

Construction of Clinical Questions for the Clinical Practice Guideline for Acupuncture: Nonspecific Low Back Pain: A Modified Delphi Method-Based Post-print

Authors: Liu Lanping, Yang Yue, pornographic comics, Ma Xiaojing, Ye Yongming, Liu Xiaoxu, Lin Huize, Zhu Kexin, Guo Shengnan, Fei Yutong, Yang Tao, Yu Jinna, Yang Tao, Yu Jinna

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Abstract

Objective: To determine the clinical questions for the World Federation of Acupuncture-Moxibustion Societies' "Clinical Practice Guideline for Acupuncture-Moxibustion: Nonspecific Low Back Pain." **Methods:** A modified Delphi method was employed to conduct survey consultations with the target population; quality control was performed by calculating the positive coefficient, coordination coefficient, and authority coefficient to determine the clinical questions to be included in the guideline. **Results:** A total of 10 clinical questions were ultimately included. **Conclusion:** The modified Delphi method was used to determine the clinical questions to be included in this guideline, which provides important guidance for the subsequent development of the guideline. The reflections and limitations regarding clinical question formulation in this guideline offer certain reference value for the development of acupuncture-moxibustion guidelines.

Full Text

Clinical Question Construction for "Clinical Practice Guideline of Acupuncture for Nonspecific Low Back Pain": Based on the Modified Delphi Method

Liu Lanping¹, Yang Yue¹, Huang Man¹, Ma Xiaojing¹, Ye Yongming¹, Liu Xiaoxu¹, Lin Huize¹, Zhu Kexin¹, Guo Shengnan², Fei Yutong³, Yang Tao¹, Yu Jinna¹

¹Department of Acupuncture-Moxibustion, Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing 100053, China

²Center for Evidence-Based Medicine, Beijing University of Chinese Medicine, Beijing 100029, China

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Corresponding Authors:

Yang Tao, Chief Physician; E-mail: 13681407218@163.com

Yu Jinna, Deputy Chief Physician; E-mail: 546872837@qq.com

Abstract

Objective: To determine the clinical questions for the World Federation of Acupuncture-Moxibustion Societies (WFAS) Clinical Practice Guideline of Acupuncture for Nonspecific Low Back Pain. **Methods:** We used a modified Delphi method to survey target stakeholders, calculating response rate, coordination coefficient, and authority coefficient for quality control to determine the clinical questions included in the guideline. **Results:** Ten clinical questions were ultimately included. **Conclusion:** The modified Delphi method successfully identified the clinical questions for this guideline, providing crucial guidance for subsequent development work. The reflections on and limitations of this clinical question construction process offer valuable insights for future acupuncture guideline development.

Keywords: Nonspecific low back pain; Acupuncture; Clinical practice guideline; Modified Delphi method

Introduction

Our working group is responsible for developing the Clinical Practice Guideline of Acupuncture for Nonspecific Low Back Pain (hereinafter referred to as “this guideline”) under the 2019 National Key R&D Program “Development of International Clinical Practice Guidelines for Acupuncture.” The guideline received approval from the World Federation of Acupuncture-Moxibustion Societies (WFAS) on September 30, 2020. The development team has now completed construction of clinical questions for acupuncture treatment of nonspecific low back pain using the modified Delphi method. This article details the specific operational procedures for clinical question construction in this guideline and summarizes our experiences and reflections to provide reference for subsequent acupuncture clinical practice guideline development.

Methods

1.1 Formation of Guideline Working Groups We established a guideline drafting group and a Guideline Development Group (GDG). The drafting group was responsible for collecting and summarizing clinical question survey results, drafting the clinical question list, and compiling and publishing Delphi survey results. The GDG was responsible for analyzing each clinical question, rating its importance, and voting on inclusion decisions [1].

1.2 Initial Question Formulation **1.2.1 First-round questionnaire survey:** We distributed questionnaires to target stakeholders, collecting basic demographic information and detailed opinions on four key aspects: “patient population characteristics, interventions, comparators, and outcomes,” along with several open-ended questions [2].

1.2.2 Expert interviews and preliminary question formulation: After compiling first-round questionnaire results, we conducted semi-structured interviews with six relevant experts. Based on questionnaire findings and expert interview feedback, we drafted an initial list of clinical questions following the PICO (Participants, Interventions, Comparisons, Outcomes) framework.

1.3 Modified Delphi Process **1.3.1 First Delphi round:** Using an online survey platform, GDG members rated the necessity of including each drafted clinical question in the guideline. A 5-point scale was used based on “whether a recommendation is necessary in the guideline” (must include = 5, should include = 4, consider including = 3, may not include = 2, do not include = 1). “Must include” and “should include” were counted as “agree to include.” Respondents who selected “must include” or “do not include” were required to provide justification. Additionally, GDG members rated the authority coefficient for each clinical question.

1.3.2 Second Delphi round: We organized a GDG consensus meeting. Based on first-round results, members engaged in thorough discussion of questions with low consensus, followed by anonymous “yes/no” voting. If necessary, experts could propose additional clinical questions for inclusion.

1.3.3 Third Delphi round: After clinical questions were established in the second round, new questions emerging during subsequent work were circulated to the expert panel again for feedback, with results compiled and published by the drafting group.

1.4 Consensus Meeting Rules **Modified Delphi criteria:** If a clinical question received agreement from $\geq 75\%$ of voting experts with a coefficient of variation $< 25\%$, it was included without further rounds. If agreement was $< 75\%$ with coefficient of variation $< 25\%$, the question was excluded. If coefficient of variation $\geq 25\%$, the question proceeded to subsequent Delphi rounds.

Response rate: In Delphi surveys, this refers to the completion rate among GDG members. A response rate $\geq 75\%$ was considered high engagement [3].

Coordination coefficient: We used coefficient of variation to represent GDG member coordination. A coefficient of variation $< 25\%$ indicated good consensus among members [4].

Authority coefficient: Comprising both judgment coefficient and familiarity coefficient, GDG members rated each clinical question's authority coefficient. A coefficient ≥ 0.7 was considered high authority [3].

Results

GDG member characteristics are shown in Table 1.

Table 1 Members of GDG in the Clinical Practice Guideline of Acupuncture: Nonspecific Low Back Pain

Name	Country/Region	Institution	Expertise
Lin Wu	Canada/Toronto	Centre for Health and Sports Medicine	Acupuncturist
Wang Xi-aoming	Japan/Tokyo	Teikyo Heisei University	Acupuncturist
Dong Hong-guang	Switzerland/Geneva	University of Geneva	Acupuncturist
Zhao Shihui	New Zealand/Auckland	Yan's Chinese Medicine	Acupuncturist
Nam Dong-woo	South Korea/Seoul	Department of Acupuncture & Moxibustion, College of Korean Medicine, Kyung Hee University	Acupuncturist

Name	Country/Region	Institution	Expertise
[Additional Chinese experts from Guang'anmen Hospital, General Hospital of PLA, Beijing University of Chinese Medicine, etc.]	China/Beijing	Various institutions	Acupuncture specialists, Orthopedics specialists, Pain medicine specialists, Methodology experts, Patient representatives

2.1 First-Round Questionnaire Survey **2.1.1 Basic information:** We collected 51 questionnaires. Geographically, 42 were from China (27 from Beijing, others from various provinces), 3 from South Korea, 2 from Japan, 2 from New Zealand, 1 from the United States, and 1 from Canada. By professional title: 1 practicing physician, 7 resident physicians, 13 attending physicians, 12 deputy chief physicians, 5 chief physicians, 1 nurse manager, 10 with unspecified titles, 1 patient, and 1 from medical insurance bureau. By specialty: 39 from Chinese medicine (acupuncture/moxibustion, internal medicine), 10 from Western medicine (orthopedics, pain medicine), 1 nursing, and 1 medical insurance professional.

2.1.2 Results analysis: Due to substantial variation in PICO content across open-ended responses and low similarity among clinical questions, direct voting was not feasible. Instead, we analyzed four aspects:

(1) Patient population characteristics: Analysis revealed high attention to pain severity, etiology, pain location, and age (supported by 23, 20, 13, and 13 votes respectively). Moderate attention was given to occupation, gender, special populations (elderly, military personnel, pregnant women, menstruating women), and disease duration (9, 6, 4, and 3 votes respectively).

(2) Interventions: Desired acupuncture treatments, ranked by vote count, were: manual acupuncture, electroacupuncture, moxibustion, and cupping (Figure 1 [Figure 1: see original paper]).

(3) Comparators: For acute nonspecific low back pain (ANSLBP), the top three comparator therapies were: NSAIDs, bed rest, and physical therapy. For chronic nonspecific low back pain (CNSLBP), the top three were: NSAIDs,

physical therapy, and exercise (Figure 2 [Figure 2: see original paper]).

(4) Outcomes: Ranked by attention: pain (32 votes), safety (30 votes), health economics (19 votes), functional recovery (17 votes), and quality of life changes (16 votes).

2.2 Expert Interviews **2.2.1 Interview subjects:** Six experts were interviewed (4 male, 2 female), including 3 renowned acupuncture experts, 1 chief of acupuncture department, 1 chief of spinal surgery, and 1 attending orthopedic surgeon.

2.2.2 Interview format: Semi-structured interviews covering project background and soliciting opinions on workflow and clinical question selection.

2.2.3 Interview results: After analyzing the six expert interviews and discussion with methodology experts, we adopted eight recommendations: (1) Clearly define “nonspecific low back pain” and its staging, excluding studies on lumbar disc herniation. (2) Given the variety of acupuncture therapies and international dissemination goals, include only traditional acupuncture methods (“acupuncture [manual/electro], moxibustion, cupping alone or in combination, with acupuncture required”). (3) Clarify guideline users, target population, treatment objectives, therapy selection under different conditions, and acupuncture’s role in treatment. (4) Merge related therapies (e.g., “spinal manipulation,” “physical therapy” as “non-pharmacological therapies”; “acupuncture plus moxibustion,” “acupuncture plus cupping” as “combined acupuncture therapies”) to reduce question numbers. (5) Add: “Is acupuncture needed during low back pain remission?” (6) Retain pregnant women as a special population. (7) Include health economics evaluation. (8) Ensure broad applicability and clinical practicality.

Based on first-round surveys and expert interviews, the drafting group initially formulated 15 clinical questions (Table 2).

2.3 Delphi Rounds **2.3.1 First Delphi round:** GDG members reached consensus on questions 1, 2, 3, 4, 5, 6, 8, 9, 14, and 15.

2.3.2 Second Delphi round: During the consensus meeting, after thorough discussion, Question 9 on “low back pain remission period” was removed as no clear definition was found in literature. Given the significance of acupuncture for pregnant women, questions 10 and 11 were re-voted and reinstated. After this meeting, 11 clinical questions were confirmed (Table 2).

2.3.3 Third Delphi round: During subsequent literature review, we found pregnant nonspecific low back pain is reported by gestational weeks rather than acute/subacute/chronic staging. The drafting group proposed merging questions 10 and 11 into: “For pregnant women with nonspecific low back pain, what is the efficacy and safety of acupuncture treatment?” All GDG members agreed.

The final guideline includes 10 clinical questions (Table 2).

2.4 Quality Control Results **Response rate:** First Delphi round: 11/12 questionnaires returned (91.7% response rate). Second round: 12/12 returned (100% response rate).

Authority coefficient: All 15 clinical questions received authority coefficient ratings >0.70 from GDG members.

Table 2 Results of Clinical Question Investigation by Modified Delphi Method

Clinical Question	Round 1	Round 2	Round 3	Final
For patients with acute/subacute nonspecific low back pain, is filiform needle therapy more effective than Western medicine? (Filiform needle includes manual/electroacupuncture; Western medicine includes NSAIDs, muscle relaxants)	√	√	√	√
For patients with acute/subacute nonspecific low back pain, is filiform needle therapy more effective than other non-pharmacological therapies? (Other non-pharmacological includes physical therapy, bed rest, tuina)	√	√	√	√

Clinical Question	Round 1	Round 2	Round 3	Final
For patients with acute/subacute nonspecific low back pain, is combined acupuncture therapy more effective than oral Western medicine? (Combined therapy includes filiform needle + moxibustion, filiform needle + cupping, filiform needle + moxibustion + cupping; Western medicine includes NSAIDs, muscle relaxants)	√	√	√	√
For patients with acute/subacute nonspecific low back pain, is combined acupuncture therapy more effective than other non-pharmacological therapies? (Combined therapy includes filiform needle + moxibustion, filiform needle + cupping, filiform needle + moxibustion + cupping; Other non-pharmacological includes tuina)	√	√	√	√
For patients with acute/subacute nonspecific low back pain, is combined acupuncture therapy more effective than filiform needle therapy alone?	√	√	√	√

Clinical Question	Round 1	Round 2	Round 3	Final
For patients with chronic nonspecific low back pain, is filiform needle therapy more effective than other non-pharmacological therapies? (Other non-pharmacological includes tuina, core stability training, physical therapy plus exercise)	√	√	√	√
For patients with chronic nonspecific low back pain, is combined acupuncture therapy more effective than other non-pharmacological therapies?	×	×	×	×
For patients with chronic nonspecific low back pain, is combined acupuncture therapy more effective than filiform needle therapy alone?	√	√	√	√
For patients with chronic nonspecific low back pain in remission, is long-term outcome the same with or without acupuncture treatment?	×	×	×	×
For patients with acute/subacute nonspecific low back pain, is motion acupuncture superior to conventional acupuncture?	×	×	×	×

Clinical Question	Round 1	Round 2	Round 3	Final
For patients with acute/subacute nonspecific low back pain, what treatment frequency should be recommended if acupuncture is selected (1×/week, 2×/week, 3×/week or more)?	✓	✓	✓	✓
For patients with chronic nonspecific low back pain, what treatment frequency should be recommended if acupuncture is selected (1×/week, 2×/week, 3×/week or more)?	✓	✓	✓	✓
For pregnant women with nonspecific low back pain, what is the efficacy and safety of acupuncture treatment?	(merged)	(merged)	✓	✓

Note: ✓ = included as clinical question; × = not included

Discussion

Clinical practice guidelines are essential tools for guiding clinical practice, promoting standardized diagnosis and treatment, reducing healthcare costs, and improving service quality. In 2011, the Institute of Medicine (IOM) updated the definition of clinical practice guidelines as “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options” [1]. Determining clinical questions is the most critical step in guideline development, serving as the hub that directly determines the scope of systematic reviews, guideline coverage, and number of recommendations. Clinical questions should be generated around clinical decision-making needs after identifying the target population.

International guideline development organizations such as WHO, NICE, and SIGN describe their clinical question generation processes in their manuals. Currently, China lacks a dedicated guideline development institution, and methods

for determining clinical questions vary across research groups. Some guidelines survey clinicians to obtain original questions—for example, during COVID-19 guideline development, clinical data from physicians treating the disease were collected as empirical evidence [5]. Others rely on expert-proposed questions refined through literature review and consultation, as when Song Haikuo et al. [6] used expert consensus to develop preventive medicine guidelines, emphasizing expert experience when modern literature was insufficient. Still others conduct preliminary literature reviews to identify high-quality evidence, then refine questions through expert consultation, as Hua Rongrong et al. [11] did for stroke dysphagia guidelines.

Domestic guideline development incorporates consensus processes and outcomes, which are key factors affecting guideline quality [12]. Clinical question construction relies on expert interviews, questionnaires, and consensus formation, including Delphi method, nominal group technique, consensus conference method, and modified Delphi method [1][13][16]. The modified Delphi method, also called the RAND/UCLA Appropriateness Method, combines Delphi and nominal group techniques and is the most commonly used formal consensus method in guideline development [17]. It leverages both methods' strengths while overcoming Delphi's limitation of lacking face-to-face discussion on controversial issues and nominal group's tendency for overly dispersed opinions [18]. Its application is gaining recognition. Wang Yaoxian et al. [19] used it to determine clinical questions for the "Yinhua Miyanning Tablet for Simple Lower Urinary Tract Infections" expert consensus. Nordic dermatologists and ophthalmologists used it to reach consensus on managing ocular manifestations of atopic dermatitis [20]. Sabrina H et al. used it to establish research priorities for renal cell carcinoma [21].

Our guideline group used the modified Delphi method to construct clinical questions, with the following experiences and reflections for future research verification.

3.1.1 GDG Member Composition Guideline development is a multidisciplinary participatory decision-making process. Inviting representative stakeholders, declaring and managing conflicts of interest, and employing standardized, transparent processes are essential for high-quality evidence-based guidelines [22]. Following WFAS guideline development procedures and considering disease and acupuncture discipline characteristics, we ensured multidisciplinary representation and end-user needs. Our GDG members came from worldwide locations including Canada, Netherlands, Switzerland, Japan, South Korea, and China, providing disciplinary and geographic representation. All members signed WFAS standard conflict of interest declarations before guideline development, confirming no conflicts related to this guideline [23].

3.1.2 Application of Modified Delphi Method Our clinical question construction process involved: (1) Distributing questionnaires, collecting data, con-

ducting expert interviews, determining question scope, and drafting 15 clinical questions; (2) Presenting the workflow and PICO elements to GDG members; (3) Conducting three Delphi rounds, calculating agreement rates, coefficients of variation, expert opinions, rationale, and authority coefficients. Ten clinical questions were ultimately included.

3.1.3 Combining Open Clinician Surveys with Expert Interviews Before clinical question construction, we conducted open surveys of acupuncture practitioners and related professionals across different professional titles, ages, and countries/regions, providing multi-angle, comprehensive investigation. Respondents spanned 3 continents and 6 countries, all professional titles, varying work experience, and educational levels from bachelor's to doctoral degrees across multiple departments. Combined with semi-structured expert interviews, the resulting clinical questions are highly representative.

3.2.1 Limitations Due to limited experience in questionnaire design, the overly open format yielded diverse, superficial, and incomplete responses, making question list compilation difficult.

3.2.2 Pandemic Challenges The guideline development period coincided with COVID-19, requiring online consensus meetings. Time zone differences and network issues among GDG members sometimes led to insufficient discussion and delayed voting.

Conclusion

Through the modified Delphi method, this study completed clinical question construction, providing important guidance for subsequent guideline development. By detailing this process, its strengths and weaknesses, we hope to inform future acupuncture guideline development.

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