Application of Grading of Recommendations Assessment, Development, and Evaluation (GRADE) to the guideline development for clinical practice with acupuncture and moxibustion

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Abstract Grading of Recommendations Assessment, Development, and Evaluation (GRADE) offers a worldwide approach to guideline development for clinical practice. For the clinical practice of acupuncture therapy, 18 evidence-based guidelines have been developed in China using GRADE. In this study, we review the advantages and limitations of the GRADE approach in the guideline development for acupuncture and moxibustion and propose some solutions to these limitations. Scientific advantages of rating the quality of evidence, outcome-centric direction, overall progression to develop recommendations, and strength of recommendations providing specific clinical guidance are the advantages of GRADE. The limitations of GRADE in the development of guidelines for acupuncture and moxibustion include rating the quality of evidence for ancient literature and literature on famous traditional Chinese medicine experts’ experiences and specific guidelines for formulating recommendations from evidence. In the guideline development for clinical practice with acupuncture and moxibustion, we suggest that a specific method should be explored based on the GRADE approach and the characteristics of acupuncture therapy.

Keywords guideline; acupuncture; GRADE

Introduction

The Grading of Recommendations Assessment, Development, and Evaluation (GRADE), which is a systematic approach to rate the quality of scientific evidence and to grade the strength of recommendations, was developed by 19 countries and international organizations and is based on a series of research papers [1]. GRADE offers a method of rating the quality of evidence and grading the strength of recommendations in systematic reviews, health technology assessments, and clinical practice guidelines addressing alternative management options [2].

In the past 10 years, with the development of evidence-based medicine (EBM) and guideline-development methodology, guidelines for traditional Chinese medicine (TCM) have been gradually established. Under the organization of the standardization committee of the China Association of Acupuncture Therapy and with reference to the GRADE approach, over 10 domestic organizations have contributed to the development of evidence-based guidelines for the clinical practice of acupuncture therapy. To date, the clinical practice of acupuncture therapy has 18 guidelines, which include treatments of herpes zoster [3], depression [4], migraine [5], Bell’s palsy, post-stroke pseudobulbar palsy [6], primary dysmenorrhea, low back pain [7], chronic constipation, adult bronchial asthma [8], insomnia, allergic rhinitis, simple obesity, and chronic atrophic gastritis [9]. We have applied GRADE to the development of these guidelines and have recorded the results of these applications. We have demonstrated both the advantages and limitations of the GRADE approach in guideline development.
development [10,11]. To direct more Chinese guideline developers of acupuncture and moxibustion to use GRADE correctly, we reviewed the advantages and limitations of the GRADE approach in the guideline development for acupuncture and moxibustion and propose some solutions to these limitations.

**Advantages of GRADE in the guideline development for acupuncture and moxibustion**

**Scientific advantages of rating quality of evidence**

In comparison with other tools that rate the quality of scientific evidence, GRADE specifies clearly and comprehensively the criteria for rating the quality of evidence from high to low based on different types of research. The quality of most clinical studies on acupuncture therapy is low, and the quality of randomized controlled trials is particularly poor [12,13]. However, controlled studies and case series studies often provide important clinical treatment information. The GRADE approach identifies three factors that can increase the quality of evidence of observational studies and may enable them to be cited as high-quality supporting evidence. The GRADEpro software permits an automatic summary of the quality of evidence upon input of specific study information. Therefore, this flexible and transparent system of quality assessment for different types of evidence is especially applicable to rate the quality of evidence in the field of acupuncture therapy.

**Outcome-centric direction**

The GRADE approach requires guideline developers to state in detail the significance of all the outcomes and to distinguish the critical outcomes from the important but non-critical ones. Acupuncture therapy usually has positive effects on clinical symptoms. The GRADE approach examines disease outcomes; identifies the evidence quality of each outcome; clarifies the impact of acupuncture therapy on each critical outcome and non-critical outcome; determines the effects of acupuncture therapy on clinical symptoms, TCM patterns/syndromes, quality of life, and laboratory tests and endpoints; and provides guideline information about the characteristics and advantages of acupuncture therapy. For example, the outcomes for chronic atrophic gastritis include stomach pathological manifestation, endpoint gastric cancer incidence, gastrointestinal and systemic symptoms, quality of life scale, laboratory tests, and TCM syndrome score. These outcomes can reflect the difference in acupuncture effects in different aspects. The panels of guideline assessed the evidence and developed the recommendations according to different outcomes. They recommended that compared to pathology changes and laboratory tests, acupuncture therapy is more effective in improving symptoms, quality of life, and TCM syndrome symptoms. This recommendation will help the guideline user to better understand the advantages of acupuncture therapy.

**Overall progression to develop recommendations**

The GRADE approach uses evidence to develop recommendations. The guideline-development group considers the overall balance of four domains that determine the strength of a recommendation: patient values and preferences, the relationship of desirable and undesirable consequences, resource use, and quality of evidence [14]. This helps to provide clear and practical interpretations for clinicians, patients, and policymakers [15]. This procedure embodies the EBM approach and reflects the TCM conception of individualized diagnosis and treatment. When making decisions in clinical practice, clinicians should fully consider patient values and preferences, the balance between desirable and undesirable consequences, and the medical cost-effectiveness of treatment. Acupuncture has a long history of use in China and has been extensively applied to the treatment of many diseases because of its unique characteristics as a simple and low-cost treatment. Although evidence of its efficacy for some disorders has not yet been determined, many patients and medical staff have accepted acupuncture because of its minimal side effects and lower medical costs than Western medicine and other therapies. Hence, in developing guideline recommendations, the GRADE approach highlights the advantages of acupuncture therapy in terms of the balance between desirable and undesirable consequences, resource use, and patient preferences. For example, acupuncture therapy for depression has the advantage of fewer side effects and lower costs, and it eases the symptoms of depression while also alleviating the complications as compared to antidepressant drugs. However, patients with depression need to be treated for many sessions. The panels developed recommendations based on a comprehensive consideration.

**Strength of recommendations providing specific clinical guidance**

The GRADE approach classifies the strength of a recommendation as strong or weak. The classification of recommendation strength has specific implications for patients, clinicians, and policymakers [16]. A strong recommendation implies that most patients would want the recommended treatment and only a small proportion would not and that clinicians should provide most patients with the recommended treatment. For policymakers, a strong recommendation can be adopted as a policy in most