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题目：世界针灸学会联合会《针灸临床实践指南：偏头痛》推荐意见概述(英文)

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Standard and Guideline

World Federation of Acupuncture-Moxibustion Societies (WFAS) *Clinical Practice Guideline on Acupuncture and Moxibustion: Migraine* Recommendation Summaries

世界针灸学会联合会《针灸临床实践指南：偏头痛》推荐意见概述

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摘要
《针灸临床实践指南：偏头痛》（WFAS 007.8-2023)是世界针灸学会联合会 2023 年 10 月 9 日正式发布的针灸临床实践指南，也是首个针灸治疗偏头痛的国际指南。本指南的制定严格遵循循证方法学的流程及要求，包含指南目的、范围、适用人群、适用环境，针灸治疗偏头痛概况，指南制定过程和推荐意见。为帮助指南使用者更好地理解指南和应用本指南，最终能够更好地指导全球范围内针灸治疗偏头痛的临床决策，本文对指南共计 18 条推荐意见进行概述。

关键词
针灸；偏头痛；推荐意见；指南

ABSTRACT
Clinical Practice Guideline on Acupuncture and Moxibustion: Migraine (WFAS 007.9-2023) is a clinical practice guideline officially released by the World Federation of Acupuncture-Moxibustion Societies (WFAS) on October 9, 2023, and is the first international guideline on the treatment of migraine with acupuncture. This international standard was developed under the guidance of rigorous evidence-based methodology, and it contains guideline purpose, scope, applicable population, applicable settings, overview of acupuncture for migraine, guideline development process and recommendations. For promoting the understanding and application of this guideline, this article summarizes a total of 18 recommendations in order to assist clinical decisions for migraine with acupuncture.

Keywords:
Acupuncture and Moxibustion

Migraine
Recommendations
Guideline

1.Introduction

The World Federation of Acupuncture-Moxibustion Societies (WFAS) officially published the Clinical Guideline on Acupuncture and Moxibustion: Migraine (WFAS 007.8-2023) on October 9, 2023. The guideline was drafted by the Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences (CACMS) and commenced implementation on 31 December 2023. This is the first international guideline for using acupuncture to treat migraines.

The efficacy and safety of acupuncture for migraine have been demonstrated in several high-quality systematic reviews [1,2] and clinical studies [3-5]. However, the utilization of acupuncture in mainstream migraine guidelines has been notably limited. In the systematic review and assessment of complementary and alternative medicine recommendations in the *2021 Headache and Migraine Clinical Practice Guidelines*, Jeremy Y. Ng and Christina Hanna [6] identified that of the 13 guidelines they included, only two recommended acupuncture. This indicates that there is a paucity of clinical decision-making guidelines for the treatment of migraine with acupuncture.

In order to ascertain the actual international demand for acupuncture for migraine, an international survey was conducted [7]. The results of the survey demonstrated a clear global demand for international guidelines for acupuncture for migraine, taking into account the differences in demand across different countries. In accordance with the evidence-based methodology, the research team rigorously adhered to the process and requirements of formulating clinical questions, conducting an extensive literature search and screening, evidence synthesis, and multiple rounds of expert consensus and expert opinion solicitation, culminating in the draft guideline.

This guideline encompasses the purpose, scope, applicable population, and applicable settings, an overview of acupuncture for migraine, the guideline development process, and recommendations. The complete edition of *Clinical Practice Guideline on Acupuncture and Moxibustion: Migraine* was published as a book in 2024 by Standard Press of China. While, this article presents an overview of the 18 recommendations included in the guidelines by following the naming rule of *WHO international standard terminologies on traditional Chinese medicine*，which can assist the guideline users in comprehending the guidelines and implementing it.

2.Forming process of this guideline

The development of this guideline strictly follows the basic principles and procedures of the *WHO Handbook for Guideline Development*. The development process includes a series of technical links, such as establishing development team, conducting international surveys, registering guideline, formulating clinical questions, identifying and rating critical outcomes, evidence retrieval and quality assessment, integrating historical and contemporary evidence of acupuncture recommendation protocols, formulating recommendations through expert consensus, drafting draft guideline, consulting with experts, revising draft guideline based on experts' feedback ultimately forming the guideline. The main process of forming recommendations of the guideline are as follows.

2.1. Development of clinical questions

The drafting group conducted two rounds of international questionnaire surveys to gather input from potential users of this guideline. Using statistical analysis of completed surveys, the migraine populations, interventions, controls, and outcomes were found. The clinical questions for the guideline were preliminary selected, and the outcomes were prioritized. Using the consensus meeting method, consensuses were reached by voting within the expert committee in the guideline group, and 18 clinical questions and 13 critical outcomes (six for the attack stage, six for prophylactic treatments, and one for safety) were identified and ranked in order of importance [8].

2.2. Construction of evidence body

Firstly, the modern clinical research literature was searched, screened, and extracted. Then, the quality of modern clinical research literature was evaluated using the GRADE system, a systematic review and Bayesian network meta-analysis was conducted at the same time by our research group. Afterwards, the ancient and modern medical practitioner's empirical evidences were also retrieved, screened and extracted, and modern clinical experts interviewed. Moreover, we scored the coincidence degree of acupoints selections in ancient and modern literature, and assessed the clinical value of the acupuncture treatment protocols. Finally, the integration of ancient and modern evidences was integrated and completed for acupuncture clinical protocols.

2.3. Process of forming recommendations

The GRADE grid approach was applied for the recommendations. Following four rounds of expert consensus meetings, the expert committee formed recommendations for this guideline by voting on the basis of consensus, which thoroughly considered twelve dimensions. The consensus threshold is 50%.

Twenty of the 59 migraine acupuncture treatment protocols included in the randomized controlled trials (RCTs) were deemed to have "clinical value" by the core acupuncture clinical specialists who evaluated the protocols' clinical worth using a variety of sources of evidence. The research group considered the characteristics of acupuncture fully, sorted out the evidence from four aspects, including RCTs, ancient books and literature, the experience of modern famous doctors, and interviews with contemporary clinical experts of acupuncture. In the process of determining the guideline recommendation scheme, the two key steps of integrating the verified data of ancient and modern doctors (four-in-one) and expert consensus of clinical value evaluation can provide reliable evidences for the formation of guideline recommendation opinions [9].

3.Recommendations

3.1 Overview of the 18 recommendations

The 18 recommendations were summarized in Table 1.

Table 1 Recommendations of WFAS *Clinical Practice Guideline on Acupuncture and Moxibustion: migraine*

Clinical question No.	Recommendations	Strength	Range of quality of evidence of all the outcomes
1	For migraine patients in attack stage, we suggest filiform needle therapy, rather than conventional oral medications and conventional medications administered by subcutaneous injection.	Conditional recommendation	Low/very low
2	For migraine patients in attack stage, we suggest filiform needle therapy, rather than sham acupuncture.	Conditional recommendation	Very low
3	For migraine patients, we suggest filiform needle therapy, rather than conventional oral medications, as prophylactic treatment.	Conditional recommendation	Low/very low
4	For migraine patients, we suggest filiform needle /electroacupuncture, especially filiform needle therapy, rather than non-treatment/sham acupuncture, as prophylactic treatments.	Conditional recommendation	Moderate/ Low/very low
5	For migraine patients with comorbidity of depression/anxiety, we suggest acupuncture, rather than conventional oral medications, as prophylactic treatment.	Conditional recommendation	Low/very low
6	For migraine patients with comorbidity of depression/anxiety, we suggest the combination of acupuncture and conventional oral medications, rather than conventional oral medications alone, as prophylactic treatment.	Conditional recommendation	Expert empirical consensus
7	For migraine patients with comorbidity of depression/anxiety, we suggest acupuncture, rather than other non-drug treatments, as prophylactic treatment.	Conditional recommendation	Expert empirical consensus
8	For migraine patients with comorbidity of depression/anxiety, we suggest filiform needle therapy or electroacupuncture, especially filiform needle therapy, rather than sham acupuncture or non-treatment, as prophylactic treatment.	Conditional recommendation	Moderate/ Low/very low

Clinical question No.	Recommendations	Strength	Range of quality of evidence of all the outcomes
9	For migraine patients with analgesic dependence, we suggest acupuncture, rather than conventional oral medications, as prophylactic treatment.	Conditional recommendation	Very low
10	For migraine patients with analgesic dependence, we suggest filiform needle therapy, rather than non-treatment or sham acupuncture, as prophylactic treatment.	Conditional recommendation	Expert empirical consensus
11	For pregnant migraine patients in attack stage, we suggest filiform needle therapy, rather than other non-drug treatments.	Conditional recommendation	Expert empirical consensus
12	For pregnant migraine patients in attack stage, we suggest filiform needle therapy, rather than non-treatment or sham acupuncture.	Conditional recommendation	Expert empirical consensus
13	For lactating migraine patients in attack stage, we suggest filiform needle therapy, rather than conventional oral medications.	Conditional recommendation	Expert empirical consensus
14	For lactating migraine patients in attack stage, we suggest filiform needle therapy, rather than other non-drug treatments.	Conditional recommendation	Expert empirical consensus
15	For menstrual migraine patients and menstrual-related migraine patients in attack stage, we suggest blood-letting at collaterals/acupoints and filiform needle therapy (either applied alone or together), rather than conventional oral medications.	Conditional recommendation	Empirical evidence of ancient and modern physicians / Expert empirical consensus
16	For menstrual migraine patients and menstrual-related migraine patients, we suggest ear pressure therapy, rather than conventional oral medications, as prophylactic treatment.	Conditional recommendation	Very low
17	For menstrual migraine patients and menstrual-related migraine patients in attack stage, we suggest blood-letting at collaterals/acupoints and filiform needle therapy (either applied alone or together), rather than non-treatment and sham	Conditional recommendation	Empirical evidence of ancient and modern physicians/ Expert empirical consensus

Clinical question No.	Recommendations	Strength	Range of quality of evidence of all the outcomes
	acupuncture.		
18	For menstrual migraine patients and menstrual-related migraine patients, we suggest filiform needle therapy , rather than sham acupuncture, as prophylactic treatment.	Conditional recommendation	Moderate/ Low/very low

3.2. Overview of the 18 clinical questions

The above 18 recommendations were developed by the following 18 clinical questions, which were developed by following the P (patient) I (intervention) C (comparison) O (outcome) principle.

3.2.1. Clinical question 1: Compared with conventional oral medications and conventional medications administered by subcutaneous injection, can acupuncture provide more benefits to migraine patients in attack stage?

Recommendation No. 1: For migraine patients in attack stage, we suggest filiform needle acupuncture treatment, rather than oral medications and medications administered by subcutaneous injection. (Conditional recommendation; based on low and very low quality evidence.)

This recommendation is applicable to adult migraine patients in attack stage, who are unable or unwilling to take conventional medications. The oral medications and the medications administered by subcutaneous injection in this recommendation include five types of conventional medications for migraine patients in attack stage, i.e. non-steroidal anti-inflammatory drugs (NSAIDs), combination agents, triptans, ergotamines, and sedatives and hypnotics.

The benefits come from two aspects, effectiveness and safety.

3.2.2. Clinical question 2: Compared with sham acupuncture, can blood-letting therapy, filiform needle therapy, electroacupuncture/transcutaneous electrical nerve stimulation (TENS), scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to migraine patients in attack stage?

Recommendation No. 2: For migraine patients in attack stage, we suggest filiform needle acupuncture treatment, rather than sham acupuncture. (Conditional recommendation; based on very low quality evidence.)

This recommendation is applicable to adult migraine patients in attack stage, who are unable or unwilling to take conventional medications. The sham acupuncture methods in this recommendation include needling at the peripheral areas of irrelevant acupoints at conventional depth with arrival of *qi*, needling at peripheral areas of relevant acupoints without arrival of *qi*, and shallow needling at peripheral areas of relevant acupoints.

The benefits come from two aspects, effectiveness and safety.

3.2.3. Clinical question 3: Compared with conventional oral medications, can prophylactic acupuncture treatment provide more benefits to migraine patients?

Recommendation No. 3: For migraine patients, we suggest filiform needle acupuncture,

rather than oral medications, as prophylactic treatment. (Conditional recommendation; based on low and very low quality evidence.)

This recommendation applies to intermittent/remitting migraine patients (except pregnant women). The acupuncture treatments in this recommendation include filiform needle acupuncture, electroacupuncture, ear acupuncture/ear pressure therapy, scalp acupuncture, catgut-embedding therapy, blood-letting therapy, needle-embedding therapy alone or a combination of two methods. The oral medications in this recommendation include five types of conventional medications for migraine prophylactic treatment, i.e. calcium channel blockers (flunarizine hydrochloride), antiepileptics (valproic acid, topiramate), beta blockers (metoprolol), sedatives and tranquilizers (diazepam), and NSAIDs (acetaminophen, compound aminopyrine phenacetin, naproxen).

The benefits come from three aspects, namely effectiveness, safety, and economy.

3.2.4. Clinical question 4: Compared with non-treatment/sham acupuncture, can prophylactic treatments of blood-letting therapy, filiform needle therapy, electroacupuncture/TENS, scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to migraine patients?

Recommendation No. 4: For migraine patients, we suggest filiform needle acupuncture/electroacupuncture, especially filiform needle acupuncture, rather than non-treatment/sham acupuncture, as prophylactic treatments. (Conditional recommendation; based on moderate, low, and very low quality evidence.)

This recommendation applies to intermittent/remitting migraine patients (except pregnant women). The sham acupuncture methods in this recommendation include needling at the relevant acupoints at conventional depth without arrival of *qi*, needling at peripheral areas of relevant acupoints at conventional depth without arrival of *qi*, needling at non-acupoints at conventional depth without arrival of *qi*, shallow needling at non-acupoints, shallow needling at peripheral areas of relevant acupoints, non-acupoints without insertion. The recommendation is based on the evidences from adult migraine patients with and without aura in China, Germany, Iran, Australia, and France. This recommendation is applicable to all types of adult migraine patients (except pregnant patients).

The benefits come from three aspects, namely effectiveness, safety, and economy.

3.2.5. Clinical question 5: Compared with conventional oral medications, can prophylactic acupuncture treatment provide more benefits to migraine patients with comorbidity of depression/anxiety?

Recommendation No.5: For migraine patients with comorbidity of depression/anxiety, we suggest acupuncture, rather than oral medications, as prophylactic treatment. (Conditional recommendation; based on low and very low evidence.)

This recommendation is applicable to adult migraine patients with comorbidity of depression/anxiety as prophylactic treatment (including pregnant patients and lactating patients). The oral medications in this recommendation include two types of conventional medications for migraine prophylactic treatment, antiepileptic drugs (topiramate) and beta-blockers (metoprolol).

The benefits come from two aspects, effectiveness and safety.

3.2.6. Clinical question 6: Compared with taking conventional oral medications alone, can prophylactic treatment of acupuncture combining with oral medications provide more benefits to migraine patients with comorbidity of depression/anxiety?

Recommendation No.6: For migraine patients with comorbidity of depression/anxiety, we suggest the combination of acupuncture and oral medications, rather than oral medications alone, as prophylactic treatment. (Conditional recommendation; expert empirical consensus)

This recommendation is applicable to adult migraine patients with comorbidity of depression/anxiety (including pregnant patients and lactating patients). The oral medications in this recommendation include 5 types of conventional medications for migraine prophylactic treatment, i.e. calcium channel blockers (flunarizine hydrochloride), antiepileptics (valproic acid, topiramate), beta blockers (metoprolol), sedatives and tranquilizers (diazepam), and NSAIDs (acetaminophen, compound aminopyrine phenacetin, naproxen).

The benefits come from two aspects, effectiveness and economy.

3.2.7. Clinical question 7: Compared with other non-drug treatments, can prophylactic acupuncture treatment provide more benefits to migraine patients with comorbidity of depression/anxiety?

Recommendation No.7: For migraine patients with comorbidity of depression/anxiety, we suggest acupuncture, rather than other non-drug treatments, as prophylactic treatment. (Conditional recommendation; expert empirical consensus)

This recommendation is applicable to adult migraine patients with comorbidity of depression/anxiety (including pregnant patients and lactating patients). The non-drug treatments in this recommendation include two types, namely behavioral medicine (e.g. biofeedback training, neurofeedback, relaxation skills, cognitive reconstruction, psychotherapy and psychological counseling), and physical intervention techniques (e.g. regular exercise and physical therapy).

The benefits come from two aspects, effectiveness and economy.

3.2.8. Clinical question 8: Compared with sham acupuncture or non-treatment, can prophylactic treatments of filiform needle therapy, blood-letting therapy, electroacupuncture/TENS, scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to migraine patients with comorbidity of depression/anxiety?

Recommendation No.8: For migraine patients with comorbidity of depression/anxiety, we suggest filiform needle acupuncture or electroacupuncture, especially filiform needle acupuncture, rather than sham acupuncture or non-treatment, as prophylactic treatment. (Conditional recommendation; based on moderate, low and very low quality evidence.)

This recommendation is applicable to adult migraine patients with comorbidity of depression/anxiety as prophylactic treatment (including pregnant patients and lactating patients).

The benefits come from two aspects, effectiveness and safety.

3.2.9.Clinical question 9: Compared with conventional oral medications, can prophylactic acupuncture treatment provide more benefits to migraine patients with analgesic dependence?

Recommendation No.9: For migraine patients with analgesic dependence, we suggest acupuncture, rather than oral medications, as prophylactic treatment. (Conditional recommendation; based on very low quality evidence.)

The oral medication in this recommendation refers the conventional medication for migraine prophylactic treatment, such as antiepileptics (topiramate).

The benefits come from effectiveness.

3.2.10. Clinical question 10: Compared with non-treatment or sham acupuncture, can prophylactic treatments of filiform needle therapy, blood-letting therapy,

electroacupuncture/TENS, scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to migraine patients with analgesic dependence?

Recommendation No.10: For migraine patients with analgesic dependence, we suggest filiform needle acupuncture, rather than non-treatment or sham acupuncture, as prophylactic treatment. (Conditional recommendation; expert empirical consensus)

This recommendation is applicable to adult migraine patients with analgesic dependence as prophylactic treatment (including pregnant patients and lactating patients). The oral medication in this recommendation refers the conventional medication for migraine prophylactic treatment, antiepileptics (topiramate).

The benefits come from effectiveness.

3.2.11. Clinical question 11: Compared with other non-drug treatments, can acupuncture provide more benefits to pregnant migraine patients in attack stage?

Recommendation No.11: For pregnant migraine patients in attack stage, we suggest filiform needle acupuncture, rather than other non-drug treatments. (Conditional recommendation; expert empirical consensus)

The non-drug treatments in this recommendation are the same as clinical question 7.

The benefits come from two aspects, effectiveness and safety.

3.2.12. Clinical question 12: Compared with non-treatment or sham acupuncture, can blood-letting therapy, filiform needle therapy, electroacupuncture/TENS, scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to pregnant migraine patients in attack stage?

Recommendation No.12: For pregnant migraine patients in attack stage, we suggest filiform needle acupuncture, rather than non-treatment or sham acupuncture. (Conditional recommendation; expert empirical consensus)

The benefits come from two aspects, effectiveness and safety.

3.2.13. Clinical question 13: Compared with conventional oral medications, can acupuncture provide more benefits to lactating migraine patients in attack stage?

Recommendation No.13: For lactating migraine patients in attack stage, we suggest filiform needle acupuncture, rather than oral medications. (Conditional recommendation; expert empirical consensus)

The oral medications in this recommendation include 5 types of conventional medications for migraine in attack stage, i.e. NSAIDs, combination agents, triptans, ergotamines, sedatives and tranquilizers.

The benefits come from two aspects, effectiveness and safety.

3.2.14. Clinical question 14: Compared with other non-drug treatments, can acupuncture provide more benefits to lactating migraine patients in attack stage?

Recommendation No.14: For lactating migraine patients in attack stage, we suggest filiform needle acupuncture, rather than other non-drug treatments. (Conditional recommendation; expert empirical consensus)

The non-drug treatments in this recommendation are the same as *Clinical question* 7.

The benefits come from two aspects, effectiveness and safety.

3.2.15. Clinical question 15: Compared with conventional oral medications, can acupuncture provide more benefits to menstrual migraine patients and menstrual-related migraine patients in attack stage?

Recommendation No.15: For menstrual migraine patients and menstrual-related migraine patients in attack stage, we suggest blood-letting at collaterals/acupoints and filiform needle acupuncture (either applied alone or together), rather than oral medications. (Conditional recommendation; expert empirical consensus)

The oral medications in this recommendation include 5 types of conventional medications for migraine patients in attack stage, i.e. NSAIDs, combination agents, triptans, ergotamines, and sedatives and hypnotics.

The benefits come from two aspects, effectiveness and safety.

3.2.16. Clinical question 16: Compared with conventional oral medications, can prophylactic acupuncture treatment provide more benefits to menstrual migraine patients and menstrual-related migraine patients?

Recommendation No.16: For menstrual migraine patients and menstrual-related migraine patients, we suggest ear pressure therapy, rather than oral medications, as prophylactic treatment. (Conditional recommendation; based on very low quality evidence.)

The oral medication in this recommendation refers to calcium channel blocker flunarizine. This recommendation applies to menstrual migraine patients and menstruation-related migraine patients. This treatment protocol mainly applies to patients one week before menstruation. The application of this recommendation should be combined with filiform needle acupuncture during the attack stage.

The benefits come from three aspects, i.e. effectiveness, safety and economy.

3.2.17. Clinical question 17: Compared with non-treatment or sham acupuncture, can blood-letting therapy, filiform needle therapy, electroacupuncture/TENS, scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to menstrual migraine patients and menstrual-related migraine patients in attack stage?

Recommendation No.17: For menstrual migraine patients and menstrual-related migraine patients in attack stage, we suggest blood-letting at collaterals/acupoints and filiform needle acupuncture (either applied alone or together), rather than non-treatment and sham acupuncture. (Conditional recommendation; expert empirical consensus)

The benefits come from two aspects, effectiveness and safety.

3.2.18. Clinical question 18: Compared with sham acupuncture, can prophylactic treatments of filiform needle therapy, blood-letting therapy, electroacupuncture/TENS, scalp acupuncture, and ear acupuncture/electrical stimulation of auricular points provide more benefits to menstrual migraine patients and menstrual-related migraine patients?

Recommendation No.18: For menstrual migraine patients and menstrual-related migraine patients, we suggest filiform needle acupuncture, rather than sham acupuncture, as prophylactic treatment. (Conditional recommendation; based on moderate, low and very low quality evidence.)

The benefits come from effectiveness.

4 Recommendations to different stages of migraine

Migraine is a disease with typical characteristic by stages. When applying acupuncture treatment, we should also follow the characteristic of migraine itself and deliver the intervention by stages. Therefore, the guideline first clearly distinguishes between attack stage treatment and prophylactic treatment and provides the recommendations, respectively. It should be noted that

the superiority of acupuncture treatment of migraine is prophylactic treatment considering the effectiveness and safety. Therefore, the recommendations of the guideline focus on prophylactic treatment.

In the evidence pyramid of evidence-based medicine, RCTs consistently provide the highest level of evidence among original study [10], and are often considered the gold standard for evaluating the effectiveness and safety of clinical interventions [11]. Of the 18 clinical questions identified, only 9 clinical questions had RCT evidences, and the other 9 clinical questions were not supported by the evidences from modern literature.

Note: The specific recommended treatment protocols are omitted here, please see the guideline if necessary.

4.1. Recommendations to acupuncture prophylactic treatment of migraine

4.1.1. Recommendations with RCT evidence

(1) Recommendation of c*linical question* 3

For migraine patients, we suggest filiform needle acupuncture, rather than oral medications, as prophylactic treatment.

A total of thirty RCTs involving eight outcomes are included in this clinical question. Among them, the quality of evidence of physiological domain of functional health and health-related quality of life (critical outcome) is low; the quality of evidence of headache intensity (critical outcome), headache days (critical outcome), headache frequency (critical outcome), effective rate (critical outcome), the mental domain of functional health and health-related quality of life (critical outcome), incidence of adverse reactions (critical outcome), effects on medication during attack stage (important outcome), and symptom improvement score (important outcome) are very low. Compared with oral medications, the critical outcomes of prophylactic acupuncture treatment show trivial to very large desirable effects and trivial undesirable effects. This may indicate that prophylactic acupuncture treatment has good benefit-cost ratio and acceptability.

This recommendation is based on evidence from adult migraine patients with and without aura in China, Italy, Czech, Germany, Iran, Turkey, and Russia. Therefore, it is applicable to all types of adult migraine patients (except pregnant women). Subgroups are set at critical time points of outcome evaluation (immediately after treatment, four weeks after treatment, twelve weeks after treatment, and twenty-four weeks after treatment).

(2) Recommendation of c*linical question* 4

For migraine patients, we suggest filiform needle acupuncture/electroacupuncture, especially filiform needle acupuncture, rather than non-treatment/sham acupuncture, as prophylactic treatments.

A total of thirty-five RCTs involving nine outcomes are included in this clinical question. Among them, the quality of evidence of incidence of adverse reactions (critical outcome) is moderate, the quality of evidence of headache attack times (critical outcome), headache-related quality of life (critical outcome) are moderate to very low, the quality of evidence of headache days (critical outcome) is low, the quality of evidence of headache intensity (critical outcome) is low to very low, the quality of evidence of headache frequency (critical outcome), functional health and health-related quality of life (critical outcome), symptom improvement score (important outcome), effects on medication during attack stage (important outcome) are very low. Compared with sham acupuncture or non-treatment, the critical outcomes of filiform needle acupuncture/electroacupuncture show trivial to large desirable effects; compared with sham

acupuncture, filiform needle acupuncture shows trivial undesirable effects, but electroacupuncture shows larger undesirable effects; prophylactic treatments of filiform needle acupuncture/electroacupuncture may have better benefit-cost ratio. In addition, prophylactic acupuncture treatment can be easily accepted by migraine patients and doctors, thus have good acceptability.

The subgroups are set with the interventions in the control group (sham acupuncture, blank). The subgroups are set at critical time points of outcome evaluation (immediately after treatment, four weeks after treatment, and twelve weeks after treatment).

(3) Recommendation of c*linical question* 5

For migraine patients with comorbidity of depression/anxiety, we suggest acupuncture, rather than oral medications, as prophylactic treatment.

A total of two RCTs involving seven outcomes are included in this clinical question. Among them, the quality of evidence of the incidence of adverse reactions (critical outcome) is low, the quality of evidence of headache days (critical outcome), headache frequency (critical outcome), headache intensity (critical outcome), depression/anxiety level (critical outcome), quality of life (critical outcome), effects on medication during attack stage (important outcome) are very low.

Compared with oral conventional medications, the critical outcomes of prophylactic acupuncture treatment of migraine patients with comorbidity of depression/anxiety show very large desirable effects (in terms of depression/anxiety level), large desirable effects (in terms of quality of life), small desirable effects (in terms of headache intensity), or equivalent effects (in terms of headache days and headache frequency), and trivial undesirable effects (in terms of incidence of adverse reactions), respectively. In addition, prophylactic acupuncture treatment can be easily accepted by migraine patients and doctors, thus has good acceptability.

This recommendation is based on the evidences from adult migraine patients with comorbidity of depression/anxiety in China and Germany. Subgroups are set at critical time points of outcome evaluation (immediately after treatment and twelve weeks after treatment).

(4) Recommendation of c*linical question* 8

For migraine patients with comorbidity of depression/anxiety, we suggest filiform needle acupuncture or electroacupuncture, especially filiform needle acupuncture, rather than sham acupuncture or non-treatment, as prophylactic treatment.

A total of four RCTs involving eight outcomes are included in this clinical question. Among them, the quality of evidence of headache intensity (critical outcome) is moderate, the quality of evidence of incidence of adverse reactions (critical outcome) is low, the quality of evidence of headache days (critical outcome), headache frequency (critical outcome), effectiveness (critical outcome), headache-related quality of life (critical outcome), functional health and health-related quality of life (critical outcome), and depression/anxiety level (critical outcome) are very low.

Compared with sham acupuncture or non-treatment, the critical outcomes of filiform needle acupuncture/electroacupuncture show moderate to very large desirable effects and trivial undesirable effects. Filiform needle acupuncture/electroacupuncture may have better benefit-cost ratio, may increase health equity, and might be easily accepted by migraine patients and doctors.

This recommendation is based on the evidences from adult migraine patients with comorbidity of depression/anxiety in China and Germany. Subgroups are set with the

interventions in the control group (sham acupuncture, blank), and at critical time points of outcome evaluation (after treatment, four weeks after treatment, and twelve weeks after treatment).

(5) Recommendation of c*linical question* 9

For migraine patients with analgesic dependence, we suggest acupuncture, rather than oral medications, as prophylactic treatment.

One RCT involving three critical outcomes (headache days, effects on medication during attack stage, and functional health and health-related quality of life) is included in this clinical question. The quality of evidence of all three outcomes are very low. Compared with oral medications, filiform needle acupuncture shows large to very large desirable effects on critical outcome of quality of life and small desirable effects on critical outcome of effects on medication during attack stage, and might be easily accepted by migraine patients and doctors. However, there is no direct evidence of safety and benefit-cost ratio so far.

(6) Recommendation of c*linical question* 16

For menstrual migraine patients and menstrual-related migraine patients, we suggest ear pressure therapy, rather than oral medications, as prophylactic treatment.

One RCT involving one critical outcome (effective rate) is included in this clinical question. The quality of evidence is very low. Compared with oral medications, the critical outcomes of prophylactic acupuncture treatment of menstrual migraine patients and menstrual-related migraine patients show equivalent effects; no significant advantages in terms of effectiveness is found. Although there is no direct evidence in terms of safety and health economics, ear pressure therapy has trivial undesirable effects, and it is easy to apply with extremely low cost, thus has big health economics advantages. In addition, it can be easily accepted by migraine patients and doctors, has good acceptability.

(7) Recommendation of c*linical question* 18

For menstrual migraine patients and menstrual-related migraine patients, we suggest filiform needle acupuncture, rather than sham acupuncture, as prophylactic treatment.

A total of six RCTs involving seven outcomes are included in this clinical question. Among them, the quality of evidence of headache days (critical outcome) is moderate, the quality of evidence of incidence of adverse reactions (critical outcome) is low, the quality of evidence of headache intensity (critical outcome), headache attack times (critical outcome), effective rate (critical outcome), headache-related quality of life (critical outcome), effects on medication during attack stage (important outcome) are very low.

Compared with sham acupuncture, the critical outcome (headache-related quality of life) of prophylactic filiform needle acupuncture for menstrual migraine patients and menstrual-related migraine patients shows large desirable effects and trivial undesirable effects. It may have better benefit-cost ratio and might be easily accepted by migraine patients and doctors.

This recommendation is based on the evidences from menstrual migraine patients and menstrual-related migraine patients in China, Germany, and Canada. The subgroups are set at the critical time points of outcome evaluation (immediately after treatment and four weeks after treatment).

4.1.2. Recommendations without RCT evidence

(1) Recommendation of c*linical question* 6

For migraine patients with comorbidity of depression/anxiety, we suggest the combination

of acupuncture and oral medications, rather than oral medications alone, as prophylactic treatment.

This recommendation is based on the evidences from expert interviews (answers to the specific questions targeted for this clinical question by 5 clinical experts in acupuncture field) and personal experience of core experts in guideline development group (GDG), and has been voted to reach a consensus by the GDG.

(2) Recommendation of c*linical question* 7

For migraine patients with comorbidity of depression/anxiety, we suggest acupuncture, rather than other non-drug treatments, as prophylactic treatment.

This recommendation is based on personal experience of GDG experts, and has been voted to reach a consensus by the GDG.

(3) Recommendation of c*linical question* 10

For migraine patients with analgesic dependence, we suggest filiform needle acupuncture, rather than non-treatment or sham acupuncture, as prophylactic treatment.

This recommendation is based on the personal experience of GDG experts, and has been voted to reach a consensus by the GDG.

4.2. Recommendations to acupuncture treatment of migraine in attack stage

4.2.1. Recommendations with RCT evidence

(1) Recommendation of c*linical question* 1

For migraine patients in attack stage, we suggest filiform needle acupuncture treatment, rather than oral medications and medications administered by subcutaneous injection.

A total of four RCTs involving three outcomes are included in this clinical question. Among them, the quality of evidence for the incidence of adverse reactions (critical outcome) is low, and that for headache intensity (critical outcome) and headache relief time (critical outcome) is very low. Compared with oral medications and medications administered by subcutaneous injection, the critical outcomes of acupuncture treatment show small desirable effects and trivial undesirable effects.

This recommendation is based on the evidences from adult migraine patients in attack stage in China and Germany. Subgroups are set at critical time points of outcome evaluation (0.5 h, 1 h, 2 h, 4 h, and 24 h after treatment).

(2) Recommendation of c*linical question* 2

For migraine patients in attack stage, we suggest filiform needle acupuncture treatment, rather than sham acupuncture.

A total of nine RCTs involving three critical outcomes (headache intensity, headache relief time, incidence of adverse reactions) are included in this clinical question. The quality of evidence for all outcomes are very low. Compared with sham acupuncture, two critical outcomes (headache intensity and headache relief time) of filiform needle acupuncture show trivial to small desirable effects or equivalent effects to that of sham acupuncture; the undesirable effects (incidence of adverse reactions) of filiform needle acupuncture is trivial.

This recommendation is based on the evidences from adult migraine patients in attack stage in China. Subgroups are set at critical time points of outcome evaluation (0.5 h, 1 h, 2 h, 4 h, and 24 h after treatment).

4.2.2 Recommendations without RCT evidence

(1) Recommendation of c*linical question* 11

For pregnant migraine patients in attack stage, we suggest filiform needle acupuncture, rather than other non-drug treatments.

This recommendation is based on the personal experience of GDG experts, and has been voted to reach a consensus by the GDG.

(2) Recommendation of c*linical question* 12

For pregnant migraine patients in attack stage, we suggest filiform needle acupuncture, rather than non-treatment or sham acupuncture.

This recommendation is based on the personal experience of GDG experts, and has been voted to reach a consensus by the GDG.

(3) Recommendation of c*linical question* 13

For lactating migraine patients in attack stage, it is suggested that filiform needle acupuncture, rather than oral medications.

This recommendation is based on the personal experience of GDG members, and has been voted to reach a consensus by the GDG.

(4) Recommendation of c*linical question* 14

For lactating migraine patients in attack stage, we suggest filiform needle acupuncture, rather than other non-drug treatments.

This recommendation is based on the personal experience of GDG core acupuncture experts, and has been voted to reach a consensus by the GDG.

(5) Recommendation of c*linical question* 15

For menstrual migraine patients and menstrual-related migraine patients in attack stage, we suggest blood-letting at collaterals/acupoints and filiform needle acupuncture (either applied alone or together), rather than oral medications.

This recommendation is based on the empirical evidence of ancient and modern physicians and personal experience of core acupuncture experts in GDG, and has been voted to reach a consensus by the GDG.

(6) Recommendation of c*linical question* 17

For menstrual migraine patients and menstrual-related migraine patients in attack stage, we suggest blood-letting at collaterals/acupoints and filiform needle acupuncture (either applied alone or together), rather than non-treatment and sham acupuncture.

This recommendation is based on the empirical evidence of ancient and modern physicians and the personal experience of GDG, and has been voted to reach a consensus by the GDG.

5. Summary

Half of the recommendations on clinical questions in this guideline were supported by RCTs evidence (medium/low/very low quality evidence), and the other half did not have modern literature research evidence and were based on the ancient and modern medical practitioners' empirical evidence or the empirical consensus of GDG. Therefore, all guideline recommendations are conditional. The publication of this guideline can provide practical guidance for clinical, teaching, and research personnel involved in migraine, and is able to better lead to clinical decision-making in migraine.

6.Discussion

During the development of this guideline, some quality-related issues have been found in

clinical studies of acupuncture for migraine. It is advised to carry out an evidence-based research approach and exploratory studies before conducting a new RCT of acupuncture, with the aim to improve the quality of acupuncture RCTs [12]. Besides, since this guideline is a clinical guideline for acupuncture, real-world research on acupuncture is still insufficient [13]. In order to improve the clinical applicability of this guideline, it is encouraged that health and safety economic indicators may be prioritized through investigation. In the future, more researches will be conducted to enhance the quality of the evidence derived from real-world studies on acupuncture for migraine [13].

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Declaration of competing Interest
The authors declare that there are no competing interests that could have influenced the work of this paper.

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