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慢性便秘

Clinical guideline on acupuncture and moxibustion—
Chronic constipation

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Foreword

This guideline aims to provide a standardized set of recommendations and protocols for acupuncture and moxibustion interventions for chronic constipation.

This guideline is developed in accordance with the technical procedures and rules established by the Standardization Working Committee of the World Federation of Acupuncture-Moxibustion Societies.

This guideline is endorsed and published by the World Federation of Acupuncture-Moxibustion Societies.

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We thank Fei Yutong and Chang Liguo，experts of Beijing University of Chinese Medicine，who pro-

vided guidance and help on evidence-based medical methodology and ancient TCM literature during the development of this guideline.

Please note that some of the contents of this guideline may involve patents. The issuing organization of this guideline does not assume the responsibility for identifying patents.

Clinical guideline on acupuncture and moxibustion—Chronic constipation

1 Introduction

1.1 Terminology

1.1.1
acupuncture

According to ISO/TC 249 NP 20520[1], which is being formulated by the International Standard Organization, acupuncture therapy refers to the whole process of inserting acupuncture needles into the body and using corresponding techniques after the insertion. Acupuncture needles refer to medical instruments that, according to traditional medical theories, stimulate specific areas of the body by piercing them to prevent and cure diseases or improve health.

In the actual clinical work, acupuncture needles refers to filiform needles.

In this guideline, acupuncture refers to the treatment of puncturing the local skin of acupoints by needles with different lengths and diameters, namely, filiform needle.

As a common clinical stimulation method, electroacupuncture is usually performed together with filiform needle acupuncture. In this guideline, electroacupuncture can be used as appendages of filiform needle acupuncture.

In this guideline, hand acupuncture means that doctor uses his hand for manipulations as lifting and twisting without using electric stimulation.

1.1.2
moxibustion

Moxibustion refers to the treatment of lighting moxa sticks or moxa cone made from Artemisia argyi to do moxibustion at acupoints, including warm-needle moxibustion, moxa sticks mild moxibustion and intermedium moxibustion, but excluding direct moxibustion.

1.1.3
oral medication for constipation

Oral medication in this guideline refers to: prokinetic drugs (including prucalopride, mosapride), osmotic laxatives (including lactulose oral solution, polyethylene glycol powder), irritant laxatives (including bixacogidine, diarrhea), volumetric laxatives (including psyllium, wheat bran, methylcellulose). This guideline does not include Chinese medicine decoction and oral Chinese patent medicine.

1.2 Aims and objectives

C*linical guideline on acupuncture and moxibustion—Chronic constipation* aims to help clinicians and their patients make appropriate decisions regarding acupuncture & moxibustion treatment for chronic constipation based on the clinical situation and best clinical evidence, combined with each patient's values and level of willingness.

1.3 Scope

This guideline is intended to be used by acupuncture practitioners, healthcare workers and patients who desire information about the utility of acupuncture for the management of chronic constipation related to a wide range of factors.

1.4 Target audience

This guideline is good for professionals including: ① qualified acupuncture and moxibustion practitioners worldwide; ② teachers and students of traditional Chinese medicine institutions; and ③ scientific researchers engaged in acupuncture and moxibustion majors.

1.5 Settings

This guideline can be applied worldwide in hospitals, clinics containing acupuncture specialties, medical schools containing acupuncture specialties, and acupuncture-related scientific research and evaluation institutions worldwide.

1.6 Summary of recommendations

No.	PICO question / Recommendation
	Recommendation
1	For chronic constipation patients, how is the effectiveness of acupuncture compared with sham acupuncture?
	For patients with chronic functional constipation, the guideline panel recommends using acupuncture to improve the clinical symptoms related to constipation rather than sham acupuncture. (Strong recommendation based on high-quality evidence body.)

(*continued*)

<table>
<tr><td rowspan="2">No.</td><td>PICO question</td></tr>
<tr><td>Recommendation</td></tr>
<tr><td rowspan="2">2</td><td>For chronic constipation patients of different genders, how is the effectiveness of acupuncture compared with sham acupuncture?</td></tr>
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<tr><td rowspan="2">5</td><td>For chronic constipation patients, how is the effectiveness of EA with deep insertion compared with EA with shallow insertion?</td></tr>
<tr><td>For patients with chronic functional constipation, the guideline panel cannot determine whether deep needle insertion on abdominal acupoints with electroacupuncture can bring greater benefits and ensure the safety comparing to shallow needle insertion.(No consensus on recommendation was reached, based on high-quality evidence body.)</td></tr>
<tr><td rowspan="2">6</td><td>For chronic constipation patients, how is the effectiveness of acupuncture compared with western oral medicine?</td></tr>
<tr><td>For patients with chronic constipation, guideline panel suggests acupuncture therapy to improve their clinical symptoms and quality of life, rather than taking oral western medicine (including proprietorial capsules, mosapride tablets, lactulose oral solution, and polyethylene glycol powder).(Conditional recommendation, based on moderate-quality evidence body.)</td></tr>
<tr><td rowspan="2">7</td><td>For chronic constipation patients, how is the effectiveness of acupuncture compared with biofeedback therapy?</td></tr>
<tr><td>For patients with chronic constipation due to UPFS, the guideline panel recommends acupuncture therapy to improve the clinical symptoms, quality of life and anorectal manometry index.(Strong recommendation, based on moderate-quality evidence.)</td></tr>
</table>

(*continued*)

No.	PICO question / Recommendation
8	For chronic constipation patients, how is the effectiveness of acupuncture with moxibustion compared with solo acupuncture?
	For patients with chronic constipation, compared with acupuncture alone, the guideline panel suggests the use of acupuncture combined with moxibustion therapy to improve the clinical symptoms of patients.(Conditional recommendation, based on moderate-quality evidence.)
9	For chronic constipation patients, how is the effectiveness of acupuncture with western medicine compared with solo western medicine?
	For patients with chronic constipation, compared with solo oral western medicine, the guideline panel recommends using acupuncture combined with oral western medicine to improve the clinical symptoms.(Strong recommendation, based on low-quality evidence.)
10	For chronic constipation patients, how is the effectiveness of moxibustion with western medicine compared with solo western medicine?
	For patients with chronic functional constipation, compared with the use of solo western medicine, the guideline panel suggests the use of moxibustion combined with western medicine.(Based on expert consensus, no RCT evidence.)
11	For chronic constipation patients, how do the risks of acupuncture compare with existing treatments?
	For patients with chronic constipation, acupuncture therapy has a lower incidence of adverse events compared with oral western medicine (including lactulose oral solution, prucalopride capsules, and mosapride tablets). From the perspective of safety, the guideline panel recommends the use of acupuncture therapy rather than oral western medicine.(Strong recommendation, based on moderate-quality evidence.)
12	For chronic constipation patients, how do the time and financial burdens of acupuncture compare with existing treatments?
	For patients with chronic constipation, where acupuncture has a lower cost-effective ratio compared to oral mosapride, the guideline panel suggests to use acupuncture therapy from the perspective of economic burden.(Conditional recommendation, based on low-quality evidence.)

1.7 Contacts

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2 Overview of the disease

2.1 Clinical characteristics

Chronic constipation involves common clinical symptoms of constipation that exceed 6 months' duration and seriously affect the quality of life of patients. For chronic constipation, conventional strategies include lifestyle changes, medication, psychotherapy, biofeedback therapy or surgery [2]. Acupuncture for constipation has a history dating back to the age of "*Inner Canon of Yellow Emperor* (*Huang Di Nei Jing*)" (About 99 BC to 26 BC). At the same time, acupuncture treatment of chronic constipation is becoming a hot spot in the field of acupuncture clinical research. Even though, guideline of acupuncture for chronic constipation is still in lacking. A search of the literature uncovered four clinical guidelines concerning constipation that have been published in western countries[3-6].However, none of these included acupuncture.

Chronic constipation involves common clinical symptoms of constipation that exceed 6 months' duration and seriously affect the quality of life of patients. The prevalence has been estimated to be as high as 30%[7-12]. Chronic constipation includes functional constipation, which is defined as constipation without an organic etiology, and organic constipation caused by diet, medication, metabolic or neurological disorders, and psycho social issues. Most cases involve functional constipation. According to the pathophysiologic characteristics, chronic constipation can be classified into Slow Transit Constipation (STC), defecatory disorder, and Normal Transit Constipation (NTC)[13].However, in reality, many patients demonstrate symptoms attributable to more than one constipation sub-types.

2.2 Diagnosis

Functional constipation is diagnosed according to the symptom-based Rome criteria, which were first developed for adults in 1989[14-16]. These criteria have been updated several times, and are now internationally recognized and used for both research and clinical purposes. The Rome Ⅱ criteria were published in 1999 and were the first criteria for pediatric functional gastrointestinal disorders. The Rome Ⅲ criteria for functional constipation include at least two of the following symptoms during ⩾ 25% of defecations: straining, lumpy or hard stools; sensation of incomplete evacuation; sensation of anorectal obstruction or blockage; relying on manual maneuvers to promote defecation; and having less than three unassisted bowel movements per week[17].

The etiology of constipation includes diet, medication, metabolic or neurological disorders, and psycho social issues. The variable nature and symptom severity of constipation necessitate an individualized approach to evaluation and treatment. The revised Rome Ⅳ criteria — *For childhood and adult functional constipation* — were published in 2016[18].

2.3 Conventional managements

Western medicine treats chronic constipation using lifestyle changes, medication, psychotherapy, biofeedback therapy or surgery. Dietary recommendations, including the need for a healthy intake of dietary fiber and water, are the first interventions in the treatment of constipation. Osmotic laxatives such as lactulose and polyethylene glycol are the first-choice maintenance therapy recommended for functional constipation[19]. Other frequently used laxatives include mineral oil and magnesium hydroxide[20]. If symptoms persist, a stimulant laxative such as bisacodyl or senna is recommended in clinical guidelines for both children and adults. Surgery for functional constipation is regarded as a last resort, and only considered when maximal conventional therapies have failed and symptoms are greatly disrupting quality of life.

2.4 Syndrome differentiation of constipation in Traditional Chinese Medicine (TCM)

2.4.1 *The consensus on TCM diagnosis and treatment of chronic constipation* formulated by The Branch of Spleen and Stomach Diseases of the Chinese Society of TCM 2011 (Beijing)[21], divided constipation into the following five TCM syndromes.

2.4.1.1 Intestinal heat syndrome

Main symptoms: ① dry stool; ②reddish tongue with yellow coating.

Secondary symptoms: ① abdominal distension or pain; ②dry mouth and bad breath; ③restless and upset mood; ④small volumes of dark yellow urine; ⑤ rapid pulse.

2.4.1.2 Intestinal Qi stagnation syndrome

Main symptoms: ① difficulty in defecation; ②abdominal fullness or abdominal pain.

Secondary symptoms: ① frequent flatulence; ② frequent belching; ③irritable or depressed mood; ④poor appetite; ⑤thin and greasy tongue coating; ⑥string pulse.

2.4.1.3 Lung and spleen Qi deficiency syndrome

Main symptoms: ① difficulty in defecation; ②shortness of breath.

Secondary symptoms: ① fatigue; ②unwilling to speak; ③whitish tongue; ④weak pulse.

2.4.1.4 Spleen-kidney Yang deficiency syndrome

Main symptoms: ① dry stool, difficulty in defecation; ②slow pulse.

Secondary symptoms: ① cold pain in the abdomen; ②diuresis; ③coldness in extremities; ④ pale complexion; ⑤pale tongue with white coating.

2.4.1.5 Blood deficiency syndrome

Main symptoms：① dry stool；②reddish tongue with thin white coating.

Secondary symptoms：① dry mouth；② vertigo or tinnitus；③weakness in waist and knee joints；④palpitation；⑤reddish cheeks；⑥weak pulse.

2.4.2 Another method for syndrome differentiation is described in the [22] which classified constipation into three syndromes.

2.4.2.1 Heat constipation syndrome

Symptoms：dry stool；difficulty in defecation；prolonged discharging interval；anal fissure；blood in stool；bitter and dry mouth；Small volumes of dark yellow urine；reddish tongue with yellow coating；rapid pulse.

2.4.2.2 Qi stagnation constipation：difficulty in defecation；abdominal distension and pain；frequent belching；string-like pulse.

2.4.2.3 Cold constipation：normal defecation；weakness；shortness of breath；cold extremities；abdominal pain；fat，pale tongue；heavy，thin pulse.

3 Guideline development process

3.1 Development of clinical questions

PICO questions were formulated through locating population，intervention，comparator，and outcome. Electrical survey questionnaires were drafted and distributed with an on-line tool（https://www.wjx.cn/）.The questionnaire is available in English and Chinese，and was distributed to both Chinese and foreign users. 2 rounds of electric Delphi survey were performed.

At the same time，the Guide Development Group（GDG）conducted a series of expert interviews. On March 6，2021，a ZOOM meeting was held with Chinese and foreign experts for consensus on PICO questions and outcomes（conference no. 62884055546）. After online voting and discussion，GDG analyzed the results through Delphi statistical indicators such as expert activity index，familiarity index，authority index，importance distribution mean and Kendall coordination index. Finally，12 clinical PICO problems were identified.

Meanwhile，the panel members rated the importance of clinical outcomes according to the GRADE grading method and gained consensus by voting. There were 3 critical outcomes-the severity of constipation，including Complete Spontaneous Bowel Movements（CSBMs），Spontaneous Bowel Movements（SBMs），Cleveland Clinic Score（CCS），Knowles-Eccersley-Scott Symptom score

(KESS). Patient treatment satisfaction and treatment effectiveness. There were 5 important outcomes—Patient Assessment of Constipation Quality Of Life questionnaire (PAC-QOL), treatment safety, objective evaluation indicators including colon transit time, anorectal pressure measurement, health economics indicators and emotional psychological indicators.

3.2 Construction of evidence body

GDG entrusts the Institute of Traditional Chinese Medicine Information of China Academy of Chinese Medicine Sciences to formulate the literature retrieval strategy of the guideline and conduct the literature search. GDG signed a formal literature search service agreement with the institution and was approved by Guang'anmen Hospital.

GDG completed RCTs screening and systematic review/meta-analysis (if possible) for all clinical questions. Part of the system reviews has been published in journals.

As a traditional Chinese medicine therapy, RCT evidence is only one aspect of the recommendations for acupuncture and moxibustion in treating chronic constipation. In order to form recommendations which is consistent with the theory of TCM and can better guide the clinical practice, this guideline also retrieved the experience of acupuncture and moxibustion in treating chronic constipation from ancient medical books and famous Chinese medicine experts in modern times.

We conducted a series of interviews with ancient Chinese medicine bibliography experts to determine the scope of ancient Chinese medicine literature and the methods to obtain evidence of constipation treatment from these literature. Eventually, TCM classics including 〈*Simple Questions*〉(*Su Wen*), 〈*Ling Shu*〉, 〈*Treatise on Febrile Diseases*〉(*Shang Han Lun*), 〈*Synopsis of the Golden Chamber*〉(*Jing Gui Yao Lue*) were included as major literature. Other books as 〈*Zhen Jiu Jia Yi Jing*〉, 〈*Zhou Hou Bei Ji Fang*〉, 〈*Bei Ji Qian Jin Yao Fang*〉, 〈*Sheng Ji Zong Lu*〉, 〈*Zhen Jiu Zi Sheng Jing*〉, 〈*Pu Ji Fang*〉, 〈*Zhen Jiu Ju Ying*〉, 〈*Zhen Jiu Da Cheng*〉, 〈*Lei Jing Tui Yi*〉, 〈*Ci Jiu Xin Fa Yao Jue*〉, 〈*Zhen Jiu Ji Cheng*〉, 〈*Jin Zhen Mi Chuan*〉 were also included.

Doggerel (Ge Fu) is a summary of the experience of medical scholars in past dynasties. We also included 〈*Bian Que Shen Ying Jing*〉, 〈*Yu Long Jing*〉, 〈*Sheng Yu Ge*〉, 〈*Xi Hong Fu*〉, 〈*Za Bing Xue Fa Ge*〉, 〈*Bai Zheng Fu*〉, et al.

In terms of modern experts' experience, we selected 9 representative acupuncture experts-Tian Conghuo, Zhou Dean, He Puren, Lu Shouyan, Cheng Danan, Jin Bohua, Yang Jiasan, Wang Leting and Zheng Kuishan. We turned to professionals of institute of information on TCM for help in this part of the literature. They searched CNKI, VIP, Wanfang database for articles concerning clinical experiences of these experts. For monographs, they searched Du Xiu and Chao Xing electric book database.

3.3 Development of recommendations

The RCT evidence of each PICO question was systematically reviewed and the detailed contents of the evidence bodies were recorded with Summary of Findings (SoF) tables.

Evidence to Decision (EtD) framework was used as a tool for making recommendations. In this tool, 12 factors were involved to help users to make comprehensive judgement[23].

Online consensus meetings were held to decide the direction and strength of recommendations. The expert panel was composed of 15 experts from circles of acupuncture, Chinese and western digestive medicine, Chinese and western anorectal medicine, Chinese and western nursing, integrative medicine and methodology.The region covered China (Hong Kong), Malaysia, Canada and Singapore. Online voting and discussion were adopted for the consensus of recommendations.

The expert consensus statements were based on voting by all expert panel members. The GRADE grid method was used to determine the direction and strength of consensus[24].

On the basis of expert consensus, we developed detailed treatment plans for each clinical question. These plans contained factors as points selection, stimulation methods, operations of treatment and precautions. The above factors were mainly based on RCT studies where the critical outcome had a positive result in this PICO question.

In the absence of RCT studies, consensus recommendations were generated according to experience of ancient books and modern doctors in treating constipation with acupuncture. Factors to be considered for expert consensus include: ① Is the intervention intuitive and repeatable, and can it be used in clinical practice? ② Is the curative effect accurate? Is it better than conventional intervention? ③Whether it can inspire or guide clinical diagnosis and treatment?

The guideline document was reviewed several times by all GDG members, and modified using a Delphi approach until consensus was reached.

4 Recommendations

Question 1: For chronic constipation patients, how is the effectiveness of acupuncture compared with sham acupuncture?
(1) Recommendation
For patients with chronic functional constipation, the guideline panel recommends using acupuncture to improve the clinical symptoms related to constipation rather than sham acupuncture. (Strong recommendation based on high-quality evidence body.)

(*continued*)

(2) Summary of findings

① A systematic review published in 2020 analyzed the efficacy of acupuncture and sham acupuncture on chronic Functional Constipation (FC) in adults [25]. This review included 8 RCT studies[26-33]. The outcome measures included the severity of constipation (CSBMs, BSFS, CCS), the responder rate, and the safety of the treatment.

The meta-analysis showed that the acupuncture group had significantly better efficacy in increasing the CSBMs than in the sham acupuncture group($P<0.00001$; MD = 0.84 [95% CI, 0.65 to 1.03]; I^2 = 0%). Similar results were also obtained for improved stool form scores, the responder rate and CCS. No increased risk of adverse events was observed in the acupuncture group ($P=0.44$; RR = 1.18 [95% CI, 0.77 to 1.81]; I^2 = 0%). The effect size is small.

Evidence body quality rating is high.

Of the eight included RCT studies, bilateral Tianshu (ST25) was used as the major points. In addition, 3 studies have selected the bilateral Fujie (SP14) and the Shangjuxu (ST37) as the major points.

Through the investigation of ancient literature, we found that the functions of Tianshu (ST25), Fujie (SP14) and Shangjuxu (ST37) are similar. They all have the function of dredging qi stagnation, which is suitable for the symptoms of intestinal stagnation in chronic constipation. With the combined application, the three points will play a synergistic effect.

In ＜*Zhen Jiu Jia Yi Jing-Volume 8*＞, it was said: Distention at large intestine may be treated with Tianshu. Distention at large intestine here refers to qi stagnation in large intestine and hard to discharge tool, which are commonly seen in chronic constipation.

In ＜*Zhen Jiu Jia Yi Jing-Volume 11*＞, it was said: Pain around the navel, qi rushing up to the heart, coldness in abdomen and diarrhea may be treated with Fujie. Qi rushing up to the heart and coldness in abdomen here refers to coldness stagnated qi circulation in abdomen, which are commonly seen in "Qi constipation" and "Cold constipation" now.

In ＜*Suwen Shui Re Xue Lun*＞, it was said: Qijie, Sanli, Shangjuxu and Xiajuxu, these eight points may be used for letting out heat in stomach. In the ancient medical books, the function of the stomach usually includes the intestine. The above discussion shows that Shangjuxu is applicable to the heat constipation of later generations.

Seven of the eight studies used electroacupuncture with a dilatational wave of 10/50 Hz and a current intensity of 0.1 to 1mA depending on the participant's comfort level .

All eight RCT studies selected a treatment frequency of 5 sessions per week for 3 to 4 weeks in the treatment course. For the 8-week long-course study, the treatment frequency was reduced to 3 times per week at weeks 3 to 8.

(*continued*)

② Sham acupuncture control is necessary to clarify the net effect of acupuncture, so this question has a priority. Compared with sham acupuncture, acupuncture showed a desirable effect in improving constipation severity, and did not increase the risk. Patients with chronic constipation, especially those with severe constipation, urgently need effective treatment options, and acupuncture therapy is in line with the wishes of most patients. Most countries have the practice of acupuncture and moxibustion and carried out legislative work. The necessary resources of acupuncture make it feasible for patients to receive this therapy. Sham acupuncture only act as a control in clinical studies and is not used as a treatment, so research on the cost of sham acupuncture is lacking. The cost of acupuncture treatment varies widely from region to region, depending on the local medical policy and income level. At present, there is a lack of research on acupuncture cost and benefit comparison and health-related equity both at home and abroad. Based on above arguments, the guideline recommendation consensus panel voted to strongly recommend acupuncture for the treatment of chronic functional constipation.
(3) Explanation
● Subgroup One RCT compared the efficacy of Electroacupuncture (EA) and Sham Acupuncture (SA) in adults with Chronic Severe Functional Constipation (CSFC) [28]. The primary outcome measure is changes in mean weekly CSBM versus baseline, other outcome measures include the proportion of patients with a mean of 3 or more CSBMs per week, and the incidence of acupuncture-related adverse events.The increase from baseline in mean weekly CSBMs during weeks 1 to 8 was 1.76 [95% CI, 1.61 to 1.89] in the EA group and 0.87 [95% CI, 0.73 to 0.97] in the SA group (between-group difference, 0.90 [95% CI, 0.74 to 1.10]; $P < 0.001$).Acupuncture-related adverse events during treatment were infrequent in both groups, and all were mild or transient.The effect size is moderate. The results suggested that 8 weeks of electroacupuncture treatment increased weekly CSBMs and was safe for patients of chronic severe functional constipation.

(*continued*)

Severe functional constipation refers to patients with an average number of CSBMs twice or less per week for more than 3 months. ● Implementation Electroacupuncture should not be used in patients with cardiac pacemaker implantation. ● Monitoring and evaluation ① To monitor the proportion of patients with chronic functional constipation seeking acupuncture treatment, especially those with severe chronic functional constipation. ② To evaluate the extent of symptom improvement after acupuncture treatment and safety in chronic functional constipation, especially in patients with severe chronic functional constipation. ● Research priorities We suggest future studies to explore more sham acupuncture methods, longer follow-up and health economics assessment.
(4) Application of recommendation
① This recommendation is applicable to adults (≥18 years old) patients with chronic functional constipation. ② For IBS constipation type or drug-induced constipation, or constipation secondary to endocrine, metabolic, neurological diseases or constipation after surgery, acupuncture treatment still lacks high-quality research evidence, and it is not applicable to this recommendation. ③ When using this recommendation, appropriate acupoints can be added and decreased according to the patient's TCM syndrome type or concurrent symptoms.
(5)Recommended treatment protocol
● Selection of acupoints Bilateral Tianshu (ST25), Fujie(SP14) and Shangjuxu(ST37). A dilatational wave of 10/50 Hz and a current intensity of 0.1 to 1 mA depending on the participant's comfort level may be used for stimulation.

(*continued*)

- Operation

When participants are supine, 0.30 mm × 50 mm or 0.35 mm × 75mm needles are inserted approximately 30 to 70 mm into Tianshu (ST25) and Fujie(SP14) slowly and vertically, without manipulation, until they pierce the muscle layer of the abdominal wall.In addition, the 0.30 mm × 40mm needle is inserted vertically into Shangjuxu about 30mm.

- Treatment frequency

Treatment frequency is 3 to 5 times in the first week and 2 to 3 times per week after efficacy appear.

- Treatment course

Treatment courses ranged from 4 to 8 weeks. For severe functional constipation, a longer course of treatment is recommended.

Question 2:For chronic constipation patients of different genders, how is the effectiveness of acupuncture compared with sham acupuncture?
(1) Recommendation
For women with severe chronic functional constipation, the guideline panel recommends acupuncture therapy to improve the clinical symptoms, rather than sham acupuncture.(Strong recommendation based on high-quality evidence body.)
(2) Summary of findings
① One RCT published in 2019 evaluated the efficacy of Electroacupuncture (EA) versus SA in 822 women with chronic severe functional constipation[34]. The primary outcome was percentage of the sustained CSBMs responders for the subset of women with severe constipation, other outcome measures consisted of mean weekly CSBMs, mean weekly SBMs, BSFS and PAC-QOL. After 8 weeks of treatment, and after 12 weeks of follow-up, the percentage of the sustained CSBMs responders was significantly higher in the EA group (24.3%) than in the SA group (8.1%) with difference of 13.1% [95%CI, 6.5% to 19.7%; $P < 0.001$]. The incidence of adverse events (AEs) related to acupuncture was not statistically significant between the two groups. This study showed that EA at 8 weeks of treatment improved the spontaneity and completeness of defecation in female patients with severe functional constipation, and the effect persisted for 12 weeks after cessation of treatment.The effect size is moderate. Evidence quality rating is high.

(*continued*)

Bilateral Tianshu (ST25), Fujie (SP14) and Shangjuxu (ST37) were the major points, and no other points were selected. ② Women are more likely to be affected by chronic constipation because of their different physiological characteristics. The efficacy of acupuncture in female patients with chronic constipation may differ from that in the general population. Therefore, exploring the efficacy of acupuncture to female patients with chronic constipation has a priority . Compared with sham acupuncture, acupuncture showed a desirable effect in improving the constipation severity and quality of life in female patients, and it did not increase the risk. Factors as cost, resources, and patient will are the same as PICO question 1. At present, there is a lack of research on the equity of acupuncture in female patients and the cost-effect comparison between acupuncture and sham acupuncture. Based on above arguments, the guideline recommendation consensus panel voted to strongly recommend acupuncture for the treatment of chronic functional constipation.
(3) Explanation
● Subgroup Only one RCT article was included in this PICO question, with no subgroup study. ● Implementation ① Women should be more careful in acupuncture treatment during menstruation and lactation, and should communicate well with patients. ② Electroacupuncture should not be used in patients with cardiac pacemaker implantation. ● Monitoring and evaluation ① To monitor the proportion of women seeking acupuncture treatment for severe chronic functional constipation. ② To assess the improvement of symptoms after acupuncture treatment and safety in women with severe chronic functional constipation. ● Research priorities We suggest future studies focus on patients' satisfaction to treatment and health economics assessments.

(*continued*)

(4) Application of recommendation
① This recommendation is applicable to female adults (≥18 years old) patients with chronic functional constipation. ② Severe functional constipation refers to patients with an average number of complete spontaneous bowel movement (CSBMs) twice or less per week for more than 3 months. ③ Because acupuncture on abdominal acupoints has obvious risks for pregnant women, this recommendation is not suitable for constipation treatment in pregnant women (even if the patient meets the diagnostic criteria for severe functional constipation).
(5) Recommended treatment protocol
● Selection of acupoints Same with PICO question 1. ● Operation Same with PICO question 1. ● Treatment frequency Treatment frequency is 3 to 5 times in the first week and 2 to 3 times per week after efficacy appear . ● Treatment course We recommend a total treatment course of 8 weeks.

Question 3: For chronic constipation patients of different ages, how is the effectiveness of acupuncture compared with sham acupuncture?
(1) Recommendation
For older patients (>65 years old) with chronic functional constipation, guideline panel suggests acupuncture therapy rather than sham acupuncture. (Based on experts' consensus with no RCT evidence.)

(*continued*)

(2) Summary of findings
For chronic constipation in the elderly, ancient doctors emphasized the pathogenesis and the formulation of treatment principles based on physical characteristics. < *Jing Yue Quan Shu* · *constipation* > said: Constipation of senile person is due to either deficiency of Qi and blood or over consumption of fluid[35]. Zhu Zhen Hen, a famous doctor of Yuan dynasty said: Constipation of elderly or deficient person should be treated mildly but not heavily. Otherwise complex condition will appear because of the exhaustion of Qi and blood[36]. As can be seen from above ancient books, the causes of constipation in the elderly are Qi and blood deficiency, which is similar to deficiency constipation (Xu Bi). For treatment, the elderly constipation patients should not use strong and fast effect laxatives. This treatment principle is similar to moistening intestines and defecation method (Run Chang Tong Bian). There is no record of specific points for the elderly constipation in the ancient books. Yang Jiasan, a modern acupuncture master, classifies senile constipation with heat, Qi stagnation, deficiency and coldness, and gives the corresponding points selection plan[37]. According to clinical epidemiological studies of chronic constipation, older people have a higher incidence of constipation and respond poorly to conventional treatment. The curative effect of acupuncture on constipation in the elderly has a priority. Clinical research evidence of PICO question 1 showed that acupuncture works better than sham acupuncture in patients with chronic constipation, including the elderly, providing indirect evidence for the efficacy of acupuncture in elderly patients with chronic constipation. The health-related equity of the elderly should be concerned because of physical decline and increased underlying diseases. There is still a lack of health economics research on acupuncture therapy in the constipation group among the elderly. Based on the above arguments, the guideline recommendation consensus expert group voted to recommend acupuncture for chronic functional constipation in the elderly in the form of expert consensus.

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(3) Explanation
● Subgroup None. ● Implementation This recommendation is not applicable to older patients with severe cardiovascular disease, cognitive dysfunction, psychiatric disorders, or diseases that may affect patient collaboration. ● Monitoring and evaluation ① To monitor the proportion of elderly patients with chronic functional constipation seeking acupuncture treatment. ② To evaluate the symptom improvement and safety after acupuncture treatment in elderly patients with chronic functional constipation. ● Research priorities We suggest future clinical studies focus on acupuncture for chronic constipation in the elderly with control group of sham acupuncture to clarify the efficacy of acupuncture in this population.
(4) Application of recommendation
① This recommendation is based on the expert consensus opinion. ② This recommendation comes from the ancient literature and modern expert experience, without RCT research support. ③ Users need to conduct acupoint grouping according to the physical characteristics and basic diseases of the elderly , and decide the amount of stimulation.
(5) Recommended treatment protocol
The following acupoints may be selected to treat elderly constipation: ① Heat constipation (Re Bi): reduce Zusanli (ST36), Tianshu (ST25); tonify Zhaohai (KI6), Zhigou (TE6); ② Qi stagnation constipation (Qi Bi): reduce Dadun (LR1), Zusanli (ST36); tonify Zhigou (TE6), Taibai (SP4);

(*continued*)

③ Deficiency constipation (Xu Bi): tonify Qihai (CV6), Zusanli (ST36), Pishu (BL20), Weishu (BL21); ④ Cold constipation (Han Bi): tonify Dachangshu (BL25), Shenshu (BL23), Zhigou (TE6), Zhaohai (KI6).

Question 4: For chronic constipation patients, how is the effectiveness of EA compared with hand acupuncture?
(1) Recommendation
For patients with chronic functional constipation, rather than manual acupuncture, the guideline panel suggests the use of electroacupuncture as a stimulation method to relieve their symptoms and improve their quality of life. (Conditional recommendation based on moderate-quality evidence body.)
(2) Summary of findings
① A total of five RCTs of electroacupuncture vs hand acupuncture for chronic functional constipation patients, including 378 patients, were included[38-42]. The outcome measures include the severity of constipation (SBMs, BSFS, CCS), and PAC-QOL. The meta-analysis suggested that the improvement of PAC-QOL was significantly better in the electroacupuncture group than in the hand acupuncture group after 2 to 4 weeks of treatment($P<0.01$; MD = 4.24 [95% CI −6.78 to 1.70]; $I^2=79\%$), and the total responder rate in the electroacupuncture group was significantly higher than in the hand acupuncture group($P<0.01$; RR = 1.30 [95% CI, 1.14 to1.48]; $I^2=0$). The effect size is moderate. Evidence body quality rating was moderate. Bilateral Tianshu (ST25) and Shangjuxu (ST37) were selected in four studies, and Fujie (SP14), selected in three studies. One study used different acupoints according to TCM syndrome differentiation. ② Compared with hand acupuncture, electroacupuncture demonstrated desirable effects in improving constipation severity and improving quality of life. However, existing studies did not evaluate whether electroacupuncture poses an additional risk compared to hand acupuncture. Therefore, some experts, especially those outside China, expressed their concern and therefore chose conditional recommendations.

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According to interviews with guideline consensus experts, electroacupuncture has been widely used in clinical practice in North America, Southeast Asia and some other places, with good resource access and feasibility. In order to relieve the disease as soon as possible, most patients have good compliance with electroacupuncture, which is in line with their wishes. The electroacupuncture does not charge otherwise in most areas and does not add an additional economic burden. At present, studies on the cost-effect comparision of hand acupuncture and electroacupuncture and treatment equity are lacking at home and abroad. Based on above arguments, the guideline recommendation consensus panel voted to conditionally recommend electroacupuncture for the treatment of chronic functional constipation.
(3) Explanation
● Subgroup A subgroup analysis comparing electroacupuncture versus hand acupuncture is currently lacking. ● Implementation ① Electroacupuncture equipment shall be produced by qualified manufacturers and introduced through formal channels. Electroacupuncture devices requires regular maintenance. ② Electroacupuncture should not be used in patients with cardiac pacemaker implantation. ● Monitoring and evaluation ① To monitor the proportion of patients with chronic functional constipation receiving electroacupuncture treatment. ② To evaluate the extent of symptom improvement and safety after electroacupuncture treatment in patients with chronic functional constipation. ● Research priorities We suggest future studies to evaluate safety of electroacupuncture , efficacy of different electroacupuncture wave forms, and electroacupuncture health economics.

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(4) Application of recommendation
① This recommendation is applicable to adults (≥18 years old) patients with chronic functional constipation. ② For IBS constipation type or drug-induced constipation, or constipation secondary to endocrine, metabolic, neurological diseases or constipation after surgery, acupuncture treatment still lacks high-quality research evidence, and it is not applicable to this recommendation.
(5) Recommended treatment protocol
● Selection of acupoints Bilateral Tianshu (ST25), Fujie (SP14) and Shangjuxu (ST37) may be selected as the major points. According to patient's TCM syndrome differentiation, bilateral Hegu (LI4) and Quchi (LI11) may be used to treat heat constipation; Qihai (CV7) to treat Qi stagnation constipation; bilateral Pishu (BL21) to treat deficiency constipation and Guanyuan (CV6) to treat cold constipation. ● Operation When using the electroacupuncture, the paired alligator clip of the electrode may be laterally attached to the bilateral Tianshu point (ST25) and Fujie (SP14) needle handles. The electroacupuncture stimulation usually lasts for 30 minutes, with a 2/15 or 10/50Hz dilatational wave, and a current intensity of 0.1 to 1mA, depending on the patient's tolerance (preferably the skin around the acupoints shakes slightly without pain).

Question 5: For chronic constipation patients, how is the effectiveness of EA with deep insertion compared with EA with shallow insertion?
(1) Recommendation
For patients with chronic functional constipation, the guideline panel cannot determine whether deep needle insertion on abdominal acupoints with electroacupuncture can bring greater benefits and ensure the safety comparing to shallow needle insertion.(No consensus on recommendation was reached, based on high-quality evidence body.)
(2) Summary of findings
① A systematic review published in 2019 analyzed the efficacy of deep needle insertion with electroacupuncture versus shallow needle insertion with electroacupuncture in patients with chronic functional constipation[43].

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A total of 9 RCT articles were included in this review, and the outcome measures included mean weekly SBMs and CCS[44-52]. Meta-analysis suggested that after 4 weeks of treatment, effect of deep puncturing group was significantly better than that of the shallow puncturing group in improving SBMs ($P<0.01$; MD = 1.01 [95%CI, 0.79 to 1.23]; $I^2 = 0$) and CCS ($P<0.01$; MD = 1.52 [95%CI, −1.89 to −1.15]; $I^2 = 0$). The deep needle insertion group was better than the shallow needle insertion group .The effect size is small.

This systematic review conducted a descriptive analysis of the safety of different insertion depths with electroacupuncture. It seemed that deep electroacupuncture acupuncture may cause more symptoms of discomfort, especially the local pain of acupuncture, but the meta-analysis was not performed.

Evidence body quality rating is high quality.

9 included studies chose bilateral Tianshu (ST25) as only acupoint and electroacupuncture as stimulation method.

② Needle insertion depth is the key factor to the clinical treatment of acupuncture. As early as in the time of < *Huang Di Nei Jing* >, the needling depth of acupuncture has been discussed. Therefore, the question has priority.

Compared with the shallow insertion electroacupuncture at abdominal acupoints, deep insertion showed desirable effects in improving the severity of constipation.

For Tianshu (ST25), deep or shallow acupuncture are charged the same fee in China. For other acupoints, such as limb points and waist acupoints, deep acupuncture may be charged higher. There is no evidence of whether there is a difference charging between deep and shallow acupuncture in other areas.

Abdominal acupoint deep acupuncture therapy is a common therapy in China, and there is no definite evidence of its acceptance in other countries and regions.

Because deep needle insertion may bring more discomfort to patients, it is possible to affect patient acceptance and reduce the feasibility of treatment.

At present, there is no research on cost-effect comparison of different depth acupuncture at home and abroad.

During the consensus expert discussion, some experts, especially those from outside China, expressed their concern about a deeper needle depth, especially pierced into the peritoneum, could lead to more risks. Therefore, they felt uncertain whether a deeper acupuncture depth should be recommended.

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Based on the above arguments, the guideline recommendation consensus expert group did not form a consensus on the electroacupuncture deep acupuncture method in the treatment of chronic constipation after two rounds of voting.
(3) Explanation
● Subgroup A subgroup analysis of acupuncture with different needle insertion depth for chronic constipation is lacking. ● Implementation ① The guideline panel is not yet able to provide a recommendation for deep acupuncture on abdominal acupoints for chronic constipation because no consensus could be reached. ② When determining the depth of acupuncture, doctors should consider their own skill level, patients' physical condition and willingness. ③ Practitioners should consider the possible clinical and legal risks of a deeper abdominal acupoint acupuncture depth, and consult with patients as required by local regulations and laws. ④ Informed consent from patients may be necessary when treated with deep stabbing. ● Monitoring and evaluation The guideline panel is not yet able to provide a recommendation for electroacupuncture deep insertion treatment for chronic constipation according to the discussion of the guideline consensus expert group. Therefore, the monitoring and evaluation method for the recommendation cannot be determined at present. ● Research priorities We suggest future studies to explore the efficacy of different acupuncture depths at more acupoints on chronic constipation. It is suggested to have individualized definition to the depth of acupuncture. It is suggested to use the objective index as stool routine test to study the safety of acupuncture of different depths.

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(4) Application of recommendation
① 15 members of the guideline consensus panel failed to reach a consensus on the recommendation direction after two rounds of voting. ② Bilateral Tianshu (ST25) was used in all 9 involved RCTs as a single acupuncture point. ③ Deep insertion in this PICO question refers to the acupuncture needle insert into Tianshu (ST25) point until it pierce the peritoneum. Shallow insertion refers to acupuncture with depth of 0.6 to 1.5 cun (30 to 40 mm).

Question 6: For chronic constipation patients, how is the effectiveness of acupuncture compared with western oral medicine?
(1) Recommendation
For patients with chronic constipation, guideline panel suggests acupuncture therapy to improve their clinical symptoms and quality of life, rather than taking oral western medicine (including prucalopride capsules, mosapride tablets, lactulose oral solution, and polyethylene glycol powder).(Conditional recommendation, based on moderate-quality evidence body.)
(2) Summary of findings
① A systematic review published in 2020 analyzed the efficacy of acupuncture and western medicine on chronic constipation[25]. A total of 13 RCT studies were included in the review, and the outcome measures included the mean weekly CSBMs, BSFS, PAC-QOL, total responder rate, and adverse event incidence[39,53-64]. The meta-analysis results showed that the acupuncture group was better than oral prucalopride capsule group in increasing weekly mean CSBMs ($P = 0.000\ 4$; WMD = 0.32 [95% CI, 0.14 to 0.5]; $I^2 = 29\%$), acupuncture group over oral mosapride tablet group and lactulose oral solution group in improving BSFS, and acupuncture group over oral polyglycol group and oral prucalopride capsule group in improving PAC-QOL. In terms of adverse events, the acupuncture group was lower than the lactulose oral solution and oral prucalopride group. The effect size is small. Evidence body quality rating was moderate. The points selection of included studies were mainly of the spleen and stomach meridian. 10 out of the 13 studies selected bilateral Tianshu (ST25), 6 selected bilateral Shangjuxu (ST37), and 6 selected bilateral Fujie (SP14) as the major points.

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In one study, Zhongliao (BL32) was used to treat severe straining, and Baihui (GV20) ,Shenting (GV24) were used to treat anxiety and depression. 8 of 13 studies used electroacupuncture and the others used hand acupuncture. ② Compared with oral western medicine (including prucalopride capsules, mosapride tablets, lactulose oral solution and polyethylene glycol powder), acupuncture showed a desirable effect in improving constipation severity and quality of life, and did not increase the risk. Most countries have carried out acupuncture practice and legislative work, so that acupuncture treatment has a better feasibility. The cost of acupuncture and western medicine varies greatly between different countries and regions, which is related to the local health insurance policies. Relatively speaking, receiving acupuncture treatment may cause patients to pay more time. Patients' wishes and values need to be determined in combination with the local specific conditions. At present, there is no research on equity of acupuncture and western at home and abroad. Based on above arguments, the guideline recommendation consensus panel voted to conditionally recommend acupuncture for the treatment of chronic functional constipation.
(3) Explanation
● Subgroup There was a high-quality non-inferiority study comparing the efficacy of electroacupuncture with oral prucalopride for severe chronic constipation (SCC), with a total of 560 patients enrolled[65]. The primary outcome measure is the proportion of patients with mean CSBMs $\geqslant$3 at weeks 3 to 8. The results showed that after a total of 28 electroacupuncture treatments in 8 weeks, the electroacupuncture group was not inferior to oral prucalopride (36. 2% vs 37. 8%, with a difference of 21.6% [95% confidence interval, 28% to 4.7%], $P<0.001$ for noninferiority). There were 49 adverse events(17.69%) in the electroacupuncture group and 123 (44.24%) in the oral prucalopride group.The effect size is big. This study concluded that the curative effect of electroacupuncture in treating severe chronic constipation is not inferior to that of oral prucalopride and the safety is better. The effect can last for 24 weeks after 8 weeks of electroacupuncture treatment. Electroacupuncture is a promising non-inferior-option therapy for severe chronic constipation. The recommendation contents for this subgroup was the same as above.

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Severe functional constipation refers to patients with an average number of CSBMs less than 2 times per week for more than 3 months. ● Implementation Electroacupuncture should not be used in patients with cardiac pacemaker implantation. ● Monitoring and evaluation ① To monitor the proportion of patients with chronic functional constipation seeking acupuncture treatment，especially those with severe chronic functional constipation. ② To evaluate the extent of symptom improvement and safety after acupuncture treatment in chronic functional constipation，especially in patients with severe chronic functional constipation. ● Research priorities We suggest future studies to explore the efficacy comparison of acupuncture and more types of western oral medicines. The health and economic evaluation of acupuncture compared with western medicine is suggested.
(4) Application of recommendation
① This recommendation is applicable to adults（≥18 years old）patients with chronic functional constipation. ② For IBS constipation type or drug-induced constipation，or constipation secondary to endocrine，metabolic，neurological diseases or constipation after surgery，acupuncture treatment still lacks high-quality research evidence，and it is not applicable to this recommendation. ③ Oral western medicine other than prucalopride capsules，mosapride tablets，lactulose oral solution and polyethylene glycol powder are in lacking of RCT evidence and users need to use this recommendation according to their own experience and patients' wills.
(5) Recommended treatment protocol
● Selection of acupoints Bilateral Tianshu（ST25），Fujie(SP14) and Shangjuxu(ST37) may be selected as the major points. According to the patient's concurrent symptoms，following points may be considered：bilateral Zhongliao(BL32) may be added to treat serious straining，Baihui（GV20）and Shenting(GV24) to relieve anxiety and depression.

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● **Operation** Same as PICO 1. ● **Treatment frequency** Treatment frequency is 3 to 5 times in the first week and 2 to 3 times per week after efficacy appear. ● **Treatment course** Treatment courses ranged from 4 to 8 weeks. For severe functional constipation, a longer course of treatment is recommended.

Question 7: For chronic constipation patients, how is the effectiveness of acupuncture compared with biofeedback therapy?
(1) **Recommendation**
For patients with chronic constipation due to UPFS, the guideline panel recommends acupuncture therapy to improve the clinical symptoms, quality of life and anorectal manometry index.(Strong recommendation, based on moderate-quality evidence.)
(2) **Summary of findings**
① This PICO question included 2 RCTs comparing acupuncture and biofeedback for chronic constipation, with a total of 110 patients[66,67]. The type of chronic constipation involved in the two studies were all constipation caused by UPFS, including three outcome measures: anorectal manometry, total responder rate, and quality of life of patients with constipation. The meta-analysis suggested that the improvement of anal systolic pressure of acupuncture group was superior to the biofeedback group ($P<0.01$; MD= −6.78 [95% CI, −11.30 to −2.26]; I^2 = 0).The effect size is moderate. The evidence quality rating was moderate. Bilateral Baliao(BL31-34) were major points in all two studies. Low-frequency electroacupuncture was used as stimulation in all two studies.

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② Compared with biofeedback therapy, acupuncture showed favorable results in improving anorectal manometry indicators. Biofeedback requires one-to-one operation, and special equipment and sites. In contrast, acupuncture treatment has low requirements in personnel and equipment, and has better feasibility. Patients are more likely to receive acupuncture treatment than biofeedback needs to put electrodes into the body. At present, there is no research on the cost-effect comparison of acupuncture and biofeedback therapy both at home and abroad. Based on above arguments, the guideline recommendation consensus panel voted to strongly recommend acupuncture for the treatment of chronic constipation due to UPFS.
(3) Explanation
● Subgroup A subgroup study on chronic constipation due to UPFS is currently lacking. ● Implementation ① Acupuncturing on Baliao (BL31-34) should be based on the correct positioning. There should be sufficient anatomical foundation and acupuncture practice before acupuncture. ② The operator should pay attention to the patient's body size, sacral development and other factors, and determine the acupuncture depth and stimulation amount according to the patient's tolerance. ③ Use of electroacupuncture equipment shall comply with local regulations. ● Monitoring and evaluation ① To monitor the proportion of patients with chronic constipation due to UPFS receiving acupuncture rather than biofeedback treatment. ② To evaluate the changes in the severity, safety, and economic burden of constipation after acupuncture treatment in patients with chronic constipation due to UPFS.

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● Research priorities We suggest future studies to explore more clinical outcomes such as weekly average CSBMs, patients' satisfaction with treatment. At the same time, it is recommended to study more subtypes of constipation caused by pelvic floor muscle coordination disorders, such as constipation caused by pelvic floor muscle relaxation.
(4) Application of recommendation
① This recommendation is only applicable to adult patients (≥18 years old) with chronic constipation due to UPFS. ② Patients with UPFS should have a definite diagnosis by digital anal rectal examination, anorectal manometry and defecation graphy. ③ Considering the lack of basis for the safety of acupuncture on the lumbosacral acupoints for pregnant women, this recommendation is not suitable for the treatment of pregnant women with chronic constipation (even if the diagnostic criteria of UPFS are met).
(5) Recommended treatment protocol
● Selection of acupoints Bilateral Baliao(BL31-34) may be selected as the major points. ● Operation A low-frequency electroacupuncture of 2 to 4 Hz may be used as the stimulation method. The acupuncture depth of Baliao (BL31-34) is recommended to be 40 to 90 mm.Needles may be retained for 30 minutes. ● Treatment frequency 3 to 5 times per week. ● Treatment course 4 consecutive weeks.

Question 8：For chronic constipation patients，how is the effectiveness of acupuncture with moxibustion compared with solo acupuncture？

（1）Recommendation

For patients with chronic constipation，compared with acupuncture alone，the guideline panel suggests the use of acupuncture combined with moxibustion therapy to improve the clinical symptoms of patients.（Conditional recommendation，based on moderate-quality evidence.）

（2）Summary of findings

① This PICO questions included 6 RCTs of acupuncture combined with moxibustion and acupuncture alone，with a total of 554 patients[68-73]. The outcome measures included the KESS score，total responder rate，and PAC-QOL.

The meta-analysis suggested that acupuncture combined with moxibustion group was superior to acupuncture alone in terms of improving KESS score（$P<0.01$；MD = −2.71 [95% CI，−4.02 to −1.4]；$I^2=12\%$）and overall responder rate（$P<0.01$；RR = 1.19 [95% CI，1.06 to 1.33]；$I^2=0$）. The effect size is small.

A study has reported one case of faint at needle and one case of abdominal muscle tension. None of the six studies reported any adverse events related to moxibustion.

The evidence GRADE quality rating was moderate.

2 RCTs clarified that the patient's syndrome type of TCM to be qi deficiency type，and that acupuncture combined with wheat grain moxibustion was used as the treatment measure. In terms of acupoint，bilateral Tianshu（ST25），Guanyuan（CV6），bilateral Shangjuxu（ST37）and bilateral Zusanli（ST36）were selected as major points.

The remaining four studies did not mention the TCM syndrome type.

The electroacupuncture was not used in all six studies.

② Acupuncture and moxibustion is the most commonly used therapy combination by acupuncturists. Whether acupuncture and moxibustion together can achieve greater clinical efficacy is a common concern of acupuncture clinicians.

Compared with acupuncture alone，acupuncture combined with moxibustion show a desirable effect in improving constipation symptoms.

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The most common adverse effect of moxibustion is scald. Although the included studies did not reported this adverse event, possible clinical risks should be considered in terms of pros and disadvantages analysis. After discussion, the guideline consensus expert group suggested that direct moxibustion is not recommended. Instead, safer moxibustion type as mild moxibustion was recommended. Consensus experts from North America are concerned that the smoke produced by moxibustion may cause discomfort in some patients, so the ventilation conditions of the clinic and the wishes of the patients should be considered. If some patients in the same consulting room can not accept moxibustion smoke, it may lead to the problem of equity. Therefore, they gave conditional recommendations. The cost of acupuncture combined with moxibustion should be higher than that of acupuncture alone, and the cost-benefit ratio is currently lacking in research evidence. Based on above arguments, the guideline recommendation consensus panel voted to conditionally recommend acupuncture combined with moxibustion for the treatment of chronic functional constipation.
(3) Explanation
● Subgroup The subgroup study of acupuncture and moxibustion for chronic constipation is currently lacking. ● Implementation ① Moxibustion should be performed in an environment with good ventilation conditions. ② The use of moxibustion should comply with the local regulations. ③ The wishes of the recipient and the patients in the same room should be considered for moxibustion treatment. ④ Patients should be asked about the feelings of moxibustion treatment to avoid scald. ⑤ If scald occurs, it should be treated in time according to the severity, and severe scald needs specialized diagnosis and treatment.

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- Monitoring and evaluation

① To monitor the proportion of patients with chronic constipation receiving acupuncture combined with moxibustion treatment.

② To evaluate the changes in the severity, safety and economic burden of constipation in patients receiving acupuncture combined with moxibustion.

- Research priorities

We suggest future studies to explore more clinical outcomes such as weekly average CSBMs, patients' satisfaction with treatment. At the same time, it is recommended to evaluate the health economics of acupuncture and moxibustion therapy.

(4) Application of recommendation

① Moxibustion therapy is suitable for chronic constipation patients with TCM syndrome differentiation as deficiency syndrome.

② This recommendation is applicable to adults (≥18 years old) patients with chronic functional constipation.

③ For IBS constipation type or drug-induced constipation, or constipation secondary to endocrine, metabolic, neurological diseases or constipation after surgery, acupuncture treatment still lacks high-quality research evidence, and it is not applicable to this recommendation.

(5) Recommended treatment protocol

- Selection of acupoints

Bilateral Tianshu (ST25), Guanyuan (CV6), bilateral Shangjuxu (ST37), and bilateral Zusanli (ST36) may be selected as the major points.

Patients with Qi deficiency constipation may use Qihai(CV5).

- Operation

We recommend the use of acupuncture with mild moxibustion. Moxibustion may be conducted for 3 to 5 minutes on each points until local skin flushes.

Question 9：For chronic constipation patients，how is the effectiveness of acupuncture with western medicine compared with solo western medicine?
（1）Recommendation
For patients with chronic constipation，compared with solo oral western medicine，the guideline panel recommends using acupuncture combined with oral western medicine to improve the clinical symptoms.（Strong recommendation，based on low-quality evidence.）
（2）Summary of findings
① This PICO questions included one RCT of patients with acupuncture combined with oral mosapride tablet compared with oral mosapride tablet alone for chronic constipation，resulting in a total of 43 patients[74]. This study only evaluated the total responder rate of the two groups，and the results suggested that the acupuncture group and the oral mosapride tablet group 90%（18/20）was higher than the oral mosapride tablet alone group 65%（15/23）.The effect size is small. The quality of evidence is low. In this study，bilateral Tianshu（ST25），Zhigou（TE6），Zusanli（ST36），Shangjuxu（ST37），and Zhongwan（CV12）were selected as acupuncture points. Hand acupuncture was used. ② As a complementary and alternative therapy，whether the combination of acupuncture and western medicine can achieve greater clinical efficacy is of great significance for patients and doctors to rationally choose treatment options. Only one small size RCT published in China suggested that acupuncture combined with oral western medicine obtained desirable results，and whether the combination of the two therapies resulted to increased risk was not reported. Most acupuncture and TCM experts believe that adding acupuncture treatment according to oral western medicine will bring additional benefits. And，as a physical therapy，acupuncture does not exacerbate the original side effects of oral western medicine. Most patients with chronic constipation will continue to take western medicine when receiving acupuncture treatment. In most cases，acupuncturists do not require patients to stop taking western medicine during acupuncture treatment，so the combination of acupuncture with oral medicine is in line with the patient's wishes. The cost of acupuncture combined with western medicine should be higher than that of western medicine alone. However，research evidence for the cost-effect ratio is lacking.

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Experts in the field of western medicine gastroenterology believe that medication is more enough to solve most of the problems for patients with moderate severity of chronic constipation, so she was uncertain whether to recommend oral medication in the absence of a subgroup study of acupuncture based on severity. Based on above arguments, the guideline recommendation consensus panel voted to strongly recommend acupuncture combined with oral western medicine for the treatment of chronic functional constipation.
(3) Explanation
● Subgroup There is a lack of subgroup studies on acupuncture and oral western medicine for chronic constipation. ● Implementation Since acupuncture combined with western medicine has the potential to increase the economic burden of the patients, this recommendation should be implemented with the consent of the patients. ● Monitoring and evaluation ① To monitor the proportion of chronic constipation patients receiving acupuncture combined with oral western medicine treatment. ② To evaluate the changes in the severity, safety, and economic burden of constipation in chronic constipation patients after acupuncture combined with oral western medicine treatment. ● Research priorities We suggest future studies focus on subgroup study of acupuncture and oral western medicine for the treatment of chronic constipation.
(4) Application of recommendation
① This recommendation is applicable to adults (≥18 years old) patients with chronic functional constipation.

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② For IBS constipation type or drug-induced constipation, or constipation secondary to endocrine, metabolic, neurological diseases or constipation after surgery, acupuncture treatment still lacks high-quality research evidence, and it is not applicable to this recommendation.

③ Users of this recommendation may make appropriate acupoint adjustments according to the patient's concurrent symptoms and TCM syndrome differentiation.

④ Users of this recommendation may choose whether to use the electroacupuncture according to their own experience and patient wills.

(5) Recommended treatment protocol

- **Selection of acupoints**

Bilateral Tianshu (ST25), Zhigou (TE6), Zusanli (ST36), Shangjuxu (ST37), and Zhongwan (CV12) can be selected as acupuncture points.

- **Frequency of treatment**

3 to 5 times / week.

- **Course of treatment**

4 weeks.

Question 10: For chronic constipation patients, how is the effectiveness of moxibustion with western medicine compared with solo western medicine?

(1) Recommendation

For patients with chronic functional constipation, compared with the use of solo western medicine, the guideline panel suggests the use of moxibustion combined with western medicine. (Based on expert consensus, no RCT evidence.)

(2) Summary of findings

① Moxibustion treatment of constipation has long been recorded in the ancient books of traditional Chinese medicine.＜*Bei Ji Qian Jin Yao Fang · fifteenth edition · constipation*＞said: For constipation with Qi stagnation in the chest, use Shimen (CV5). The type of constipation here is similar to Qi constipation (Qi Bi) in terms of traditional Chinese medicine syndrome differentiation.

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In terms of TCM syndrome differentiation, He Puren, a modern acupuncture master, proposed that moxibustion is mostly used in the treatment of cold constipation[75].

According to the theory of traditional Chinese medicine, moxibustion has a good curative effect in treating constipation. Such as ＜*Zhen Jiu Ju Ying* • 4*th volume* • *miscellaneous disease*＞ said: Three hundred cones of moxibustion on Zhongwan (CV12) has the most rapid effect for constipation.

In terms of moxibustion points, ancient books suggest that Chengjin (BL56), Shimen (CV5), Dadun (LR1) and Baliao (BL31-34) can be used.

He Puren proposed in ＜*Clinical Application of Acupuncture Ge Fu*＞: cold constipation should be moxibustion in Zhongwan (CV12).

At present, there is a lack of direct clinical research evidence of comparing moxibustion with oral western medicine and solo oral western medicine.

Review in the clinical PICO question 8 "For chronic constipation patients, how is the effect of acupuncture with moxibustion compared with solo acupuncture?" In it, there is RCT evidence that moxibustion can bring additional clinical benefits. This can serve as circumstantial evidence for PICO question 10.

② For some chronic constipation of specific TCM syndrome types, such as deficiency constipation and cold constipation, moxibustion is adopted by many acupuncturists because of its theoretical advantages. Therefore, the combination of moxibustion method with other therapies has a priority.

Considerations for moxibustion in safety and equity are same with PICO question 8.

The cost of moxibustion therapy combined with western medicine should be higher than that of western medicine alone. Research evidence is lacking for the cost-effect ratio.

Based on the above arguments, the guideline recommendation consensus expert group voted to recommend moxibustion combined with western medicine in the treatment of chronic functional constipation in the form of expert consensus.

(*continued*)

(3) Explanation
● Subgroup None. ● Implementation ① This recommendation applies to qualified practitioners who have received the necessary training and comply with local regulations and laws. ② This recommended protocol is applicable to the medical facilities with the necessary equipment. ③ The implementation instructions about moxibustion are consistent with the PICO question 8. ● Monitoring and evaluation ① To monitor the proportion of patients receiving moxibustion combined with western medicine for the treatment of chronic functional constipation. ② To evaluate the improvement and safety of symptoms in patients with moxibustion and western medicine for chronic functional constipation. ● Research priorities We suggest the future study to explore the effect of moxibustion with western medicine in the treatment of chronic constipation with RCT design.
(4) Application of recommendation
① This recommendation is based on the expert consensus opinion. ② This recommendation comes from the ancient literature and modern expert experience, without RCT research support. ③ Users need to decide whether to use moxibustion therapy based on patient's TCM syndrome differentiation.

(*continued*)

(5) Recommended treatment protocol
● Selection of acupoints For patients with cold constipation, Zhongwan(CV12) may be selected as the moxibustion point. ● Operation Mild moxibustion or device moxibustion may be used.

Question 11: For chronic constipation patients, how do the risks of acupuncture compare with existing treatments?
(1) Recommendation
For patients with chronic constipation, acupuncture therapy has a lower incidence of adverse events compared with oral western medicine (including lactulose oral solution, prucapride capsules, and moxapride tablets). From the perspective of safety, the guideline panel recommends the use of acupuncture therapy rather than oral western medicine. (Strong recommendation, based on moderate-quality evidence.)
(2) Summary of findings
① A total of 10 RCTs concerning acupuncture safety were included[33,47,51,65,76-81]. Clinical outcome measures was the incidence of adverse events. The 10 studies were divided into 2 subgroups according to points selection. In group 1, Tianshu (ST25) was used as the only acupuncture point. The meta-analysis showed that for electroacupuncture with deep needle insertion (penetrating the peritoneal) at Tianshu (ST25) and electroacupuncture with shallow needle insertion (0.6 to 1.5 cun) at Tianshu (ST25), the incidence of adverse events in the electroacupuncture group was lower than in the oral lactulose group($P<0.01$; RR = 0.42 [95% CI, 0.22 to 0.81]; $I^2 = 0$); ($P<0.01$; R = 0.16 [95% CI, 0.03 to 0.85]; $I^2 = 0$). Group 2 selected a set of acupuncture points including Tianshu (ST 25) and compared with oral gastrointestinal motility (including prucalopride and mosapride). The meta-analysis suggested that the incidence of adverse events in the acupuncture group was lower than in the prokinetic group ($P<0.01$; RR = 0.42[95% CI, 0.32 to 0.55]; $I^2 = 51\%$). The effect size is small. The evidence body grade evaluation was moderate.

(*continued*)

Group 1 chose bilateral Tianshu (ST25) as only acupoint and stimulation was electroacupuncture. In addition to bilateral Tianshu (ST25), group 2 also includes bilateral Zusanli (ST36), Zhigou (TE6), Shangjuxu (ST37), Guanyuan (CV4), and Fujie (SP14). The stimulation mode was dominated by hand acupuncture. ② Acupuncture therapy has once been labeled as "green therapy without toxic effects and side effects". However, with the continuous expansion of its application scope, the enhancement of clinical scientific research awareness and the increased reporting of adverse medical events of acupuncture, the attention to the safety of acupuncture has also increased. In international applications, acupuncture safety is the focus of more attention. Therefore, this problem has a priority. Tianshu (ST25) is a common acupoint of acupuncture for the treatment of chronic constipation. The safety study has found that compared with the commonly used oral western medicine, the safety of acupuncture at Tianshu (ST25), alone or with other acupoints, has desirable effects. Safety is an important component of the cost-effect analysis, for adverse events may lead to increased treatment costs. However, there is still a lack of studies on the cost-effect comparison related to the safety of acupuncture. Good safety will increase the willingness to receive acupuncture. There is a lack of studies on medical equity related to acupuncture safety. Based on above arguments, the guideline recommendation consensus panel voted to strongly recommend acupuncture for the treatment of chronic functional constipation from safety perspective.
(3) Explanation
● Subgroup There is a lack of subgroup studies on the safety of acupuncture in patients with chronic constipation, starting from the patient population. ● Implementation Acupuncturist should operate carefully according to the anatomical characteristics of the acupoints and the patient's constitution to ensure the due safety when using this recommendation.

(*continued*)

● Monitoring and evaluation ① To monitor the proportion of patients with chronic constipation receiving acupuncture treatment. ② To evaluate the safety of acupuncture in patients with chronic constipation. ● Research priorities We suggest future studies to explore acupuncture safety at more acupoints.
(4) Application of recommendation
① This recommendation is applicable to adults (≥18 years old) patients with chronic functional constipation. ② For IBS constipation type or drug-induced constipation, or constipation secondary to endocrine, metabolic, neurological diseases or constipation after surgery, acupuncture treatment still lacks high-quality research evidence, and it is not applicable to this recommendation. ③ The clinical evidence of this recommendation comes from limited range of acupoints as Tianshu (ST25), the risk of other acupoints needs to be evaluated according to the clinical practice.
(5) Recommended treatment protocol
● Selection of acupoints Bilateral Tianshu (ST25) may be selected as the major point. Other optional acupoints include bilateral Zusanli (ST36), Zhigou (TE6), Shangjuxu (ST37), Fujie (SP14), and Guanyuan (CV4). ● Operation Users may choose electroacupuncture or hand acupuncture according to the specific situation.

Question 12：For chronic constipation patients，how do the time and financial burdens of acupuncture compare with existing treatments？
（1）Recommendation
For patients with chronic constipation，where acupuncture has a lower cost-effective ratio compared to oral mosapride，the guideline panel suggests to use acupuncture therapy from the perspective of economic burden.（Conditional recommendation，based on low-quality evidence.）
（2）Summary of findings
① An RCT study published in 2013 and supported by the National Key Basic Research Development Program（the 973 Program）assessed the cost-effect ratio of electroacupuncture to mosapride through a model-based economic evaluation（MBEE）. The results showed that the cost-effect ratio in the acupuncture group（8.02%）was lower than that in the western medicine group（8.93%）. Roughly，the total cost of patients includes the following categories：① direct medical cost：acupuncture fee（including consumables）；② indirect costs：transportation costs；③ other costs：lost of wages. So far，we didn't retrieve comprehensive data on this.This study was conducted in China and all subjects were from Foshan，Guangdong[82]. This RCT is of low-quality evidence.The effect size is small. This study chose bilateral Tianshu（ST25），Dachangshu（BL25），Quchi（LI11），and Shangjuxu（ST37）were selected as major points. The electroacupuncture was used as the stimulation method. The course of treatment is 4 weeks. ② Acupuncture treatment is generally considered to be simple，convenient，tested and inexpensive in China，but the medical system policies are different around the world. The cost-effect of acupuncture has been systematically evaluated abroad，but its diseases do not include chronic constipation. Therefore，there is a lack of large-scale health economics research on acupuncture for chronic constipation. Several previous clinical PICO questions involved studies that suggest acupuncture has a beneficial effect and a low clinical risk，and the balance of advantages and disadvantages tends to favor acupuncture therapy. Acupuncture requires relatively more time，including waiting time，treatment time and travel to and from the hospital. For patients with mobility problems，this also includes time spent with caregivers.

(*continued*)

The single RCT included in this time suggested a lower cost-effect ratio in the acupuncture group than in the oral western medicine group. In general, from the perspective of economic burden, the balance of advantages and disadvantages favors the acupuncture group. However, the sample size included in this study was small and the survey area was limited. The above reasons lead to most experts to choose conditionally recommended acupuncture treatment. There is a lack of health equity research related to health economics. Based on above arguments, the guideline recommendation consensus panel voted to conditionally recommend acupuncture for the treatment of chronic functional constipation from final cost perspective.
(3) Explanation
● Subgroup There is currently a lack of subgroup studies on the health economics of acupuncture for chronic constipation. ● Implementation ① This recommendation applies to qualified practitioners who have received the necessary training and comply with local regulations and laws. ② This recommendation applies to medical institutions with the necessary equipment. ● Monitoring and evaluation ① To monitor the proportion of patients with chronic constipation receiving acupuncture considering economic cost. ② To evaluate the changes in the severity, safety, and economic burden of constipation in patients with chronic constipation after acupuncture treatment. ● Research priorities We suggest future studies to explore the health economics of acupuncture for chronic constipation in different parts of the world.

(*continued*)

(4) Application of recommendation
① This recommendation is applicable to adults (≥18 years old) patients with chronic functional constipation. ② For IBS constipation type or drug-induced constipation, or constipation secondary to endocrine, metabolic, neurological diseases or constipation after surgery, acupuncture treatment still lacks high-quality research evidence, and it is not applicable to this recommendation. ③ Users may add and subtract the acupoints according to patient's TCM syndrome differentiation.

5 Access to the guideline

This guideline is published on the website of the World Federation of Acupuncture-Moxibustion Societies, and the paper version is published by Standards Press of China. This guideline is available to users through the above channels.

6 Implication for future research

To carry out high-quality RCT study of different depth acupuncture for chronic constipation, and research on the economic burden and health economic evaluation of acupuncture for chronic constipation.

7 Limitations

7.1 Due to the arrangement of the research cycle and project schedule, the literature search of this guideline is up until March 2021, and the literature after this time point is not included in this guideline.

7.2 The modern clinical research evidence in this guideline is mainly limited to RCT and does not include non-RCT clinical studies.

7.3 As an important part of TCM, the clinical treatment of acupuncture and moxibustion is deeply influenced by the theory of TCM and ancient medical experience. When formulating the recommendation plan of this guideline, we tried to draw on the experience of ancient and modern doctors. However, the way of applying these experiences to recommended options is still being explored.

Annex A
Members of guideline working group

This guideline was drafted by Guang'anmen Hospital, China Academy of Traditional Chinese Medical Sciences.

A.1 The guideline development group (GDG) members

Name	Country	Role/Expertise	Organization
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Wang Linpeng	China	Acupuncture expert	Beijing TCM Hospital
Zhang Jianbin	China	Acupuncture expert	The 2nd TCM Hospital of Jiangsu Province
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Tong Yuanyuan	China	Literature expert	Institute of information on TCM
Kong Yuanyuan	China	Methodologist	Beijing Friendship Hospital, Capital Medical University
Ms. Xiao	China	Representative of chronic constipation patients	—

A.2 The guideline drafting group members

Name	Role/Expertise	Organization
Zhang Wei	Overall organizing and drafting this guideline	Guang'anmen Hospital, China Academy of Traditional Chinese Medical Sciences
Wang Rui	Drafting this guideline	Guang'anmen Hospital, China Academy of Traditional Chinese Medical Sciences
Lian Jie	Drafting this guideline	Beijing University of Chinese Medicine

Annex B
Abbreviations

Abbreviations	Full name
CFC	Chronic Functional Constipation
GDG	Guideline Development Group
WFAS	World Federation of Acupuncture-Moxibustion Societies
ISO	International Standard Organization
SA	Sham Acupuncture
EA	Elctroacupuncture

Annex C
Summary of clinical questions

No.	clinical questions
1	For chronic constipation patients, how is the effectiveness of acupuncture compared with sham acupuncture?
2	For chronic constipation patients of different genders, how is the effectiveness of acupuncture compared with sham acupuncture?
3	For chronic constipation patients of different ages, how is the effectiveness of acupuncture compared with sham acupuncture?
4	For chronic constipation patients, how is the effectiveness of EA compared with hand acupuncture?
5	For chronic constipation patients, how is the effectiveness of EA with deep insertion compared with EA with shallow insertion?
6	For chronic constipation patients, how is the effectiveness of acupuncture compared with western oral medicine?
7	For chronic constipation patients, how is the effectiveness of acupuncture compared with biofeedback therapy?
8	For chronic constipation patients, how is the effectiveness of acupuncture with moxibustion compared with solo acupuncture?
9	For chronic constipation patients, how is the effectiveness of acupuncture with western medicine compared with solo western medicine?
10	For chronic constipation patients, how is the effectiveness of moxibustion with western medicine compared with solo western medicine?
11	For chronic constipation patients, how do the risks of acupuncture compare with existing treatments?
12	For chronic constipation patients, how do the time and financial burdens of acupuncture compare with existing treatments?

前　言

本指南的制定旨在为慢性便秘的针灸干预提供标准化的推荐方案。

本指南依据世界针灸学会联合会标准工作委员会制定的技术流程和规则研制。

本指南由世界针灸学会联合会(World Federation of Acupuncture-Moxibustion Societies,WFAS)归口并发布。

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本指南的制定得到了中华人民共和国科技部-国家重点研发计划中医药现代化研究重点专项项目国际针灸临床实践指南、技术操作规范和服务标准的研制(项目编号:2019YFC1712200)中国际针灸临床实践指南研制(课题编号:2019YFC1712203)的基金支持。

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请注意本指南的某些内容可能涉及专利。本指南的发布机构不承担识别专利的责任。

针灸临床实践指南
慢性便秘

1 指南概要

1.1 名词术语

1.1.1

针刺治疗

根据国际标准化组织(International Standard Organization，ISO)制定的ISO/TC 249 NP 20520[1]标准，针刺疗法是指将针灸针刺入人体，并在刺入后使用相应手法的过程。针灸针是指根据传统医学理论，通过刺激身体特定部位以预防和治疗疾病或增进健康的医疗器械。

在实际的临床工作中，针灸针指的是不锈钢材质为主的毫针。

在本指南中，针刺是指用不同长度和直径的不锈钢材质的毫针，刺入穴位局部皮肤的疗法。

电针作为一种常见的临床刺激方法，通常与针刺配合使用。在本指南中，电针是与针刺同时使用的方法。

在本指南中，手针是指医生用手进行提插捻转等操作，而不使用电针刺激。

1.1.2

艾灸治疗

艾灸是指用艾绒制成的艾条或艾炷在穴位上施灸的治疗方法，包括温针灸、艾条温和灸和温灸器灸等。本指南不包括直接灸法。

1.1.3

药物治疗

本指南中的药物治疗是指：促动力药(包括普芦卡必利、莫沙必利)，渗透性泻药(包括乳果糖口服液、聚乙二醇散剂)，刺激性泻药(包括比沙可啶、番泻叶)，容积性泻药(包括欧车前、麦麸、甲基纤维素)。本指南的药物治疗不包括中药汤剂和口服中成药。

1.2 目的

WFAS《针灸临床实践指南　慢性便秘》(以下简称本指南)旨在帮助临床医生和患者根据临床实际情况和最佳临床证据，结合每个患者的价值观和意愿，对慢性便秘的针灸治疗作出适当的决策。

1.3 范围

本指南可以供针灸从业者，以及希望了解针灸治疗慢性便秘相关问题的其他医疗保健工作者和患者使用。

1.4 适用人群

本指南的适用人群为全球范围内与慢性便秘临床、教学和科研相关的专业人员，包括：① 世界范围内的具备相关资质的针灸从业者；② 中医院校的教师和学生；③ 从事针灸专业的科研工作者。

1.5 适用场所

本指南可以在世界范围内包含针灸学专科的医院、诊所，包含针灸学专业的医学院校，针灸学相关

的科研及评价机构中应用。

1.6 推荐意见汇总

编号	临床问题 / 推荐意见
1	对于慢性便秘患者，针刺与假针刺的疗效相比如何？
	对于慢性功能性便秘患者，相比于假针刺，便秘指南制定小组推荐使用针刺疗法，以改善患者便秘相关的临床症状。（强推荐，基于高质量证据）
2	对于不同性别的慢性便秘患者，针刺与假针刺的疗效相比如何？
	对于女性严重慢性功能性便秘患者，相比于假针刺，便秘指南制定小组推荐使用针刺疗法，以改善患者的临床症状。（强推荐，基于高质量证据）
3	对于不同年龄的慢性便秘患者，针刺与假针刺的疗效相比如何？
	对于老年（＞65 岁）慢性功能性便秘患者，相比于假针刺，便秘指南制定小组推荐使用针刺疗法。（专家共识性意见，无临床研究证据）
4	对于慢性便秘患者，电针与手针的疗效相比如何？
	对于慢性功能性便秘患者，相比于手针，便秘指南制定小组推荐使用电针作为刺激方式，以缓解患者症状并提高其生活质量。（有条件的推荐，基于中等质量证据）
5	对于慢性便秘患者，电针深刺法与电针浅刺法相比效果如何？
	对于慢性功能性便秘患者，相比于腹部穴位电针浅刺法，便秘指南制定小组不能确定腹部穴位电针深刺法能够给患者带来更大的效益并保证其安全性。（未达成推荐意见共识，基于高质量证据）
6	对于慢性便秘患者，针刺与口服西药相比效果如何？
	对于慢性便秘患者，与口服西药（包括普芦卡必利胶囊、莫沙必利片、乳果糖口服液和聚乙二醇散剂）相比，便秘指南制定小组推荐使用针刺疗法，以改善患者的临床症状和生活质量。（有条件的推荐，基于中等质量证据）
7	与生物反馈疗法相比，针刺对于慢性便秘患者的疗效如何？
	对于盆底失弛缓综合征（Unrelaxed Pelvic Floor Syndrome，UPFS）引起的慢性便秘患者，相比于生物反馈疗法，便秘指南制定小组推荐使用针刺疗法，以改善患者的临床症状、生活质量和肛门直肠测压指标。（强推荐，基于中等质量证据）
8	对于慢性便秘患者，针刺结合艾灸与单纯使用针刺相比疗效如何？
	对于慢性便秘患者，相比于单纯针刺治疗，便秘指南制定小组推荐使用针刺结合艾灸疗法，以改善患者的临床症状。（有条件的推荐，基于中等质量证据）
9	对于慢性便秘患者，针刺结合西药与单纯使用西药相比疗效如何？
	对于慢性便秘患者，相比于单纯口服西药，便秘指南制定小组推荐使用针刺联合口服西药的方法，以改善患者的临床症状。（强推荐，基于低质量证据）

（续）

编号	临床问题 推荐意见
10	对于慢性便秘患者，艾灸结合西药与单纯使用西药相比疗效如何？
	对于慢性功能性便秘患者，相比单纯使用西药，便秘指南制定小组推荐使用艾灸结合西药。（专家共识性意见，无临床研究证据）
11	对于慢性便秘患者，针刺与现有治疗相比风险性如何？
	对于慢性便秘患者，相比于口服西药（包括乳果糖口服液、普芦卡必利胶囊、莫沙必利片），针刺疗法的不良事件发生率更低，从安全性角度出发，便秘指南制定小组推荐使用针刺疗法。（强推荐，基于中等质量证据）
12	对于慢性便秘患者，针刺与现有治疗相比时间和经济负担情况如何？
	对于慢性便秘患者，相比于口服莫沙必利，针刺疗法的成本效益比更低，从经济负担角度出发，便秘指南制定小组推荐使用针刺疗法。（有条件的推荐，基于低质量证据）

1.7 联系人

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2 疾病概述

2.1 临床特征

慢性便秘是一种常见临床问题，其特点是排便次数减少，排便困难，且持续时间超过 6 个月，严重影响患者的生活质量。对于慢性便秘，常用的治疗策略包括改变生活方式、药物治疗、心理治疗、生物反馈疗法或手术疗法[2]。针灸治疗便秘的历史可以追溯到《黄帝内经》时代（约公元前 99 年至公元前 26 年），现已广泛临床应用。同时，针灸治疗慢性便秘已经成为针灸临床研究领域的热点，取得了不少国际公认的突破性成果。通过文献检索发现，在西方国家已经发布了 4 部关于慢性便秘的临床实践指南[3-6]。但是，这些指南都没有涉及针灸治疗。

据估计，该疾病的患病率高达 30%[7-12]。慢性便秘包括功能性便秘，即没有器质性病因的便秘，以及由饮食、药物、代谢或神经障碍、社会心理问题引起的器质性便秘。临床上见到的大多数便秘病例属于功能性便秘。根据病理生理特点，慢性便秘可分为慢传输型便秘（STC）、排便障碍和正常传输型便秘（NTC）[13]。然而，在现实中，许多患者表现出的症状可归因于不止一种便秘亚型。

2.2 诊断

功能性便秘的诊断依据是以症状为基础的罗马标准，该标准于 1989 年首次发布[14-16]。迄今为止，这些标准已被多次更新，现已得到国际广泛认可并用于临床和研究领域。Rome Ⅱ标准于 1999 年发布，是涉及儿童功能性胃肠疾病的第一个标准。罗马Ⅲ功能性便秘标准包括：排便≥25%的时间至少出现以下两种症状：大便干硬、结块或硬便；排便不完全的感觉；肛门直肠阻塞感；依靠手抠促进排便；每周无辅助排便少于 3 次[17]。

便秘的病因包括饮食、药物、代谢或神经紊乱以及社会心理问题。修订后的 Rome Ⅳ标准——《儿童和成人功能性便秘标准》，已于 2016 年发布[18]。

2.3 西医治疗概况

西医治疗慢性便秘的方法包括改变生活方式、口服药物、心理疗法、生物反馈疗法或手术治疗。合理的膳食，包括合理地摄入膳食纤维和水，是治疗便秘的首要干预措施。乳果糖和聚乙二醇等渗透性泻药是功能性便秘的首选维持治疗[19]。其他常用泻药包括矿物油和氢氧化镁。高选择性 5-羟色胺受体激动剂普芦卡必利能缩短结肠传输时间，且耐受性良好[20]。如果症状持续，在儿童和成人的临床指南中建议使用刺激性泻药，如比沙可啶或番泻叶。手术治疗是功能性便秘最后的治疗手段，只有在所有的常规治疗均告失败和症状严重影响生活质量时才会考虑。

2.4 中医辨证

2.4.1 中华中医药学会脾胃病分会在 2011 年北京会议上制定的《慢性便秘中医诊疗共识》将便秘分为以下 5 种中医证型[21]。

2.4.1.1 肠道实热证

主症：① 大便干结；② 舌红苔黄燥。

次症：① 腹中胀满或胀痛；② 口干口臭；③ 心烦不寐；④ 小便短赤；⑤ 脉滑数。

2.4.1.2 肠道气滞证

主症：① 欲便不得出，或便而不爽，大便干结或不干；② 腹满胀痛。

次症：① 肠鸣矢气；② 嗳气频作；③ 烦躁易怒或郁郁寡欢；④ 纳食减少；⑤ 舌苔薄腻；⑥ 脉弦。

2.4.1.3 肺脾气虚证

主症：① 大便并不干硬，虽有便意，但排便困难；② 用力努挣则汗出短气。

次症：① 便后乏力；② 神疲懒言；③ 舌淡苔白；④ 脉弱。

2.4.1.4 脾肾阳虚证

主症：① 大便干或不干，排出困难；② 脉沉迟。

次症：① 腹中冷痛，得热则减；② 小便清长；③ 四肢不温；④ 面色㿠白；⑤ 舌淡苔白。

2.4.1.5 津亏血少证

主症：① 大便干结，便如羊粪；② 舌红少苔或舌淡苔白。

次症：① 口干少津；② 眩晕耳鸣；③ 腰膝酸软；④ 心悸怔忡；⑤ 两颧红；⑥脉弱。

2.4.2 《中药新药研究指导原则》将便秘分为以下 3 种证型[22]。

2.4.2.1 热秘

症状：大便干，排便困难，肛裂，便血，口苦口干，尿少色黄，舌红苔黄，脉数。

2.4.2.2 气秘

症状：排便困难，腹胀腹痛，呃逆，舌暗，脉弦。

2.4.2.3 冷秘

症状：排便困难，气短，畏寒肢冷，腹痛。舌淡苔白，脉细。

以上为两种较为常用的中医辨证分型方法，除此之外，中医医师还可以根据中医理论和自身见解对便秘进行分型。

3 指南制定过程

3.1 临床问题的确定

本指南的临床 PICO 问题由患者（Participant）、干预措施（Intervention）、对照措施（Comparator）和临床结局（Outcome）4 个因素构成。指南制定组通过问卷星线上调研平台（https://www.wjx.cn/）起草和发布了中、英文两个版本的德尔菲（Delphi）调研问卷，以便了解世界不同地区针灸从业者对针灸治疗慢性便秘的需求。

同时指南制定组(Guideline Development Group，GDG)进行了一系列的专家访谈，并于2021年3月6日通过ZOOM企业版采用同声传译的方式召开了由中外专家参与的指南临床问题与临床结局专家小组共识会议(会议号:62884055546)。会议通过网上投票，采用专家活跃度指数、熟悉度指数、权威度指数、重要性分配均值和Kendall协调系数等德尔菲统计指标对结果进行分析。最终，确定临床PICO问题12个。

同时，专家组成员根据GRADE分级方法对于临床结局的重要性进行了评级并通过投票获得了共识。确定关键结局(Critical Outcomes)3项，分别为便秘严重程度，包括完全自主排便次数(Complete Spontaneous Bowel Movements ,CSBMs)，自主排便次数(Spontaneous Bowel Movements,SBMs)，克利夫兰诊所评分(Cleveland Clinic Score,CCS)，凯斯评分(Knowles-Eccersley-Scott Symptom Score ,KESS)；患者治疗满意度和治疗有效率。重要结局(Important Outcomes)5项，分别为生存质量(Patient Assessment of Constipation Quality of Life questionnaire,PAC-QOL)；治疗安全性；客观评价指标，包括结肠通过时间，肛门直肠测压；卫生经济学指标和情绪心理指标。

3.2 证据体的检索、评价与综合

本指南委托中国中医科学院中医药信息研究所制定中英文文献检索策略并进行文献检索。GDG与该机构签订了正式的文献检索服务协议，并得到广安门医院的批准。

GDG完成了所有临床PICO问题的RCT筛选，并对其进行系统评价/Meta分析，部分系统评价已经发表在期刊上。

为了形成符合中医理论的推荐方案，更好地指导临床实践，本指南还检索了古代医籍和现代著名针灸专家有关针灸治疗慢性便秘的经验。

指南制定组对古代中医文献专家进行了一系列访谈，确定了古代中医文献的范围以及从这些文献中获取便秘治疗证据的方法。最终，《素问》《灵枢》《伤寒论》《金匮要略》等中医经典被列为主要文献。其他书籍如《针灸甲乙经》《肘后备急方》《备急千金要方》《圣济总录》《针灸资生经》《普济方》《针灸聚英》《针灸大成》《类经图翼》《医宗金鉴　刺灸心法要诀》《针灸集成》《金针秘传》等也被收录。

歌赋是历代医学家经验的总结。本指南还纳入了《扁鹊神应经》《玉龙经》《胜玉歌》《席弘赋》《杂病穴法歌》《百症赋》等。

指南制定组选取了9位具有代表性的现代针灸专家——田从豁、周德安、贺普仁、陆瘦燕、承淡安、金伯华、杨甲三、王乐亭、郑魁山。为发掘其便秘治疗经验，指南制定组委托中国中医科学院中医药信息研究所的专业人员进行检索。搜索中国知网、维普、万方数据库中有关这些专家的临床经验性文章。对于专著，搜索了读秀和超星电子图书数据库。

3.3 推荐意见的形成

每一个临床PICO问题的RCT证据经过系统评价之后形成证据体，并用证据概要表(Summary of Findings,SoF)对证据体的详细内容进行记录。

本指南采用由证据到决策框架(Evidence to Decision framework，EtD)作为形成推荐意见的工具。该工具共涉及问题的优先性，预期正面、负面效应的大小等12个因素，帮助用户进行综合判断[23]。

为确定推荐意见的方向和力度，指南制定组召开了网上专家共识会议。专家组由针灸、中西医消化医学、中西医肛肠医学、中西医护理、中西医结合医学、方法学等领域的15位专家组成，来自于包括中国(香港)、马来西亚、加拿大和新加坡等不同地区。通过网上投票和讨论达成共识意见。

专家共识意见是在所有专家组成员投票的基础上达成的。采用GRADE网格法(GRADE grid)，依据得票数确定意见一致程度。本指南投票总数为2轮，如果2轮投票仍然没有达成共识，则该临床问题不能产生推荐意见[24]。

在专家共识的基础上，指南制定组为每个临床问题制定了详细的治疗方案。治疗方案包括穴位选择、刺激方法、操作手法、治疗频率和疗程等因素。以上因素主要依据本临床问题证据体中关键结局(Critical Outcomes)为阳性结果的RCT研究。

在某些临床PICO问题缺乏RCT研究的情况下，本指南主要依据古代医籍和现代医家针灸治疗便秘的经验，通过专家共识的方式产生共识性推荐意见。需要专家达成共识的因素包括：该干预方法是否

直观、可重复，能否应用于临床实践，疗效是否确切，是否优于传统的干预方法，是否能启发或指导临床诊疗等。

所有 GDG 成员对指南文件进行了多次审查并进行修改，直到达成一致意见。

4 推荐意见

临床问题 1：对于慢性便秘患者，针刺与假针刺的疗效相比如何？
（1）推荐意见
对于慢性功能性便秘患者，相比于假针刺，便秘指南制定小组推荐使用针刺疗法，以改善患者便秘相关的临床症状。（强推荐，基于高质量证据）
（2）证据概述
① 2020 年发表的一篇系统评价分析了针刺与假针刺对成人慢性功能性便秘（FC）的疗效[25]，纳入了 8 篇 RCT[26-33]。结局指标包括便秘的严重程度（CSBMs、BSFS、CCS）、有效率和治疗的安全性。 Meta-分析结果表明，针刺组在增加 CSBMs 方面的疗效显著优于假针刺组（$P<0.000\ 01$；MD＝0.84 [95% CI，0.65～1.03]；$I^2=0\%$）。改善大便性状评分、提高有效率和改善 CCS 评分方面亦获得相似结果。未观察到针刺组不良事件风险增加（$P=0.44$；RR ＝ 1.18 [95% CI，0.77～1.81]；$I^2=0\%$）。效应量小。 证据体质量评级为高质量。 纳入的 8 项 RCT 研究中，均采用双侧天枢穴（ST25）为主穴。除此之外，还有 3 项研究选取了双侧腹结穴（SP14）和上巨虚穴（ST37）为主穴。 通过对古文献的考察，我们发现“天枢、腹结、上巨虚”3 个穴位的功能主治相似，均具有行气导滞的功能，适用于慢性便秘造成的肠道积滞症状，三者配合应用，会起到协同作用。 如《针灸甲乙经　卷八》云：“大肠胀者，天枢主之。”此处之“大肠胀”即包含大肠气滞，闭塞不通之意，在慢性便秘患者当中亦为常见。 《针灸甲乙经　卷十一》云：“绕脐痛，抢心，腹寒，注利，腹结主之。”此处之“抢心，腹寒”为寒邪凝滞，气机运行不畅的表现，在慢性便秘之“气秘”“寒秘”当中较为常见。 《素问　水热穴论》云：“气街、三里、巨虚上下廉，此八者，以泻胃中之热也。”古代医籍当中，胃的功能通常也包括肠在内，以上论述说明上巨虚适用于后世之热性便秘。 8 项研究中有 7 项使用了电针，波形为 10/50 Hz 疏密波，电流强度为 0.1 mA～1 mA，取决于患者的耐受程度。 8 项 RCT 研究的疗程为 4 周～8 周。疗程的初始阶段，多数研究选择了每周 5 次的治疗频率，并持续 3 周～4 周。对于 8 周的长疗程研究，在第 3 周～8 周治疗频率降低到每周 3 次。 ②假针刺对照是明确针刺净效应的必要环节，因此本问题具备优先性。 与假针刺相比，针刺在改善便秘严重程度方面体现出有利效果，且并未增加风险性。 慢性便秘患者，特别是严重便秘患者，迫切需要行之有效的治疗方法，针刺疗法符合多数患者的意愿。 多数国家已经有针灸应用并进行了立法工作，具备了使用针刺疗法的必需资源条件，使得针刺治疗具备了较好的可实施性。 假针刺仅限于临床研究，不作为治疗手段，因此缺乏有关假针刺花费情况的研究。 针刺治疗的花费情况各地区存在较大差异，需视当地医疗政策及收入水平而定。 目前，国内外均缺乏针刺与假针刺成本-效益对比以及健康相关公平性的研究。 基于以上论据，指南推荐意见共识专家组投票决定强烈推荐针刺用于慢性功能性便秘的治疗。

（续）

(3) 推荐说明
● 亚组考虑 1 项 RCT 比较了电针(EA)和非穴点假针刺(SA)对成人慢性严重功能性便秘(CSFC)患者的疗效[28]。首要结局指标为第 1 周～第 8 周平均每周 CSBMs 与基线的变化,其余结局指标包括平均每周有 3 次或以上 CSBMs 的患者比例以及针刺相关的不良事件发生率。结果提示针刺组第 1 周～第 8 周平均每周 CSBMs 与基线的变化为 1.76 (95% CI, 1.61 ～1.89),显著高于假针刺组的 0.87 (95%CI , 0.73～0.97),组间差值为 0.90 ([95%CI, 0.74 ～1.10]; P<0.001)。治疗期间与针刺相关的不良事件在两组中均不常见,且均为轻度或短暂性。效应量中等。 该研究结果提示 8 周的电针治疗增加了周 CSBMs,且对慢性严重功能性便秘的治疗是安全的。 重度功能性便秘是指平均每周完全自主排便次数(CSBMs)2 次及以下,持续 3 个月以上的患者。 ● 实施考虑 心脏起搏器植入患者不应使用电针。 ● 监察与评估 ① 监测慢性功能性便秘,特别是严重慢性功能性便秘患者寻求针刺治疗的比例。 ② 评估慢性功能性便秘,特别是严重慢性功能性便秘患者针刺治疗后症状改善程度和安全性。 ● 科研的优先考虑 未来研究建议进一步探索更多的假针刺方法,进行更长时间的随访并进行卫生经济学评估。
(4) 推荐意见使用说明
① 本推荐方案适用于成人(≥18 岁)的慢性功能性便秘患者。 ② IBS 便秘型或药物引起的便秘,或继发于内分泌、代谢、神经疾病或手术后的便秘,针刺治疗尚缺乏高质量研究,不适用此推荐方案。 ③ 在使用本推荐方案时,可根据患者中医证型或兼夹症状进行适当的穴位加减。
(5) 治疗方案
● 取穴 可以选取双侧天枢穴(ST25)、腹结穴(SP14)和上巨虚穴(ST37)为主穴。 可以使用 10/50 Hz 的疏密波电针作为刺激方式,强度以患者自觉舒适为度。 ● 操作方法 治疗时患者仰卧,用 0.30 mm×50 mm 或 0.35 mm×75 mm 毫针缓慢垂直刺入上述穴位,深度约 30 mm～70 mm。腹部穴位不使用提插捻转手法,针尖刺入腹壁肌肉层即可。另外,将 0.30 mm×40 mm针垂直刺入上巨虚约 30 mm。 ● 治疗频率 治疗频率初始第一周 3 次～5 次,起效后每周 2 次～3 次。 ● 疗程 疗程从 4 周～8 周不等。对于严重的功能性便秘,建议采用较长的疗程。

临床问题2：对于不同性别的慢性便秘患者，针刺与假针刺的疗效相比如何？
（1）推荐意见
对于女性严重慢性功能性便秘患者，相比于假针刺，便秘指南制定小组推荐使用针刺疗法，以改善患者的临床症状。（强推荐，基于高质量证据）
（2）证据概述
① 2019年发表的1项RCT研究评估了电针（EA）与SA对比，对于822例慢性严重功能性便秘妇女的疗效[34]。首要结局指标为平均每周CSBMs≥3次的患者比例，其他结局指标包括平均每周CSBMs、平均每周SBMs、BSFS和PAC-QOL。 治疗8周后，以及随访12周后，EA组平均每周CSBMs≥3次的患者比例EA组为24.3%，SA组为8.1%，差异率为13.1%（[95%CI，6.5%～19.7%]；P<0.001）。与针刺相关的不良事件（AEs）发生率，两组间无统计学意义。本研究表明，在治疗8周时，EA改善了女性严重功能性便秘患者排便的自发性和完全性，停止治疗后效果持续了12周。效应量中等。 证据质量评级为高质量。 该研究以双侧天枢穴（ST25）、腹结穴（SP14）和上巨虚穴（ST37）为主穴，未选取其他配穴。 ② 女性因其生理特点不同，更容易受慢性便秘的影响。针刺对于女性慢性便秘患者人群的效能可能与普通人群有所差异。因此，针刺对于女性慢性便秘患者的效能问题具有优先性。 与假针刺相比，针刺在改善女性患者便秘严重程度和生活质量方面体现出有利效果，且并未增加风险性。 成本、资源及患者意愿同PICO问题1。 目前，国内外均缺乏针刺对于女性患者公平性以及针刺与假针刺成本-效益对比的研究。 基于以上论据，指南推荐意见共识专家组投票决定强烈推荐针刺用于慢性功能性便秘的治疗。
（3）推荐说明
• **亚组考虑** 本临床问题仅纳入1篇RCT，无亚组研究。 • **实施考虑** ① 女性月经期及哺乳期针刺治疗需更加谨慎，应与患者进行良好沟通。 ② 心脏起搏器植入患者不应使用电针。 • **监察与评估** ① 监测女性严重慢性功能性便秘患者寻求针刺治疗的比例。 ② 评估女性严重慢性功能性便秘患者针刺治疗后症状改善程度和安全性。 • **科研的优先考虑** 未来研究建议进行患者满意度及卫生经济学评估。
（4）推荐意见使用说明 ① 本推荐方案适用于成年（≥18岁）女性的严重慢性功能性便秘患者。 ② 严重功能性便秘是指平均每周完全自主排便次数（CSBMs）2次及以下，持续3个月以上的患者。 ③ 由于针刺腹部穴位对于孕妇有明显的风险，故本推荐方案不适用于孕妇的便秘治疗（即使患者符合严重功能性便秘的诊断标准）。

（续）

(5) 治疗方案
• **取穴** 同 PICO 问题 1。 • **操作方法** 同 PICO 问题 1。 • **治疗频率** 治疗频率初始第一周 3 次～5 次，起效后每周 2 次～3 次。 • **疗程** 建议总疗程 8 周。

临床问题 3：对于不同年龄的慢性便秘患者，针刺与假针刺的疗效相比如何？
(1) 推荐意见 对于老年(＞65 岁)慢性功能性便秘患者，相比于假针刺，便秘指南制定小组推荐使用针刺疗法。(专家共识性意见，无临床研究证据)
(2) 证据概述
对于老年人慢性便秘，古代医家强调从体质特点出发，探讨发病机制，制定治疗原则。 《景岳全书・秘结》云："秘结证，凡属老人、虚人，多有病为燥结者，盖此非气血之亏，即津液之耗。"[35] 元代朱震亨云："老人、风人、虚人，津液少而秘者，宜以药而滑之，不可用峻利之药攻逐，否则津液走，气血耗，虽可暂通，但过后复秘，且变生他病。"[36] 由以上古籍记载可以看出，老年人便秘的病因多为气血亏虚加之津亏，与虚秘较为类似。治则方面，老年人便秘以"滑"为主，不可用峻猛通利的方法。此治则与现代润肠通便法类似。 古籍当中并无针对老年人便秘具体取穴的记载。 现代针灸名家杨甲三以热秘、气秘、虚秘、冷秘对老年便秘进行分型，并给出相应的取穴方案[37]。 据慢性便秘的临床流行病学研究，老年人具有更高的便秘发生率，而且对常规治疗的反应较差。针刺对于老年人便秘的疗效问题具备优先性。 PICO 问题 1 的临床研究证据表明，对于包括老年人在内的慢性便秘患者，针刺的疗效优于假针刺，为针刺对于老年慢性便秘患者的效能问题提供了间接证据。 老年人因为体力衰退和基础病增多，其健康相关公平性应该受到关注。 目前，尚缺乏针灸疗法在老年人便秘群体当中的卫生经济学研究。 基于以上论据，指南推荐意见共识专家组投票决定以专家共识的形式推荐针刺用于老年人慢性功能性便秘的治疗。

（续）

（3）推荐说明
● 亚组考虑 无。 ● 实施考虑 患有严重的心血管疾病、认知功能障碍、精神障碍或可能影响患者合作的疾病的老年患者不适用本推荐。 ● 监察与评估 ① 监测老年慢性功能性便秘患者寻求针刺治疗的比例。 ② 评估老年慢性功能性便秘患者针刺治疗后症状改善程度和安全性。 ● 科研的优先考虑 未来建议进行针刺治疗老年慢性便秘的临床研究，建议对照组选择假针刺/安慰针刺，以明确针刺对于该人群的效能。
（4）推荐意见使用说明
① 本推荐方案基于专家共识性意见。 ② 本推荐方案来源于古代文献及现代专家经验，无 RCT 研究支撑。 ③ 使用者需要根据老年人体质特点和基础疾病进行穴位配伍，并决定手法、刺激量等。
（5）治疗方案
可以选取以下穴位治疗老年便秘： ① 热秘：泻足三里（ST36）、天枢（ST25）；补照海（KI6）、支沟（TE6）； ② 气秘：泻大敦（LR1）、足三里（ST36）；补支沟（TE6）、太白（SP4）； ③ 虚秘：补气海（CV6）、足三里（ST36）、脾俞（BL20）、胃俞（BL21）； ④ 冷秘：补大肠俞（BL25）、肾俞（BL23）、支沟（TE6）、照海（KI6）。

临床问题 4：对于慢性便秘患者，电针与手针的疗效相比如何？
（1）推荐意见
对于慢性功能性便秘患者，相比于手针，便秘指南制定小组推荐使用电针作为刺激方式，以缓解患者症状并提高其生活质量。（有条件的推荐，基于中等质量证据）
（2）证据概述
① 共纳入电针 vs 手针治疗慢性功能性便秘患者的 5 项 RCT 研究，包括患者 378 例[38-42]。结局指标包括便秘的严重程度（SBMs、BSFS、CCS）和 PAC-QOL。 Meta 分析提示治疗 2 周～4 周后电针组 PAC-QOL 的改善情况明显优于手针组（$P<0.01$；MD＝4.24 [95% CI，−6.78～1.70]；$I^2=79\%$），电针组的总有效率显著高于手针组（$P<0.01$；RR＝1.30 [95% CI，1.14～1.48]；$I^2=0$）。效应量中等。

（续）

证据体质量评级为中等质量。 4 项研究选择双侧天枢穴（ST25）和上巨虚穴（ST37）作为主穴，3 项研究选择腹结穴（SP14）作为主穴。1 项研究根据患者中医辨证分型采用了不同配穴。 ② 与手针相比，电针在改善便秘严重程度，提高生活质量方面体现出有利效果。 但是，现有研究没有评价电针相较于手针是否会带来额外的风险。因此，部分专家，特别是中国以外地区的专家表达了对此的关切，并因此选择有条件的推荐。 根据对指南共识专家的访谈，电针在北美、东南亚等地均已广泛应用于临床，资源获得性及可实施性良好。 患者为尽快缓解病情多数对电针具有良好的依从性，符合患者的意愿。 电针在多数地区并不另外收费，不会增加额外的经济负担。 目前，国内外均缺乏手针与电针成本-效益对比和治疗公平性的研究。 基于以上论据，指南推荐意见共识专家组投票决定有条件的推荐电针用于慢性功能性便秘的治疗。
（3）**推荐说明**
● **亚组考虑** 目前，缺乏电针与手针比较的亚组分析。 ● **实施考虑** ① 电针设备应由合格的制造商生产并通过正规途径引进。电针仪需要定期维护。 ② 心脏起搏器植入患者不应使用电针。 ● **监察与评估** ① 监测慢性功能性便秘患者接受电针治疗的比例。 ② 评估慢性功能性便秘患者电针治疗后症状改善程度和安全性。 ● **科研的优先考虑** 未来研究建议进一步进行电针安全性、不同电针波形疗效差异及电针卫生经济学的评估。
（4）**推荐意见使用说明**
① 本推荐方案适用于成人（≥18 岁）的慢性功能性便秘患者。 ② IBS 便秘型或药物引起的便秘，或继发于内分泌、代谢、神经疾病或手术后的便秘，针刺治疗尚缺乏高质量研究，不适用此推荐方案。
（5）**治疗方案**
● **取穴** 可以选取双侧天枢穴（ST25）、腹结穴（SP14）和上巨虚穴（ST37）为主穴。 根据患者的中医辨证可采用双侧合谷（LI4）、曲池（LI11）治疗热秘，气海（CV7）治疗气秘，双侧脾俞（BL21）治疗虚秘，关元（CV6）治疗寒秘。

（续）

- **操作方法**

在使用电针时，电极的配对鳄鱼夹可以横向连接到双侧天枢穴（ST25）和腹结穴（SP14）针柄上。通常电针刺激持续 30 min，可选用 2/15 Hz 或 10/50 Hz 疏密波，电流强度为 0.1 mA～1 mA，取决于患者的耐受度（最好是穴位周围的皮肤轻微颤抖而无疼痛）。

临床问题 5：对于慢性便秘患者，电针深刺法与电针浅刺法相比效果如何？

（1）推荐意见

对于慢性功能性便秘患者，相比于腹部穴位电针浅刺法，便秘指南制定小组不能确定腹部穴位电针深刺法能够给患者带来更大的效益并保证其安全性。（未达成推荐意见共识，基于高质量证据）

（2）证据概述

① 2019 年发表的一篇系统评价分析了电针深刺与电针浅刺对慢性功能性便秘患者的疗效[43]。

共纳入 9 篇 RCT，结局指标包括周平均 SBMs 和 CCS[44-52]。Meta-分析提示经过 4 周治疗后，在改善 SBMs 方面，深刺组明显优于浅刺组（$P<0.01$；MD=1.01［95%CI，0.79～1.23］；$I^2=0$），在改善 CCS 方面亦获得相同结果（$P<0.01$；MD=1.52［95%CI，−1.89～−1.15］；$I^2=0$）。效应量小。

该系统评价对不同深度电针的安全性进行了描述性分析，认为电针深刺会引起更多的不适症状，特别是针刺局部的疼痛，但并未进行 Meta-分析。

证据体质量评级为高质量。

纳入的 9 篇文献均以双侧天枢穴（ST25）作为针刺选穴，并采用电针作为刺激方式。

② 针刺深度是针灸临床治疗的关键。早在《黄帝内经》当中就已经对针刺深度做了论述。因此，该问题具有一定的优先性。

与腹部穴位电针浅刺法相比，腹部穴位电针深刺法在改善便秘严重程度方面体现出有利效果。

对于天枢穴（ST25），深刺与浅刺在中国国内收费相同，对于其他穴位，如肢体部位、腰部穴位，深刺可按照芒针收费，可能高于浅刺。其他地区深刺与浅刺收费是否有差别缺乏证据。

腹部穴位深刺疗法在中国国内是一种常用疗法，对于其他国家与地区，其接受度尚无确切证据。

由于深刺可能会给患者带来更多的不适感，因此有可能影响患者的接受度，降低治疗的可行性。

目前，国内外均缺乏不同深度针刺成本-效益对比的研究。

在共识专家讨论当中，一些专家，尤其是来自中国以外地区的专家，表示虽然当地并没有对针刺深度的明确限制，但更深的针刺深度，尤其是刺入腹膜，可能会导致更多的风险。因此，不确定是否应该推荐更深的针刺深度。

基于以上论据，指南推荐意见共识专家组经过 2 轮投票，最终没有对电针深刺法治疗慢性便秘形成共识。

（3）推荐说明

- **亚组考虑**

目前，缺乏针对不同深度针刺治疗慢性便秘的亚组分析。

（续）

● **实施考虑** ① 便秘指南制定小组尚不能根据指南共识专家组的决议提供腹部穴位电针深刺法治疗慢性便秘的推荐方案。 ② 医生在决定针刺深度时，应考虑自身技术水平、患者的身体状况和意愿。 ③ 从业人员应考虑更深的腹部穴位针刺深度可能带来的临床和法律风险，并根据当地法规和法律的要求与患者协商。 ④ 在采用深刺治疗时，患者的知情同意可能是必要的。 ● **监察与评估** 便秘指南制定小组尚不能根据指南共识专家组的决议提供电针深刺法治疗慢性便秘的推荐方案。 故目前不能确定针对推荐方案的监测与评估方法。 ● **科研的优先考虑** 未来研究建议进一步探索更多穴位不同针刺深度对于慢性便秘的疗效。 建议对针刺深度进行个体化界定。 建议采用大便常规等客观指标系统研究不同深度针刺的安全性。
（4）推荐意见使用说明
① 15 位便秘指南共识专家组成员经过 2 轮投票均未能就推荐方向达成共识。 ② 本临床问题涉及的 9 篇 RCT 均取双侧天枢穴（ST25）作为单一针刺穴位。 ③ 本临床问题中的深刺是指将针灸针刺入天枢穴直至刺穿腹膜。浅刺是指针灸针刺入深度为 0.6 寸～1.5 寸（30 mm～40 mm）。

临床问题 6：对于慢性便秘患者，针刺与口服西药相比效果如何？
（1）推荐意见
对于慢性便秘患者，与口服西药（包括普芦卡必利胶囊、莫沙必利片、乳果糖口服液和聚乙二醇散剂）相比，便秘指南制定小组推荐使用针刺疗法，以改善患者的临床症状和生活质量。（有条件的推荐，基于中等质量证据）
（2）证据概述
① 2020 年发表的一篇系统评价分析了针刺与西药对慢性便秘的疗效[25]。共纳入 13 篇 RCT，结局指标包括周平均 CSBMs、BSFS、PAC-QOL、总有效率和不良事件发生率[39,53-64]。 Meta-分析结果表明，针刺组在增加周平均 CSBMs 方面优于口服普芦卡必利胶囊组（$P=0.000\ 4$；MD=0.32[95% CI，0.14～0.5]；$I^2=29\%$）；针刺组在改善 BSFS 方面优于口服莫沙必利片组和乳果糖口服液组；针刺组在改善 PAC-QOL 方面优于口服聚乙二醇组和普芦卡必利胶囊组。不良事件发生率方面针刺组低于乳果糖口服液和口服莫沙必利组。效应量小。 证据体质量评级为中等质量。

（续）

纳入研究的选穴总体以脾胃经穴位为主。13 项研究中有 10 项选取双侧天枢穴(ST25)，6 项选取双侧上巨虚穴(ST37)，6 项选取双侧腹结穴 (SP14)作为主穴。 1 项研究选用中髎穴治疗严重的排便费力，采用百会、神庭穴治疗焦虑、抑郁。 13 项研究中有 8 项使用了电针，另外 5 项使用手针。 ② 与口服西药(包括普芦卡必利胶囊、莫沙必利片、乳果糖口服液和聚乙二醇散剂)相比，针刺在改善便秘严重程度和生活质量方面体现出有利效果，且并未增加风险性。 多数国家已经有针灸应用并进行了立法工作，使得针刺治疗具备了较好的可实施性。 不同国家和地区针刺和西药的花费情况有较大差异，与当地的医保政策有关。相对来说，接受针刺治疗可能会导致患者付出更多的时间。患者的意愿与价值观需要结合当地具体情况判定。 目前，国内外均缺乏针刺与西药医疗公平性的研究。 基于以上论据，指南推荐意见共识专家组投票决定有条件的推荐针刺用于慢性功能性便秘的治疗。
(3) 推荐说明
• **亚组考虑** 有一项高质量的非劣效研究比较了电针与口服普芦卡必利治疗重度慢性便秘(SCC)的疗效，共纳入 560 名患者[65]。首要结局指标是第 3 周～8 周 CSBMs 均值≥3 的患者比例。结果显示，经过 8 周共 28 次的电针治疗，电针组疗效不劣于口服普芦卡必利(36.2% vs 37.8%, with a difference of 21.6% [95% CI, 28%～4.7%], P<0.001 for noninferiority)。电针组有 49 人(17.69%)发生不良事件，口服普芦卡必利组有 123 人(44.24%)发生不良事件。效应量大。 本研究得出结论：电针治疗重度慢性便秘的疗效不逊于口服普芦卡必利且安全性更好。8 周电针治疗后效果可持续 24 周。电针是治疗重度慢性便秘的一种有前途的非劣选疗法。 针对该亚组的推荐方案与前相同。 重度功能性便秘是指平均每周完全自主排便次数(CSBMs)少于 2 次，持续 3 个月以上的患者。 • **实施考虑** 心脏起搏器植入患者不应使用电针。 • **监察与评估** ① 监测慢性功能性便秘，特别是严重慢性功能性便秘患者寻求针刺治疗的比例。 ② 评估慢性功能性便秘，特别是严重慢性功能性便秘患者针刺治疗后症状改善程度和安全性。 • **科研的优先考虑** 未来研究建议进一步探索针刺与更多西药种类的疗效对比。建议进行针刺与西药对比的卫生经济学评估。
(4) 推荐意见使用说明
① 本推荐方案适用于成人(≥18 岁)的慢性功能性便秘患者。 ② IBS 便秘型或药物引起的便秘，或继发于内分泌、代谢、神经疾病或手术后的便秘，不适用此推荐方案。 ③ 除普芦卡必利胶囊、莫沙必利片、乳果糖口服液和聚乙二醇散剂以外的口服西药目前缺乏证据支持，使用者需根据自身经验和患者意愿推荐本方案。

（续）

(5) 治疗方案
● **取穴** 可以选取双侧天枢穴(ST25)、腹结穴(SP14)和上巨虚穴(ST37)为主穴。 根据患者的兼夹症状随症配穴：可加用双侧中髎穴(BL32)治疗严重的排便费力，配用百会穴(GV20)、神庭穴(GV24)缓解其焦虑、抑郁症状。 ● **操作方法** 针刺方法及电针使用方法同 PICO 问题 1。 ● **治疗频率** 初始第一周 3 次～5 次，起效后每周 2 次～3 次。 ● **疗程** 疗程从 4 周～8 周不等。对于严重的功能性便秘，建议采用较长的疗程。

临床问题 7：与生物反馈疗法相比，针刺对于慢性便秘患者的疗效如何？
(1) 推荐意见
对于盆底失弛缓综合征(Unrelaxed Pelvic Floor Syndrome，UPFS)引起的慢性便秘患者，相比于生物反馈疗法，便秘指南制定小组推荐使用针刺疗法，以改善患者的临床症状、生活质量和肛门直肠测压指标。(强推荐，基于中等质量证据)
(2) 证据概述
① 本临床问题纳入针刺与生物反馈对比治疗慢性便秘的 2 项 RCT，共 110 例患者[66,67]。 2 项研究所涉及的慢性便秘类型均为 UPFS 所致便秘，包括肛门直肠测压、总有效率和便秘患者生活质量 3 个结局指标。 Meta-分析提示肛门收缩压针刺组优于生物反馈组($P<0.01$；MD＝－6.78 [95% CI，－11.30～－2.26]；$I^2=0$)。效应量中等。 证据体 GRADE 质量评级为中等质量。 2 项研究均选用双侧八髎穴(BL31-34)为主穴。2 项研究均选用低频电针作为刺激方式。 ② 与生物反馈疗法相比，针刺在改善肛门直肠测压指标方面体现出有利效果。 生物反馈需要专人一对一操作，需要专用的设备和场地。相比较而言，针刺治疗在人员、设备方面的要求较低，有较好的可实施性。 相比生物反馈需要将电极置入体内，患者更容易接受针刺治疗。 目前，国内外均缺乏针刺与生物反馈疗法成本-效益对比的研究。 基于以上论据，指南推荐意见共识专家组投票决定强烈推荐针刺用于 UPFS 所致便秘患者的治疗。

（续）

（3）推荐说明
● **亚组考虑** 目前，缺乏针对 UPFS 所致慢性便秘的亚组研究。 ● **实施考虑** ① 针刺八髎穴应以正确定位为基础。针刺八髎穴前应有充分的解剖学基础和针灸实践。 ② 术者应注意患者的体型、骶骨发育情况等因素，并根据患者耐受程度决定针刺深度及刺激量。 ③ 电针设备的使用应遵守当地法规。 ● **监察与评估** ① 监测 UPFS 所致慢性便秘患者接受针刺治疗，而非生物反馈治疗的比例。 ② 评估 UPFS 所致慢性便秘患者在接受针刺治疗后的便秘严重程度、安全性和经济负担的变化。 ● **科研的优先考虑** 未来研究建议进一步探索更多的临床结局，如周平均完全自主排便次数、患者对治疗的满意度等。同时，建议针对盆底肌肉协调障碍所致便秘的更多亚型，如盆底肌肉松弛所致便秘进行研究。
（4）推荐意见使用说明
① 本推荐意见仅适用于 UPFS 所致成年慢性便秘患者。 ② UPFS 患者应通过肛门直肠指诊、肛门直肠测压和排便造影以明确诊断。 ③ 考虑到针刺腰骶部穴位对于孕妇的安全性尚缺乏依据，故本推荐不适用于孕妇合并慢性便秘的治疗（即使患者符合 UPFS 的诊断标准）。
（5）治疗方案
● **取穴** 可以选取双侧八髎穴（BL31-34）为主穴。 ● **操作方法** 可采用 2 Hz～4 Hz 的低频电针作为刺激方法。 八髎穴的针刺深度建议控制在 40 mm～90 mm。每次治疗留针 30 min。 ● **治疗频率** 每周治疗 3 次～5 次。 ● **疗程** 建议连续治疗 4 周。

临床问题 8：对于慢性便秘患者，针刺结合艾灸与单纯使用针刺相比疗效如何？
（1）推荐意见
对于慢性便秘患者，相比于单纯针刺治疗，便秘指南制定小组推荐使用针刺结合艾灸疗法，以改善患者的临床症状。（有条件的推荐，基于中等质量证据）
（2）证据概述
① 本临床问题纳入了 6 项针刺加艾灸与单纯针刺对比治疗慢性便秘患者的 RCT，共 554 例患者[68-73]。结局指标包括 KESS 评分、总有效率和 PAC-QOL。 Meta-分析提示在改善 KESS 评分（$P<0.01$；MD＝－2.71［95％CI，－4.02～1.4］；$I^2=12\%$）和总有效率方面（$P<0.01$；RR＝1.19［95％CI，1.06～1.33］；$I^2=0$），针刺结合艾灸组优于单纯针刺组。效应量小。 有研究报道了 1 例晕针和 1 例腹肌紧张。6 项研究均未报道与艾灸相关的不良事件。 证据体 GRADE 质量评级为中等。 2 篇 RCT 明确了患者的中医证型为气虚型并采用针刺结合麦粒灸为治疗措施。取穴方面，选取了双侧天枢穴（ST25）、关元穴（CV6）、双侧上巨虚穴（ST37）、双侧足三里穴（ST36）为主穴。并配合气海穴（CV5）。 其余 4 篇研究未提及中医证型。 所有 6 篇研究均未采用电针。 ② 针刺配合艾灸是针灸医师最为常用的一种疗法组合。针刺与艾灸同用是否能获得单纯使用针刺更大的临床效能是针灸临床医师普遍关注的问题。 与单纯针刺相比，针刺结合艾灸在改善便秘症状方面体现出有利效果。 艾灸最为常见的不良反应是烫伤，虽然纳入的研究并未报道相关的不良事件，但是在利弊分析方面应该考虑可能的临床风险。指南共识专家组经过讨论，建议不推荐直接灸法（如麦粒灸），推荐较为安全的艾条温和灸。 来自于北美的共识专家担心艾灸产生的烟雾可能会引起部分患者不适，因此应考虑诊室的通风条件和患者的意愿。如果同一诊室的患者有人不能接受艾灸烟雾，则可能导致公平性的问题。因此给予有条件的推荐。 针刺联合艾灸的成本应该高于单纯针刺，其成本-效益比目前缺乏研究证据。 基于以上论据，指南推荐意见共识专家组投票决定有条件的推荐针刺结合艾灸用于慢性便秘患者的治疗。

（续）

(3) 推荐说明
● **亚组考虑** 目前，缺乏针刺结合艾灸治疗慢性便秘的亚组研究。 ● **实施考虑** ① 艾灸应该在具备良好通风条件的环境下进行。 ② 艾灸的使用应遵守当地法规。 ③ 进行艾灸治疗应考虑接受者和同诊室患者的意愿。 ④ 艾灸治疗过程中应询问患者的感受，避免烫伤。 ⑤ 如果发生烫伤应根据严重程度及时处理，重度烫伤需要专科诊治。 ● **监察与评估** ① 监测慢性便秘患者接受针刺结合艾灸治疗的比例。 ② 评估慢性便秘患者在接受针刺结合艾灸治疗后的便秘严重程度、安全性和经济负担的变化。 ● **科研的优先考虑** 未来研究建议进一步探索更多的临床结局，如周平均完全自主排便次数、患者对治疗的满意度等。同时，建议进行针刺结合艾灸疗法的卫生经济学评估。
(4) 推荐意见使用说明
① 艾灸疗法适用于中医辨证属于虚证的慢性便秘患者。 ② 本推荐方案适用于成人(≥18 岁)的慢性功能性便秘患者。 ③ IBS 便秘型或药物引起的便秘，或继发于内分泌、代谢、神经疾病或手术后的便秘，针灸治疗尚缺乏高质量研究，不适用此推荐方案。
(5) 治疗方案
● **取穴** 可以选取双侧天枢穴(ST25)、关元穴(CV6)、双侧上巨虚穴(ST37)、双侧足三里穴(ST36)为主穴。 气虚型便秘患者可配合气海穴(CV5)。 ● **操作方法** 建议采用针刺结合艾条温和灸，每个穴位艾灸 3 min～5 min，至穴位局部皮肤潮红。

临床问题 9：对于慢性便秘患者，针刺结合西药与单纯使用西药相比疗效如何？
(1)推荐意见
对于慢性便秘患者，相比于单纯口服西药，便秘指南制定小组推荐使用针刺联合口服西药的方法，以改善患者的临床症状。(强推荐，基于低质量证据)

（续）

（2）证据概述
① 本临床问题纳入针刺结合口服莫沙必利片与单纯口服莫沙必利片对比治疗慢性便秘的1项RCT，共43例患者[74]。 该项研究仅评价了两组的总有效率，结果提示针刺结合口服莫沙必利片组总有效率90％(18/20)高于单纯口服莫沙必利片组65％(15/23)。效应量小。 证据质量低。 该研究选取双侧天枢(ST25)、支沟(TE6)、足三里(ST36)、上巨虚（ST37)、中脘(CV12)作为针刺穴位。刺激方式为手针。 ② 针刺作为一种补充替代疗法，针刺与西药的结合是否能够获得更大的临床效能对于患者和医生合理选择治疗方案有重要意义。 仅有1项发表于中国国内的小样本RCT提示针刺结合口服西药获得了有利结果，未报道两种疗法的结合使用是否导致了风险性的增加。多数的针灸和中医专家认为在口服西药基础上加用针刺治疗会带来额外的效益。并且，作为一种物理性治疗，针刺并不会加剧口服西药原本的副作用。 大部分慢性便秘患者在接受针刺治疗时会继续服用西药。多数情况下，针灸医生并不会要求患者在接受针刺治疗的过程中停止服用西药，因此，针刺与口服药物结合符合患者的意愿。 针刺结合西药的费用应该高于单纯使用西药。但二者的成本-效益比缺乏研究证据。 来自于西医消化科领域的专家认为对于严重程度一般的慢性便秘患者，药物治疗能够解决大部分问题，因此，在缺乏根据病情严重程度进行的亚组研究的情况下，不确定是否应该推荐针刺联合口服药物治疗。 基于以上论据，指南推荐意见共识专家组投票决定强烈推荐针刺联合口服西药用于慢性便秘患者的治疗。
（3）推荐说明
• **亚组考虑** 目前，缺乏针对针刺结合口服西药治疗慢性便秘的亚组研究。 • **实施考虑** 由于针刺联合西药有可能增加患者的经济负担，故本方案应该在患者同意的情况下实施。 • **监察与评估** ① 监测接受针刺结合口服西药治疗的慢性便秘患者的比例。 ② 评估慢性便秘患者在接受针刺结合口服西药治疗后的便秘严重程度、安全性和经济负担的变化。 • **科研的优先考虑** 未来研究建议进行针刺结合口服西药治疗慢性便秘的亚组研究。

（续）

（4）推荐意见使用说明
① 本推荐方案适用于成人(≥18 岁)的慢性功能性便秘患者。 ② IBS 便秘型或药物引起的便秘,或继发于内分泌、代谢、神经疾病或手术后的便秘,针灸治疗尚缺乏高质量研究,不适用此推荐方案。 ③ 本推荐方案的使用者可根据患者的兼夹症状和中医辨证进行适当的穴位调整。 ④ 本推荐方案的使用者可以根据自身经验和患者意愿选择是否使用电针。
（5）治疗方案
● **取穴** 可以选取双侧天枢(ST25)、支沟(TE6)、足三里(ST36)、上巨虚（ST37)、中脘（CV12)作为针刺穴位。 ● **治疗频率** 3 次/周～5 次/周。 ● **疗程** 疗程为 4 周。

临床问题 10：对于慢性便秘患者,艾灸结合西药与单纯使用西药相比疗效如何?
（1）推荐意见
对于慢性功能性便秘患者,相比单纯使用西药,便秘指南制定小组推荐使用艾灸结合西药。(专家共识性意见,无临床研究证据)
（2）证据概述
① 艾灸治疗便秘在中医古籍当中早有记载。《备急千金要方・卷十五・秘涩第六》:大便闭塞,气结心坚满,灸石门百壮。此处之“大便闭塞”在中医辩证分型方面与气秘类似。 在中医辨证方面,现代针灸名家贺普仁在《针灸歌赋临床应用》当中提出:艾灸多用于治疗冷秘[75]。 根据中医理论,艾灸治疗便秘有良好的疗效。如《针灸聚英・卷四下・杂病歌》云:假如大小便不通,三百壮灸胃脘穴,功效最速如神通。此处之胃脘,现代认为即中脘穴(RN12)。 艾灸取穴方面,古籍当中提出可以使用承筋穴、石门穴、大敦穴、八髎穴等。 贺普仁在《针灸歌赋临床应用》提出:冷秘宜艾灸中脘。 目前,缺乏艾灸结合口服西药与单纯口服西药对比的直接临床研究证据。 回顾在临床 PICO 问题 8:“对于慢性便秘患者,针刺结合艾灸与单纯使用针刺相比疗效如何?”当中,有艾灸可以带来额外的临床效益的 RCT 证据,可以作为本临床问题的间接证据。 ② 对于某些特定中医证型的慢性便秘,比如虚秘、冷秘,灸法因其理论优势,被很多针灸医师采用。因此,艾灸法与其他疗法结合的问题具备优先性。 艾灸在安全性、治疗公平性方面的考虑同 PICO 问题 8。 艾灸疗法结合西药的成本应该高于单纯使用西药。二者的成本-效益比缺乏研究证据。 基于以上论据,指南推荐意见共识专家组投票决定以专家共识的形式推荐艾灸结合西药用于慢性功能性便秘的治疗。

（续）

（3）推荐说明
● **亚组考虑** 无。 ● **实施考虑** ① 本推荐方案适用于经过必要培训、符合当地法规和法律的合格从业人员。 ② 本推荐方案适用于拥有必要设备的医疗机构。 ③ 其余有关艾灸的实施说明同 PICO 问题 8。 ● **监察与评估** ① 监测接受艾灸结合西药治疗慢性功能性便秘患者的比例。 ② 评估慢性功能性便秘患者接受艾灸结合西药治疗后症状改善程度和安全性。 ● **科研的优先考虑** 未来建议进行艾灸结合西药与单纯使用西药对比治疗慢性便秘的临床研究。
（4）推荐意见使用说明
① 本推荐方案基于专家共识性意见。 ② 本推荐方案来源于古代文献及现代专家经验，无直接 RCT 研究支撑。 ③ 使用者需要根据患者的中医辨证决定是否使用艾灸疗法。
（5）治疗方案
● **取穴** 对于冷秘患者，可以选取中脘穴（CV12）作为艾灸穴位。 ● **操作方法** 可采用艾条温和灸或温灸器灸。

临床问题 11：对于慢性便秘患者，针刺与现有治疗相比风险性如何？
（1）推荐意见
对于慢性便秘患者，相比于口服西药（包括乳果糖口服液、普芦卡必利胶囊、莫沙必利片），针刺疗法的不良事件发生率更低，从安全性角度出发，便秘指南制定小组推荐使用针刺疗法。（强推荐，基于中等质量证据）
（2）证据概述
① 共纳入 10 篇有关针刺安全性的 RCT[33,47,51,65,76-81]。临床结局指标为不良事件发生率。 根据取穴的不同，10 个研究分为 2 个亚组。 第 1 组以天枢穴（ST25）为唯一针刺穴位。Meta-分析显示电针深刺（穿透腹膜）天枢穴（ST25）和电针浅刺（0.6 寸～1.5 寸）天枢穴（ST25）与口服乳果糖比较，电针组不良事件发生率均低于口服乳果糖组（$P<0.01$；RR＝0.42［95％ CI，0.22～0.81］；$I^2=0$）；（$P<0.01$；RR＝0.16［95％ CI，0.03～0.85］；$I^2=0$）。

（续）

第2组选取了包括天枢穴（ST25）在内的一组穴位，并与口服胃肠动力药（包括普芦卡必利和莫沙必利）对比。Meta-分析提示针刺组不良事件发生率低于促动力剂组（$P<0.01$；$RR=0.42$［95%CI，0.32～0.55］；$I^2=51\%$）。效应量小。 证据体等级评价中等。 第1组取穴为双侧天枢穴（ST25），刺激方式为电针。 第2组取穴除双侧天枢穴（ST25）外，还包括双侧足三里穴（ST36）、支沟穴（TE6）、上巨虚穴（ST37）、关元穴（CV4）、腹结穴（SP14）。刺激方式以手针为主。 ② 针灸疗法曾经被人们冠以“无毒副作用的绿色疗法”，但随着其应用范围不断扩大，临床科研意识的增强及针刺不良医疗事件报导逐渐增多，对针刺安全性的关注也随之增多。在国际应用中，针刺安全性更是关注的焦点。故本问题具备优先性。 天枢穴是针刺治疗慢性便秘的常用穴位，单独使用天枢穴，或者以天枢穴为主组成穴方，安全性研究发现与常用口服西药相比，针刺的安全性具备有利效果。 安全性是成本-效益分析的重要组成部分，不良事件可能会导致治疗成本的增加。但目前尚缺乏与针刺安全性相关的成本-效益对比的研究。 良好的安全性会提高患者接受针刺治疗的意愿。 目前，缺乏与针刺安全性相关的医疗公平性的研究。 基于以上论据，指南推荐意见共识专家组投票决定从安全性考虑，强烈推荐针刺用于慢性便秘患者的治疗。
（3）推荐说明
• **亚组考虑** 目前，缺乏从患者群体出发，针对慢性便秘患者针刺安全性的亚组研究。 • **实施考虑** ① 本推荐意见适用于经过必要培训、符合当地法规和法律的合格从业人员。 ② 针灸医师在使用本推荐方案时应根据穴位的解剖特点和患者体质，谨慎操作，以保证应有的安全性。 ③ 本推荐意见适用于拥有必要设备的医疗机构。 • **监察与评估** ① 监测慢性便秘患者接受针刺治疗的比例。 ② 评估慢性便秘患者接受针刺治疗后的安全性。 • **科研的优先考虑** 未来研究建议进一步探索更多穴位或穴方的针刺安全性。
（4）推荐意见使用说明
① 本推荐方案适用于成人（≥18岁）的慢性功能性便秘患者。 ② IBS便秘型或药物引起的便秘，或继发于内分泌、代谢、神经疾病或手术后的便秘，针灸治疗尚缺乏高质量研究，不适用此推荐方案。 ③ 本推荐方案的临床证据来自于以天枢穴（ST25）为主的有限范围，针刺其他穴位的风险性需要根据临床实际加以评估。

（续）

（5）治疗方案
● 取穴 可以选取双侧天枢穴（ST25）为主穴。 其他可选穴位包括双侧足三里穴（ST36）、支沟穴（TE6）、上巨虚穴（ST37）、腹结穴（SP14）、关元穴（CV4）。 ● 操作方法 可以根据具体情况选用电针或手针。

临床问题 12：对于慢性便秘患者，针刺与现有治疗相比时间和经济负担情况如何？
（1）推荐意见
对于慢性便秘患者，相比于口服莫沙必利，针刺疗法的成本效益比更低，从经济负担角度出发，便秘指南制定小组推荐使用针刺疗法。（有条件的推荐，基于低质量证据）
（2）证据概述
① 发表于 2013 年的 1 项由国家重点基础研究发展计划（973 计划）支持的 RCT 研究通过基于模型的经济评价（MBEE）评估了电针与莫沙必利的成本-效益比。结果表明，针刺组的成本-效益比（8.02％）低于西药组（8.93％）。 本研究在中国开展，所有研究对象均来自广东佛山[82]。在该研究当中，患者的总费用大致包括以下几类：直接医疗费用：针灸费用（包括消耗品）；间接费用：运输费用；其他费用：工资损失等。 本 RCT 属于低质量证据，效应量小。 本研究选取双侧天枢穴（ST25）、大肠俞、曲池、上巨虚为主穴。采用电针为刺激方式。疗程 4 周。 ② 针灸治疗在中国国内普遍被认为具有简、便、验、廉的特点，但世界各地医疗体系政策不同。国外曾进行过针灸的成本-效益系统评价，但其病种并不包括慢性便秘。故目前缺乏针刺治疗慢性便秘的大规模卫生经济学研究。 之前数个临床问题涉及的临床研究提示，在临床疗效方面，针刺具有有利效果，且临床风险低，利弊平衡倾向于针刺疗法。 针灸需要相对较多的时间，包括等待时间、治疗时间和往返医院的时间。对于有行动障碍的患者，这也包括与护理人员在一起的时间。 本次纳入的单一 RCT 提示针刺组的成本-效益比低于口服西药组。总体来说，从经济负担角度出发，利弊平衡偏向于针刺组。但是，本次纳入的研究样本量小，且调查区域有限。以上原因导致多数专家选择了有条件的推荐针刺治疗。 目前，缺乏与卫生经济学相关的医疗公平性研究。 基于以上论据，指南推荐意见共识专家组投票决定从经济花费角度出发，有条件的推荐针刺用于慢性便秘患者的治疗。

（续）

（3）推荐说明
● 亚组考虑 目前，缺乏针刺治疗慢性便秘卫生经济学的亚组研究。 ● 实施考虑 ① 本推荐意见适用于经过必要培训、符合当地法规和法律的合格从业人员。 ② 本推荐意见适用于拥有必要设备的医疗机构。 ● 监察与评估 ① 监测慢性便秘患者考虑经济花费因素，接受针刺治疗的比例。 ② 评估慢性便秘患者在接受针刺治疗后的便秘严重程度、安全性和经济负担的变化。 ● 科研的优先考虑 未来研究建议进一步探索世界不同地区针刺治疗慢性便秘的卫生经济学情况。
（4）推荐意见使用说明
① 本推荐方案适用于成人（≥18 岁）的慢性功能性便秘患者。 ② IBS 便秘型或药物引起的便秘，或继发于内分泌、代谢、神经疾病或手术后的便秘，针灸治疗尚缺乏高质量研究，不适用此推荐方案。 ③ 使用者可以根据患者病情和中医辨证，在本推荐方案的基础上进行穴位加减。

5 获取途径

本指南在世界针灸学会联合会网站发布，纸质版由中国标准出版社出版。用户可通过上述途径获取本指南。

6 未来可开展的研究

开展不同深度针刺治疗慢性便秘的高质量 RCT 研究，进行对于慢性便秘经济负担的研究和卫生经济学评价。

7 局限和不足

7.1 由于研究周期和项目进度的安排，本指南的文献检索工作截止到 2021 年 3 月，这一时间点之后的文献不包括在本指南中。

7.2 本指南中的现代临床研究证据主要局限于 RCT，不包括非 RCT 临床研究。

7.3 针灸作为中医的重要组成部分，其临床治疗深受中医理论和古代医学经验的影响。我们在制定本指南的推荐方案时，尝试借鉴了古今医家的经验。然而，将这些经验应用于推荐方案的方式仍在探索中。

附 录 A
指南工作组成员

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附　录　B
缩略语表

缩略语	英文全称	中文全称
CFC	Chronic Functional Constipation	慢性功能性便秘
GDG	Guideline Development Group	指南研制组
WFAS	World Federation of Acupuncture-Moxibustion Societies	世界针灸学会联合会
ISO	International Standard Organization	国际标准组织
SA	Sham Acupuncture	假针刺
EA	Elctroacupuncture	电针

附　录　C
临床问题汇总

编号	临床问题
1	对于慢性便秘患者,针刺与假针刺的疗效相比如何?
2	对于不同性别的慢性便秘患者,针刺与假针刺的疗效相比如何?
3	对于不同年龄的慢性便秘患者,针刺与假针刺的疗效相比如何?
4	对于慢性便秘患者,电针与手针的疗效相比如何?
5	对于慢性便秘患者,电针深刺法与电针浅刺法相比效果如何?
6	对于慢性便秘患者,针刺与口服西药相比效果如何?
7	与生物反馈疗法相比,针刺对于慢性便秘患者的疗效如何?
8	对于慢性便秘患者,针刺结合艾灸与单纯使用针刺相比疗效如何?
9	对于慢性便秘患者,针刺结合西药与单纯使用西药相比疗效如何?
10	对于慢性便秘患者,艾灸结合西药与单纯使用西药相比疗效如何?
11	对于慢性便秘患者,针刺与现有治疗相比风险性如何?
12	对于慢性便秘患者,针刺与现有治疗相比时间和经济负担情况如何?

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