Acupuncture Standards in China

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Content

1. To review international acupuncture standards
2. Acupuncture standardization in China
3. Discussion
4. Suggestion
Acupuncture standardization

- To promote application
- To promote legislation
- To promote academic excellence
- To promote information exchanges
- To ensure the safety and effectiveness of clinical practice
I. The international acupuncture standards
International acupuncture standards

- 1989 Standard Acupuncture Nomenclature
- 1995 Guidelines for Clinical Research in Acupuncture
- 1998 Guidelines on Basic Training and Safety in Acupuncture
- 2008 WHO standard Acupuncture Points Locations in the Western Pacific Region
Ⅱ The acupuncture standardization in China
Review ancient acupuncture standards

- Miraculous Pivot (BC 430~)
- there is description of nine needles.
- Actually it can be called standardization of needles.
Yellow Emperor Mingtang Classic, (BC138年～AC106年)

- acupuncture points were compiled as a system, the location and indications of acupuncture points were identified. This is the first standardization of acupuncture points.
“Illustration of acupuncture points of bronze model” in Song Dynasty.

- A more typical example is the government-sponsored project of acupuncture point standard.
The national standards of *Acupuncture* in China on 1970s

- Acupuncture needles
- Nomenclature and location of acupuncture points
- Nomenclature and location of auricular points
Acupuncture Needles of standardization in China

- The location standard in 1974.
- First version of the national standard in 1980.
- It has been revised in 1983, 1987, and 1994.
The national standard of *Nomenclature and Location of Acupuncture Points*

- First version in 1990.
- It has been revised in 2002 and in 2006 two times.
- It laid a foundation of international standard of Acupuncture Points Locations (China drafted).
The national standard of Nomenclature and Location of Auricular Points

- It has been revised in 2006 and in 2008.
The manipulation standards of acupuncture
The Standardized manipulations of acupuncture and moxibustion

1. Part 1: Moxibustion (GB/T 21709.1-2008)
2. Part 2: Scalp acupuncture (GB/T 21709.2-2008)
3. Part 3: Ear acupuncture (GB/T 21709.3-2008)
4. Part 4: Three-edged needle (GB/T 21709.4-2008)
5. Part 5: Cupping therapy (GB/T 21709.5-2008)
6. Part 6: Point injection (GB/T 21709.6-2008)
7. Part 7: Skin needle (GB/T 21709.7-2008)
8. Part 8: Intradermal needle (GB/T 21709.8-2008)
11. Part 11: Electroacupuncture (GB/T 21709.11-2009)
15. Part 15: Eye needle (GB/T 21709.15-2009)
16. Part 16 (GB/T 21709.16-2009) Abdomen needle
17. Part 17: Nose needle (GB/T 21709.17-2009)
18. Part 18: Mouth and lip needle (GB/T 21709.18-2009)
20. Part 20: Basic manipulation of filiform needle (GB/T 21709.20-2009)

Illustration of acupuncture points location (GB/T 22163-2008)
Body measurement of acupuncture points location (GB/T 23237-2009)
2. The Methods of Acupuncture National Standardization in China

- Standardization is a unified regulation for repeated objects and concepts in certain range. And it is a kind of regular documents approved by the accredited institution.
Regulation of developing Acupuncture National Standardization

- The procedure
- The content
- The compilations
The procedures of developing Acupuncture National Standardization

1. Present Stage
2. Draft Stage
3. Examine Stage
4. Peer Review Stage
5. Approval Stage
6. Reexamine Stage
7. Publishing Stage
8. Annullment Stage
9. Project Setting Stage
III. The development of Clinical Practice Guideline of Evidence Based Acupuncture in China

- Depression
- Herpes zoster
- Apoplectic dysphagia
- Migraine headache
- Bell’s facial palsy
In general, clinical practice guidelines have been defined as “systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances”.

Values of Clinical Practice Guidelines on Evidence-based Acupuncture

- Growing demands for globalization
- Shifting from experience to evidence-based
- Promoting the proper use*
  - Upgrading level of clinical practice*
  - Objectifying clinical practice
  - Ensuring reliability and reproducibility
  - Cost-effective practice*
Values of Clinical Practice Guidelines on Evidence-based Acupuncture

- Conducting overall assessment of acupuncture clinical research
- Facilitating scientific clinical trials
- Enforcing harmonisations with WM
- Providing higher standards of education and training* (adopted as textbooks or manuals)
- Strengthening international cooperation among experts
Methods of the Acupuncture CPG:

1. Developing Clinical Practice Guide of Evidence-based Acupuncture Committee (CGC)

<table>
<thead>
<tr>
<th>Clinical Guideline Committee</th>
<th>Component</th>
<th>Membership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Group leader</td>
<td>CPG organizer</td>
</tr>
<tr>
<td></td>
<td>Guide-writing committee</td>
<td>Deputy supervisor, guide-writers, researchers for literature search, etc.</td>
</tr>
<tr>
<td></td>
<td>Specialists committee</td>
<td>Clinical acupuncturist, psychiatrist, neuropathist, dermatologist</td>
</tr>
<tr>
<td></td>
<td>Patients</td>
<td>Patients’ delegate</td>
</tr>
<tr>
<td></td>
<td>Medical care Faculty</td>
<td>The delegate of every degrees of the medical care personnel, such as nurses, the care people, etc.</td>
</tr>
</tbody>
</table>
2. Screening and Confirming Critical Clinical Questions

- **Operator:** Guide-writing committee
- **Principle:** following PICO (Patient, Intervention, Comparison and Outcome) model, medical economics
- **Method and instrument:** screening by questionnaire and discussion
- **Result:** final critical clinical questions will be launched
3. Search methods and strategy for clinical evidence

- **Methods**: Systematic clinical literature review strategies.
- **Scope**: Modern literature, Chinese classical literature.
- **Database**: Cochrane Library, EMBASE, MEDLINE, CBM, CMCC and the websites of important professional societies and publishing organizations of the Guide.
- **Additional**: The database and the website of clinical studies related to the Guide should also be included.
- **Langue and Nations**: The search should also include the literature in Japanese, Korean and other countries’ classical literature and related publications.
- Manual search can make sure that all evidence related to the topic is included.
- **Instrument**: set up database for the literature (include the electric literature and the papery literature, such as classical literature, and famous doctors literature.)
According to different property and feature of researches, clinical researches of acupuncture can be divided as ancient literature, high-experienced TCM physicians, and modern research evidence.

A

Classical literature

B

Famous doctors literature

C

Modern literature

Meta-analysis

RCT

Non-RCT

Case array research

Case report and summary

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Developing Database:

- Design
- Enter data
- Conserve data
- Search data
- Evaluate data
4. Evaluation of the strengths and quality of evidence

- **Considering:**
  - The characteristics of acupuncture and literature.
  - Making the evidence evaluating criterion by consulting experts and discussing among groups.
  - Based on CONSORT Scale and Jadad Scale.
  - Evaluate and grade the literature according to the evaluating criterion.
  - **One paper** should be evaluated by three reviewers. The reviewers should contact the authors for the missing information, discuss the disputes and adopt the literature of high grade after strict screening.
As for modern research evidence, evidence classification criteria are made according to the two common used classification system: AHCPR and SIGN.

Table 1  Modern clinical research evidence levels of acupuncture

<table>
<thead>
<tr>
<th>Evidence levels</th>
<th>Classification of evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Ia  Meta-analysis of high quality of randomized controlled trial</td>
</tr>
<tr>
<td></td>
<td>Ib  Randomized controlled trial</td>
</tr>
<tr>
<td>II</td>
<td>Non-randomized controlled trial</td>
</tr>
<tr>
<td>III</td>
<td>Case array research</td>
</tr>
<tr>
<td>IV</td>
<td>Case report and summary or report of narration clinical material</td>
</tr>
<tr>
<td>Recommendation level</td>
<td>Evidence level</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------</td>
</tr>
</tbody>
</table>
| A                    | Consistent with one of them:  
1. Level Ia evidence of the same acupuncture treatment schema  
2. High quality RCT evidence of the same acupuncture treatment schema + level II and III evidence with low bias or ancient literature evidence or expert experience evidence |
| B                    | Consistent with one of them:  
1. High quality evidence of the same acupuncture treatment schema  
2. One or several moderate quality RCT evidence of the same acupuncture treatment schema + level II evidence with low bias or ancient literature evidence or expert experience evidence  
3. Level II evidence with low bias + ancient literature evidence or expert experience evidence |
| C                    | Consistent with one of them:  
1. Moderate quality RCT evidence of the same acupuncture treatment schema  
2. Level II evidence with low bias of the same acupuncture treatment schema  
3. Ancient literature evidence of acupuncture treatment schema  
4. Expert experience evidence of the same acupuncture treatment schema |
| GPP                  | Expert consensus |

Caution: 1. The same acupuncture schema refers to acupuncture treatment plan with the same acupoints and manipulation.
5. Making group decisions and consensus

1. Discussing the recommendations one by one by approaches such as questionnaire, telephone and conference to confirm the final recommendations.

2. Disputes and the way to consensus will be recorded. Rules and management of local healthcare and examination for doctor’s license should be considered during the process.
6. Extending Consultation Process

To consummate the revisal of guideline and finalize the manuscript, after the first draft was completed, the working group obtained the opinions and suggestions from the experts on the recommendation of main treatment protocols of the guideline by three round of soliciting comments from experts in the range of China.
7. Dissemination

- The related academic and administrative organizations should pay more attention on the management of normal propagating through the colony of doctors by means of news release, websites, lectures, tutorial classes, manuals, periodical reviewing etc., which will help the doctors to know, understand, as well as master and apply the guideline thoroughly.

- At the same time, the patient-specific reminders and certain knowledge of migraine in the guideline can be executed to display boards or the propagating materials exhibiting in hospitals, outpatient clinics, nursing stations, where patients may facilitate browsing, so that patients may know the guideline in time. The propagating methods of guideline can be flexible and various, adapting for different patients and different demands.
8. Implementation

- Instead of compulsory criteria, the guideline aims to supervise and help doctors make correct decisions towards the acupuncture treatment for such as Bell’s palsy, and it cannot include all the questions and problems in the acupuncture treatment.

- So when the clinical doctors face a certain patient, they are welcomed to refer to the optimal clinical evidence of the guideline, and suggested to consider the state of the illness, the willing of the patient, and combine the situation of the country, the level, characteristic, resources of local medical treatment, as well as their experiences & knowledge together, in order to establish the correct treatment protocol.
The structure and content of ACPG

(1) **Hard cover page**
Title – Clinical Practice Guideline of Traditional Medicine for _______
WHO WPR
version 1/2006
date of publication
official announcement of approval by authority, e.g. WHO

(2) **Introduction** – development, objective, search method, grading system – level of evidence, grading of recommendations

(3) **Background/Preface**
(a) **Definition of disease** using ICD and Chinese definition with Chinese character and put in pinyin
(b) Epidemiology (prevalence of disease) and risk factor, medical history of the disease, rationale and modalities of TRM treatment
(c) Other points to include in background: to state that there is no ideal therapy but TRM shows some effectiveness for AMD (to put response rate, if data are available), to add magnitude of disease such as increasing ageing population, and reason for this CPG (WHO recognizes the medical benefit of TRM in treating wet AMD)

(4) Prevention and early detection – not needed for AMD, may be needed in other eye diseases

(5) Clinical features – patient’s history, symptoms and signs (symptoms mean patient’s complaints or feeling and signs mean physical findings including findings from FFA, ICG and OCT)
(6) Diagnostic criteria
(a) AMD diagnostic criteria stated on table in page 6, 1986 – suggest to find latest reference
(b) TRM approach related to 4 patterns/syndromes – main and secondary manifestations

(7) Management
(a) Treatment- to have a statement on the unique individualized and holistic approach of TRM
(i) to state conventional treatment, if there is well accepted
(ii) to focus on TRM treatment – refer to Table on TRM approach to treat the 4 patterns/syndromes (refer to Table and appendix for formula)
(b) Treatment outcome – to add parameters for assessment on clinical response/effectiveness based on patient reported outcome [PRO]

(8) Recommendation – to recommend based on level of evidence of references cited in the guideline;

(9) Reference - citation of reference, if available to include quality, efficacy or safety data, or patients’ records as this is important for TRM therapy because there is no control. (Case report, case series, Ph D students’ thesis, unpublished data, textbook, expert opinion)

(10) Summary of this CPG

(11) Appendix – authors [full name, full title, and their credibility/background/qualification] and their institutions, as well as other participants – advisory board e.g. Australia, Malaysia

(12) Glossary
Clinical Practice Guidelines for Acupuncture in the Treatment of HERPES ZOSTER

EXECUTIVE SUMMARY

1) Key issues
This is a reliable guideline set up for clinicians. Its contents include an introduction to Herpes Zoster (HZ), HZ guideline implementation processes, principles of acupuncture treatment of HZ, other recommendations and points to note...

2) Key recommendations

<table>
<thead>
<tr>
<th>Key recommendations</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture treatment should be similarly targeted and points to be selected along the nerve skin excitation (or Ashi points), or Huahuojiaji points should be chosen from the affected area.</td>
<td>A</td>
</tr>
<tr>
<td>Early intervention is recommended to HZ patients.</td>
<td>B</td>
</tr>
</tbody>
</table>

Prodromal Phase

For patients during prodromal phase, it is suggested to use bloodletting with pyrones and needle method.

Vesicular Phase

Points during the vesicular phase with neurailgia and red spots, papules or small vesicles are recommended to undergo bloodletting of Ashi points with cupping. Vesicles on the head and neck region should be combined with DU14 Dazhui (大椎). And vesicles on the trunk should be combined with relevant Jiaji points.

Needling on Ashi points is recommended during the vesicular phase of HZ. Cases with neurailgia and skin lesion which consists of small vesicles, such as red spots or papules, should be combined with fire needle with cupping. Skin lesion which consists of large vesicles should be treated with moxibustion and fire needle.

Patients in the vesicular phase are recommended to be treated with moxibustion on Ashi points, especially for skin lesion which consists of large vesicles.

Patients in the vesicular phase with neurailgia are recommended to be treated on Ashi points with surrounding needleing and electro-acupuncture.

Patients with PHN are recommended to be treated with surrounding needleing on Ashi points.

Patients with radiating pain or hyperesthesia in the PHN phase are suggested to undergo electro-acupuncture on Jiaji points.

Bloodletting and cupping method on Ashi points is recommended for HZ patient in the PHN phase.

Implementation processes...
IV. The establishment of organizations for acupuncture standardization
China National Organizations of Acupuncture-Moxibustion

1979, China Association of Acupuncture-Moxibustion (CAAM)

2005, “CAAM Standardization Committee”

2007, establishing national Technical Committees (TC) of Acupuncture standardization

2008, China National Standardization Technical Committee proposed on TCM-TC in the ISO

2009, ISO organized voting on the proposal among its 106 members. Finally, more than two-thirds of members voted to approve the proposal
Discussion

- Is it necessary to develop acupuncture standards?
- Will the standardization hinder the development of acupuncture?
- As a discipline with unique characteristic of individuality, can acupuncture be standardized?
Is it necessary to develop acupuncture standards?

- Acupuncture standards existed since ancient times and have made great contribution to the development of acupuncture.
- It can be said that the continuous development of acupuncture for thousands of years, largely owed to the development of standards of acupuncture.
In the past, international standard-setting projects were proposed to solve specific issues during the development of internationalization of acupuncture, such as Standard Acupuncture Nomenclature and Guidelines for Clinical Research in Acupuncture.

At present, with the access to clinical studies, scientific research and education in each country, the time is ripe to establish a standard system of relevant terminology, education, health care, personnel and equipment in acupuncture.
Will the standardization hinder the development of acupuncture?

- Standardization means to reach consensus on things with common features.

- Suitable standardization of acupuncture
  - For the suitable part, undoubtedly, we should put it in the plan of standardization, apply for project and carry out it as soon as possible;
  - For those unsuitable parts, especially issues in clinical practice which cannot be described by simple and unified theory, we should avoid too much standardization, in case of losing the unique characteristics of acupuncture by “standards”.
As a characteristic of individuality, can acupuncture be standardized?

Although during clinical practice of acupuncture, special emphasis was put on individuality, it does not affect or exclude standardization.

- The individuality – diagnosis and treatment.
- The standardization – SOP, terminologies, location of points.
1. Need to systematic plan and developing strategy

- The development of international standardization of acupuncture is a long-term and complicated project
- To select the most needed project in clinical practice
Suggestion

2. To develop firstly “standard of standards”, such as general principles and guidelines

3. Specialized organization of acupuncture standardization
Suggestion

4 World Federation of Acupuncture-Moxibustion Societies (WFAS) responsibility of developing international standards of acupuncture
Thanks