



Efficacy and safety of auriculotherapy based on syndrome differentiation for constipation vs. western medicine: a systematic review of randomized controlled trials

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Background: To assess the efficacy and safety of auriculotherapy based on syndrome differentiation for constipation.

Methods: A retrieval on studies concerning treatment of constipation with auriculotherapy based on syndrome differentiation was carried out in databases of VIP, CNKI, Wangfang, Sinomed and PubMed, Cochrane. And the systematic review was conducted on randomized controlled trial (RCT) which met the enrolling requirements. The quality of the included studies was evaluated by using the bias risk assessment recommended by the Cochrane manual 5.1.0, and the meta-analysis was performed by using RevMan5.3 software. Descriptive analysis was performed on the literature that could not be combined.

Results: A total number of six papers involving 468 patients were concluded and the methodological quality of these studies was not high; The results indicated that mean defecation time after auriculotherapy based on syndrome differentiation is lesser than after western medicine and statistical significance can be found [$Z=2.36$, $P<0.05$, relative risk (RR) = -0.41, 95% confidence interval (CI): -0.75, -0.07]. In the comparison of affective rate, auriculotherapy based on syndrome differentiation is higher than the western medicine ($Z=2.84$, $P<0.05$, RR = 1.23, 95% CI: 1.07, 1.42).

Discussion: Auriculotherapy based on syndrome differentiation is effective to treat constipation no worse than routine western medicine treatment on the part of mean defecation time. Also its long-term result and safety are better. However, no definitive conclusion can be made, high-quality and further rigorous RCTs adopting internationally recognized outcomes are warranted to confirm the effect and safety of auriculotherapy for constipation.

Keywords: Constipation; auriculotherapy based on syndrome differentiation; systematic review

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Constipation is characterized by reduced frequency of defecation, dry and hard stools, and/or difficulty in defecating although the stools are not dry and hard. A reduced number of defecation refers to less than 3 per week. Difficulties in defecation include laborious defecation, difficulty in discharge, imperceptible defecation, time-consuming defecation and the need for manual assistance (1,2). Constipation is mostly caused by internal factors such as mood and diet (3). The research results showed that the prevalence of constipation in China was about 3.7% (4), with different incidence in different places: the prevalence was about 20% in Beijing, 13% in Xi'an, 19% in Shenyang, 7.0% in Shanghai, 9.0% in Guangzhou, and 10% in Chengdu (5,6). At present, western medicine is often used in the clinical treatment of constipation, but the tolerance and dependence of this method are high, and the long-term effect is not ideal. Improper treatment will not only cause the occurrence of adverse drug reactions, but also degrade the function of voluntary defecation, resulting in habitual constipation, and even induce colon black stool and other precancerous lesions (7).

Ear therapy in recent years has rapidly developed, and its application in the treatment of constipation is also increasing. Currently, there are three meta-analyses on the effect of auricular point therapy on constipation, two of them (8,9) believe that the effective rate and recovery rate of auricular point group are better than that of the conventional treatment group. However, Wu *et al.* (10) believed that the effective rate of auricular point therapy was not different from that of western medicine, and the effect was not obvious in the recovery rate. The different conclusions above may be attributed to the following two reasons. On the one hand, the former belongs to the study of superior effect, while the latter belongs to the comparative study of the efficacy of auricular plaster and western medicine.

In addition, because the current operation of auricular point sticking and pressing is not standard, many studies only mention auricular point or ear pressure treatment, without syndrome differentiation according to the specific situation, which is also an important factor affecting the efficacy of auricular point. In clinical practice, the author found that auricular therapy has a definite effect on constipation, especially after traditional Chinese medicine (TCM) syndrome differentiation, but its curative effect relative to western medicine has not been fully explored. In order to make better use of auricular point technology in clinical practice, this paper intends to make a systematic review of

relevant studies, so as to discuss the efficacy and safety of dialectical auricular point in the treatment of constipation, and provide certain reference for clinical practice.

We present the following article in accordance with the PRISMA reporting checklist (available at <https://dx.doi.org/10.21037/lcm-20-41>).

Data and methodology

Information sources

In Chinese, “auricular acupuncture point” or “ear acupuncture needle” or “ear pressure” and “constipation” or “defecation difficulties” as the search terms are used by computer; in English, “auricular therapy” OR “auriculotherapy” OR “ear acupuncture” OR “auricular acupressure” AND “constipation” OR “dyschezia” are search terms via computer. The dates were all from library construction to January 31, 2021. A Cochrane recommended search strategy was used, and the search strategy was based on the different characteristics of each database, and the final search strategy was determined after multiple searches. If the abstract met the inclusion criteria, the full text was searched to read the full text and PubMed was used as an example to demonstrate the search strategy. The English literature search strategy is attached in *Table 1*.

Inclusion and exclusion criteria

Inclusion criteria

- (I) Study type: randomized controlled trials (RCTs) for constipation with or without a blind method and in all different languages;
- (II) The object of study: ≥ 18 years old, no organic disease, Constipation diagnosis accord with standard of Roman II constipation, Roman III constipation, Roman IV constipation or domestic industry standard such as “treating constipation of new drug of TCM clinical research guiding principles” (11), “standard of diagnosis of disease and curative effect of traditional Chinese medicine” (12), etc.;
- (III) Intervention methods: the experimental group adopted auricular therapy (including auricular acupuncture therapy and auricular point pressing bean method with no limitation on the drugs pressed); the control group was treated with western medicine.;
- (IV) Outcome indicators: main outcome measures:

Table 1 Retrieval strategies for English literature

Search	Query	Items found	Time
#2	Search "Constipation"[Mesh]	12,674	22:14:47
#3	Search Dyschezia	25,199	22:15:05
#4	Search #3 OR #2	25,199	22:15:27
#12	Search Auricular Acupuncture	1,181	22:20:53
#17	Search auricular therapy	5,103	22:24:13
#18	Search ear acupuncture	952	22:24:51
#19	Search Auriculotherapy	449	22:26:48
#23	Search auricular acupressure	126	22:42:16
#24	Search #23 OR #19 OR #18 OR #17 OR #12	5,748	22:43:28
#25	Search #4 AND #24	11	22:44:09

interval time between defecation; secondary outcome indicators: symptom score, defecation time, defecation traits, difficulty in defecation, total effective rate, safety and long-term curative effect.

Exclusion criteria

- (I) Excluded subjects: the included subjects were pregnant patients or patients with serious underlying diseases;
- (II) If the research is repeatedly published, the most original research will be taken;
- (III) Studies without specific treatment regimens;
- (IV) Auricular therapy not guided by dialectical thinking.

Data selection and data extraction

Two reviewers (Wang Xuejiao and Xu Lei) independently screened and eliminated the articles according to the pre-set admission standards. All the retrieved literatures were imported into the literature retrieval management system EndNote X8. Firstly, the software was used to check and delete the duplicate literatures. According to the titles, abstracts and other information retrieved independently and according to the inclusion and exclusion criteria set in this study, the two researchers screened the remaining literatures, eliminated unqualified literatures, recorded the reasons for elimination, numbered them and recorded them in an Excel table. For the research that meets the inclusion criteria, read through the full text to judge whether it meets the criteria. Finally, the two parties check the results. For the research that is in dispute, the two parties discuss and solve it. If it remains unresolved, a third party (Fang Min,

Li Bo) will rule.

To extract the data of the eventually included studies, fill in the data extraction grid, and the table includes the following contents:

- (I) Basic information table: including the title of the literature, first author, literature number, publication time, research unit, source of cases, etc.;
- (II) Trial feature table: including general clinical data, disease diagnostic criteria, inclusion and exclusion criteria, case screening records, baseline data characteristics of each group, randomized methods, randomized concealment, application of blind method, statistical analysis methods, etc.;
- (III) Intervention measures table: specific treatment plans adopted by the intervention group and the control group, including drug name, dose, route of administration, frequency, course of treatment, etc.;
- (IV) Table of test results: main outcome indicators, secondary outcome indicators, description of statistical methods, record of adverse reactions, shedding cases and follow-up, etc.

Methodological quality evaluation

The included studies were evaluated using the "risk of bias assessment" tool recommended by the Cochrane handbook, including:

- (I) Randomization method;
- (II) Allocation hiding;
- (III) Whether to use the blind method;

- (IV) Integrity of the result data;
- (V) Selective reporting of research results;
- (VI) Other sources of bias.

High risk, low risk and ambiguity were used to describe the evaluation results. Two researchers evaluated the included studies respectively, and any differences will be resolved through discussion. If no agreement is reached during the discussion, the decision shall be made by a third researcher in the relevant field.

Statistical analysis

Statistical analysis was performed using RevMan5.3 software provided by Cochrane. We will record participant demographics, treatment outcomes and adverse events by mean and standard deviation.

- (I) Chi-square test, heterogeneity test was performed on the results of each included study. If $P \geq 0.10$ and $I^2 \leq 50\%$, there was no statistical heterogeneity between the results of the included study, and the fixed-effect model could be used for analysis;
- (II) If $P < 0.10$, $I^2 > 50\%$, heterogeneity was considered to exist in statistics, and random-effect model was used for analysis.
- (III) Studies with clinical and methodological homogeneity were combined. If there was no statistical heterogeneity, a fixed-effect model was selected for meta-analysis.

If there is statistical heterogeneity, further sensitivity analysis is needed to find the source of heterogeneity. If there is no obvious clinical heterogeneity, random-effect model will be used for merger. If the heterogeneity is large, no meta-analysis will be conducted and only descriptive analysis will be conducted. Descriptive analysis was used if clinical heterogeneity or method heterogeneity was too large. Publication bias was demonstrated using a forest map drawn by RevMan5.3.

Dealing with missing data

In the case of missing data included in study, we will contact the corresponding authors. (If data from the included study is missing, we will contact the corresponding authors.) If not successful, we will analyze available data to perform the outcome and assess the potential impact in the discussion.

Forest plots

What should be observed in the forest plots of dichotomous variables:

- (I) Vertical line: invalid line, horizontal axis scale is 1, mainly used to determine whether the statistical results are statistically significant. When the diamond or horizontal line of a study intersects the vertical line, the difference between the two groups is not statistically significant. Conversely, the study was statistically significant;
- (II) Horizontal line: it is the line between the upper and lower limits of the 95% confidence interval (CI) of the study. The length of the line directly represents the range of the CI. The length of the horizontal line is negatively correlated with the sample size, that is, the longer the horizontal line is, the smaller the sample size is;
- (III) The shorter the horizontal line, the larger the sample size. The small square in the center of the horizontal line: it represents the effect size of a single study [relative risk (RR) or odds ratio (OR)]. The size of the square visually represents the weight of the study;
- (IV) Diamond: it represents the comprehensive results of various studies.

For adverse outcomes, such as mortality, adverse events, etc., horizontal or diamond lines are effective on the left side of the vertical line and invalid on the right.

The opposite is true for favorable outcomes, such as cure rates, which are effective on the right side of the vertical line and ineffective on the left.

What should be observed in the forest plots of continuous variables:

- (I) Vertical line: invalid line, horizontal axis scale is 0, meaning the same as binary variable;
- (II) Horizontal line: meaning the same as binary variable;
- (III) The small square in the center of the horizontal line represents the effect size of a single study [weighted mean difference (WMD) value or standardized mean difference (SMD) value], and the size of the square represents the weight of the study;
- (IV) Diamond: meaning the same as dichotomous variables.

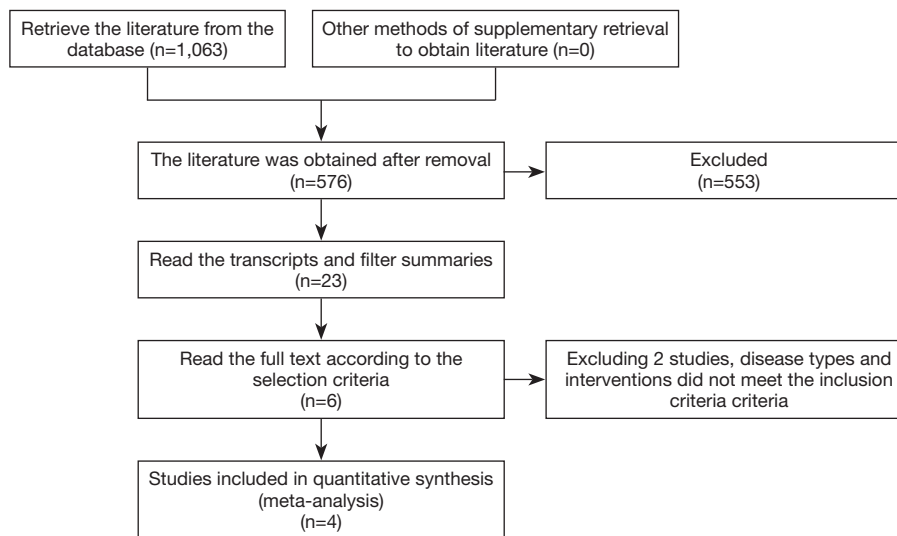


Figure 1 Literature screening flow diagram.

Registration

The study protocol has not been registered.

Results

Search results

The search strategy generated a total of 1,603 articles. A total of 519 articles were excluded after screening of title and abstract, and a further 51 articles were excluded after full-text review. The remaining six articles (13-18) were included in this review for meta-analysis. The screening process of the included studies is shown in *Figure 1*.

Baseline characteristics

A total of 468 cases were included, including 236 cases in the experimental group and 232 cases in the control group. Diagnostic criteria: three studies used the Rome II criteria and three used the TCM Internal Medicine Diagnostic Efficacy Criteria. Classification: three studies were divided into real and deficient cases, and the remaining three studies were divided into deficient cases, spleen, lung and qi deficient cases, and hot and dry intestines in that order. For details, please refer to *Table 2*.

Evaluation of the quality of the included studies

The results of study quality are shown in *Figure 2*.

Evaluation of the effectiveness of treatment

Defecation interval

The average number of days per bowel movement during treatment. Three existing (15,17,18) studies reported the interval between bowel movements, but because the time interval reported by Li (15) was measured in days and was clinically heterogeneous with the other two studies (17,18), it was not included in the meta-analysis. Li's (15) study, which was an intervention for a total of 10 days, showed a statistically significant difference ($P < 0.05$) in the interval between bowel movements in the treatment and control groups. The other two studies (17,18) intervened for 8 weeks and 20 days, respectively, and the homogeneity test $P > 0.1$ and $I^2 < 50\%$ indicated that the included studies were more homogeneous, so the fixed-effects model was used for meta-analysis, and the results showed that the interval between defecation in the experimental group was lower than that in the western medicine group, and the results were statistically significant ($Z = 2.36$, $P < 0.05$, $RR = -0.41$, 95% CI: $-0.75, -0.07$). The forest plot is shown in *Figure 3*.

Symptom points

There are two studies that reported symptom points, and the several-point criteria used by Di (13) is the Diagnostic Efficacy Criteria for Chinese Medical Evidence published in 1994, which includes five main symptoms such as the patient's defecation interval, defecation speed, stool nature index, defecation effort index, and intention to defecate, and

Table 2 Baseline characteristics

Study	Baseline sample		Measures		Outcomes	Syndrome differentiation
	Intervention	Control	Intervention	Control		
Di Yinglian, 2017	40	40	Ear acupoint burying bean method	Rhubarb sodium bicarbonate tablets	Constipation symptom score scale	Deficiency syndrome
Zhong Xin, 2007	30	30	Auricular point pressing method	Tegaserod	Effective rate; first defecation time, defecation interval time, fecal quality, defecation effort, curative effect observation of each defecation time; results of colon transit test	Lung and spleen qi deficiency type
Li Yihong, 2013	40	40	Auricular point pressing bean method	Phenolphthalein	First defecation time and defecation interval	Excessive syndrome and deficiency syndrome
Zhang Ying, 2009	30	30	Auricular point pressing bean method	Phenolphthalein	Clinical efficacy: first defecation time, total score of clinical symptoms, defecation interval, defecation speed, defecation characteristics, defecation intention and defecation difficulty symptoms	Excessive syndrome and deficiency syndrome
Huang Rong, 2016	50	50	Auricular point pressing bean method	Lactulose	Effective rate	Hot colon dryness type
He Lihong, 2012	46	42	Auricular point pressing seed method	Rhubarb soda tablets, Kaisailu	Effective rate	Excessive syndrome and deficiency syndrome

each symptom is divided into 0–4 levels according to the degree, corresponding to 0, 1, 3 and 5 points. In addition to the above main symptoms, there were comorbidities such as abdominal pain, dizziness, fatigue, bitterness in the mouth, irritability, loss of appetite, and pain in the sacrum, with 0.5 points for each comorbidity and 0 points for no manifestation. Zhang (17) used the Guidelines for Clinical Research on New Chinese Medicines issued by the Ministry of Health in 1993, which included primary symptoms (time to first defecation, interval between defecations, speed of defecation, defecation traits, difficulty of defecation, and intention to defecate), and comorbidities (abdominal distension, bleeding from anal fissures, sweating out of Nuria, memory loss, slowness of thought, and distraction). The main symptoms were scored on a three-level scale: 0, 2, and 4 points, with 0.5 points each for comorbidities and 0 points for no manifestations. The results of both studies showed that the scores of the auricular group were lower than those of the western medicine group after treatment, which was statistically significant ($P < 0.05$), indicating that the auricular group was better than the control group in improving clinical symptom scores.

Time to first bowel movement

This refers to the time interval between the start of treatment and the first bowel movement. Three studies reported the time of defecation, Li (15) and Zhang (17) reported the time in hours as the unit of measurement, while Zhong (18) converted the time of defecation into rank data for scoring, and Li and Zhang’s study was statistically analyzed. The results of Zhong’s study showed no statistical difference between the defecation time of the test group and the control group ($P > 0.05$), and the results of the other two studies (15,17) showed statistical differences between the test group and the control group ($P < 0.05$).

Stool traits

Two studies reported stool traits, Zhong (18) referred to the chronic constipation rating method of 0, 1, 2, and 3 classification, which is a four-category method, published by the Ministry of Health, and reported no statistical difference between the experimental and control groups ($P > 0.05$), and Zhang (17) used the efficacy developed according to the Clinical Research Guidelines for New Chinese Medicines The evaluation criteria, which were 0, 2, and 4 grade classification criteria, showed that the test and control groups were statistically different ($P < 0.01$). Due to the large clinical heterogeneity, no meta-analysis was

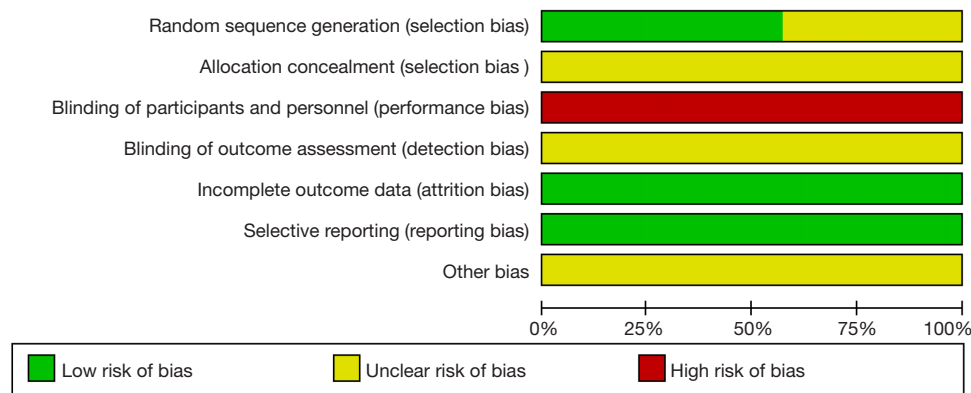


Figure 2 Risk of bias graph.

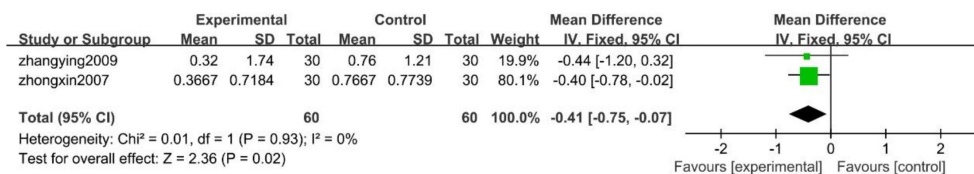


Figure 3 Forest plots of defecation interval.

performed.

Degree of defecation difficulty

The degree of defecation difficulty is indicated by the defecation difficulty index, and two studies have reported the degree of defecation difficulty, Zhong refers to the chronic constipation rating method in the 1993 edition of the Pharmaceutical Bureau of the Ministry of Health's Guidelines for Clinical Research on New Chinese Medicines (7), the 0, 1, 2, and 3 classification. The study showed no statistical difference between the test and control groups (P>0.05), and another study used the 0, 2, and 4 classification criteria (19). Considering that the clinical homogeneity was acceptable and the results of the statistical homogeneity test, P>0.1 and I²=0%, indicated that the included studies were homogeneous, the fixed-effects model was used for the meta-analysis.

The combined effect was not statistically significant (Z=0.78, P>0.05). The forest plot is shown in Figure 4.

Efficiency

Four of the six studies (14-16,18) reported efficiency, with 308 cases included 156 in the test group and 152 in the control group. The results of the homogeneity test, P>0.1

and I²<50%, indicated statistical homogeneity between the studies, and meta-analysis using a fixed-effects model showed that the efficiency of the discriminative auricular acupuncture group was statistically different than the western medicine group (Z=2.84, P<0.01, RR =1.23, 95% CI: 1.07, 1.42). The forest plot is shown in Figure 5.

Safety and long-term curative effect

Among the six corresponding studies, two studies (14,15) reported no adverse effects, while Zhong *et al.* (13,17,18) summarized and analyzed the side effects of the western medicine group in the discussion section, and Di (13) considered western medicine treatment as a stopgap measure, with more side effects after long-term application, and easy to relapse after discontinuation of the drug, long-term use not only produces dependence, but also aggravates constipation. Zhong and Zhang (17,18) discussed the respective characteristics and side effects of laxatives, such as tegaserod, which is used in the study to promote motivation, is prone to relapse after discontinuation of the drug, and is expensive, while phenolphthalein and other stimulant laxatives stimulate the intestinal wall to enhance intestinal peristalsis, thereby promoting defecation. Long-term use can lead to drug dependence and damage the

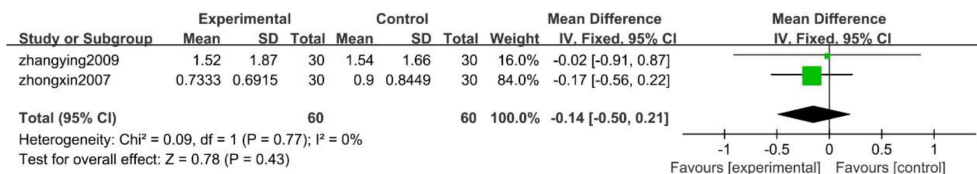


Figure 4 Forest plots of degree of defecation difficulty.

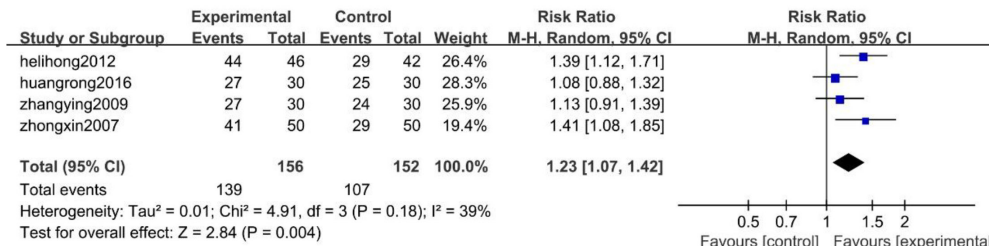


Figure 5 Forest plots of efficiency.

patient's enteric nervous system, resulting in irreversible damage. No specific adverse reactions were reported by He (16). In addition, only Di (13) reported the long-term efficacy of discriminative ear acupuncture, which showed that the difference in effect between auricular bean burial therapy and conventional drug therapy was not significant for a short period of time (<10 days), but was superior to conventional drug therapy for long-term use (≥ 20 days).

Discussion

Overall results

Data processing analysis showed that the interval between bowel movements after treatment of constipation in the auricular acupuncture group was lower than that of the western medicine group, and the efficiency was higher than that of the western medicine group. The results showed that the efficacy of the auricular acupuncture group was better than that of the western medicine group in the above aspects, but no statistically significant differences were found in the time of the first bowel movement, the shape of the bowel movement and the difficulty of bowel movement, which was also clinically appropriate. The two included studies both concluded that the total symptom score of the auricular cavity group was lower than that of the western medicine group ($P < 0.05$), but due to the large clinical heterogeneity, they could not be combined for analysis.

Stool properties

No statistical differences have been found regarding stool properties, which is somewhat at variance with clinical practice and may be related to the selected scoring criteria. The index of stool properties used by Zhang and Zhong (17,18) are based on whether the stool is dry after treatment, e.g., a score of 0 means no dryness and an increasing score indicates the degree of dryness. However, it could not accurately evaluate the side effects of the western drugs taken, such as loose stools instead, so it failed to show a statistical difference.

Limitations

Currently, Liu and Wu (20,21) used the mean weekly number of spontaneous bowel movements (SBMs) and mean weekly number of completely spontaneous bowel movements (CSBMs) as the primary outcome indexes for constipation treatment, which is internationally recognized. Three of the six studies included in this study involved the time between bowel movements indicator, which is more similar to the SBMs indicator and therefore used as the primary outcome indicator in this study. However, the included studies did not conduct more in-depth long-term efficacy observations and comparisons, and could not fully reflect the efficacy characteristics of the discriminative auricular acupuncture points. Also, safety was not adequately reported in the included studies. In addition,

due to the small number and low quality of the included studies, the frequency and intensity of auricular acupressure is highly subjective, and there is considerable variability in routine care, which will affect the reliability of the results.

Also, there may be gaps and loopholes in the inclusion of studies and in the evaluation of study quality. There are still shortcomings in the literature on the treatment of constipation at auricular acupuncture points included in this study. The principle of “pain to acupoint” is a commonly used method in TCM clinical practice, as is the principle of “pain to acupoint”. Some studies have used the “pain to acupoint” method without specifying the method of identification, but this study did not include this method.

Conclusions

In order to better reflect the effectiveness and characteristics of TCM diagnosis and treatment, a systematic review of the positive control of dialectical auricular acupuncture versus western medicine was conducted in this study. It is believed that dialectical auricular acupuncture treatment has better efficacy in terms of bowel interval compared with western medicine, and the long-term efficacy and safety of auricular acupuncture treatment may be better than that of western medicine, but the above results need to be supported by more clinical studies. This study reminds us that in future clinical research, we should strengthen scientific research methods and ideas, strengthen the scientific and practical nature of clinical research design, in the spirit of practical thinking of scientific research from the clinic and to the clinic, pay attention to the international frontier scientific research developments, adopt internationally recognized outcome indicators, and provide high-quality research evidence for clinical practice.

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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