European Journal of Integrative Medicine 8 (2016) 176–181

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim

Research paper

Clinical practice guidelines of Korean medicine for facial palsy: An evidence-based approach

Ju Ah Lee[1,a], Jong Uk Kim[1,b], Jiae Choi[c], Ji Hee Jun[c], Tae Young Choi[c], Tae Han Yook[b], Myeong Soo Lee[c,*]

[a] KM Fundamental Research Division, Korea Institute of Oriental Medicine, Daejeon, South Korea
[b] Department of Acupuncture & Moxibustion Medicine, Korean Medicine Hospital of Woosuk University, Jeonju, South Korea
[c] Clinical Research Division, Korea Institute of Oriental Medicine, Daejeon, South Korea

ARTICLE INFO

Article history:
Received 21 August 2015
Received in revised form 20 October 2015
Accepted 20 October 2015

Keywords:
Facial palsy
Clinical practice guidelines
Evidence-based medicine
Korean Medicine

ABSTRACT

Introduction: Facial palsy is a common disease, and Korean medicine (KM) is widely used to treat facial palsy in Korea. However, there are no Korean multidisciplinary guidelines for facial palsy; thus, guidelines that are adequate for domestic circumstances are required.
Methods: To establish clinical practice guidelines (CPGs), professional group formation, plans for research progress and the situation regarding CPG development were analysed. Subsequently, data from the Korean and Western medical literature regarding the CPGs for facial palsy were collected and analysed. A draft of the Korean medicine CPGs for facial palsy was then developed. After review and amendment of the guidelines by a review committee, the Korean acupuncture and moxibustion medicine society reviewed and approved the guidelines.
Results: In total, 24 recommendations were developed for the KM treatment of facial palsy. Six of the recommendations were primarily related to manual acupuncture and treatment methods. The other recommendations were related to electroacupuncture, thread embedding and other acupuncture techniques.
Conclusion: The result of this project suggests a methodology to develop CPGs that is suitable for our environment of KM but that it lacks supporting evidence; in turn, this methodology will lead to the production of evidence and recommendations for patient care in actual KM clinical settings.

1. Introduction

Clinical practice guidelines (CPGs) are defined as "systematically developed statements to assist practitioners and patients in decisions about appropriate health care for specific clinical circumstances" [1]. Facial palsy is a common disease for which many patients have sought advice from Korean medical institutions [2]. In Korean medical terms, this disease is called "Guanwasa" [3]. Facial palsy is a relatively common disease that affects 20–30 per 100,000 people [4].

However, Korean medicine CPGs regarding facial palsy are inadequate. Therefore, the development of Korean medicine CPGs is needed. Facial palsy involves symptoms in which the eye and mouth are twisted to one side due to the paralysis of facial muscles. Facial palsy is due to Bell's palsy; a few CPGs for Bell's palsy exist [5–9], but none focus on or involve Korean medicine (KM). Therefore, we aimed to develop CPGs that focused on KM.

Considering these needs, the project to develop KM CPGs seeks to increase the standard of KM practice in Korea and to establish a cooperative system that integrates conventional medicine and oriental medicine. Additionally, this project intends to standardize and improve the quality of medical practice, to reduce the risk associated with clinical practice, and to realize an optimal balance between the cost and efficacy of medical service.

2. Method

To establish CPGs, professional group formation, a plan for the research process and the situation regarding CPG development were analysed. Subsequently, data regarding the CPGs associated with facial palsy from the Korean and Western medical literature were collected and analysed. Next, a draft of the Korean medicine

* Corresponding author at: Medical Research Division, Korea Institute Research Center, 1672 Yuseongdae-ro, Yuseong-gu, Daejeon 305-811, South Korea.
Fax: +82 42 863 9299.
E-mail addresses: motoong@kiom.re.kr (J.A. Lee), ju1110@hanmail.net (J.U. Kim), ksjiae@kiom.re.kr (J. Choi), zhixi04@kiom.re.kr (J.H. Jun), superoung@kiom.re.kr (T.Y. Choi), nasiss@naver.com (T.H. Yook), drmslee@gmail.com (M.S. Lee).
[1] These authors contributed equally to this work.

http://dx.doi.org/10.1016/j.eujim.2015.10.009
1876-3820/

CPGs for facial palsy was developed. A review committee amended the CPGs, and the Korean acupuncture and moxibustion medicine society then approved the guidelines.

2.1. Establishment of a network to develop Korean medical clinical practice guidelines

2.1.1. Education program to train experts in clinical practice guidelines

We held an educational training course for the developers and users of guidelines. This program aimed to create a standard for developing rigorous and trustworthy clinical practice guidelines and thus contained varied content that included literature searches, methods for collecting data and for developing patient, intervention, comparator, and outcome (PICO) data, recommendations, the risk of bias, and formal consensus methods (Table 1).

2.1.2. Methodology workshop on evidence-based clinical practice guidelines

A methodology for developing CPGs for our KM environment that lacked supporting evidence was needed, and technical support was provided.

The Korea Institute of Oriental Medicine (KIOM) held a workshop regarding evidence-based methodologies of CPGs on January 22, 2013. The purpose of this workshop was to share information about the evidence-based methodologies of the most important elements of CPGs. We invited methodology experts, and a bond of compatibility developed among the group members.

2.2. Constitution and processes of the development committee

This standard reporting item identified several specific tasks that were required to develop the KM CPGs. First, a strategy for the groups developing CPGs should be formulated and executed. Second, high-quality-based CPGs for exact diagnoses and effective treatments should be provided to the users of the guidelines.

2.3. Literature search and quality assessment

All searches were performed by two independent reviewers in August of 2013. MEDLINE, EMBASE, AMED, and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched from the inception of each database to August 2013. The following domestic databases were searched through October 2013: OASIS, NDSL, KAMMS, JKOM, KPI, and ODD. All of the titles and abstracts of the retrieved studies and the electronic searches were reviewed by independent authors, who selected the relevant articles based on the titles and abstracts.

We conducted and reported the results according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines [10].

The risk of bias was assessed using the risk of bias assessment tool from the Cochrane Handbook, version 5.1.0 [11], which includes random sequence generation, allocation concealment, blinding of the participants and personnel, blinding of the outcome assessments, incomplete outcome data, selective reporting and other sources of bias. Our review used L, U, and H as indicators of the judgements. 'L' indicated a low risk of bias, 'unclear' (i.e., U) indicated that the risk of bias was unclear, and 'H' indicated a high risk of bias. Disagreements were resolved by discussion among all of the authors. Moreover, the Risk of Bias Assessment Tool for Non-Randomised Studies (RoBAN) was used to assess the non-randomized controlled trials (NRCTs) and case-control trials (CCTs). All assessments of the risks of bias were conducted by two or more researchers.

2.4. Data selection

All of the randomized controlled trials (RCTs) and quasi-RCTs (i.e., RCTs in which the allocation to treatment was obtained by alternation, the use of alternate medical records, data regarding birth or other predictable methods) identified with the keywords were included. Systematic reviews and meta-analyses were included. Well-designed case studies; case series; qualitative studies; uncontrolled trials; case reports; reviews and important literature were included when there were insufficient meta-analyses; systematic reviews and RCTs. We excluded literature regarding central palsy; facial palsy with certain diseases and other non-associated facial palsies. Furthermore; low quality literature was excluded. Hard copies of all articles were obtained and read in full. Data extraction and quality assessment were conducted by independent authors by using a predefined data extraction form. When disagreements about selection could not be resolved through discussions; an arbiter made the decision. Reports with a high risk of bias were excluded in a planned manner; or the evidence was downgraded according to recommendations based on expert consensus.

2.5. Classification of evidence-based statements

The level of evidence is a ranking system that is used in evidence-based practices to describe the strength of results from a clinical trial or research study [12]. Evidence-based statements reflect both the quality of evidence and the balance of benefit that is anticipated when the statement is followed. The level of evidence for each clinical question depends on the research design and the quality of the report according to these CPGs.

When clinicians or health care professionals must make decisions, they can judge the quality of the evidence and the reliability of recommendations according to the level of evidence and the grade of the recommendation. Therefore, the steps of grading evidence and recommendations are very important in the development of CPGs. Accordingly, we aimed to identify grading systems for the levels of evidence and strengths of recommendations by adopting traditional clinical environments (Table 1).

The grade of the recommendation relates to the strength of evidence on which the recommendation is based. Generally, the grade of the recommendation is rated from A to C. However, in these guidelines, we used a 4-point grading system that included

Table 1
Levels of evidence.

Level	Type of evidence
Ia	Evidence obtained from a meta-analysis and systematic review of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well-designed controlled study without randomization or cohort study
IIb	Evidence obtained from at least one other type of well-designed quasi-experimental study (observational study)
III	Evidence obtained from an expert consensus of treatment published in important historical literature
IV	Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies, and case studies
V	Evidence obtained from expert committee reports or opinions and/or clinical experiences