-term effects of acupuncture on CTT; these trials showed significant heterogeneity ($P = 0.02, I^2 = 59\%$). Reductions in CTT in patients undergoing acupuncture therapy were similar to those in patients receiving medications (SMD = −0.19; 95\% CI, −0.45 to 0.08, $P = 0.16$), including both Chinese (SMD = 0.00; 95\% CI, −0.25 to 0.25, $P = 1.00$) and Western (SMD = −0.24; 95\% CI, −0.57 to 0.09, $P = 0.15$) medications (Figure 4E). Pooled results showed that acupuncture for <15 days had a significantly greater effect than medication (SMD = −1.12; 95\% CI, −1.67 to −0.58, $P < 0.0001$), whereas their longer-term effects at ≥15 days,
Long-term effects of acupuncture versus medication

Four studies reported the effectiveness/invalidity data on long-term (≥15 days) treatment. There was significant heterogeneity among the trials ($I^2 = 88\%$). Using a random-effects model, acupuncture showed significantly greater effectiveness/invalidity than either Western (OR = 2.60; 95% CI, 1.92 to 3.31; $P = 0.003$) or Chinese (OR = 1.79; 95% CI, 1.45 to 2.13; $P = 0.001$) medications, or the two to one.
Pooled results showed that acupuncture had greater effectiveness/invalidity than medications for < 15 days (OR = 26.00; 95% CI, 2.92 to 231.31, P = 0.003), but not for ≥ 15 days (OR = 7.23; 95% CI, 0.68 to 77.00, P = 0.10) (Figure 6B). Three trials reported long-term CCS data, with significant heterogeneity among these trials (P = 0.002, I² = 80%). Using a random effects model, acupuncture showed significantly better effects than Chinese medication (SMD = −0.73; 95% CI, −0.99 to −0.47, P < 0.00001), but was similar to Western medications (SMD = −0.50; 95% CI, −1.41 to 0.41, P = 0.28).

As a result, total CCS was significantly lower in patients undergoing acupuncture than medications (SMD = −0.57; 95% CI, −1.12 to −0.03, P = 0.04) (Figure 6C). Pooled results showed that acupuncture for < 15 days yielded better results than medications (SMD = −1.40; 95% CI, −1.97 to −0.83, P < 0.0001), whereas acupuncture and medications for ≥ 15 days did not differ significantly (SMD = −0.33; 95% CI, −0.87 to 0.20, P = 0.22) (Figure 6D).

Two trials reported long-term CTT, with CTT being significantly lower in acupuncture than in medication groups (SMD = −18.60; 95% CI, −27.91 to −9.30, P < 0.0001) (Figure 6E). As participants in both trials were treated for more than 15 days, pooled results again showed that acupuncture ≥ 15 days yielded the same results (Figure 6F).

**Adverse effects**

Four of nineteen trials reported specific side effects (nausea and vomiting, bloating, bellyache, light diarrhea or positive fecal occult blood). There was no significant heterogeneity among these trials (P = 0.90, I² = 0%). Using a fixed effects model, the incidence of adverse effects was found to be significantly lower in patients undergoing acupuncture than those receiving...
Western medications (RR = 0.21; 95% CI, 0.06 to 0.72, P = 0.01) and tended to be lower in patients undergoing acupuncture than those receiving Chinese medications (RR = 0.19; 95% CI, 0.04 to 1.08, P = 0.06). The total incidence of adverse effects was significantly lower in the acupuncture than in the medication groups (RR = 0.21; 95% CI, 0.08 to 0.56, P = 0.002) (Figure 7A). Pooled results showed that the incidence of adverse effects was significantly lower in patients undergoing acupuncture than receiving medications for ≥ 15 days (RR = 0.21; 95% CI, 0.08 to 0.56, P = 0.007), but did not differ significantly between patients receiving acupuncture and medications for < 15 days (RR = 0.19; 95% CI, 0.02 to 1.53, P = 0.12) (Figure 7B).

**DISCUSSION**

FC can have deleterious effects on patient QOL. Acupuncture has been reported to have positive effects on self-regulation disorders and functional diseases. Although many clinical trials have tested acupuncture therapy for FC, few systematic reviews in English have comprehensively evaluated the effectiveness of acupuncture on FC. This review indicated that, in patients with FC, acupuncture had greater short-term and long-term efficacies than medications, especially Western medications. Moreover, a short treatment course of acupuncture for two weeks was sufficient to yield these benefits.

The effectiveness/invalidity and CCS data together comprehensively evaluated the clinical symptoms in patients with FC, including stool frequency, stool consistency and associated symptoms. Pooled effectiveness/invalidity data were dichotomized prior to analysis; this analysis reflected the numbers of patients effectively treated, but did not indicate specific effectiveness. CCS is a quantitative measure of effectiveness, which can better reflect treatment results. Moreover, CCS is considered more objective than effectiveness/invalidity, with the former incorporating definitive criteria about the degree of FC based on seven types of clinical symptoms. CTT is another objective parameter, measuring colonic transit time, and can indicate the degree of constipation. Our Meta-analysis included five studies that estimated the effectiveness using CTT.

Although our research method was strict, the quality of the included studies was relatively poor, resulting in marked heterogeneity. Pooled results demonstrated either a trend or a significant difference in favor of acupuncture therapy, although the results might have been affected by heterogeneities for short-term CCS outcomes and all long-term outcomes. Heterogeneities may have been caused by different rating scales for effectiveness/invalidity and by the characteristics of the participants enrolled in different studies. Heterogeneity may also have been affected by the different interventions in control groups, differences in stimulated acupuncture points or even differences in doctor-patient relationships. The poor quality of the included trials suggests the need for well-designed, multicenter RCTs to assess the effectiveness of acupuncture for FC. Acupuncture is regarded as generally safe, with a low incidence of side effects. In contrast, patients receiving the various medications reported various gastrointestinal side effects, including nausea and vomiting, bloating, bellyache, light diarrhea and positive fecal occult blood tests. None of the patients in any of the included trials experienced severe adverse events. These findings suggest that acupuncture may be safer than medications, especially Western medications.

This systematic review has several limitations. Firstly, all but one of the included trials were of patients in mainland China. This resulted in a high risk of selection bias. Whether the results reported here are valid and applicable to other ethnic groups remains unclear. Secondly, most of the studies were of poor quality, without a blinding method or concealment of allocation. This may have resulted in potential biases in patient selection, treatment administration and assessment of results. This may have led to an overestimation of the effectiveness of acupuncture in treating FC. Compared with medication, especially with Western medication, acupuncture yielded better outcomes in patients with FC. Acupuncture was safer and more effective, with treatment for about two weeks being sufficient. However, the low methodological quality, small sample size, unidentified risk of bias and various evaluation indexes of the trials included in this Meta-analysis indicates the need for large, multicenter RCTs assessing the effectiveness and safety of acupuncture in patients with FC.

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