The 4th Korea-Japan Collaborative Workshop on Acupuncture Medicine

Acupuncture Medicine and Evidence Based Medicine
- Clinical Practice Guideline for Acupuncture

- Time : 16th September 2012, 09:00-13:00
- Place : Seoul, COEX 2F (203A)
- Organized by : The Korean Acupuncture & Moxibustion Medicine Society, The Korean Medical Society

개회사

대한침구의학회는 제16회 ICOM(국제동양의학학술대회) 기간 중 대한한의학회와 공동으로 “침구의학과 근거중심의학－침구 시술을 위한 임상가이드라인”이라는 주제로 ‘제4회 한·일 침구의학 워크샵’을 주관하게 되었습니다.

대한침구의학회와 전일본침구의학회는 2004년 6월 일본 지바에서 처음으로 “The 1st Japan-Korea Workshop on Acupuncture and EBM”을 개최하여 학문적 교류를 시작한 이후로, 2005년 10월 대구에서 성황리에 “The 2nd Korea-Japan Workshop on Acupuncture and EBM”을 개최하였으며, 다시 2007년 일본에서 “The 3rd Japan-Korea Workshop on Acupuncture and EBM”을 Protocol development for the acupuncture trial on the osteoarthritis of the knee라는 주제를 가지고 개최하는 등 ‘근거중심의학’이라는 일관된 주제를 가지고 지속적인 교류를 해왔습니다.

‘근거중심의학’ 확립은 의학의 보편적 가치를 실현해가는 과정으로서 침구의학의 객관화와 표준화를 동시에 실현시킨다는 의미가 있습니다. 이치에 부합하고 실제적 가치의 관점에 역점을 두어 수천 년 동안 우리 민족의 건강을 지키고 백성들의 안위를 보존시켰던 민족유산인 침구의학은, 이제 세계적으로 보편적인 치료의학의 가치를 점유한 서의학적 학문집적과정과 연구방법론을 더하여, 우리 학문의 실행 가치를 세계의학으로 발전시킬 수 있는지를 모색해야 하며, 우리 대한침구의학회와 더불어 대한한의학회, 대한한의사협회 그리고 정부기관까지도 함께 힘쓰고 노력하여 자랑스러운 전통의학을 합리적이고 실용적인 가치에 기반을 둔 세계의학으로 발전시키고 발돋움시키기 위해 매진할 때인 것입니다. 또한 이러한 과정에서 목적을 공유하는 한·일 양국의 학회는 공동의 노력을 경주하고 있습니다.

이제 침구의학은 동양의 신비스러운 의술로서만이 아니라 세계 속의 보편적인 표준의학으로 자리매김하여 인류를 질병의 고통으로부터 해방시킬 수 있는 대중적이면서도 경제적 치료수단으로 다시 나야 하며, 자본주의 의학이 아닌 인본주의를 실현할 수 있는 인본의학으로서 역할을 할 수 있는 세계의학의 새로운 장을 열어가야 합니다. 또한 단순히 개인을 치료하고 건강을 회복시키는 정도를 넘어 세상을 치료할 수 있는 사회치료의학으로까지 발전해 나가야 할 것입니다.

이러한 침구의학의 의의와 역할에 대한 당위를 고려할 때, 제4회를 맞이하는 ‘한·일 침구의학 워크샵’은 앞으로의 과정에 중요한 역할을 할 것이며 내일의 희망이 되는 建極垂教의 기틀이 될 것이라 믿습니다. 아울러 일본에서 본 학술대회 참석을 위해 방한한 Ikuro Wakayama, Hitosi Yamashita, Takashi Otuski 선생님과 이번 행사준비에 열성을 쏟아주신 대한한의학회 김갑성 학회장님, 대한한의사협회 김정곤 회장님을 비롯한 관계자 및 후원해 주신 여러분들께 감사를 드립니다.

2012. 9. 16.

대한침구의학회장 趙命來

인사말

2012년 16차 국제 동양의학학술대회(ICOM)의 개최와 더불어 대한침구의학회와 전일본 침구학회가 공동으로 주최하는 제4회 한·일 침구의학 워크숍의 개최를 진심으로 축하합니다.

특히 전일본침구학회와의 공동연구 MOU는 제가 대한침구의학회 학회장으로 재임하던 2004년 2월 14일 당시 전일본침구학회 학회장이신 쇼이치 선생님과 함께 대한민국의 조선호텔에서 처음 체결하여 양국 간의 침구의학 공동 연구의 물고를 튼 추억을 간직하고 있어 더욱 뜻 깊은 행사라고 할 수 있겠습니다. 저 또한 그해 6월에는 일본 지바에서 열린 전일본침구학술대회에 참석을 하여 환대를 받은 기억 또한 생생합니다.

그 후 양국 간의 침구의학전문의 선생님들을 중심으로 공동 연구와 발표가 이어졌으나, 2006년 제3회 양국 간의 공동학술 발표회를 끝으로 더 이상의 공동연구 발표를 진행치 못하여 안타깝게 생각하던 중, 2012년 9월 제 16회 ICOM 대회를 맞이하여 한·일 간의 침구의학 공동 연구 발표회가 재개 되어 다행스럽게 생각하며, 오늘의 이 행사를 통하여 양국 간의 좀 더 활발한 연구와 교류가 이어지길 기대하는 바입니다.

금번 한·일 침구의학 공동 워크숍의 주제인 “근거중심의학-침구시술을 위한 임상가이드라인”은 한의학적 치료의 가장 근간을 이루는 침구의학이 고대의학으로만 치부되던 과거의 탈을 벗고, 침구 치료를 행하는 의사의 진료와 과학적 근거의 간격을 줄임으로써, 진료의 일관성을 유지하고, 보다 효율적이면서도 객관적이고도 과학적인 도구라고 감히 말씀드릴 수 있겠습니다. 이러한 방법은 서양의학계에서는 보편적으로 시도되는 방법 중 하나이지만 한의학계에서는 그러한 예조차 찾아보기 어려운 실정입니다.

의학계에서는 근거중심의 의학과 이를 실현하기 위한 임상진료 지침의 개발 및 무작위 임상대조군 실험 연구가 이제는 보편적이면서도 일반화된 근거중심의 자료로 활용되고 있습니다. 다행히 약 4년 전부터 대한침구의학회에서도 정부의 지원을 받아 가장 다빈도 질환인 근골격계 질환을 중심으로 임상진료지침 개발위원회를 구성하여 관련 연구를 활발하게 진행 하고 있는 것으로 알고 있으며, 가까운 기간 내에 연구 성과물이 발표될 것으로 기대하고 있습니다. 이제 우리는 어려운 발걸음을 시작했지만 양국 간의 우수한 연구 인력을 자원으로 하여 보다 한 차원 높은 침구의학의 발전을 기대해 봅니다.

끝으로 이번 학술 공동 연구를 위해 애서주신 양국의 실무집행진과 연구진께 깊은 감사와 경의를 표하며 인사를 마치도록 하겠습니다.

감사합니다.

2012. 9. 16

대한한의학회 회장 김갑성

The 4th Korea-Japan Collaborative Workshop on Acupuncture Medicine

: Acupuncture Medicine and Evidence Based Medicine (EBM)
- Clinical Practice Guideline for Acupuncture

Time	Contents	
09:00~09:30	Premeeting and Tee time of all staffs	
09:30~10:00	Welcome and Opening Remarks	
10:00~10:20	**Acupunctural Clinical Guideline for Neck Pain** - **Hong Kwon Eui** (Director of general affairs, The Korean Acupuncture & Moxibustion Medicine Society / Korea)	Moderator : **Jang Jun Hyouk, Ikuro Wakayama**
10:20~10:40	**Present Status of Clinical Practice Guidelines including Acupuncture Therapy and Development of Acupuncture Clinical Practice Guideline in Japan** - **Hitoshi Yamashita** (Director of Research Department, The Japan Society of Acupuncture and Moxibustion (JSAM) / Japan)	
10:40~11:00	**Acupunctural Clinical Guideline for Knee Pain** - **Kim Eun Jung** (Director of education Department, The Korean Acupuncture & Moxibustion Medicine Society / Korea)	
Break Time		
11:10~11:30	**Tentative Development of Evidence-Based Clinical Practice Guideline of Acupuncture Technique for Chronic Low Back Pain in Japan** - **Takashi Otsuki** (Director of Research Department, The Japan Society of Acupuncture and Moxibustion (JSAM) / Japan)	Moderator : **Jang Jun Hyouk, Ikuro Wakayama**
11:30~11:50	**Acupunctural Clinical Guideline for Low back Pain** - **Nam Dong Woo** (Director of education Department, The Korean Acupuncture & Moxibustion Medicine Society / Korea)	
11:50~12:10	Discussion	
12:10~13:00	Ending Remarks	

Acupunctural Clinical Guideline for Neck Pain

Kwon-eui Hong(홍권의)
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College of Korean Medicine
Daejeon University

PURPOSE AND BACKGROUND OF RESEARCH

- Clinical guidelines are effective tools to bridge the gap between a physician's practice in clinical settings and a scientist's research in a lab.
- During the past decade, such guidelines have been fervently developed and advocated to act as convenient tools and guidances for clinicians in improving quality of care, implemented into science labs for clinical researchers, and used as blueprints for government officials in public health care.
- Yet such guidelines related to acupuncture and traditional medicine are rare and hard to find.

Neck Pain

- Common disease in Korea
  - 30-40% of outpationts in Korean medicine
  - covers the terms cervical spondylosis, cervical sprain and strain, cervical disc disease in western medicine.
  - Called ① neck pain 頸項痛 ② stiff neck 項强 ③ torticollis斜頸 ④ strained neck捻挫
  - But, personal experiences and skills for management of these patients which is unfortunately bringing about a very unsystematic and unstandardized diagnostic and treatment process, and leading to a wide variation in treatment modalities and effectiveness.

Acupuncture

- Many people with neck pain seek out complementary and alternativemedicine (CAM) therapies.

In Korea

- At the present, the percentage of patients making up the top ten most-frequently visited out-patient list at an oriental medical hospital are those with neck pain.

But, no exist standard treatment of Acupuncture in diagnosis of Korean medicine.

The Necessity of Clinical Guideline

- Many of the oriental medical doctors are relying primarily on their personal experiences and skills
  - very unsystematic and unstandardized diagnostic and treatment process
  - leading to a wide variation in treatment modalities and effectiveness
- It is crucial to develop an acupunctural clinical guideline
  - through extensive literature research, questionnaires, and discussion among experts for musculoskeletal disorders/diseases

PURPOSE & SCOPE

The purpose

- to formulate an appropriate acupunctural clinical guideline based on domestic and international evidence and domestic specialists'opinions for knee pain
- and recommend to Korean medical field which would provide high quality care and treatment to knee pain patients and further increase public health.

Scope

- knee pain includes
  - Western medicine diagnosis of disorders such as **knee osteoarthritis, rheumatoid arthritis, and soft tissue knee injuries**.
  - excludes
    - significant, yet rare cases of fracture, dislocation, tumor, infection, inflammatory arthropathies, osteonecrosis, congenital musculoskeletal deformities, crushing injury of lower leg, frostbite with tissue necrosis, complications of internal orthopedic prosthetic devices, implants, and grafts. Furthermore, conditions characterized by pain referred from other structures (e.g. hip), such as neuropathic pain, are excluded.
- focuses on patients of 18 and over
- The aim of the guideline is to recommend a clinical diagnostic guideline which would provide high quality care and treatments to patients with knee pain

Funding

- This Clinical Guidline was developed as part of a supporting project to promote Oriental Medical Technology (B080017) funded by the Korean Ministry of Health & Welfare.
- Development Period : 2008.07.01-2010.06.30 (Clinical research to verify the effectiveness of the presented guidance are in progress and further complementary measures have been set up.)

PROCESS

Difficulties of OM Clinical Guideline Development

Different Scientific Approach of OM
Lack of Well-Designed RCTs
Various Diagnosis Systems of OM
Various Treatment Methods of OM

Lack of Well-Designed RCTs

Efforts to search domestic and international studies/
Level of recommendation was adjusted

Various Diagnosis Systems of OM

Survey on pattern identification, diagnosis system,
Delphi committee of specialists, pre-clinical study on patients.

Various Treatment Methods of OM

Survey of OM Clinicians.

1. Training of acupunctural clinical guidance

- On-board training of acupunctural clinical guidance development group and establishment of a research plan
  - Since the acupuncture clinical guideline development group lacked sufficient knowledge on basic understanding of and methods used to establish a guideline, several workshops were arranged and an expert in the field was called in to explain the strategies, methods, and developmental know-hows

2. Composition of the professional Acupunctural clinical guidance development group and the review board

3. Literature research

Traditional and Recent Texts of OM

- In order to establish standards of OM diagnosis and treatment

Search of Scientific Studies

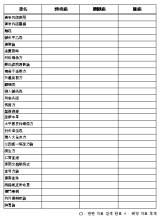
- In order to establish evidence for acupuncture efficacy

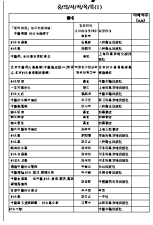
Related Clinical Guidelines

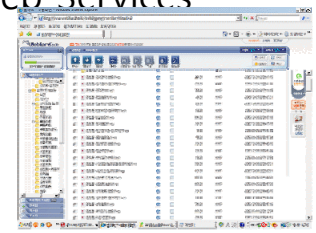
Assessment of Evidence Level

3-1. **Traditional and Recent Texts of OM**

- List of Traditional and Recent Texts to be reviewed(112)
- Search and Review
- Data Sharing Through Web Services







3-2. **Search of Scientific Studies**

- For neck pain, key words such as Neck pain, Dorsopathies, Kyphosis, Lordosis, Scoliosis, Kyphoscoliosis, Spinal osteochondrosis, Spondylolysis, Spondylolisthesis, Myelopathy, Spondylitis, Spondylopathies, Spinal enthesopathy, Osteomyelitis of vertebra, Intervertebral disc, Discitis, Spondylosis, Radiculopathy, Stenosis, Hyperostosis, Cervical disc, Cervical, HIVD, Disc, Cervicocranial, Cervicobrachial, Spinal instabilities, Dorsalgia, Cervicalgia, Myalgia, Panniculitis, Fibromyalgia, Musculoskeletal, were used.
- Korean research papers were obtained from
  - OASIS-(http://oasis.kiom.re.kr/)
  - The Journal of Korean Acupuncture and Moxibustion Society (http://www.acumoxa.or.kr/)
  - The Journal of Korean Oriental Medical Society (http://www.koms.or.kr/)
  - The Journal of Korean Academy of Oriental Rehabilitation Medicine (http://www.ormkorea.org/).
- Foreign research papers were searched through
  - pubmed(http://www.ncbi.nlm.nih.gov/pubmed/), and after going through rigorous elimination processes, a total of 59 related papers were obtained.

3-3. **Related Clinical Guidelines**

3-4. **Assessment of Evidence Level**

- it was hard to apply the level of evidence grading systems used in western medicine.
- So, the followir adopted

Complementary and alternative medicines grading system suggested by NZGG(New Zealand Guidelines Group) in 2006.

TABLE 1: LEVELS OF EVIDENCE USED IN THE TBI GUIDELINE

LEVEL OF EVIDENCE		WHERE THE EVIDENCE COMES FROM
1	Evidence with a high degree of reliability	Studies that use well tested methods to make comparisons in a fair way and where the results leave very little room for uncertainty. Trial design: usually Level 1 studies are systematic reviews or large, high-quality randomised controlled studies.
2	Evidence with reliability but open to debate	Studies that use well tested methods to make comparisons in a fair way but where the results leave room for uncertainty (for example, due to the size of the study, losses to follow-up or the method used for selecting groups for comparison). Trial design: usually Level 2 studies are systematic reviews without consistent findings, small randomised controlled trials, randomised controlled trials in which large numbers of participants are lost to follow-up, or cohort studies.
3	Some evidence without a high degree of reliability	Studies where the results are doubtful because the study design does not guarantee that fair comparisons can be made. Trial design: usually Level 3 studies are systematic reviews of case-control studies or individual case-control studies.
4	Some evidence but based on studies without comparable groups	Studies where there is a high probability that results are due to chance (for example because there is no comparison group or because the groups compared were different at the outset of the study). Trial design: usually cohort or case-control studies where the groups were not really comparable, or case-series studies.

- Another grading system was suggested by Brosseau L. in the study, 'Clinical practice guidelines for acupuncture'.

Table. Brosseau L.'s Level of evidence Clinical practice guidelines for acupuncture

Level of Evidence	Classification of Level of Evidence
I	Randomized controlled trials
II	Nonrandomized studies

Brosseau L, Wells GA, Finestone HM, Egan M, Dubouloz CJ, Graham I, Casimiro L, Robinson VA, Bilodeau M, McGowan J. Clinical practice guidelines for acupuncture. Top Stroke Rehabil 2006 Spring ; 13(2) : 65-7.

- Strength of recommendation
  - Strength of recommendation was presented as done in the study by Brosseau L, 'Clinical practice guidelines for acupuncture'.

Table. Strength of recommendation suggested in Clinical practice guidelines for acupuncture by Brosseau L

Strength of Recommendation	Level of Evidence
A	Evidence from one or more randomized controlled trials (RCTs) of a statistically significant, clinically important benefit
B	Statistically significant, clinically important benefit, if the evidence was from observational studies or controlled clinical trials (CCTs)
C+	Evidence of clinical importance but not statistical significance
C	Interventions where an appropriate outcome was measured in a study that met the inclusion criteria, but no clinically important difference and no statistical significance were shown Consensus of experts*(Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.)
D+	Evidence from one or more randomized controlled trials of a statistically significant benefit favoring the control group
D	Evidence of clinical importance without statistical significance
D-	Evidence from one or more randomized controlled trials of a clinically important benefit that was statistically significant, where the number of participants in the study is equal to or higher than 100

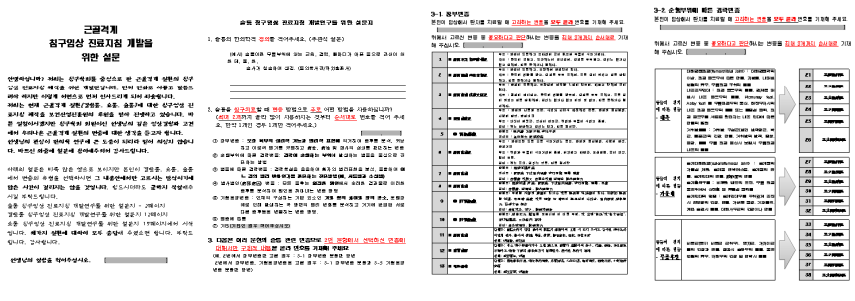
*recommendations of AHCPR(Agency for Healthcare policy and research) were taken into reference.

4. Diagnosis

- **Pattern identification**
  - Literature Review and survey
- **Diagnosis system**
  - Literature Review and survey / Delphi committee

Survey – Pattern identification

- Find out which pattern identification methods are widely applied in clinical practice.
- Date : 2009.3.26 -2009.4.29



Neck Pain

- Meridian pattern identification was the most popular OM(KM) diagnosis system. (Liver)

1. Differentiation of syndromes according to pathological changes of Jangbu organs

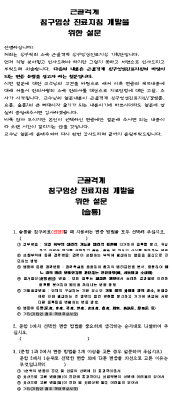
2. Differentiation according to the theory meridians and collaterals

3. Differentiation of symptoms and signs for determining the pathogenic factors of a disease

4. Differentiate syndromes by studying the pathological changes of Gi -blood & Eum-Yang

Survey – Pattern identification 2

- Subjects : Professors of OM college, Department of Acupuncture & Moxibustion
- Contents
  - Reason for pattern selection
  - Standard of pattern identification
  - Patterns that should be considered
- Date : 2009. 5 ~ 2009. 8


근골격계
침구임상 진료지침 개발을
위한 설문

근골격계
침구임상 진료지침 개발을
위한 설문
(슬통)

The answers for knee pain was low in consistency.
So, for knee pain and cervical pain, OM diagnosis system was adopted

Consensus of Specialists on OM(KM) Diagnosis System

- Based on results of literature review Delphi committee was held.
- Main symptoms were selected as standards of diagnosis.

① neck pain ② stiff neck ③ tortico llis ④ strained neck	Evidience level : C(Consensus)

Clinical study for development of a diganostic tool

Objective

- **To test the established draft of diagnosis system in clinical practice and obtain b ases for modification.**

Institutes

- Neck pain Daejoen university, wonkang university

Date

- 2010.3-2010.5

Method

- Standard study guideline for researchers was established
- Patients were surveyed and the diagnosis results were analyzed

(1) Parametric Methods

① Linear Discriminant Analysis (LDA, Fisher, 1936) /Quadratic Discriminant Analysis (QDA)

② Diagonal Linear Discriminant Analysis (DLDA) / Diagonal Quadratic Discriminant Analysis (DQDA) (Dudoit et al, 2002)

(2) Nonparametric Methods

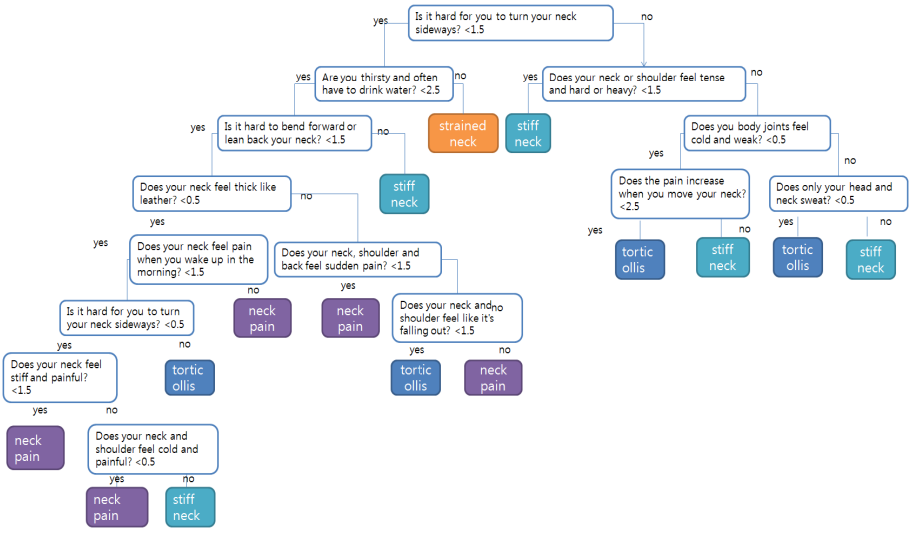
① Support Vector Machines (SVM, Vapnik, 1995)

② K-Nearest Neighbor Classification (KNN)

③ Chi-squared Automatic Interaction Detector (CHAID)

④ Classification And Regression Trees (CART, Breiman, 1984)

Classification And Regression Trees



5. Treatment

- **Acupuncture Treatment Methods**
  - Treatment according to OM(KM) diagnosis
    - Literature Review and survey
  - Treatment according to western diagnosis
    - Literature Review / Level of evidence and recommendation assessed

Survey

Phone survey

- Random sampling for visited survey

Visited Survey

- **objectives : In order to gather opinions of OM doctors and modify the guideline draft to meet the clinical needs.**
- **Date :** 2009.11.23~2010.01.09
- **Subjects** : 288 OM doctors with more than 5 years of clinical experience.

- 조사모집단: 서울 지역 한의사 5년 이상 경력자 2906명
- 표본조사 대상: 288명
- 표본추출틀: 서울시 한의사협회 회원 명부
- 목표오차: ±4.3% 포인트
- 표본추출: 서울 지역 한의사들을 25개 구로 층화하여 각 층별로 한의사들을 임의추출 (stratified random sampling)
- 층별표본할당: 각 층별 한의사 수에 비례하도록 각 층별 조사 대상 한의사 결정 (proportional allocation)
- 표본설계에 따른 모수(모비율) 추정 방법

추정치: $\hat{p}=\sum_{i=1}^{L} W_i \hat{p}_i$ W_i는 각 층별 가중치

추정분산: $\hat{V}(\hat{p})=\sum_{i=1}^{L} W_i(1-f_i)\hat{p}_i\hat{q}_i/(n-1)$, f_i는 각 층별 표본추출률

오차 범위: $\varepsilon_{\alpha/2}\sqrt{\hat{V}(\hat{p})}$

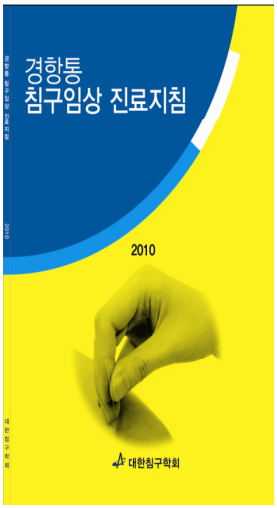
- **Diagnosis**
  - Area of pain, pain character, history taking, Swelling and malformation of neck, color, ROM, heat and cold sensation, the cause of pain reduction and increase, tender point
- **Acupuncture**
  - Sa-Am - Ashi - anatomical – five shu point
- **Point selection**
  - Local point, Local and distant together, and distant.
- **Depth of acupuncture**
  - 1.5~3cm
- **Needle used**

  diameter-0.25mm, length-40mm
- **Patient position :** face up
- **Deqi :** Deqi(78.3%), No Deqi(21.4%)
- **Enhancement and sedation :** applied(59.8%), not applied(39.7%)
- **Technique of enhancement and sedation :** nine-six, twisting, picking
- **duration:** 15- 20 min
- **stimulation :** not applied, electric acupuncture
- **Frequency of treatment:** 3times/1week

Review of Review Board

- The process of development and the draft of the guideline was reviewed and graded by the review board.

ACUPUNCTURAL CLINICAL GUIDELINE FOR NECK PAIN



Acupunctural Clinical Guideline for Knee Pain

Ⅰ. Outlines of Clinical Guideline

- Objective
- Back round
- International and Domestic Clinical Guidelines on neck pain
- Limitations
- Subjects of survey and level of evidence
- Making of clinical guideline (developers, process, verification, Funding)

Ⅱ. Introduction and diagnosis of knee pain

- Definition of neck pain
- Diagnosis of neck pain
- Mobility rate and prevalence rate of neck pain
- Neck pain evaluation tool

Treatment based on OM Diagnosis

- **Pattern Identification**
- **Treatment Method**
- Sanitation of acupuncture
- Safety of acupuncture treatment

Treatment based on western Diagnosis

- (1) Cervical spondylosis
- (2) Cervical sprain and strain
- (3) Cervical disc diseases
- patient teaching and self management / non-pharmacol ogical management (exercise, massage, weight control, elec tric therapy) /invasive treatment/ acupuncture treatment
- Other neck pain - acupuncture treatment

Consensus process of guideline development

- Pattern identification of the Neck pain

Survey (2009.3.26-2009.4.14) on Oriental medicine doctors shows that the differentiation according to the theory meridians and collaterals are most used and the most frequently used meridians were the Small Intestine Meridian, Small Intestine Meridian and Bladder Meridian. Therefore the expert committee recommends its use.	**Evidience level : C(Consensus)**

Treatment

- Acupuncture treatment
  - Basic rules

1. Between patients, hands must be washed. 2. Always use sterilized needles. 3. Treatments must be administered in sterile areas. 4. Hands must be washed in case of contamination 5. Used needles must be quarantined.	Evidience level : C(Consensus)

  - Safety

An appropriate acupuncture treatment by an oriental medicine doctor can be recommended as a safe treatment.	Evidience level : A(Systematic Review)

Treatment methods

- Here were not enough objective ground reference about acupuncture treatment for neck pain, so the Oriental medicine doctors who are targets of this clinical guideline were researched for their actual condition and practice pattern (2009.11.23~2010.1.9) to create the guideline and reflect actual conditions to it. It is recommended that patient treatments should reflect actual treatments as below.

- Applicationsof acupuncture treatments based on real case scenarios as below are recommended.

1. Differentiation according to the theory meridians and collaterals is the most frequently used differentiation method of syndromes. 2. Cervical spine ROM, area of pain and description of the pain, information obtained by pulse feeling and palpitation, history of pain, the patients usual factor and etc., are main diagnosis standards. 3. Frequently used acupuncture methods, in order of high frequency, Saam-chimbeop - asihyeol(Asihyeol-chimbeop) - five Su points five points-chimbeop - DongQi-chimbeop - acupuncture based on anotomical structures. 4. Both the normal, and the ill side of the patient are mix treated. 5. The most frequent used needling depth is about 1.5-3cm, needle thickness 0.25mm, needle length 40mm and the prone position is the most frequent used position for acupuncutre treatment. 6. De-qi and tonification-purgation are frequently performed and most of the acupuncture treatment had a duration time of over 15 minutes- below 20 minutes. Most patients were treated 3 times a week, and the treatment period for acute neck pain was under 3 weeks, and for chronic neck pain (in pain for over 3 months) were over 3 weeks and under 5 weeks.	Evidience level : C(Consensus)

Verification of clinical guideline and education

Clinical study

- Clinical study to verify the draft of acupuncture clinical guideline for Neck pain

Present Status of Clinical Practice Guidelines including Acupuncture Therapy and Development of Acupuncture Clinical Practice Guideline in Japan

Hitoshi YAMASHITA, Takashi OTSUKI, Shoko MASUYAMA
Graduate School of Health Sciences, Morinomiya University of Medical Sciences
Osaka, Japan

In Japan, there are not many but some evidence-based clinical practice guidelines which include a description on acupuncture therapy in the field of so-called Modern Western Medicine. The reason for the recent inclusion of this therapy may be because more randomized controlled trials (RCTs) on acupuncture have been published in the last decade, and this therapy has become unignorable in the name of clinical evidence. Reviewing these guidelines which include a description on acupuncture, however, there seem to be self-contradiction and prejudice.

For example, a guideline for management of alopecia areata published by Japanese Dermatological Association (2010) underestimates acupuncture, contradicting its own definition of grade of recommendation. A clinical practice guideline of lateral epicondylitis of the elbow published by The Japanese Orthopaedic Association (2006) overestimates acupuncture, contradicting a conclusion of Cochrane Systematic Review (2011). A clinical practice guideline of fibromyalgia published by Japan College of Fibromyalgia Investigation (2011) overestimates acupuncture if we compared with recently published systematic reviews. A clinical practice guideline of chronic headache developed by a research group of Health Labour Sciences Research Grant (2005) estimates acupuncture for headache more than tension-type headache, which is opposite to Cochrane Systematic Review (2009). These facts confuse patients as well as physicians and acupuncturists. Therefore, domestic clinical practice guidelines should be consistent with international evidence-based guidelines, or reason of the different conclusion should be clearly stated.

Regarding clinical practice guideline of acupuncture, as far as we know, only relevant protocols exist and there has been no complete draft if we limit it to "evidence-based" guidelines. This may be because of the lack of sufficient RCT-based evidence showing (1) efficacy of acupuncture and (2) superiority/inferiority of each acupuncture technique. We will discuss the possibility and difficulty of this work.

Present Status of Clinical Practice Guidelines Including Acupuncture Therapy and Development of Acupuncture Clinical Practice Guideline in Japan

Yamashita H, Otsuki T, Masuyama S
Graduate School of Health Sciences
Morinomiya University of Medical Sciences
Osaka, Japan

JSAM

Inclusion of acupuncture in CPGs

- **Reason**: More randomized controlled trials (RCTs) on acupuncture have been published in the last decade. Therefore, CPGs cannot ignore acupuncture anymore regarding some medical conditions in the name of clinical evidence.

- **Problem**: Most of the CPGs do not seem to grade and recommend acupuncture appropriately.

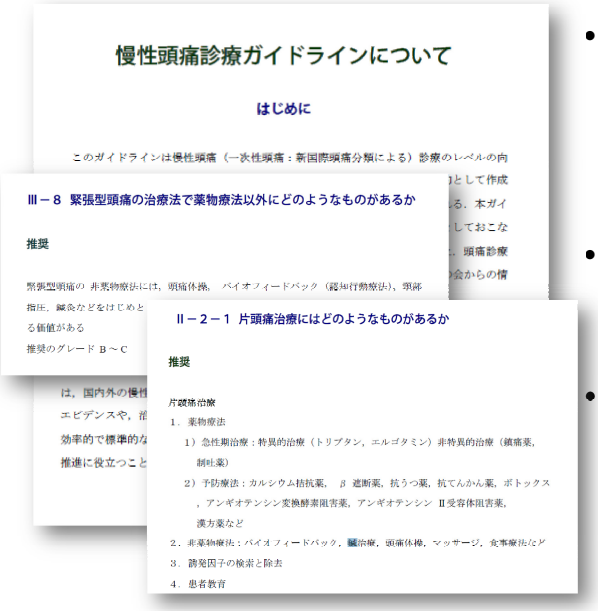
CPGs including acupuncture in Japan

CPG of acupuncture for cancer patients

Published By Tsukayama H. Research group (Chair: Shimoyama N) of Health Labour Sciences Research Grant (2010).

Symptom	Level of Evidence	Recomm-endation	Comments
Pain	1a	C	1a: SR of RCTs
Hiccup	5	C	C: no recommendation for or against
Diarrhea	5	C	
Vasomotor disorder	1b	B	B: recommend
Xerostomia	4	C	
Decreased physical strength	5	C	
Nausea or vomiting	1a	A	A: Strongly recommend
Urinary disturbance	5	C	5: expert opinion
Leukopenia	4	C	
Tiredness after chemotherapy	1b	A	1b: RCT
Anxiety	5	C	
Insomnia	3b	C	3b: case-control
Edema	5	C	
Abdominal fullness	5	C	
Constipation	5	C	
Numbness	5	C	
Acupuncture analgesia	4	C	4: case series

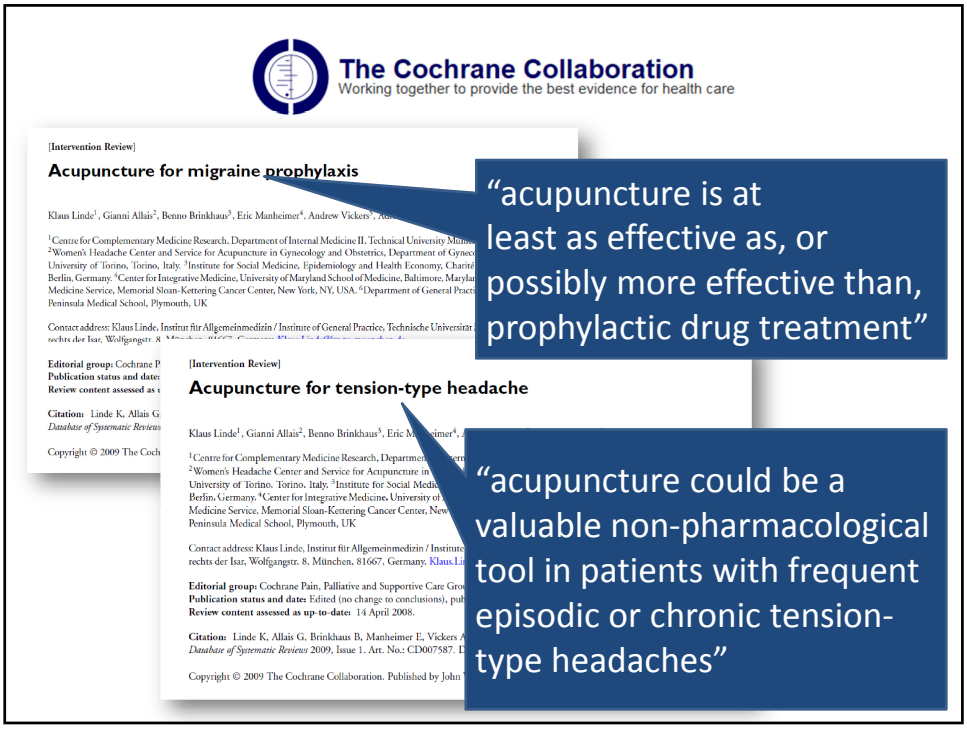
CPG for chronic headache

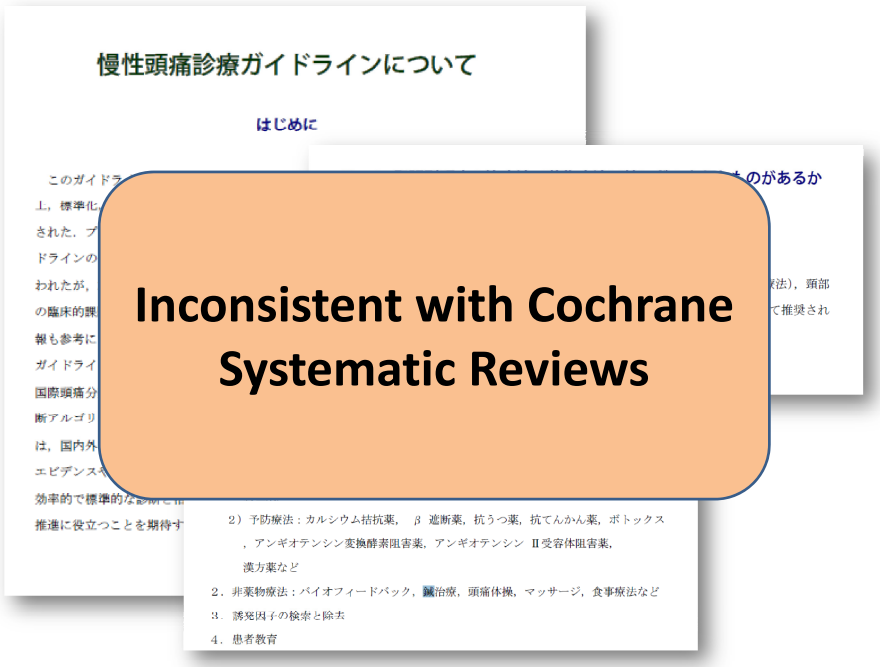


- Research group of Health Labour Sciences Research Grant (2005)
- Migraine
  - **Grade**: **A**

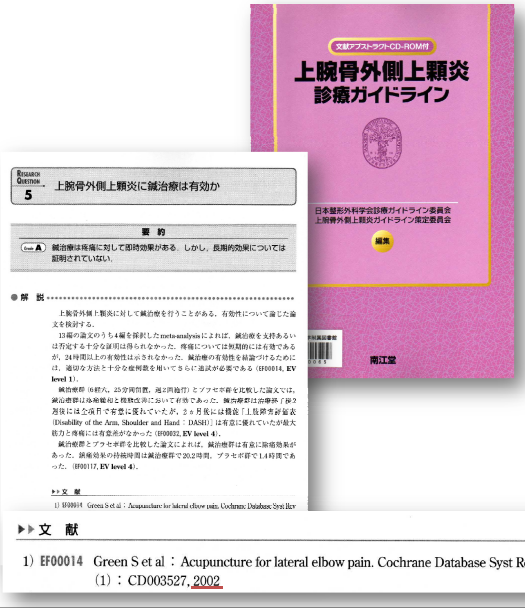
  (Strongly recommend)
- Tension-type headache
  - **Grade**: **C**

  (Uncertain evidence to recommend)



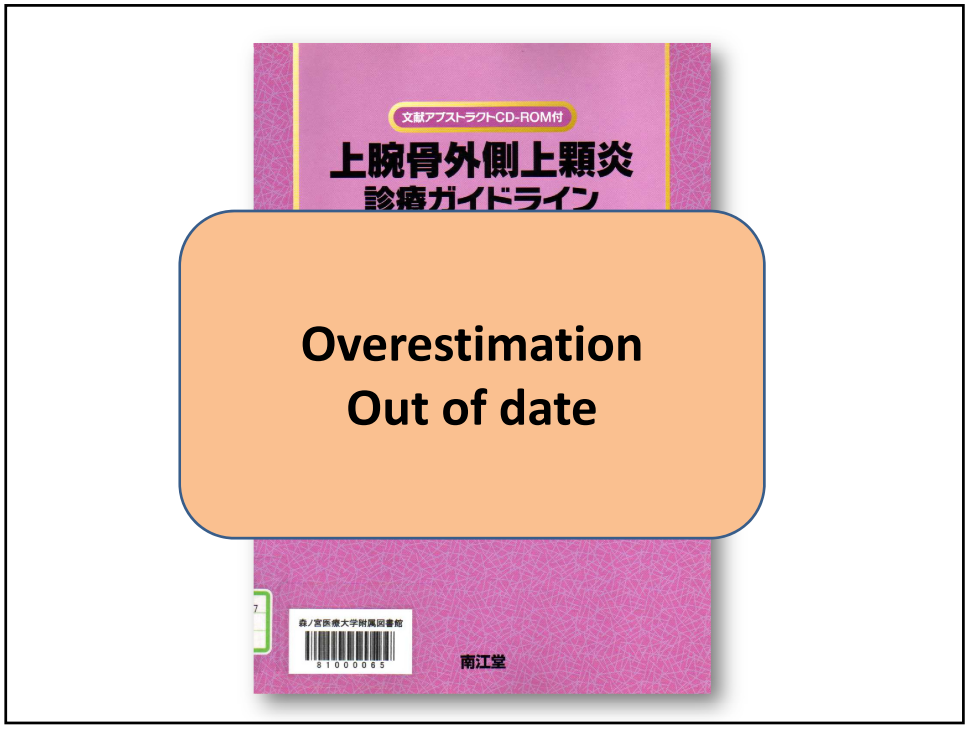


CPG for lateral epicondylitis of the elbow

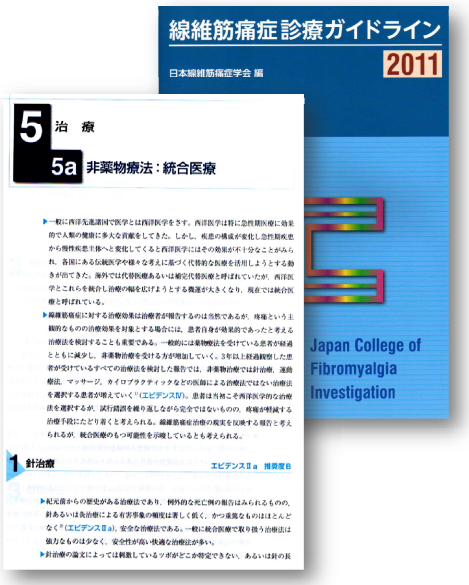


- The Japanese Orthopaedic Association (2006)
- **Grade**: **A**
  (strongly recommend)
  "Acupuncture has an immediate effect for pain, but long-term effect has not been proved"
- 1 Meta-analysis (Evd. level 1) and 2 RCTs (Evd. level 4)


The Cochrane Collaboration
Working together to provide the best evidence for health care
[Intervention Review]
Acupuncture for lateral elbow pain
Main results
Authors' conclusions
There is insufficient evidence to either support or refute the use of acupuncture (either needle or laser) in the treatment of lateral elbow pain. This review has demonstrated needle acupuncture to be of short term benefit with respect to pain, but this finding is based on the results of 2 small trials, the results of which were not able to be combined in meta-analysis. No benefit lasting more than 24 hours following treatment has been demonstrated. No trial assessed or commented on potential adverse effect. Further trials, utilising appropriate methods and adequate sample sizes, are needed before conclusions can be drawn regarding the effect of acupuncture on tennis elbow.
"insufficient evidence to either support or refute the use of acupuncture"


文献アブストラクトCD-ROM付
上腕骨外側上顆炎
診療ガイドライン
Overestimation
Out of date
南江堂

CPG for fibromyalgia



- Japan College of Fibromyalgia Investigation (2011)
- **Level of evidence**: Ⅱa
  (more than 1 RCT)
- **Recommendation**: B
  (Recommend)
- Referred to
  - 1 case-series study
  - Report of NIH Consensus Development Panel
  - 7 RCTs
  - 2 systematic reviews

Recent systematic reviews

Langhorst J, et al.

Efficacy of acupuncture in fibromyalgia syndrome--a systematic review with a meta-analysis of controlled clinical trials.

Rheumatology (Oxford)

2010; 49(4): 778-88.

CONCLUSION:
A small analgesic effect of acupuncture was present, which, however, was not clearly distinguishable from bias. Thus, **acupuncture cannot be recommended** for the management of FMS.

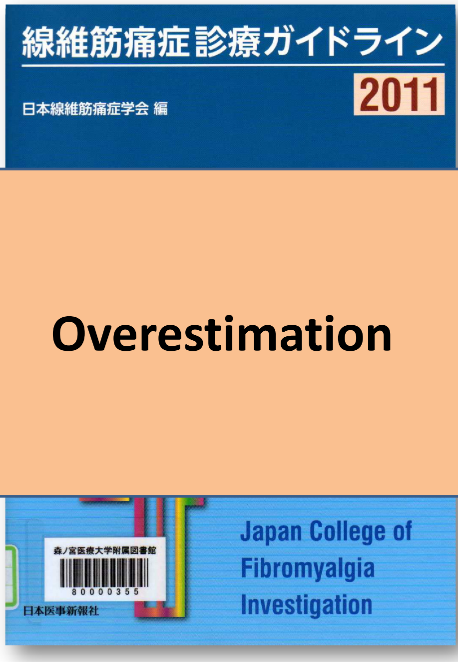
Martin-Sanchez E, et al.

Efficacy of acupuncture for the treatment of fibromyalgia: systematic review and meta-analysis of randomized trials.

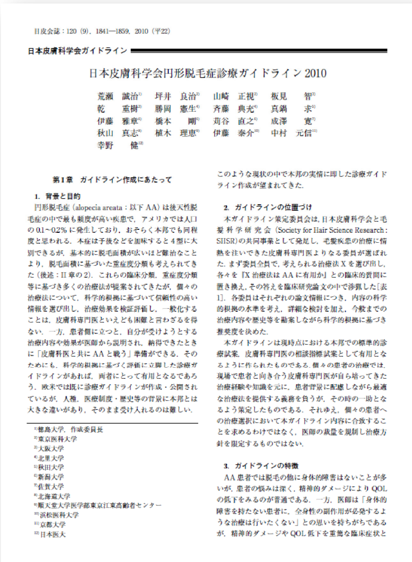
Open Rheumatol J

2009 Jun 16;3:25-9.

CONCLUSION:
This systematic review found **no evidence of benefit resulting from acupuncture versus placebo**, as a treatment for fibromyalgia.



CPG for management of alopecia areata



日皮会誌：120（9），1841—1859，2010（平22）

日本皮膚科学会ガイドライン

日本皮膚科学会円形脱毛症診療ガイドライン 2010

荒瀬 誠治[1] 坪井 良治[2] 山﨑 正視[2] 板見 智[3]
乾 重樹[3] 勝岡 憲生[4] 斉藤 典充[4] 真鍋 求[5]
伊藤 雅章[6] 橋本 剛[6] 荊谷 直之[6] 成澤 寛[7]
秋山 真志[8] 植木 理恵[9] 伊藤 泰介[10] 中村 元信[11]
幸野 健[12]

第1章 ガイドライン作成にあたって

1. 背景と目的

円形脱毛症（alopecia areata：以下 AA）は後天性脱毛症の中で最も頻度が高い疾患で，アメリカでは人口の 0.1～0.2% に発生しており，おそらく本邦でも同程度と思われる．本症は予後などを加味すると4型に大別できるが，基本的に脱毛面積が広いほど難治なことより，脱毛面積に基づいた重症度分類も考えられてきた（後述：II 章の 2）．これらの臨床分類，重症度分類等に基づき多くの治療法が提案されてきたが，個々の治療法について，科学的根拠に基づいて信頼性の高い…

このような現状の中で本邦の実情に即した診療ガイドライン作成が望まれてきた．

2. ガイドラインの位置づけ

本ガイドライン策定委員会は，日本皮膚科学会と毛髪科学研究会（Society for Hair Science Research：SHSR）の共同事業として発足し，毛髪疾患の治療に情熱を注いできた皮膚科専門医よりなる委員が選ばれた．まず委員全員で，考えられる治療法 X を選び出し，各々を『X 治療法は AA に有用か』との臨床的質問に置き換え，その答えを臨床研究論文の中で渉猟した[表1]．各委員はそれぞれの論文情報につき，内容の科学…

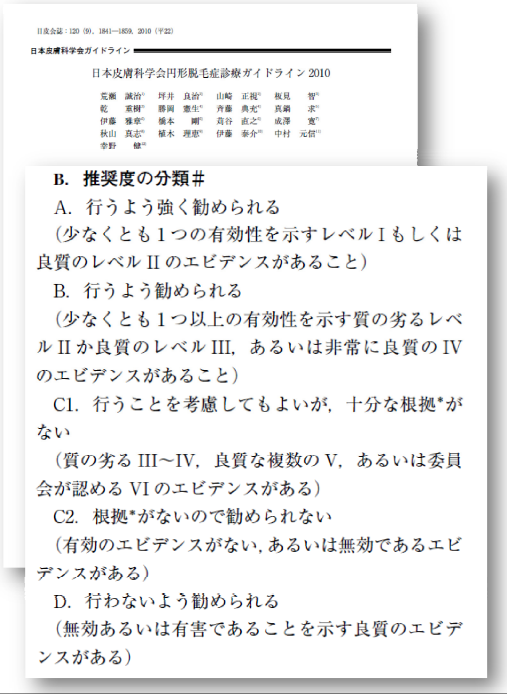
- Japanese Dermatological Association (2010)
- Recommendation grade: **D**
- “**Should not use**”

CQ20 鍼灸治療は有益か

推奨度：D

推奨文：行うべきではない．

解説：鍼灸治療の発毛効果に関して，1 編の症例集積研究と 4 編の症例報告がある．まず罹患期間，1 年未満 14 名，1 年以上 2 年未満 18 名，2 年以上 3 名の多発型および全頭型 35 例に，鍼治療を行い 50% の領域で毛髪が回復したもの 9 例，10% の領域で毛髪が回復したもの 16 例であったが，脱毛巣の個数や脱毛範囲，鍼灸施行間隔や施行回数も不明である[1]．他にも同様の治療を実施した症例報告があるが[2〜5]，いずれも病状や経過の記載が不十分で，医学的な評価をする水準に達していない．


日皮会誌：120（9），1841—1859，2010（平22）

日本皮膚科学会ガイドライン

日本皮膚科学会円形脱毛症診療ガイドライン 2010

B. 推奨度の分類＃

A. 行うよう強く勧められる
（少なくとも1つの有効性を示すレベルIもしくは良質のレベルIIのエビデンスがあること）

B. 行うよう勧められる
（少なくとも1つ以上の有効性を示す質の劣るレベルIIか良質のレベルIII，あるいは非常に良質のIVのエビデンスがあること）

C1. 行うことを考慮してもよいが，十分な根拠*がない
（質の劣るIII～IV，良質な複数のV，あるいは委員会が認めるVIのエビデンスがある）

C2. 根拠*がないので勧められない
（有効のエビデンスがない，あるいは無効であるエビデンスがある）

D. 行わないよう勧められる
（無効あるいは有害であることを示す良質のエビデンスがある）

A: Strongly recommend

B: Recommend

C1: Can consider but insufficient evidence

C2: Cannot recommend
(There is no evidence of efficacy or evidence of ineffectiveness)

D: Recommend NOT to use (There is **good-quality evidence of ineffectiveness or harm**)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日本皮膚科学会ガイドライン

日本皮膚科学会円形脱毛症診療ガイドライン 2010

Self-contradiction

Inappropriate Grading and recommendation of acupuncture

- **Problems**: Inconsistency with other systematic reviews, Self-contradiction, over-/under-estimation, out-of-date reference data, etc.
- **Possible Cause**: Prejudice, ignorance, reluctance, or conflict of interest.
- **Influence**: Incorrect information on acupuncture spreads in the medical community, and results in disadvantage for patients.
- **Countermeasures**: (1) More consciousness of responsibility of developing CPGs; (2) Thorough systematic literature search and fair judgment; and (3) Inclusion of an expert in acupuncture within each CPG working group (if possible option in a certain condition) .

Possibility of acupuncture CPG

Guideline for whom?

- Physicians (Western Med.) who instruct patients
  - Guideline for [Disease/Symptom management]
  - Possible if evidence of each therapy exists
- Patients who seek for effective therapy
  - Guideline for [Disease/Symptom management]
  - Possible if evidence exists
- Therapists or doctors who practice acupuncture
  - Guideline of [acupuncture method/technique]?
  - Difficult because of wide variety of methods
  - Need for comparison of each acup. method

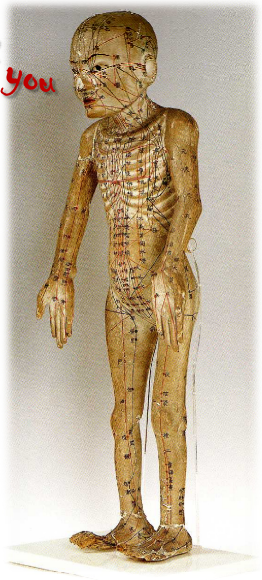
Acupuncture CPG as an extension to CPG for medical conditions

Example: Treatment of **chronic low back pain**

Treatment Option	Level of Evid.	Benefit	Grade	Extension	
Exercise	good	moderate	B	Q: What kind of exercise?	
Medication	good	moderate	B	Q: What kind of drug?	
Spinal manipulation	good	moderate	B	Q: What kind of manipulation technique?	
Acupuncture	fair	moderate	B	Q: What kind of acupuncture technique?	
Back schools	fair	small	C	No need	Grade C: no recommendation
Traction	fair	no benefit	D	No need	Grade D: recommend against

(Ref. Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society, 2007)

Thank you



はりきゅうミュージアム Museum of Traditional Medicine

Hitoshi Yamashita
Graduate School of Health Sciences
Morinomiya University of Medical Sciences
1-26-16 Nanko-Kita, Suminoe-Ku
Osaka, 559-8611, Japan

Acupoint Mannequin in *Edo* era. Collection of our Museum (www.harikyumuseum.com).

Acupunctural Clinical Guideline for Knee Pain

Dongguk University
Kim Eun Jung

Background

Knee Pain

- Knee OA(osteoarthritis)
  - 6 th cause of living with disability
  - 9.6% of men and 18.0% of women aged ≥60 years have symptomatic osteoarthritis
- Knee soft tissue injury
  - Participation in sport and recreation has been widely encouraged for all age groups for the substantial public health benefits.
  - Knee joint is subject to extremely high forces during sport and some occupational activities and its supporting soft tissue are therefore vulnerable to injury.
  - result in significant on-going disability at considerable cost both to the individual in terms of quality of life, and to society as a whole.

Acupuncture

- Many people with knee pain seek out complementary and alternative medicine (CAM) therapies.
- 41%of a nationally representative sample of people with arthritis have used a CAM therapy in the past year.

In Korea

- At the present, the percentage of patients making up the top ten most-frequently visited out-patient list at an oriental medical hospital are those with musculoskeletal pain: low back pain, neck, and knee pain.

The Necessity of Clinical Guideline

- Many of the oriental medical doctors are relying primarily on their personal experiences and skills
  - very unsystematic and unstandardized diagnostic and treatment process
  - leading to a wide variation in treatment modalities and effectiveness
- It is crucial to develop an acupunctural clinical guideline
  - through extensive literature research, questionnaires, and discussion among experts for musculoskeletal disorders/diseases

Purpose & Scope

The purpose

- To formulate an appropriate acupunctural clinical guideline based on domestic and international evidence and domestic specialists'opinions for knee pain
- And recommend to Korean medical field which would provide high quality care and treatment to knee pain patients and further increase public health.

Scope

- knee pain includes
  - Western medicine diagnosis of disorders such as **knee osteoarthritis, rheumatoid arthritis, and soft tissue knee injuries**.
  - excludes
    - significant, yet rare cases of fracture, dislocation, tumor, infection, inflammatory arthropathies, osteonecrosis, congenital musculoskeletal deformities, crushing injury of lower leg, frostbite with tissue necrosis, complications of internal orthopedic prosthetic devices, implants, and grafts. Furthermore, conditions characterized by pain referred from other structures (e.g. hip), such as neuropathic pain, are excluded.
- focuses on patients of 18 and over
- The aim of the guideline is to recommend a clinical diagnostic guideline which would provide high quality care and treatments to patients with knee pain

Funding

- This Clinical Guideline was developed as part of a supporting project to promote Oriental Medical Technology (B080017) funded by the Korean Ministry of Health & Welfare.
- Development Period : 2008.07.01-2010.06.30 (Clinical research to verify the effectiveness of the presented guidance are in progress and further complementary measures have been set up.)

Process

Difficulties of OM Clinical Guideline Development

Different Scientific Approach of OM
Lack of Well-Designed RCTs
Various Diagnosis Systems of OM
Various Treatment Methods of OM

Lack of Well-Designed RCTs

Efforts to search domestic and international studies/
Level of recommendation was adjusted

Various Diagnosis Systems of OM

Survey on pattern identification, diagnosis system,
Delphi committee of specialists, pre-clinical study on patients.

Various Treatment Methods of OM

Survey of OM Clinicians.

1. Training of acupunctural clinical guidance

- On-board training of acupunctural clinical guidance development group and establishment of a research plan
  - Since the acupuncture clinical guideline development group lacked sufficient knowledge on basic understanding of and methods used to establish a guideline, several workshops were arranged and an expert in the field was called in to explain the strategies, methods, and developmental know-hows

2. Composition of the professional Acupunctural clinical guidance development group and the review board

3. Literature research

Traditional and Recent Texts of OM

- In order to establish standards of OM diagnosis and treatment

Search of Scientific Studies

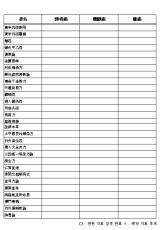
- In order to establish evidence for acupuncture efficacy

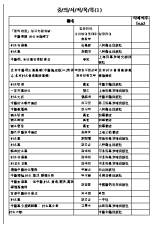
Related Clinical Guidelines

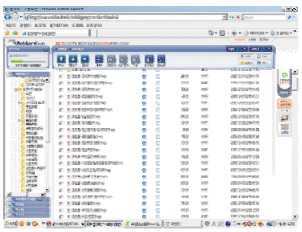
Assessment of Evidence Level

3-1. Traditional and Recent Texts of OM

- List of Traditional and Recent Texts to be reviewed(112)
- Search and Review
- Data Sharing Through Web Services







3-2. Search of Scientific Studies

- For knee pain, key words such as knee, knee pain, osteoarthritis, rheumatoid arthritis, gout, soft tissue injury, patella were used.
- Korean research papers were obtained from
  - OASIS-(http://oasis.kiom.re.kr/)
  - The Journal of Korean Acupuncture and Moxibustion Society (http://www.acumoxa.or.kr/)
  - The Journal of Korean Oriental Medical Society (http://www.koms.or. kr/)
  - The Journal of Korean Academy of Oriental Rehabilitation Medicine (http://www.ormkorea.org/).
- Foreign research papers were searched through
  - pubmed(http://www.ncbi.nlm.nih.gov/pubmed/), and after going through rigorous elimination processes, a total of 59 related papers were obtained.

3-3. Related Clinical Guidelines

3-4. Assessment of Evidence Level

- it was hard to apply the level of evidence grading systems used in western medicine.
- So, the following grading systems were adopted

Complementary and alternative medicines grading system suggested by NZGG(New Zealand Guidelines Group) in 2006.

TABLE 1: LEVELS OF EVIDENCE USED IN THE TBI GUIDELINE

LEVEL OF EVIDENCE		WHERE THE EVIDENCE COMES FROM
1	Evidence with a high degree of reliability	Studies that use well tested methods to make comparisons in a fair way and where the results leave very little room for uncertainty. Trial design: usually Level 1 studies are systematic reviews or large, high-quality randomised controlled studies.
2	Evidence with reliability but open to debate	Studies that use well tested methods to make comparisons in a fair way but where the results leave room for uncertainty (for example, due to the size of the study, losses to follow-up or the method used for selecting groups for comparison). Trial design: usually Level 2 studies are systematic reviews without consistent findings, small randomised controlled trials, randomised controlled trials in which large numbers of participants are lost to follow-up, or cohort studies.
3	Some evidence without a high degree of reliability	Studies where the results are doubtful because the study design does not guarantee that fair comparisons can be made. Trial design: usually Level 3 studies are systematic reviews of case-control studies or individual case-control studies.
4	Some evidence but based on studies without comparable groups	Studies where there is a high probability that results are due to chance (for example because there is no comparison group or because the groups compared were different at the outset of the study). Trial design: usually cohort or case-control studies where the groups were not really comparable, or case-series studies.

- Another grading system was suggested by Brosseau L. in the study, 'Clinical practice guidelines for acupuncture'.

Brosseau L, Wells GA, Finestone HM, Egan M, Dubouloz CJ, Graham I, Casimiro L, Robinson VA, Bilodeau M, McGowan J. Clinical practice guidelines for acupuncture. Top Stroke Rehabil 2006 Spring ; 13(2) : 65-7.

Table. Brosseau L.'s Level of evidence Clinical practice guidelines for acupuncture

Level of Evidence	Classification of Level of Evidence
I	Randomized controlled trials
II	Nonrandomized studies

- Strength of recommendation
  - Strength of recommendation was presented as done in the study by Brosseau L, 'Clinical practice guidelines for acupuncture'.

Table. Strength of recommendation suggested in Clinical practice guidelines for acupuncture by Brosseau L

Strength of Recommendation	Level of Evidence
A	Evidence from one or more randomized controlled trials (RCTs) of a statistically significant, clinically important benefit
B	Statistically significant, clinically important benefit, if the evidence was from observational studies or controlled clinical trials (CCTs)
C+	Evidence of clinical importance but not statistical significance
C	Interventions where an appropriate outcome was measured in a study that met the inclusion criteria, but no clinically important difference and no statistical significance were shown Consensus of experts*(Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.)
D+	Evidence from one or more randomized controlled trials of a statistically significant benefit favoring the control group
D	Evidence of clinical importance without statistical significance
D-	Evidence from one or more randomized controlled trials of a clinically important benefit that was statistically significant, where the number of participants in the study is equal to or higher than 100

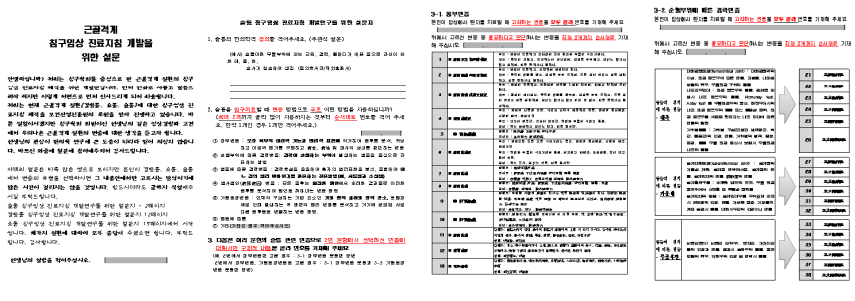
*recommendations of AHCPR(Agency for Healthcare policy and research) were taken into reference.

4. Diagnosis

- **Pattern identification**
  - Literature Review and survey
- **Diagnosis system**
  - Literature Review and survey / Delphi committee

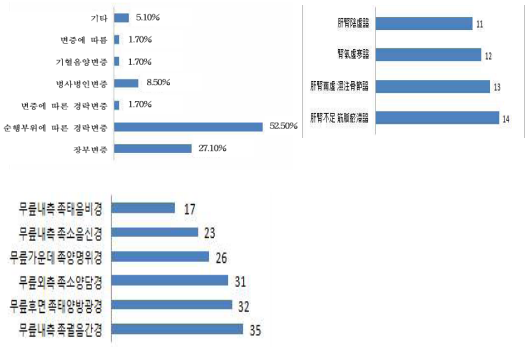
Survey – Pattern identification

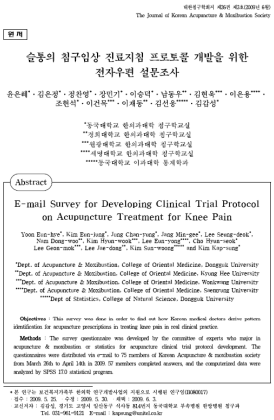
- Find out which pattern identification methods are widely applied in clinical practice.
- Date : 2009.3.26 -2009.4.29
- Subjects : 75 members of Korean Society of Acupuncture and Moxibustion



Knee Pain

- Meridian pattern identification was the most popular OM diagnosis system. (Liver)





슬통의 침구임상 진료지침 프로토콜 개발을 위한 전자우편 설문조사

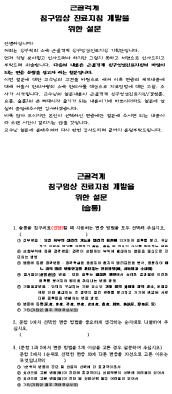
Abstract

E-mail Survey for Developing Clinical Trial Protocol on Acupuncture Treatment for Knee Pain

Survey – Pattern identification 2

- Subjects : Professors of OM college, Department of Acupuncture & Moxibustion
- Contents
  - Reason for pattern selection
  - Standard of pattern identification
  - Patterns that should be considered
- Date : 2009. 5 ~ 2009. 8

The answers for knee pain was low in consistency.
So, for knee pain and cervical pain, OM diagnosis system was adopted



근골격계
침구임상 진료지침 개발을
위한 설문

근골격계
침구임상 진료지침 개발을
위한 설문
(슬통)

Consensus of Specialists on OM Diagnosis System

- Based on results of literature review Delphi committee was held.
- Main symptoms were selected as standards of diagnosis.

Recommendation of OM Diagnosis of knee pain

- ① knee injury(膝傷) ② crane's-knee wind(鶴膝風)
- ③ arthralgia syndrome(痹症)
- ④ Youk Jeol Poung(歷節風) ⑤ gout arthritis(痛風)

Clinical study for development of a diganostic tool

Objective

- **To test the established draft of diagnosis system in clinical practice and obtain b ases for modification.**

Institutes

- Knee pain – Dongguk university, Semyeong university

Date

- 2010.3-2010.5

Method

- Standard study guideline for researchers was established
- Patients were surveyed and the diagnosis results were analyzed

(1) Parametric Methods

① Linear Discriminant Analysis (LDA, Fisher, 1936) /Quadratic Discriminant Analysis (QDA)

② Diagonal Linear Discriminant Analysis (DLDA) / Diagonal Quadratic Discriminant Analysis (DQDA) (Dudoit et al, 2002)

(2) Nonparametric Methods

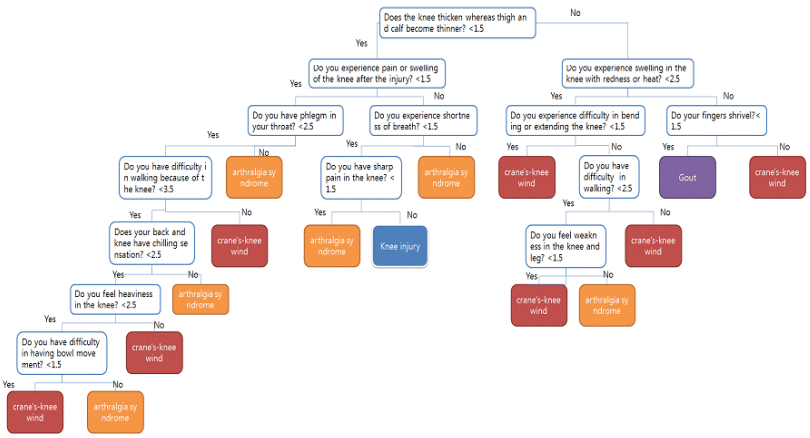
① Support Vector Machines (SVM, Vapnik, 1995)

② K-Nearest Neighbor Classification (KNN)

③ Chi-squared Automatic Interaction Detector (CHAID)

④ Classification And Regression Trees (CART, Breiman, 1984)

Classification And Regression Trees



5. Treatment

- **Acupuncture Treatment Methods**
  - Treatment according to OM diagnosis
    - Literature Review and survey
  - Treatment according to western diagnosis
    - Literature Review / Level of evidence and recommendation assessed

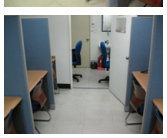
Survey

Phone survey

- Random sampling for visited survey

Visited Survey

- **objectives : In order to gather opinions of OM doctors and modify the guidelin e draft to meet the clinical needs.**
- **Date :** 2009.11.23~2010.01.09
- **Subjects** : 288 OM doctors with more than 5 years of clinical experience.



- 조사모집단: 서울 지역 한의사 5년 이상 경력자 2906명
- 표본조사 대상: 288명
- 표본추출틀: 서울시 한의사협회 회원 명부
- 목표오차: ±4.3% 포인트
- 표본추출: 서울 지역 한의사들을 25개 구로 층화하여 각 층별로 한의사들을 임의추출 (stratified random sampling)
- 층별표본할당: 각 층별 한의사 수에 비례하도록 각 층별 조사 대상 한의사 결정 (proportional allocation)
- 표본설계에 따른 모수(모비율) 추정 방법

추정치: $\hat{p}=\sum_{i=1}^{L} W_i \hat{p}_i$ W_i는 각 층별 가중치

추정분산: $\hat{V}(\hat{p})=\sum_{i=1}^{L} W_i^2(1-f_i)\hat{p}_i\hat{q}_i/(n-1)$, f_i는 각 층별 표본추출률

오차 범위: $\varepsilon_{\alpha/2}\sqrt{\hat{V}(\hat{p})}$

- **Diagnosis**
  - Area of pain, pain character, history taking, Swelling and malformation of knee, color, ROM, heat and cold sensation, the cause of pain reduction and increase, tender point
- **Acupuncture**
  - Sa-Am - Ashi - anatomical – five shu point
- **Point selection**
  - Local point, Local and distant together, and distant.
- **Depth of acupuncture**
  - 1.5~3cm
- **Needle used**

  diameter-0.25mm, length-40mm
- **Patient position :** face up
- **Deqi :** Deqi(78.3%), No Deqi(21.4%)
- **Enhancement and sedation :** applied(59.8%), not applied(39.7%)
- **Technique of enhancement and sedation :** nine-six, twisting, picking
- **duration:** 15- 20 min
- **stimulation :** not applied, electric acupuncture
- **Frequency of treatment:** 3times/1week

Review of Review Board

- The process of development and the draft of the guideline was reviewed and graded by the review board.

Acupunctural Clinical Guideline for Knee Pain

Acupunctural Clinical Guideline for Knee Pain

Ⅰ. Outlines of Clinical Guideline

- Objective
- Back round
- International and Domestic Clinical Guidelines on Knee pain
- Limitations
- Subjects of survey and level of evidence
- Making of clinical guideline (developers, process, verification, Funding)

Ⅱ. Introduction and diagnosis of knee pain

- Definition of knee pain
- Diagnosis of knee pain
- Mobility rate and prevalence rate of knee pain
- Knee pain evaluation tool

Treatment based on OM Diagnosis

- **Pattern Identification**
- **Treatment Method**
- Sanitation of acupuncture
- Safety of acupuncture treatment

Treatment based on western Diagnosis

- Knee Osteoarthritis - patient teaching and self management / non-pharmacological management (exercise, massage, weight control, electric therapy) /invasive treatment/ OA which needs operation / acupuncture treatment
- Rhuematoid arthritis - - patient teaching and self management / non-pharmacological management (exercise, massage, weight control, electric therapy) /invasive treatment / acupuncture treatment
- Soft tissue injuries - RICE / non-pharmacological management / surgical treatment and non-surgical treatments / acupuncture treatment
- Other knee pain - acupuncture treatment

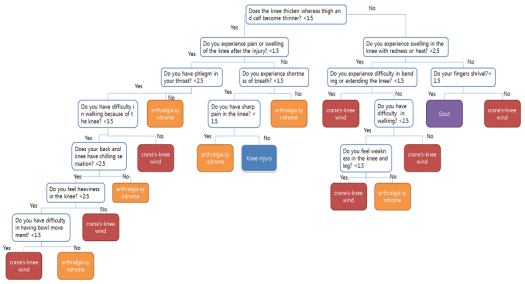
Consensus process of guideline development

Diagnosis - Knee pain

- Diagnosis system and diagnostic method of knee pain
  - As a result of discussion in specialists association via Delphi method, a definitive diagnostic system regarding knee pain is recommended as following.

① knee injury(膝傷) ② crane's-knee wind(鶴膝風) ③ arthralgia syndrome(痹症) ④ Youk Jeol Poung(歷節風) ⑤ gout arthritis(痛風)	evidence level : C(Consensus)

- A survey consisted of 46 knee pain-related symptoms was taken by 109 knee pain patients. Each patient was consulted by three oriental medicine doctors regarding the five symptoms with Classification and Regression Tree (CART, Breiman, 1984) method and diagnostic method of knee pain are recommended as follows



- Pattern identification of the knee pain

According to a survey gathered from Korean oriental medicine doctors (2009, 3, 26-2009, 4, 14), Specialist Association recommends utilization of liver Meridian of Foot Gworeum and Spleen Meridian of Foot Taeeum due to the fact that pattern identification according to meridians and collaterals methodology is most frequently used.	evidence level : C (Consensus)

Western medicine diagnosis of knee pain

- (1) Knee osteoarthritis
- (2) Rheumatoid arthritis
- (3) Soft tissue knee injuries

Treatment

- Acupuncture treatment
  - Basic rules

1. Between patients, hands must be washed. 2. Always use sterilized needles. 3. Treatments must be administered in sterile areas. 4. Hands must be washed in case of contamination 5. Used needles must be quarantined.	evidence level : C(Consensus)

  - Safety

An appropriate acupuncture treatment by an oriental medicine doctor can be recommended as a safe treatment.	evidence level : A(Systematic Review)

- Treatment methods
  - Due to the lack of objective evidence on acupuncture treatment for knee pain, actual and current state of medical treatments were comprehended by aiming oriental medicine doctors (2009, 11, 23~2010 1, 9). Such effort would reflect the development and current state of the guideline.
  - Applicationsof acupuncture treatments based on real case scenarios as below are recommended.

1. In case of deterioration, pattern identification according to meridians and collaterals is most commonly utilized. 2. Most important diagnostic standards include patient's complaints such as description of pain and its location, as well asmedical history. Also, swelling and degree of change of the knee joint, color change, ROM of the knee, patient's sensation on heat and cold, improvement and exacerbation factors of pain, pulse feeling and palpitation, information according to one of the four methods of diagnosis, and patient's normal factors are heavily considered. 3. Frequently used acupuncture techniques include Sa-am chipbeop, Ashi point, acupuncture technique based on anatomical structures (muscle, ligament, joint cavity) and five Su points. 4. Both the normal, and the ill side of the patient are mix treated. 5. Depth of needling should be 5 pun to 1 chon; thickness of the needle should be 0.25mm; and length of the needle should be 40mm. In case of the patient's position, laying down position looking at a ceiling is most commonly used. 6. De-qi and purgation were most frequently used, and for the retaining time, 15 to 20 minutes were frequently utilized. 7. In case of treatment cycle, 3 times per week were utilized most frequently. Treatment periods for acute and chronic (over 3 months) knee pain were applied for less than three weeks and three weeks to five weeks, respectively.	evidence level : C(Consensus)

- Treatments based on Western medicine diagnosis
  - Acupuncture treatment of knee osteoarthritis

Electro-acupuncture, traditional acupuncture, and other acupuncture treatments are recommended as effective and safe treatments.	evidence level : A (Systemaitc Review, RCT)

  - Acupuncture treatment of Rhuematoid arthritis

Electro-acupuncture treatments for Rhuematoid arthritis are recommended as effective. However, the quality & amount of the studies is limited and further research is highly recommended.	evidence level : A (RCT)

  - Acupuncture treatment of soft tissue injuries

Traditional acupuncture and electro-acupuncture treatments for knee soft tissue injuries are recommended as effective. However, the quality of the studies is limited to case studies and further research is highly recommended.	evidence level : C(Case study)

  - Other knee pain that is difficult to determine
    - Further research on effects of acupuncture post-total knee replacement operation is recommended due to mixed results

Acupuncture treatments for patellofemoral pain syndrome patients are recommended as effective; however, further research is required due to lack of number of studies.	evidence level : A(RCT)

Verification of clinical guideline and education

Clinical study

- Clinical study to verify the draft of acupuncture clinical guideline for Knee pain


감/사/합/니/다
야경

Tentative Development of Evidence-Based Clinical Practice Guideline of Acupuncture Technique for Chronic Low Back Pain in Japan

Takashi OTSUKI, Shoko MASUYAMA, Hitoshi YAMASHITA
Graduate School of Health Sciences, Morinomiya University of Medical Sciences
Osaka, Japan

We tentatively developed an evidence-based clinical practice guideline of acupuncture technique by comparing different acupuncture treatment methods, using published results of randomized controlled trials (RCTs). In this task, we had to start from the premise that acupuncture is effective for a condition for which the guideline is developed. Therefore we chose chronic low back pain, for which acupuncture is already concluded to be "more effective for pain relief and functional improvement than no treatment or sham treatment" in *Cochrane Database of Systematic Reviews* (2005).

First we searched for the relevant RCT papers with using PubMed and Ichushi (*Japana Centra Revuo Medicina*) Web, and then we also conducted hand-searching of the relevant literature of our own files. We included only RCTs comparing different style of acupuncture for chronic low back pain lasting for more than 12 weeks. According to a common idea of Japanese acupuncture, we regarded "sham acupuncture" group as "superficial acupuncture stimulation" group or "shallow needling" group, and included RCTs using such control groups. We excluded RCTs which compared acupuncture with treatment other than needle acupuncture such as pharmaceutical drug, injection, physical therapy, transcutaneous electrical nerve stimulation, manual therapy and laser acupuncture. We also excluded RCTs for low back pain in pregnancy, and those on auricular acupuncture. As for duplicate publications and parallel publications, full paper or detailed report was prioritized.

As a result, 21 RCT papers were located. Of these, 13 RCTs were conducted in Japan. Using these 21 RCT results, we could set eight clinical questions: shallow vs. deep needling, short-term vs. long-term treatment, insertion vs. non-insertion, acupoints vs. trigger points, tender vs. trigger points, local vs. remote point location, individualized vs. standardized treatment, and manual needling vs. electroacupuncture. For these questions, we could prepare tentative answers with showing level of evidence.

This prototype guideline is insufficient and has several problems in some aspects. We hope to have a deep discussion in the present workshop.

Tentative Development of Evidence-Based Clinical Practice Guideline of Acupuncture Technique for Chronic Low Back Pain in Japan

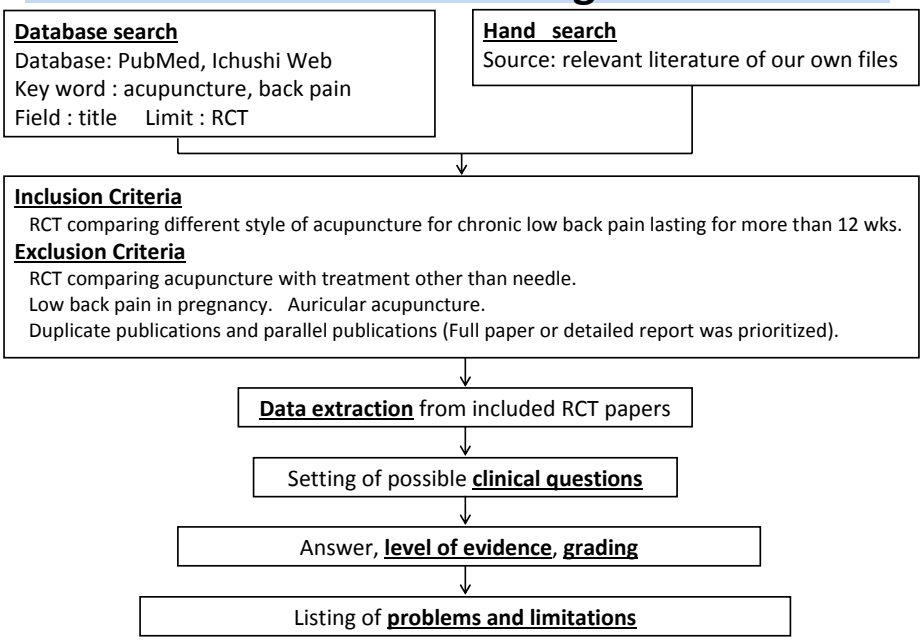
Takashi OTSUKI, Shoko MASUYAMA, Hitoshi YAMASHITA

Graduate School of Health Sciences, Morinomiya University of Medical Sciences, Osaka, Japan

Objective

To find problems in developing a clinical practice guideline (CPG) of acupuncture, we tentatively developed a guideline of acupuncture technique as an extension to an evidence-based CPG for chronic low back pain.

Process Flow Diagram



Level of Evidence

Level	Definition
1	Systematic review or Meta-analysis of RCT with a sample of 100 subjects or more
2	RCT with a sample of 100 subjects or more
3	Systematic review or Meta-analysis of RCT with a sample of less than 100 subjects
4	RCT with a sample of less than 100 subjects
5	Controlled clinical trial (CCT) or Cohort study
6	Case-control study
7	Case series
8	Case report

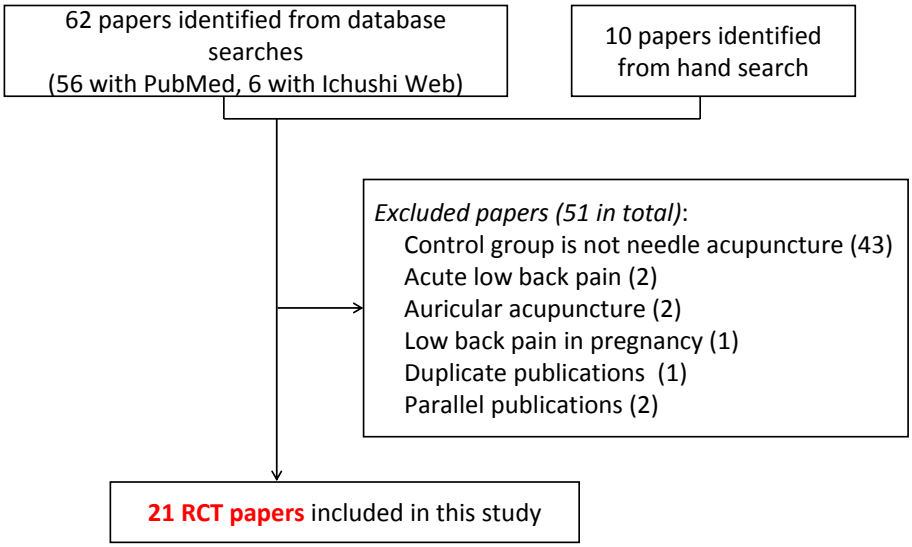
Levels 5-8 do not apply in the present study

Strength of recommendation

Grade	Definition	Supplemental explanation
A	Strong evidence to support a recommendation for use	There are more than one piece of strong evidence (level 1-4).
B	Moderate evidence to support a recommendation for use	There is one piece of strong evidence (level 1-4), or more than one piece of moderate evidence (level 5-6).
C	Poor evidence to consider a recommendation for use	There is at least one piece of moderate evidence (level 5-6).
D	Evidence to support a recommendation against use	There is no positive evidence, or at least one piece of moderate evidence (level 5-6) .
I	Insufficient evidence to recommend for or against use	Evidence is lacking or conflicting.

Grade C, D do not apply in the present study

Result: literature search



No.	Title	First author (Publication Year)
1	A randomized trial comparing acupuncture, simulated acupuncture, and usual care for chronic low back pain.	Cherkin DC (2009)
2	Different frequencies of acupuncture treatment for chronic low back pain: an assessor-blinded pilot randomised controlled trial.	Yuan J (2009)
3	German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups.	Haake M (2007)
4	Relief of low back pain immediately after acupuncture treatment--a randomised, placebo controlled trial.	Inoue M (2006)
5	Effects of trigger point acupuncture on chronic low back pain in elderly patients--a sham-controlled randomised trial.	Itoh K (2006)
6	Acupuncture in patients with chronic low back pain: a randomized controlled trial.	Brinkhaus B (2006)
7	Trigger point acupuncture treatment of chronic low back pain in elderly patients--a blinded RCT.	Itoh K (2004)
8	Correlation between the number of sessions and therapeutical effect in patients suffering from low back pain treated with acupuncture: a randomized controlled blind study.	Ceccherelli F (2003)
9	Does acupuncture improve the orthopedic management of chronic low back pain--a randomized, blinded, controlled trial with 3 months follow up.	Molsberger AF (2002)
10	Acupuncture treatment of chronic low-back pain -- a randomized, blinded, placebo-controlled trial with 9-month follow-up.	Leibing E (2002)
11	Acupuncture for Chronic Low Back Pain : A Randomized Placebo-Controlled Study With Long-Term Follow-Up	Carlsson CP (2001)
12	腰痛に対する腰部への鍼の刺入深度の違いによる治療効果の相違　ランダム化比較試験	藤本幸子 (2011)
13	ランダム化比較試験を用いた高齢者の慢性腰痛に対するトリガーポイント鍼治療の有用性の検討	伊藤里子 (2009)
14	高齢者の慢性腰痛患者に対するトリガーポイント鍼治療の試み 同一筋上に存在するトリガーポイントと圧痛点の刺激効果の違いについて	廣田里子 (2006)
15	腰痛に対する鍼治療　偽鍼を対照群に用いた多施設ランダム化比較試験	河瀬美之 (2006)
16	鍼灸とリハビリテーション　高齢者の慢性腰痛に対する阿是穴鍼療法	勝見泰和 (2004)
17	スポーツに起因した慢性腰痛に対する鍼治療の効果ートリガーポイント治療の有用性に関する検討—	寺澤宏美 (2006)
18	慢性腰痛患者を対象としたトリガーポイント治療と圧痛点治療の比較対象試験－高齢者9例に対する予備調査—	廣田里子 (2006)
19	腰痛に対する偽鍼を用いたランダム化比較試験（第2報）	井上基浩 (2001)
20	RCTによる腰痛への遠隔部刺鍼と局所刺鍼の効果比較	竹田英子 (2001)
21	腰痛に対する偽鍼を用いたランダム化比較試験の試み	井上基浩 (2000)

RCTs in red letters were conducted in Japan

Clinical Questions Developed from 21 RCT papers on chronic low back pain

CQ 1. Which is more effective: deep or shallow needling?

CQ 2. Which is more effective: short-term or long-term treatment?

CQ 3. Which is more effective: insertion or non-insertion?

CQ 4. Which is more effective: acupoints or trigger points?

CQ 5. Which is more effective: tender points or trigger points?

CQ 6. Which is more effective: local or remote point location?

CQ 7. Which is more effective: individualized or standardized treatment?

CQ 8. Which is more effective: manual needling or electroacupuncture?

Clinical Question

慢性腰痛に対して深刺と浅刺ではどちらが有効か？

要約

深刺と浅刺ではどちらが臨床効果に優れているかは証明されていない。より多くのRCTで両者の有意差が認められていない。浅刺のほうが優れているというRCTは報告されていない。

解説

真の鍼治療群（5-40mm刺入）、偽鍼治療群（1-3mm刺入）、通常治療を比較したRCTでは、真の鍼治療群と偽鍼治療群の間に有意な差はみられなかった[1]。（EV level 2）

刺鍼群（刺入深度は自由）、Sham群（腰部の痛みを感じない領域、得気なし）、無治療群を比較したRCTでは、刺鍼群とSham群の間に有意な差はみられなかった[2]。（EV level 2）

標準鍼治療、トリガーポイント深刺群（20mm、雀啄）、トリガーポイント浅刺群（3mm、10分置鍼）を比較したRCTでは、トリガーポイント深刺群においてVAS、RMQが他の治療に比べてより改善したが、各群の群間には有意な差がなかった[3]。（EV level 4）

刺入群（1-10cm）、Sham群（10mm以内、経穴から10-20mm離れた領域）、整形外科的保存療法群を比較したRCTでは、鍼刺入群がSham群より有意に改善した[4]（EV level 2）

伝統的鍼治療群、Sham群（浅刺群）、理学療法群を比較したRCTでは、伝統的鍼治療群とSham群（浅刺群）を比較した結果、有意はなかった[5]（EV level 4）

深刺群と浅刺群を比較したRCTでは浅刺群に比べ深刺群の方が有意に改善した[6]（EV level 4）

文献

1) Haake M, Muller HH, Schade-Brittinger C, et al. German Acupuncture Trials (GERAC) for Chronic Low Back Pain. Arch Intern Med. 2007;167 (17):1892-1898.

2) Brinkhaus B, Witt CM, Jena S, et al. Acupuncture in Patients With Chronic Low Back Pain : A Randomized Controlled Trial. Arch Intern Med. 2006;166(4):450-457.

3) Itoh K, Katsumi Y, Kitakoji H. Trigger point acupuncture treatment of chronic low back pain in elderly patients--a blinded RCT. Acupunct Med. 2004;22(4):170-177.

4) Molsberger AF, Mau J, Pawelec DB, et al. Does acupuncture improve the orthopedic management of chronic low back pain--a randomized, blinded, controlled trial with 3 months follow up. Pain. 2002;99(3):579-587.

5) Leibing E, Leonhardt U, Köster G, Acupuncture treatment of chronic low-back pain -- a randomized, blinded, placebo-controlled trial with 9-month follow-up. Pain. 2002;96(1-2):189-196.

6) 藤本幸子. 腰痛に対する腰部への鍼の刺入深度の違いによる治療効果の相違　ランダム化比較試験. 全日本鍼灸学会雑誌 2011;61(3):208-217.

Clinical Question　1

Which is more effective: deep or shallow needling for chronic low back pain?

Grade

Deep: **A**

No difference: **A**

Shallow: **I**

Summary

Conflicting evidence.

No evidence for superiority of shallow needling.

The number of RCTs

No significant difference in 4 RCTs（Level of Evidence: 2 x 2 papers, 4 x 2 papers）

deep > shallow in 2 RCTs（Level of Evidence: 2 x 1 paper, 4 x 1 paper）

Clinical Question 2

Which is more effective: short-term or long-term treatment for chronic low back pain?

Grade
Short-term: **I**
No difference: **B**
Long-term: **B**

Summary

Conflicting evidence.

No evidence for superiority of short-term treatment.

The number of RCTs

No significant difference in 1 RCTs（Level of Evidence: 4 x 1 paper）

long-term > short-term in 1 RCTs （Level of Evidence: 4 x 1 paper）

Clinical Question 3

Which is more effective: insertion or non-insertion for chronic low back pain?

Grade
Insertion: **A**
No difference: **A**
Non-insertion: **I**

Summary

Conflicting evidence.

No evidence for superiority of non-insertion.

The number of RCTs

No significant difference in 2 RCTs（Level of Evidence: 2 x 1 paper, 4 x 1 paper）

insertion > non-insertion in 5 RCTs（Level of Evidence: 2 x 1 paper, 4×4 papers）

Clinical Question 4

Which is more effective: acupoints or trigger points for chronic low back pain?

Grade
Acupoints: **I**
No difference: **I**
Trigger points: **B**

Summary

Trigger points may be more effective than acupoints.
(Conflict of interest and possible bias of treatment skill: the authors of the relevant RCTs are researcher of trigger points.)

The number of RCTs
trigger points > acupoints in 1 RCTs（Level of Evidence: 4 x 1 paper）

Clinical Question 5

Which is more effective: tender or trigger points for chronic low back pain?

Grade
Tender points: **I**
No difference: **B**
Trigger points: **A**

Summary

Conflicting evidence.

No evidence for superiority of tender points.

The number of RCTs
No significant difference in 1 RCTs（Level of Evidence: 4 x 1 paper）
trigger points > tender points in 2 RCTs（ Level of Evidence: 4 × 2 papers）

Clinical Question 6

Which is more effective: local or remote point location for chronic low back pain?

Grade
Local points: **I**
No difference: **B**
Remote points: **I**

Summary

No difference.

The number of RCTs

No significant difference in 1 RCTs（Level of Evidence: 4 x 1 paper）

Clinical Question 7

Which is more effective: individualized or standardized treatment for chronic low back pain?

Grade
Individualized: **I**
No difference: **B**
Standardized: **I**

Summary

No difference.

The number of RCTs

No significant difference in 1 RCTs（Level of Evidence: 2 x 1 paper）

Clinical Question 8

Which is more effective: manual needling or electroacupuncture for chronic low back pain?

Grade
Manual: **I**
No difference: **B**
Electroacupuncture: **I**

Summary

No difference.

The number of RCTs

No significant difference in 1 RCTs（Level of Evidence: 4 x 1 paper）

Problems in the present tentative CPG

1. Little evidence, no meta-analysis, and low-quality RCTs.
2. Perhaps not practical because PICO is not clear:
   - **P** (patient): Not specified other than chronic low back pain.
   - **I** (intervention): Detailed method is not described.
   - **C** (comparison): No proof that acupuncturists of RCTs were not necessarily skilled experts in both techniques.
   - **O** (outcome): Not uniform other than VAS on pain.
3. Conflict of interest in some specific techniques.
4. Lax standard of grade and level of evidence.
5. Japanese-style and TCM-style are mixed.
6. External evaluation and validation not performed.
7. No assessment on the safety of each technique.

Conclusion

- Tentatively we could develop an evidence-based clinical practice guideline (CPG) of acupuncture technique as an extension to CPG for chronic low back pain.
- In our method, we need the premise that there is good evidence for the efficacy of acupuncture.
  - e.g. for chronic low back pain, evidence of the effectiveness is shown by systematic reviews and meta-analyses.
- Many problems that need to be solved were found.
- At the current moment, our tentative CPG is not practical.
- In the future, higher-quality RCTs which clearly answer clinical questions (or PICO) or alternative methodology in developing CPG is needed.

Development of Acupuncture Clinical Guideline for Low Back Pain

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Dongwoo Nam, K.M.D, M.S., ph.D.

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I Back ground

II Objective and process

III Results of stage 1

- Literature Review
- Diagnosis – Pattern Identification (Survey)
- Diagnosis – KM diagnosis System (Survey and Clinical Study)
- Treatment (Survey)

IV plans for stage 2

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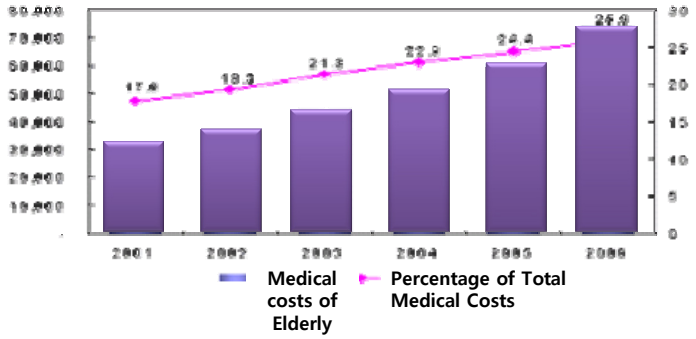
BACKGROUND

Background

Increase of Elderly Patients



(2006 Korean Health Insurance Statistics)

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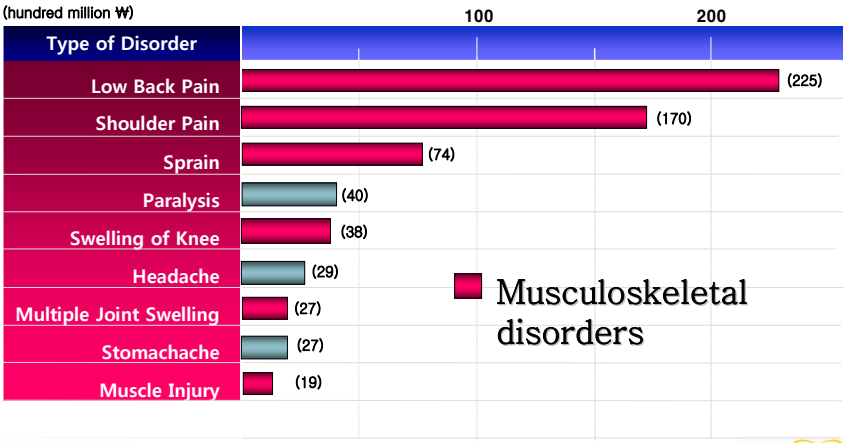
Background

2007 Top Conditions for Health Insurance Payment to Oriental Medicine Clinics and Hospitals.



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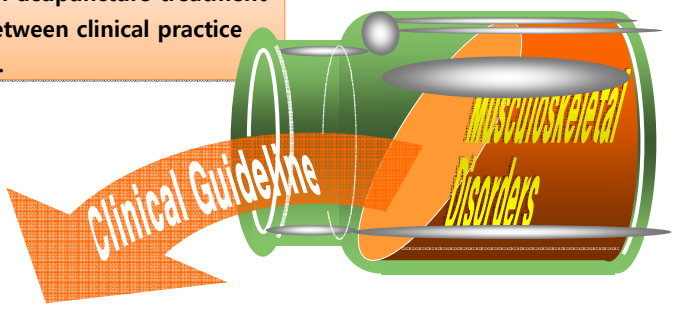
Background

Clinical guideline is a effect tool to maintain consistency of acupuncture treatment and narrow the gap between clinical practice and scientific evidence.



Standardized Treatment → Higher Efficacy → Contribute to Health and Well-being

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OBJECTIVES AND PROCESS

Objectives and Process

Objective

- To Develop acupuncture clinical guidelines for Low Back Pain by organizing a clinical guideline expert committee.

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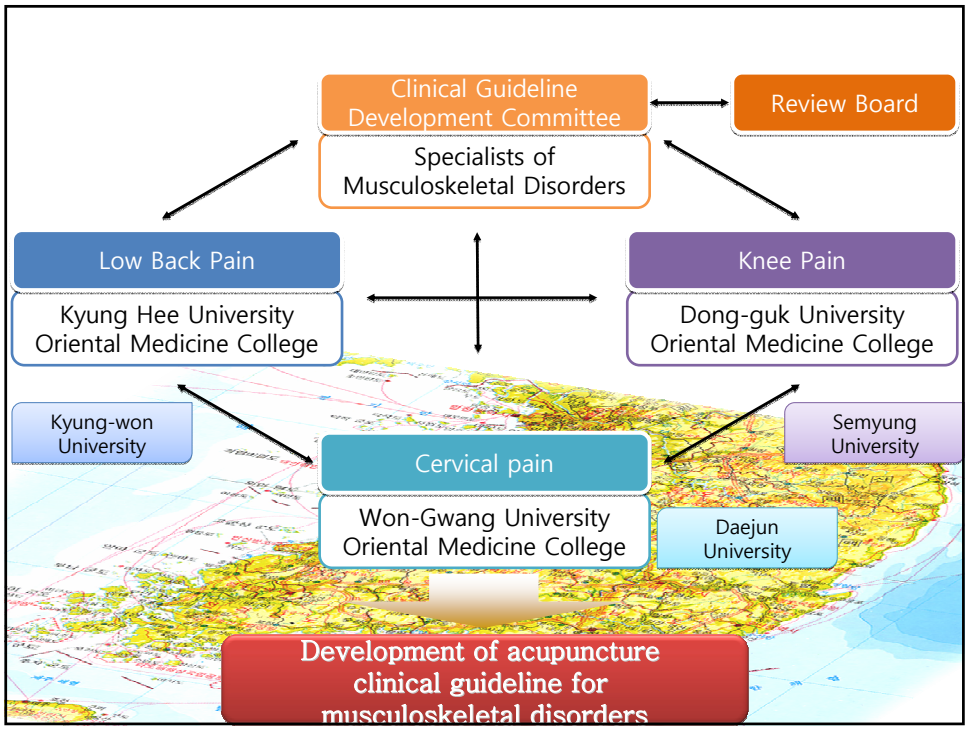
Clinical Guideline Development Committee
Review Board
Specialists of Musculoskeletal Disorders
Low Back Pain
Kyung Hee University Oriental Medicine College
Knee Pain
Dong-guk University Oriental Medicine College
Kyung-won University
Semyung University
Cervical pain
Won-Gwang University Oriental Medicine College
Daejun University
Development of acupuncture clinical guideline for musculoskeletal disorders


Difficulties of KM Clinical Guideline Development
Different Scientific Approach of KM
Lack of Well-Designed RCTs
Various Diagnosis Systems of KM
Various Treatment Methods of KM
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Lack of Well-Designed RCTs

Efforts to search domestic and international studies/
Level of recommendation was adjusted

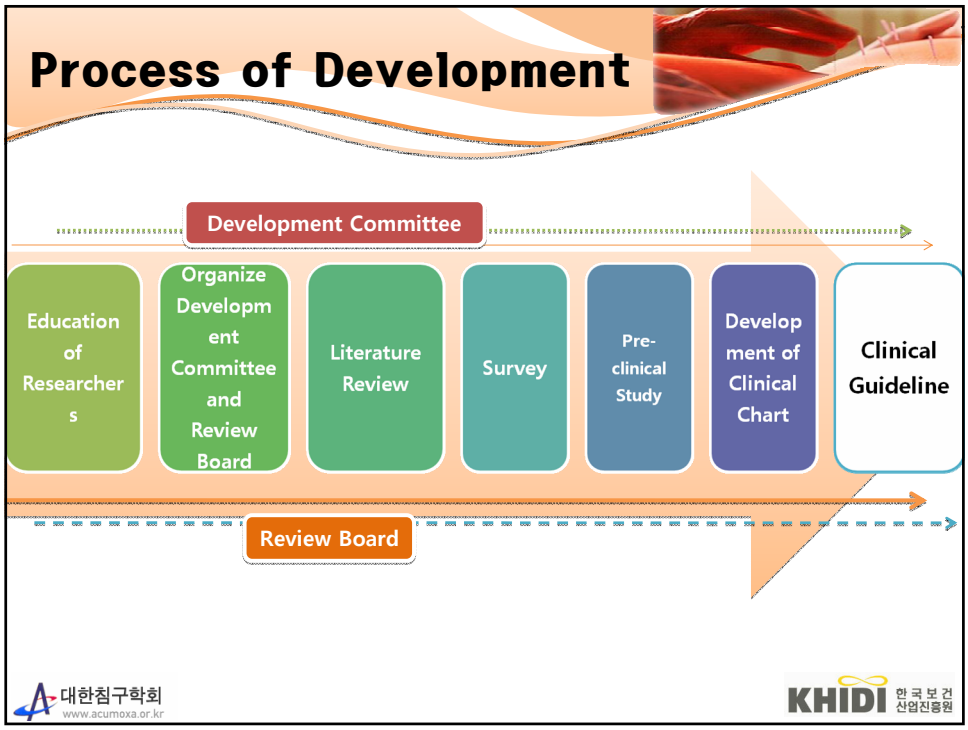
Various Diagnosis Systems of KM

Survey on pattern identification, diagnosis system,
Delphi committee of specialists, pre-clinical study on patients.

Various Treatment Methods of KM

Survey of KM Clinicians.

RESULTS OF STAGE 1


Process of Development
Development Committee
Education of Researchers
Organize Development Committee and Review Board
Literature Review
Survey
Pre-clinical Study
Development of Clinical Chart
Clinical Guideline
Review Board
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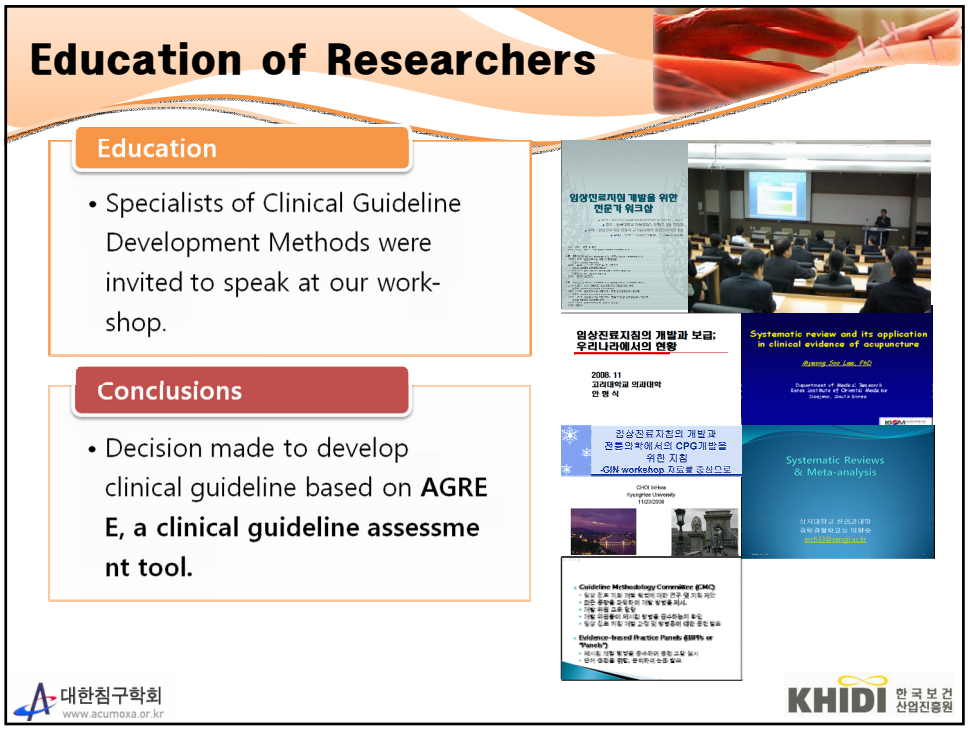
Education of Researchers
Education
• Specialists of Clinical Guideline Development Methods were invited to speak at our work-shop.
Conclusions
• Decision made to develop clinical guideline based on AGREE, a clinical guideline assessment tool.
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Education of Researchers

Numerous Workshops

- Numerous workshops to educate the methods of clinical guideline development and the assessment tool, AGREE were held.

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		남동우(경희대 침구과)	
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		김정곤(대한한의사협회 회장)	백용현(경희대 침구과)
		고경석(대한한의사협회 부회장)	안창범(동의대 침구과)
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		권기록(상지대 침구과)	조명래(동신대 침구과)
		김종인(경희대 침구과)	조은희(원광대 침구과)
			최도영(경희대 침구과)

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Literature Review

Traditional and Recent Texts of KM

- In order to establish standards of KM diagnosis and treatment

Search of Scientific Studies

- In order to establish evidence for acupuncture efficacy

Related Clinical Guidelines

Assessment of Evidence Level

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Literature Review – Traditional & Recent Texts

Meridian and Acu points (17)

KM Classics (18)

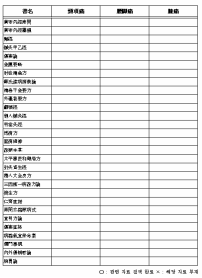
List of Traditional and Recent Texts to be reviewed(112)

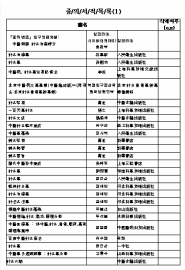
Acupuncture & Moxibustion (48)

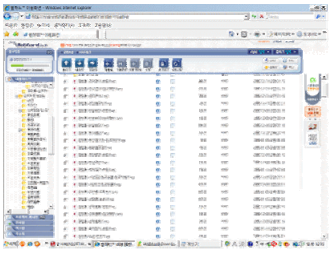
KM Rehab (29)

Search and Review

Data Sharing Through Web Services







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Literature Review – Scientific Studies

Search

- Articles up to Jan, 2010.
- Mainly PUBMED (http://www.pubmed.com) was searched.
- Korean, Chinese, Japanese databases were searched.
- Review studies and guidelines were also searched.

Search terms

- Low Back Pain : acupuncture electroacupuncture, AND back pain, lumbago, spine, disc, steonosis etc.

Check List Form.

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Literature Review - Publication

A Systematic Review of Randomized Controlled Trials on Acupuncture Treatment for Low Back Pain Based on FEAS

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Literature Review – Clinical Guidelines

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Assessment of Level of Evidence

NZGG : Complementary and alternative medicines grading system and Brosseau L : Clinical practice guidelines for acupuncture (Ottawa panel)

	Level of Evidence	Description of Evidence
1	Evidence with a high degree of reliability	Studies that use well tested methods to make comparisons in a fair way and where the results leave very little room for uncertainty. Trial design: usually Level 1 studies are systematic reviews or large, highquality randomised controlled studies.
2	Evidence with reliability but open to debate	Studies that use well tested methods to make comparisons in a fair way but where the results leave room for uncertainty (for example, due to the size of the study, losses to follow-up or the method used for selecting groups for comparison). Trial design: usually Level 2 studies are systematic reviews without consistent findings, small randomised controlled trials, randomised controlled trials in which large numbers of participants are lost to follow-up, or cohort studies.
3	Some evidence without a high degree of reliability	Studies where the results are doubtful because the study design does not guarantee that fair comparisons can be made. Trial design: usually Level 3 studies are systematic reviews of case-control studies or individual case-control studies.
4	Some evidence but based on studies without comparable groups	Studies where there is a high probability that results are due to chance (for example because there is no comparison group or because the groups compared were different at the outset of the study). Trial design: usually cohort or case-control studies where the groups were not really comparable, or case-series studies.

Evidence Levels	Classification of Evidence
Level I	Randomized controlled trials
Level II	Nonrandomized studies

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Level of Recommendation

Modified version of

Clinical practice guidelines for acupuncture Level of Recommendation was adopted.

Strength of Recommendation	Level of Evidence
A	Evidence from one or more randomized controlled trials (RCTs) of a statistically significant, clinically important benefit
B	Statistically significant, clinically important benefit, if the evidence was from observational studies or controlled clinical trials (CCTs)
C+	Evidence of clinical importance but not statistical significance
C	Interventions where an appropriate outcome was measured in a study that met the inclusion criteria, but no clinically important difference and no statistical significance were shown Consensus of experts*(Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.)
D+	Evidence from one or more randomized controlled trials of a statistically significant benefit favoring the control group
D	Evidence of clinical importance without statistical significance
D-	Evidence from one or more randomized controlled trials of a clinically important benefit that was statistically significant, where the number of participants in the study is equal to or higher than 100

*recommendations of AHCPR(Agency for Healthcare policy and research) were taken into reference.

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KM diagnosis

- **Pattern identification**
  - Literature Review and survey
- **Diagnosis system**
  - Literature Review and survey / Delphi committee

Acupuncture Treatment Methods

- Treatment according to KM diagnosis
  - Literature Review and survey
- Treatment according to western diagnosis
  - Literature Review / Level of evidence and recommendation assessed

Survey (KM Diagnosis)

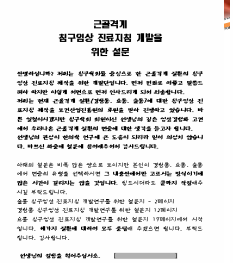
- **E-mail survey**
  - Objective : Find out which pattern identification methods are widely applied in clinical practice.
  - Date : 2009.3.26 -2009.4.29
  - Subjects : 75 members of Korean Society of Acupuncture and Moxibustion

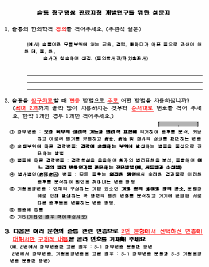
- 조사모집단: 침구학회 평생회원 321명
- 표본조사 대상: 75명
- 표본추출틀: 침구학회 회원 명부
- 목표오차: ±10% 포인트
- 표본추출: 비복원임의추출(random sampling without replacement)
- 응답율: 76%(57명)
- 표본설계에 따른 모수(모비율) 추정 방법

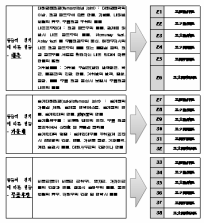
추정치: $\hat{p} = \sum_{i=1}^{n} y_i / n$, n은 표본크기

추정분산: $\hat{V}(\hat{p}) = (1-f)\hat{p}\hat{q}/(n-1)$, f는 표본추출률

오차 범위: $z_{\alpha/2}\sqrt{\hat{V}(\hat{p})}$


근골격계
침구임상 진료지침 개발을
위한 설문





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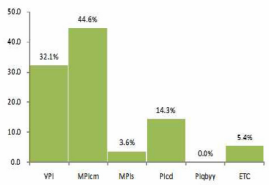
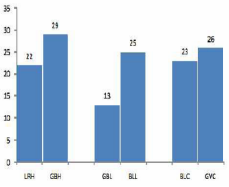
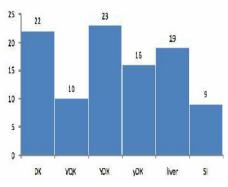
Survey (KM Diagnosis)

Low Back Pain

- Meridian pattern identification was the most popular OM diagnosis system. (Spleen, Bladder and Governor meridian) Next was five organ pattern identification (Kidney Yang deficiency, Kidney deficiency)







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Survey (KM Diagnosis)

대한침구학회지 제26권 제3호(2009년 6월)
The Journal of Korean Acupuncture & Moxibustion Society

원 저

요통에 관한 침구임상 진료지침 프로토콜 개발을 위한 전자우편 설문조사

이승훈* · 남동우* · 강중원* · 김은정** · 김현욱*** · 송호섭**** · 김선웅***** · 김갑성** · 이전목*** · 이재동*

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****광림대학교 한의과대학 침구학교실
*****동국대학교 이과대학 통계학과

Abstract

E-mail Survey for Developing Clinical Guideline Protocol on Acupuncture Treatment for Low Back Pain

Lee Seung-hoon*, Nam Dong-woo*, Kang Jung-won*, Kim Eun-jung**, Kim Hyun-wook***, Song Ho-sueb****, Kim Sun-woong*****, Kim Kap-sung**, Lee Geon-mok*** and Lee Jae-dong*

*Dept. of Acupuncture & Moxibustion, College of Oriental Medicine, Kyung Hee University
**Dept. of Acupuncture & Moxibustion, College of Oriental Medicine, Dongguk University
***Dept. of Acupuncture & Moxibustion, College of Oriental Medicine, Wonkwang University
****Dept. of Acupuncture & Moxibustion, College of Oriental Medicine, Kwangwon University
*****Dept. of Statistics, College of Natural Science, Dongguk University

Objectives : This survey was done in order to find out how Korean medical doctors derive pattern identification for acupuncture prescriptions in treating low back pain in real clinical practice.

Methods : The survey questionnaire was developed by the committee of experts who major in acupuncture & moxibustion or statistics for acupuncture clinical trial protocol development. The questionnaires were distributed via e-mail to 75 members of Korean Acupuncture & moxibustion society from March 26th to April 14th in 2009. 57 members completed answers, and the computerized data were analyzed by SPSS 17.0 statistical program.

• 본 연구는 보건복지가족부 한의학연구개발사업의 지원으로 시행된 연구임(B080017)
· 접수 : 2009. 5. 22. · 수정 : 2009. 6. 9. · 게재 : 2009. 6. 9.
· 교신저자 : 이재동, 서울특별시 동대문구 회기동 1번지 경희의료원 한방병원 침구과
Tel. 02-958-9208 E-mail : ljdacu@khmc.or.kr

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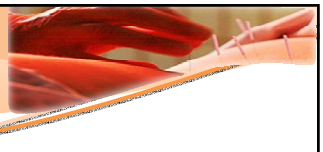
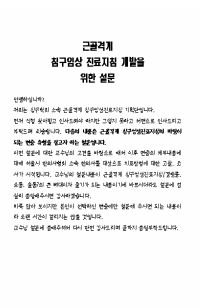
Survey (KM Diagnosis)

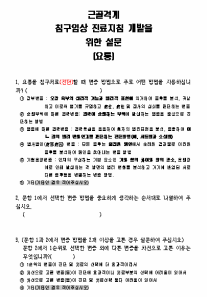


Survey for Establishing Pattern identification System

- Subjects : Professors of OM college, Department of Acupuncture & Moxibustion
- Contents
  - Reason for pattern selection
  - Standard of pattern identification
  - Patterns that should be considered
- Date
  - 2009. 5 ~ 2009. 8



근골격계
침구임상 진료지침 개발을
위한 설문



근골격계
침구임상 진료지침 개발을
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[요통]

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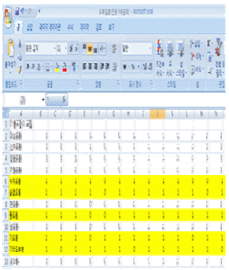
Consensus of Specialists on KM Diagnosis System



Method

- Based on results of literature review Delphi committee was he ld.
- Main symptoms were selected as standards of diagnosis.

Recommendation of KM Diagnosis of low back pain

- Low back pain : ① kidney deficiency ② dampness ③ coldness ④ ki ⑤ blood stagnation ⑥ phlegm ⑦ dyspepsia ⑧ wind ⑨ heat and dampness ⑩ other

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Clinical Application of developed diagnosis system – pilot study

Objective

- **To test the established draft of diagnosis system in clinical pr actice and obtain bases for modification.**

Institutes

- Low Back pain – Kyung Hee university, Kyugwon university

Date

- 2010.3-2010.5

Method

- Standard study guideline for researchers was established
- Patients were surveyed and the diagnosis results were analyzed

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Clinical Application of developed diagnosis system – pilot study

Low Back Pain

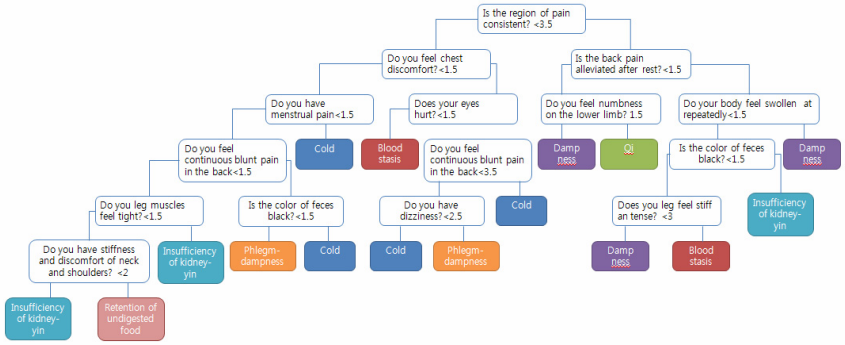
- Diagnosis Consistency ; kappa value 0.9110 ($p<0.0001$) – high
- The KM low back pain questionnaire showed low correlation with VAS, and SF-36.
- KM low back pain questionnaire showed relatively high correlation with **RMDQ** (0.58, pearson correlation: $p<0.0001$).

> The OM low back pain questionnaire is more focused on assessing functional disorders than pain.

Clinical Application of developed diagnosis system – pilot study

(1) Parametric Methods
① Linear Discriminant Analysis (LDA, Fisher, 1936) /Quadratic Discriminant Analysis (QDA)
② Diagonal Linear Discriminant Analysis (DLDA) / Diagonal Quadratic Discriminant Analysis (DQDA) (Dudoit et al, 2002)

(2) Nonparametric Methods
① Support Vector Machines (SVM, Vapnik, 1995)
② K-Nearest Neighbor Classification (KNN)
③ Chi-squared Automatic Interaction Detector (CHAID)
④ Classification And Regression Trees (CART, Breiman, 1984)
⑤ QUEST, C4.5 etc.



Survey - Treatment

Phone survey

- Random sampling for visited survey

Visited Survey

- **objectives : In order to gather opinions of KM doctors and modify the guideline draft to meet the clinical needs.**
- **Date :** 2009.11.23~2010.01.09
- **Subjects** : 288 KM doctors with more than 5 years of clinical experience.

- 조사모집단: 서울 지역 한의사 5년 이상 경력자 2906명
- 표본조사 대상: 288명
- 표본추출틀: 서울시 한의사협회 회원 명부
- 목표오차: ±4.3% 포인트
- 표본추출: 서울 지역 한의사들을 25개 구로 층화하여 각 층별로 한의사들을 임의추출 (stratified random sampling)
- 층별표본할당: 각 층별 한의사 수에 비례하도록 각 층별 조사 대상 한의사 결정 (proportional allocation)
- 표본설계에 따른 모수(모비율) 추정 방법

추정치: $\hat{p}=\sum_{i=1}^{L} W_i \hat{p}_i$, W_i는 각 층별 가중치

추정분산: $\hat{V}(\hat{p})=\sum_{i=1}^{L} W_i^2(1-f_i)\hat{p}_i\hat{q}_i/(n_i-1)$, f_i는 각 층별 표본추출률

오차 범위: $z_{\alpha/2}\sqrt{\hat{V}(\hat{p})}$

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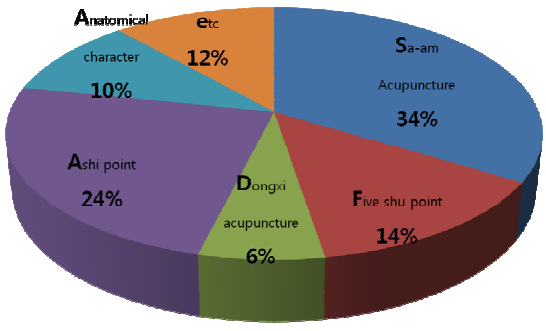
Survey - Treatment



Low Back Pain

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Survey - Treatment

Low Back Pain

Diagnosis : Area of pain, pain character, history taking, swelling or curvature of back, ROM, the cause of pain reduction and increase, tender point.
Acupuncture : Sa-Am - Ashi - anatomical – five shu point
Point selection : Local point, Local and distant together, and distant.
Depth of acupuncture : 3~6 cm
Needle used : diameter-0.25mm~0.30mm, length-40mm
Patient position : face down, sideways
Deqi : Deqi(78.2%), No Deqi(20.51%)
Enhancement and sedation : applied(66.24%), not applied(33.3%)
Technique of enhancement and sedation : nine-six, twisting, picking
duration: 15- 20 min
stimulation : not applied, electric acupuncture
Frequency of treatment: 3times/1week

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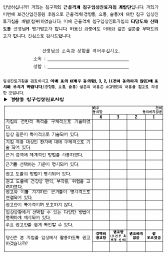
Review of Review Board

검토위원회 (대한침구학회, 재활의학과학회, 약침학회, 침도학회, 대한한의사협회, 대한한의학회, 대한경락경혈학회)	위원장	이건목(원광대 침구과)
	간사	김은정(동국대 침구과)
	위원	이원철(부산한의전문대학원장) 김호준(동국대 재활의학과) 김정곤(대한한의사협회 회장) 백용현(경희대 침구과) 고경석(대한한의사협회 부회장) 안창범(동의대 침구과) 김장현(대한한의학회 전회장) 육태한(우석대 침구과) 김기현(대한한의학회 수석부회장) 윤현민(동의대 침구과) 장준혁(대한약침학회) 이경민(대구대 침구과) 송춘호(대한경락경혈학회장) 이상훈(경희대 침구과) 이명종(한방재활의학과학회 학회장) 이승덕(동국대 침구과) 강미숙(경원대 침구과) 정석희(경희대 재활의학과) 권기록(상지대 침구과) 조명래(동신대 침구과) 김종인(경희대 침구과) 조은희(원광대 침구과) 최도영(경희대 침구과)



Review

• The process of development and the draft of the guideline was reviewed and graded by the review board.

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Acupuncture Clinical Guideline

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Contents of Clinical Guideline

Acupunctural Clinical Guideline for Low Back Pain

Ⅰ. Outlines of Clinical Guideline

- Objective
- Back round
- International and Domestic Clinical Guidelines on Low Back Pain
- Limitations
- Subjects of survey and level of evidence
- Making of clinical guideline (developers, process, verification, Funding)

Ⅱ. Introduction and diagnosis of Low Back Pain

- Definition of Low Back Pain
- Diagnosis of Low Back Pain
- Mobility rate and prevalence rate of Low Back Pain
- Low Back Pain evaluation tool

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Contents of Clinical Guideline

Ⅲ. Treatment of Low Back Pain

Treatment based on KM Diagnosis

- Diagnosis system and method of diagnosis
- Differentiation of syndromes for Low back pain
- Sanitation of acupuncture
- Safety of acupuncture treatment

Treatment based on western Diagnosis

- (1) Degenerative Disease of the spine (2) Paget's disease (3) Scheuermann's kyphosis
- (4) Scoliosis (5) Spondylolisthesis (6) Spinal disc herniation (HIVD)
- (7) Spinal stenosis (8) Compression Fracture (9) Myofascial pain syndrome
- (10) Lumbar sprain & strain (11) Cauda equina syndrome (12) Ankylosing spondylitis
- (13) Spinal tumor (14) Osteoporosis (15) Low back pain syndrome

Consensus process of guideline development

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Diagnosis system and method of diagnosis

① Lumbago due to Insufficiency of kidney-yin	
② Lumbago due to Phlegm-dampness	
③ Lumbago due to Retention of undigested food	
④ LBP of Bad blood stasis	
⑤ Lumbago due to Ki	
⑥ Lumbago due to dampness	
⑦ Lumbago due to Damp-heat	
⑧ Lumbago due to Cold	
⑨ Lumbago due to Wind	
⑩ Other types of Lumbago	

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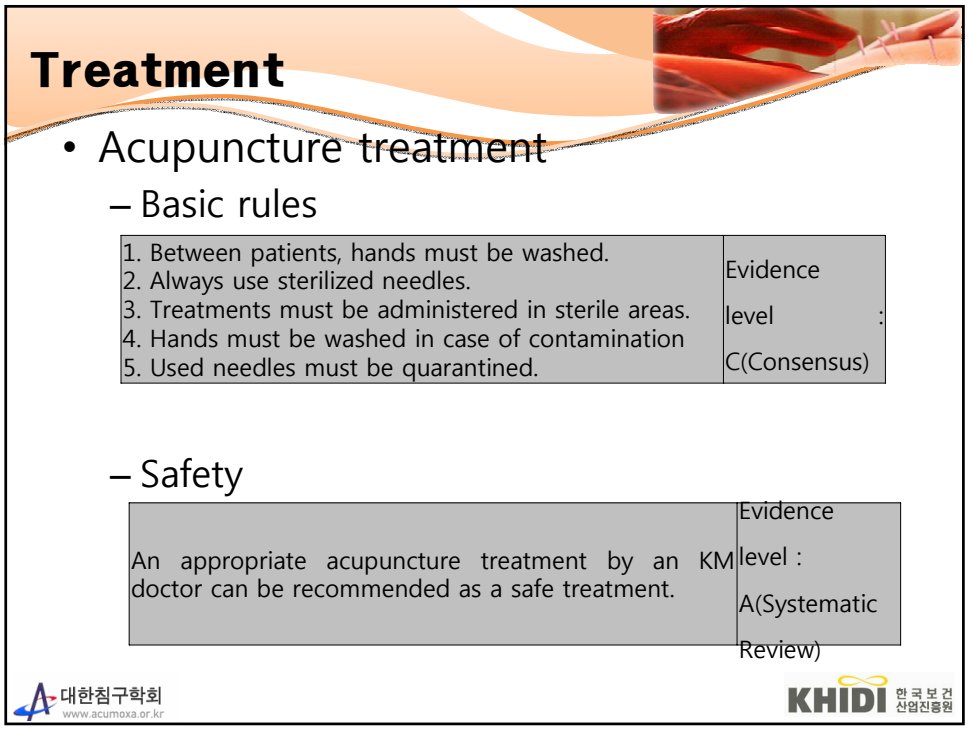

1. Differentiation according to the theory meridians and collaterals is the most frequently used differentiation method of syndromes. 2. Area of pain and description of the pain, information obtained by pulse feeling and palpitation, degree of thoraco-lumbar swelling & incurvation, lumbar spine ROM, history of pain, the patients usual factor and etc., are main diagnosis standards. 3. Frequently used acupuncture methods, in order of high frequency, Saam-chimbeop - ashihyeol(Ashihyeol-chimbeop) - five Su points five points-chimbeop - acupuncture based on anotomical structures. 4. Both the normal, and the ill side of the patient are mix treated. 5. The most frequent used needling depth is about 1.5-3cm, needle thickness 0.25mm, needle length 40mm and the prone position is the most frequent used position for acupuncutre treatment. 6. De-qi and tonification-purgation are frequently performed and most of the acupuncture treatment had a duration time of over 15 minutes- below 20 minutes. Most patients were treated 3 times a week, and the treatment period for acute low back pain was under 1 week, and for chronic neck pain (in pain for over 3 months) were over 3 weeks and under 5 weeks.	Evidience level : C(Consensus)

Treatment

- Acupuncture for Degenerative Disease of the spine

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions for treating degenerative disease of the spine. But more studies supporting the effects and safety of these interventions are in need.	Evidence level : C (Case study)

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Treatment

- Acupuncture for Scoliosis

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions for treating Scoliosis. But more studies supporting the effects and safety of these interventions are in need.	Evidence level : C (Case study)

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Treatment

- Acupuncture for HIVD

Electrial acupuncture, acupuncture and other acupuncture treatments are recommended as effective and safe treatment interventions.	Evidence level : A (RCT, CCT, Case study)

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Treatment

- Acupuncture for Spinal stenosis

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions for treating Spinal stenosis. But more studies supporting the effects and safety of these interventions are in need.	Evidence level : B (CCT, Case study)

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Treatment

- Acupuncture for Compression Fracture

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions for treating Compression fracture. But more studies supporting the effects and safety of these interventions are in need.	Evidence level : B (CCT, Case study)

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Treatment

- Acupuncture for Lumbar sprain & strain

Electrical acupuncture, acupuncture and other acupuncture treatments are recommended as effective and safe treatment interventions. for treating Lumbar sprain & strain.	Evidence level : A (RCT, CCT, Case study)

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Treatment

- Acupuncture for Spinal tumor

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions for treating Spinal tumor. But more studies supporting the effects and safety of these interventions are in need.	Evidence level : C (Case study)

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Treatment

- Acupuncture for Low back pain syndrome

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions for treating Low back pain syndrome.	Evidence level : A (RCT, CCT, Case study)

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Treatment

- Acupuncture for Paget's disease, Scheuermann's kyphosis, Myofascial pain syndrome, Cauda equina syndrome, Ankylosing spondylitis, Osteoporosis,

Electrical acupuncture, acupuncture, and other acupuncture treatments are recommended as effective and safe interventions. But more studies supporting the effects and safety of these interventions are in need.

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Verification of clinical guideline and education.

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Assessed by AGREE

Scope and Purpose	The overall objective of the guideline is specifically described. The clinical question(s) covered by the guideline is(are) specifically described. The patients to whom the guideline is meant to apply are specifically described.
STAKEHOLDER INVOLVEMENT	The guideline development group includes individuals from all the relevant professional groups. The patients' views and preferences have been sought. The target users of the guideline are clearly defined. The guideline has been piloted among target users.
RIGOUR OF DEVELOPMENT	**Systematic methods were used to search for evidence. / The criteria for selecting the evidence are clearly described.** /The methods used for formulating the recommendations are clearly described./ The health benefits, side effects and risks have been considered in formulating the recommendations. /There is an explicit link between the recommendations and the supporting evidence. / The guideline has been externally reviewed by experts prior to its publication./ A procedure for updating the guideline is provided.
CLARITY AND PRESENTATION	The recommendations are specific and unambiguous. /The different options for management of the condition are clearly presented./Key recommendations are easily identifiable./ The guideline is supported with tools for application.
APPLICABILITY	The potential organisational barriers in applying the recommendations have been discussed./ The potential cost implications of applying the recommendations have been considered./ The guideline presents key review criteria for monitoring and/or audit purposes.

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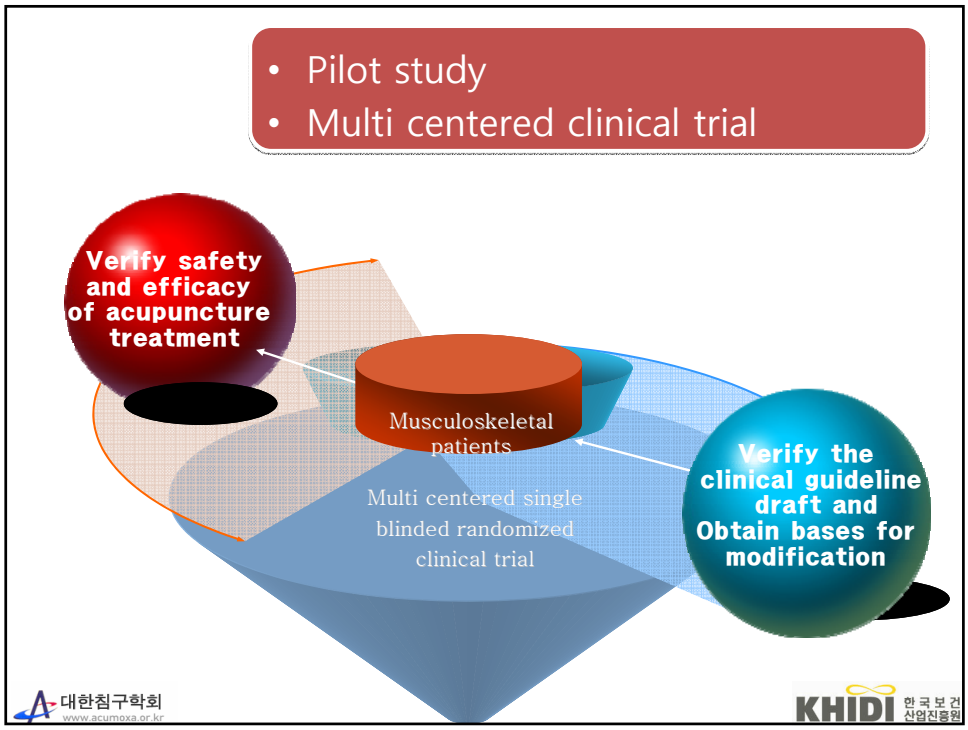
STAGE 2 PLANS


• Pilot study
• Multi centered clinical trial
Verify safety and efficacy of acupuncture treatment
Musculoskeletal patients
Multi centered single blinded randomized clinical trial
Verify the clinical guideline draft and Obtain bases for modification
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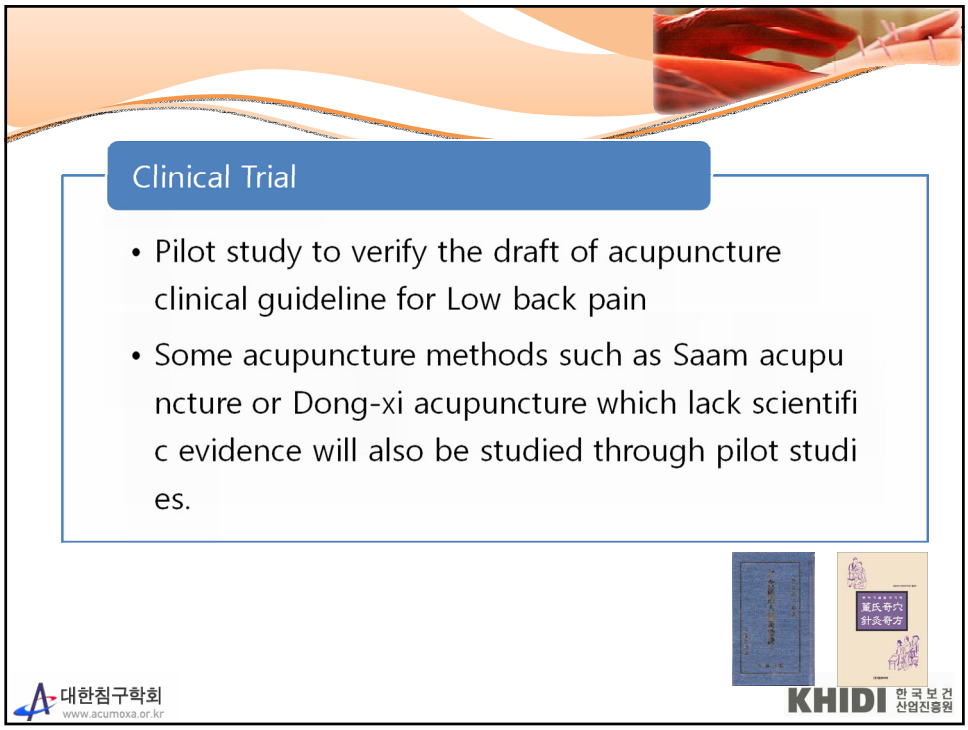
Clinical Trial
• Pilot study to verify the draft of acupuncture clinical guideline for Low back pain
• Some acupuncture methods such as Saam acupu ncture or Dong-xi acupuncture which lack scientifi c evidence will also be studied through pilot studi es.
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Thank You
야경

Acupunctural Clinical Guideline for MUsculoskeletal pain
– neck pain, low back pain, knee pain –

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A. Purpose and background of research

Clinical guidelines are effective tools to bridge the gap between a physician's practice in clinical settings and a scientist's research in a lab. During the past decade, such guidelines have been fervently developed and advocated to act as convenient tools and guidances for clinicians in improving quality of care, implemented into science labs for clinical researchers, and used as blueprints for government officials in public health care. Yet such guidelines related to acupuncture and traditional medicine are rare and hard to find.

At the present, the percentage of patients making up the top ten most-frequently visited out-patient list at an oriental medical hospital are those with musculoskeletal pain: low back pain, neck, and knee pain.
However, in practice, many of the oriental medical doctors are relying primarily on their
personal experiences and skills for management of these patients which is unfortunately bringing about a very unsystematic and unstandardized diagnostic and treatment process, and leading to a wide variation in treatment modalities and effectiveness.

Therefore, it is crucial to develop an acupunctural clinical guideline through extensive literature research, questionnaires, and discussion among experts for musculoskeletal disorders/diseases related to the cervice, lumbar, and knee joint.

Under the auspices of the Korea Health Industry Development Institute, The Korean Acupuncture and Moxibustion society has formed a committee to develop such acupunctural clinical guideline 2010 for neck, low back, and knee pain.

The purpose of this study is to formulate an appropriate acupunctural clinical guideline based on domestic and international evidence and domestic specialists' opinions and recommend it for use in the Korean medical field hoping that it will ensure the quality of care and treatment for patients.

B. Scope of Neck pain, Low Back pain and Knee pain studied in this clinical

guideline

Neck pain covers the terms cervical spondylosis, cervical sprain and strain, cervical disc disease in western medicine.

Generally, the term 'back pain' covers Low back pain, Back pain, and Lumbago under Western medical diagnosis as well as their derivatives such as Degenerative Disease of the spine, Spondylosis, Facet syndrome, Paget's Disease, Scheuermann's Kyphosis, Scoliosis, Spondylolisthesis, Spinal disc herniation(HIVD; Herniation of Inter-Vertebral Disc), Spinal stenosis, Compression Fracture, Myofacial pain syndrome, Lumbar sprain & strain, Cauda equina syndrome, Ankylosing spondylitis, Spinal tumor, Osteoporosis, Low back pain syndrome.

And generally, knee pain includes Western medicine diagnosis of disorders such as knee osteoarthritis, rheumatoid arthritis, and soft tissue knee injuries. The guideline is based on acupunctural guideline which focuses on patients of 18 and over which excludes significant, yet rare cases of fracture, dislocation, tumor, infection, inflammatory arthropathies, osteonecrosis, congenital musculoskeletal deformities, crushing injury of lower leg, frostbite with tissue necrosis, complications of internal orthopedic prosthetic devices, implants, and grafts. Furthermore, conditions characterized by pain referred from other structures (e.g. hip), such as neuropathic pain, are excluded.

The aim of the guideline is to recommend a clinical diagnostic guideline which would provide high quality care and treatments to patients with neck, low back and knee pain

B. Developmental Process

1. On-board training of acupunctural clinical guidance development group and establishment of a research plan

Since the acupuncture clinical guideline development group lacked sufficient knowledge on basic understanding of and methods used to establish a guideline, several workshops were arranged and an expert in the field was called in to explain the strategies, methods, and developmental know-hows.

2. Composition of the professional Acupunctural clinical guidance development group and the review board

3. Literature research

Research of ancient texts: Ancient texts were thoroughly researched for contents on neck, low back, and knee pain

Paper research: To establish scientific evidence on the effectiveness of acupuncture treatment, domestic and international papers were also searched.

4. Acupunctural clinical guidance - Diagnosis

A) Western Medicine Diagnosis

: The professional Acupuncture clinical guideline development group determined and set the limits on how far and how much diagnostically related illnesses were to be included in the guide. The western medicine diagnostic methods used were supported by available research papers and previous guidelines.

B) Oriental Medicine Diagnosis

1) The arrangement of a diagnostic criteria and sub-criteria through substantial discussion and evaluation between experts

: Since there was no previously established terminology for oriental medical diagnosis, another team of experts (Delphi method) perused through literature and research papers to identify and confirm Oriental medical diagnosis most compatible with the Western-style diagnosis of neck, low back, and knee pain.

2) Clinical study for development of a diganostic tool

: An extensive survey was conducted among patients inflicted with neck, low back, and knee pain using questionnaires to ensure that the established western-syle diagnosis and oriental-style diagnosis was compatible with clinical symptoms. The questionnaires were issued by hospital residents and nurses that were thoroughly trained for clinical studies. A statistics expert suggested that we develop by statistical analysis a diagnostic tool using the CART method.

3) Diagnosis including the Differentiation of syndromes

: Since there are no research findings or literature reviews on diagnosis including the differentiation of syndromes, a primary survey was done among members and oriental medicine doctors of The Korean Acupuncture and Moxibustion Society and a secondary survey was done among a total of 234 oriental medicine doctors located in Seoul, Korea. The survey identified methods and diagnostic criteria used to differentiate syndromes.

5. Acupuncture Clinical Guideline – Treatment

A) The safety and hygiene of acupuncture treatment

B) Western medicine treatment

Based on domestic and international guidelines, the conventional methods of treatment (patient education, management, and physical therapy etc) were outlined and adviced accordingly. As for acupuncture treatment, much literature were available for symptoms with western medical terminology. The treatment effects were divided to the electroacupuncture treatment group, the general acupuncture treatment group, and others (beevenom acupuncture treatment, pharmacopuncture). (Yet, compared to the purely conventional treatment group, the number and quality of these literature available to form an adequate level of evidence and level of recommendation was still comparatively scarce and hence had to be supplemented by standard of Complementary medicine.)

C) Oriental Medicine Treatment

It was impossible to form a treatment guideline using the meager number of literature available on treatment effects of symptoms diagnosed according to oriental medicine diagnosis. Thus, once again, a questionnaire survey was conducted on 234 oriental medicine doctors asking about the types of treatment they use, and the results were analyzed and investigated by a group of experts.

– The questionnaire was formed on the basis of treatment methods mentioned in ancient and modern oriental texts

– The questionnaire on the development of a protocol for acupunctural treatment methods

– The statistical analysis of the questionnaire on the development of a protocol for acupunctural treatment methods

– Evaluation by experts

6. The presentation of the acupuncture clinical guideline

– The guidance was established through the aforementioned processes and evaluated by the committee of specialists and workshops.

– It has been approved by The Korean Acupuncture and Moxibustion Soceity, Tuina Society, and Chimdo Society.

– The presentation and education of the guidance to clinicians for efficient

implementation through workshops and seminars.

– Clinical research to verify the effectiveness of the presented guidance are in progress and further complementary measures have been set up.

D. Funding

This Clinical Guidline was developed as part of a supporting project to promote Oriental Medical Technology (B080017) funded by the Korean Ministry of Health & Welfare.

Development Period : 2008.07.01–2010.06.30 (Clinical research to verify the effectiveness of the presented guidance are in progress and further complementary measures have been set up.)

C. Research topic and level of evidence

Search term

(A) Neck pain

The search terms used were Neck pain, Dorsopathies, Kyphosis, Lordosis, Scoliosis, Kyphoscoliosis, Spinal osteochondrosis, Spondylolysis, Spondylolisthesis, Myelopathy, Spondylitis, Spondylopathies, Spinal enthesopathy, Osteomyelitis of vertebra, Intervertebral disc, Discitis, Spondylosis, Radiculopathy, Stenosis, Hyperostosis, Cervical disc, Cervical, HIVD, Disc, Cervicocranial, Cervicobrachial, Spinal instabilities, Dorsalgia, Cervicalgia, Myalgia, Panniculitis, Fibromyalgia, Musculoskeletal, Deformity – all of them comprising the subcategories of the Diseases of the musculoskeletal system and connective tissue in ICD10. Korean research papers were obtained from Oriental Medical Advanced Searching Integrated System (OASIS–(http://oasis.kiom.re.kr/), The Journal of Korean Acupuncture and Moxibustion Society (http://www.acumoxa.or.kr/), The Journal of Korean Oriental Medical Society (http://www.koms.or. kr/), The Journal of Korean Academy of Oriental Rehabilitation Medicine (http://www.ormkorea.org/), and foreign papers were researched from pubmed (http://www.ncbi.nlm.nih.gov/pubmed/) with the aforementioned key words.

(B) Back Pain

All research papers related to back pain were obtained from OASIS–(http://oasis.kiom.re.kr/) and Pubmed (http://www.ncbi.nlm.nih.gov/pubmed/) using the search key words 'Low back pain', Back pain', Lumbago', ‘spine' in English, with advanced search words such as 'Degenerative Disease of the spine', 'Spondylosis', 'Facet syndrome', 'Paget's Disease', 'Scheuermann's Kyphosis', 'Scoliosis', 'Spondylolisthesis', 'Spinal disc herniation' (HIVD; Herniation of Inter–Vertebral Disc), 'Spinal stenosis', 'Compression Fracture', 'Myofacial pain syndrome', 'Lumbar sprain & strain', 'Cauda equina syndrome', 'Ankylosing spondylitis', 'Spinal tumor', 'Osteoporosis', 'Low back pain syndrome'. Papers with less than satisfactory results were further

searched through Pubmed or www.Emedicine.com.

(C) Knee Pain

For knee pain, key words such as knee, knee pain, osteoarthritis, rheumatoid arthritis, gout, soft tissue injury, patella were used. Korean research papers were obtained from OASIS-(http://oasis.kiom.re.kr/) , The Journal of Korean Acupuncture and Moxibustion Society (http://www.acumoxa.or.kr/), The Journal of Korean Oriental Medical Society (http://www.koms.or. kr/), The Journal of Korean Academy of Oriental Rehabilitation Medicine (http://www.ormkorea.org/). Foreign research papers were searched through pubmed(http://www.ncbi.nlm.nih.gov/pubmed/), and after going through rigorous elimination processes, a total of 59 related papers were obtained.

2. Level of evidence

(A) Grading the Level of evidence

Due to the characters of oriental medicine, it was hard to apply the level of evidence grading systems used in western medicine. So, the following grading systems were adopted.

Complementary and alternative medicines grading system suggested by NZGG(New Zealand Guidelines Group) in 2006.

Table. Complementary and alternative medicines grading system(NZGG 2006)

Level of Evidence		Description of Evidence
1	Evidence with a high degree of reliability	Studies that use well tested methods to make comparisons in a fair way and where the results leave very little room for uncertainty. Trial design: usually Level 1 studies are systematic reviews or large, highquality randomised controlled studies.
2	Evidence with reliability but open to debate	Studies that use well tested methods to make comparisons in a fair way but where the results leave room for uncertainty (for example, due to the size of the study, losses to follow-up or the method used for selecting groups for comparison). Trial design: usually Level 2 studies are systematic reviews without consistent findings, small randomised controlled trials, randomised controlled trials in which large numbers of participants are lost to follow-up, or cohort studies.
3	Some evidence without a high degree of reliability	Studies where the results are doubtful because the study design does not guarantee that fair comparisons can be made. Trial design: usually Level 3 studies are systematic reviews of case-control studies or individual case-control studies.
4	Some evidence but based on studies without comparable groups	Studies where there is a high probability that results are due to chance (for example because there is no comparison group or because the groups compared were different at the outset of the study). Trial design: usually cohort or case-control studies where the groups were not really comparable, or case-series studies.

Another grading system was suggested by Brosseau L. in the study, 'Clinical practice guidelines for acupuncture'.

Brosseau L, Wells GA, Finestone HM, Egan M, Dubouloz CJ, Graham I, Casimiro L, Robinson VA, Bilodeau M, McGowan J. Clinical practice guidelines for acupuncture. Top Stroke Rehabil 2006 Spring ; 13(2) : 65-7.

Table. Brosseau L,'s Level of evidence Clinical practice guidelines for acupuncture

Level of Evidence	Classification of Level of Evidence
I	Randomized controlled trials
II	Nonrandomized studies

(B) Strength of recommendation

Strength of recommendation was presented as done in the study by Brosseau L, 'Clinical practice guidelines for acupuncture'.

Table. Strength of recommendation suggested in Clinical practice guidelines for acupuncture by Brosseau L

Strength of Recommendation	Level of Evidence
A	Evidence from one or more randomized controlled trials (RCTs) of a statistically significant, clinically important benefit
B	Statistically significant, clinically important benefit, if the evidence was from observational studies or controlled clinical trials (CCTs)
C+	Evidence of clinical importance but not statistical significance
C	Interventions where an appropriate outcome was measured in a study that met the inclusion criteria, but no clinically important difference and no statistical significance were shown Consensus of experts*(Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.)
D+	Evidence from one or more randomized controlled trials of a statistically significant benefit favoring the control group
D	Evidence of clinical importance without statistical significance
D-	Evidence from one or more randomized controlled trials of a clinically important benefit that was statistically significant, where the number of participants in the study is equal to or higher than 100

*recommendations of AHCPR(Agency for Healthcare policy and research) were taken into reference.

F. Recommendation of this guideline

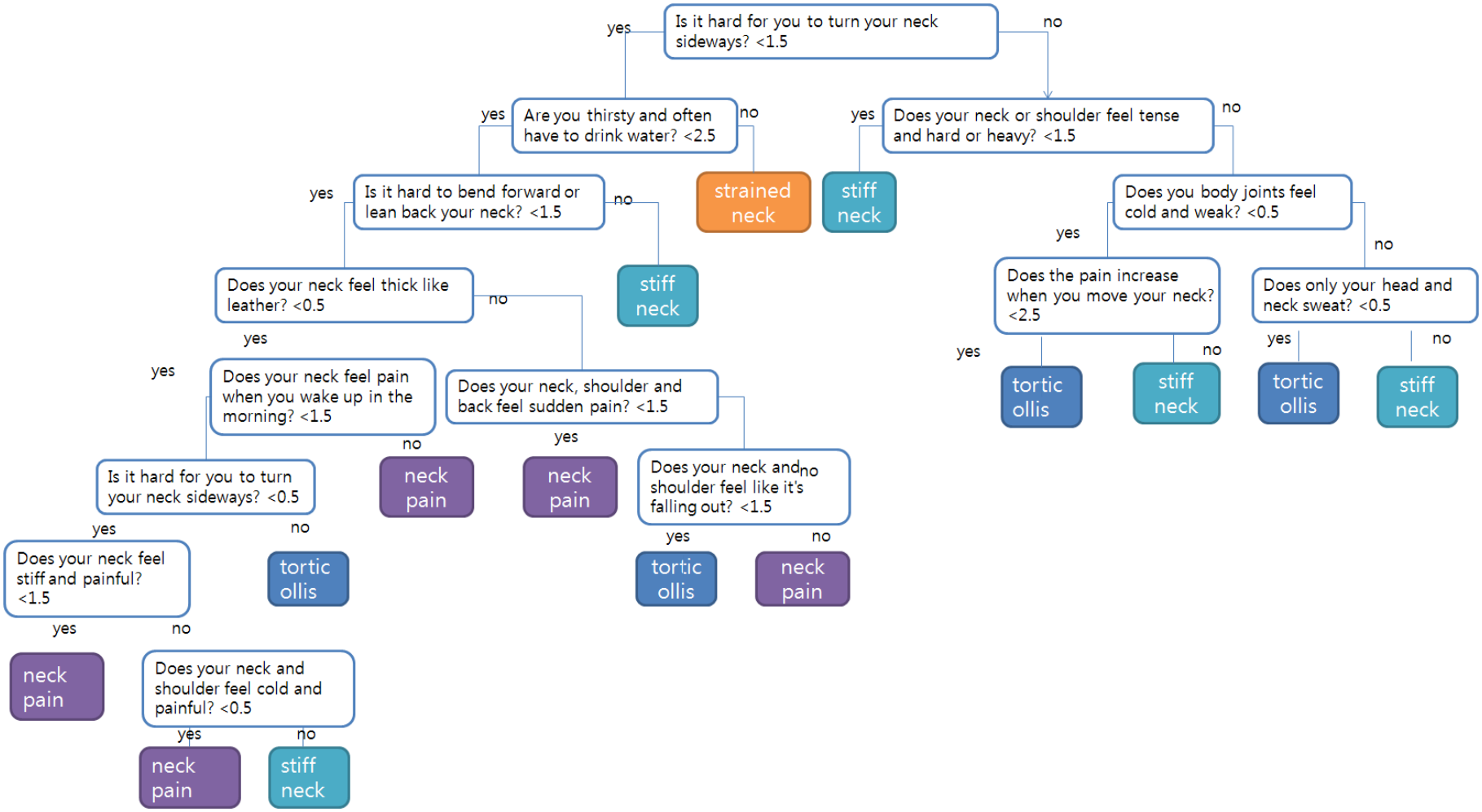
1. Diagnosis – Neck pain

(A) Diagnosis system and method of diagnosis

Using the Delphi method which is an expert consensus achieving method, the final diagnosis system for neck pain that was consented in a expert committee is as follows.

① neck pain ② stiff neck ③ torticollis ④ strained neck	Evidience level : C(Consensus)

A questionnaire which consists of 48 different sypmtoms related to neck pain was given out to 103 neck pain patients. Through interviewing each of the patients by 3 oriental medicine doctors, Oriental medical diagnosis (above 4) was done and the analysis by Classification And Regression Trees (CART, Breiman, 1984) results in the diagnosis of neck pain to be as follows.



Evidience level : Consensus

(B) Differentiation of syndromes for neck pain

As a result of discussion through an expert committee, the differentiation of syndromes for neck pain is as follows.

(1) Differentiation of syndromes according to pathological changes of Jangbu organs

This differentiation is based on the physiological function and pathological expression of the five viscera and six bowels. Symptoms are analysed and inducted, pathogenesis is revealed, lesions, charateristics of disease, the struggle between the vital principal and the pathogenic factors are decided through this.

Insufficiency and impairment of liver-kidney essence +Exopathogen/ Deficiency of Liver-yin and Kidney-yin / Hyperactivity of Liver-yang

(2) Differentiation according to the theory meridians and collaterals

This differentiation occurs where the meridian system of meridians and collaterals circulate. This diagnosis method finds out which of the meridian has been ailed by analysing and putting together the patient's expression of pathology applying the theory of meridians and collaterals.

(3) Differentiation of symptoms and signs for determining the pathogenic factors of a disease

Every symptom is a result of a certain factor, and this differentiation is to find out the factor by analysing these symptoms.

Wind-cold-dampness pathogen /Affection by wind-dampness exopathogen/ Wind-cold pathogen/ Obstruction of collateral by phlegm-dampness/Damp-heat/Wind-heat pathogen with dampness

(4) Differentiate syndromes by studying the pathological changes of Gi -blood & Eum-Yang

This differentiation analyses the difference in between Gi and blood, the decrease in Yang, and circulation problems which causes various pathological changes and also discriminates different symptoms that reflect this.

Blood stasis due to Qi Stagnancy/ Qi and Blood deficiency/stasis of blood and muscle pulse

Survey (2009.3.26-2009.4.14) on Oriental medicine doctors shows that the differentiation according to the theory meridians and collaterals are most used and the most frequently used meridians were the Small Intestine Meridian, Small Intestine Meridian and Bladder Meridian. Therefore the expert committee recommends its use.	Evidience level : C(Consensus)

(C) Western medicine diagnosis of neck pain

The most frequent causes of neck pain in western medicine are ervical spondylosis, cervical sprain and strain, cervical disc diseases and these are diagnosed as follows.

(1) Cervical spondylosis
(2) Cervical sprain and strain
(3) Cervical disc diseases

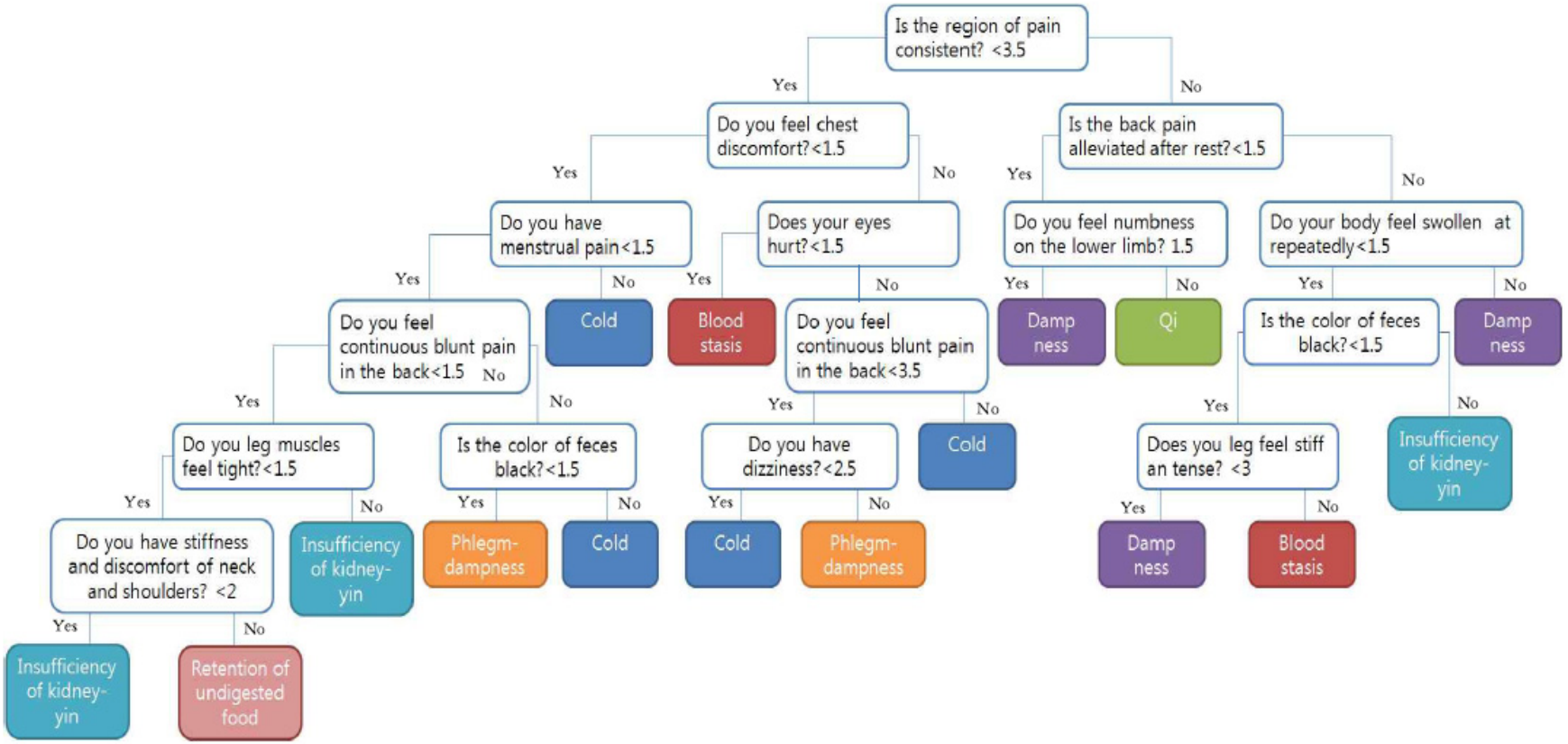
2. Diagnosis – Low back pain

(A) Diagnosis system and method of diagnosis

Using the Delphi method which is an expert consensus achieving method, the final diagnosis system for low back pain that was consented in a expert committee is as follows

① Lumbago due to Insufficiency of kidney-yin ② Lumbago due to Phlegm-dampness ③ Lumbago due to Retention of undigested food ④ LBP of Bad blood stasis ⑤ Lumbago due to Qi ⑥ Lumbago due to dampness ⑦ Lumbago due to Damp-heat ⑧ Lumbago due to Cold ⑨ Lumbago due to Wind ⑩ Other types of Lumbago	Evidience level : C(Consensus)

A questionnaire which consists of 65 different symptoms related to low pain was given out to 103 neck pain patients. Through interviewing each of the patients by 3 oriental medicine doctors, Oriental medical diagnosis (above 9) was done and the analysis by Classification And Regression Trees (CART, Breiman, 1984) results in the diagnosis of low back pain to be as follows.



Evidience level : C(Consensus)

Developing Low Back Pain Diagnosis Tool using Classification And Regression Trees

(B) Differentiation of syndromes for Low back pain

Therefore the expert committee recommends 'Differentiation of syndromes according to Ten types of Lumbago' in Dong-Eui-Bo-Kham .

Survey (2009.3.26-2009.4.14) on Oriental medicine doctors shows that the differentiation according to the 'theory meridians and collaterals' and 'pathological changes of Jangbu organs' are most used. Therefore the expert committee recommends 'Differentiation of syndromes according to Ten types of Lumbago'.	Evidience level : C(Consensus)

(C) Western medicine diagnosis of Low back pain

Main reasons for back pain are Degenerative Disease of the spine, Spondylosis, Facet syndrome, Paget's Disease, Scheuermann's Kyphosis, Scoliosis, Spondylolisthesis, Spinal disc herniation(HIVD; Herniation of Inter-Vertebral Disc), Spinal stenosis, Compression Fracture, Myofacial pain syndrome, Lumbar sprain & strain, Cauda equina syndrome, Ankylosing spondylitis, Spinal tumor, Osteoporosis, Low back pain syndrome. The Western diagnostic procedure is as follows.

(1) Degenerative Disease of the spine
(2) Paget's disease
(3) Scheuermann's kyphosis
(4) Scoliosis
(5) Spondylolisthesis
(6) Spinal disc herniation (HIVD)
(7) Spinal stenosis
(8) Compression Fracture
(9) Myofascial pain syndrome
(10) Lumbar sprain & strain
(11) Cauda equina syndrome
(12) Ankylosing spondylitis
(13) Spinal tumor
(14) Osteoporosis
(15) Low back pain syndrome

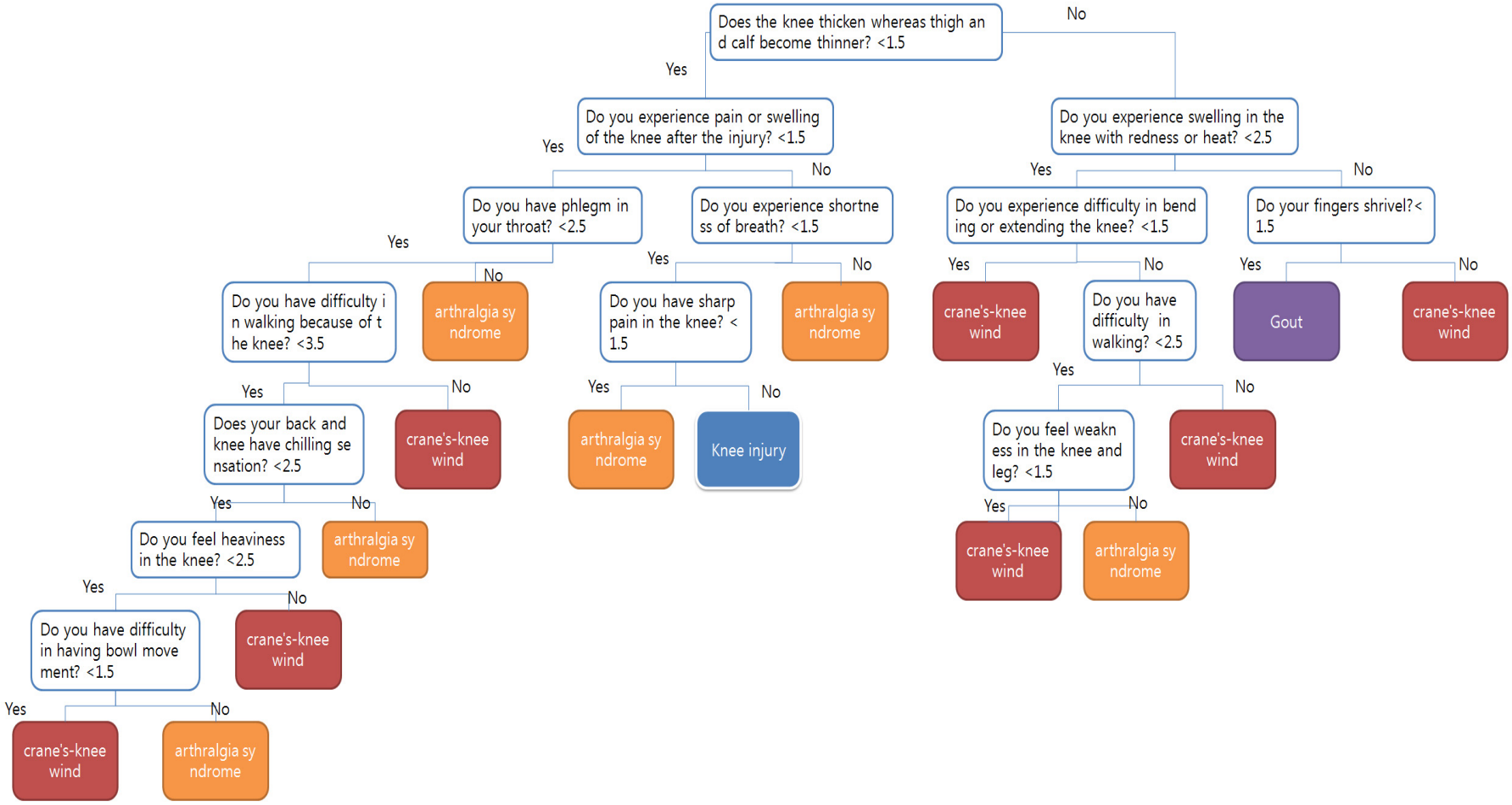
3. Diagnosis – Knee pain

(A) Diagnosis system and diagnostic method of knee pain

As a result of discussion in specialists association via Delphi method, a definitive diagnostic system regarding knee pain is recommended as following.

① Knee injury ② crane's-knee wind ③ arthralgia syndrome ④ acute arthritis ⑤ gout	Evidience level : C(Consensus)

A survey consisted of 46 knee pain-related symptoms was taken by 109 knee pain patients. Each patient was consulted by three oriental medicine doctors regarding the five symptoms with Classification and Regression Tree (CART, Breiman, 1984) method and diagnostic method of knee pain are recommended as follows



Evidience level : Consensus

(B) Pattern identification of the knee pain

According to the result of the discussion by the specialist association, Deterioration of a case of the knee is recommended as below.

(1) Differentiation according to the theory of Jangbu organs

Demonstration of judgments on sites and characteristics of disease and prosperity or decline of the vital principle and the pathogen, based on biological function and pathologic expression of five viscera & six bowels. Thus, analyze symptoms inductively and investigate pathogenesis

deficiency of liver and kidney/ Eum deficiency of liver and kidney/ deficiency and cold of kidney Gi/ weakness of the spleen and stomach/ impairment of body fluid due to lung heat

(2) Pattern identification according to meridians and collaterals

Pattern identification according to meridians and collaterals is a symptom that occurs in vicinity of circulation of meridian system. By applying theory of meridians, it analyzes and gathers patient's presentation of pathology and determines specific meridian that is affected with the pathology.

(3) Pattern identification according to the etiology and pathogenic factor

A pattern identification based on a belief that all symptoms arise from consistent cause and the cause is determined via symptom analysis

wind-cold/wind-heat/cold/damp/wind-damp/cold-damp/damp-phlegm /damp-heat /malnutrition of tendon and blood channel/breaking and wound of muscles and tendons/heat toxins/toxious damp

(4) Pattern identification according to Gi (energy) and the blood, Yin and Yang.

Analysis of pathologic changes that are caused by reduction in fundamental factors of physiology, Gi (energy) and blood. It also differentiates symptoms related to the changes.

Deficiency of both Gi(energy) and blood / stagnation of Gi(energy) and blood stasis / Gi deficiency/ blood stagnation/deficiency of Yin/ deficiency of Yang

According to a survey gathered from Korean oriental medicine doctors (2009, 3, 26-2009, 4, 14), Specialist Association recommends utilization of liver Meridian of Foot Gworeum and Spleen Meridian of Foot Taeeum due to the fact that pattern identification according to meridians and collaterals methodology is most frequently used.	Evidience level : C(Consensus)

(C) Western medicine diagnosis of knee pain

Knee pain is commonly induced by knee osteoarthritis, rheumatoid arthritis, and soft tissue knee injuries and diagnosis for the disorders are as follows.

(1) Knee osteoarthritis
(2) Rheumatoid arthritis
(3) soft tissue knee injuries

4. Treatment

(A) Acupuncture treatment

(1) Basic rules

1. Between patients, hands must be washed. 2. Always use sterilized needles. 3. Treatments must be administered in sterile areas. 4. Hands must be washed in case of contamination 5. Used needles must be quarantined.	Evidience level : C(Consensus)

(2) Safety

An appropriate acupuncture treatment by an oriental medicine doctor can be recommended as a safe treatment.	Evidience level : A(Systematic Review)

(3) Treatment methods

A) Neck pain

here were not enough objective ground reference about acupuncture treatment for neck pain, so the Oriental medicine doctors who are targets of this clinical guideline were researched for their actual condition and practice pattern (2009.11.23~2010.1.9) to create the guideline and reflect actual conditions to it.

It is recommended that patient treatments should reflect actual treatments as below.

1. Differentiation according to the theory meridians and collaterals is the most frequently used differentiation method of syndromes. 2. Cervical spine ROM, area of pain and description of the pain, information obtained by pulse feeling and palpitation, history of pain, the patients usual factor and etc., are main diagnosis standards. 3. Frequently used acupuncture methods, in order of high frequency, Saam-chimbeop - asihyeol(Asihyeol-chimbeop) - five Su points five points-chimbeop - DongQi-chimbeop - acupuncture based on anotomical structures. 4. Both the normal, and the ill side of the patient are mix treated. 5. The most frequent used needling depth is about 1.5-3cm, needle thickness 0.25mm, needle length 40mm and the prone position is the most frequent used position for acupuncutre treatment. 6. De-qi and tonification-purgation are frequently performed and most of the acupuncture treatment had a duration time of over 15 minutes-below 20 minutes. Most patients were treated 3 times a week, and the treatment period for acute neck pain was under 3 weeks, and for chronic neck pain (in pain for over 3 months) were over 3 weeks and under 5 weeks.	Evidience level : C(Consensus)

B) Low back pain

There were not enough objective ground reference about acupuncture treatment for low back pain, so the Oriental medicine doctors who are targets of this clinical guideline were researched for their actual condition and practice pattern (2009.11.23~2010.1.9) to create the guideline and reflect actual conditions to it.

It is recommended that patient treatments should reflect actual treatments as below.

1. Differentiation according to the theory meridians and collaterals is the most frequently used differentiation method of syndromes. 2. Area of pain and description of the pain, information obtained by pulse feeling and palpitation, degree of thoraco-lumbar swelling & incurvation, lumbar spine ROM, history of pain, the patients usual factor and etc., are main diagnosis standards. 3. Frequently used acupuncture methods, in order of high frequency, Saam-chimbeop - ashihyeol(Ashihyeol-chimbeop) - five Su points five points-chimbeop - acupuncture based on anotomical structures. 4. Both the normal, and the ill side of the patient are mix treated. 5. The most frequent used needling depth is about 1.5-3cm, needle thickness 0.25mm, needle length 40mm and the prone position is the most frequent used position for acupuncutre treatment. 6. De-qi and tonification-purgation are frequently performed and most of the acupuncture treatment had a duration time of over 15 minutes- below 20 minutes. Most patients were treated 3 times a week, and the treatment period for acute low back pain was under 1 week, and for chronic neck pain (in pain for over 3 months) were over 3 weeks and under 5 weeks.	Evidience level : C(Consensus)

C) Knee pain

Due to the lack of objective evidence on acupuncture treatment for knee pain, actual and current state of medical treatments were comprehended by aiming oriental medicine doctors (2009, 11, 23~2010 1, 9). Such effort would reflect the development and current state of the guideline.

Applicationsof acupuncture treatments based on real case scenarios as below are recommended.

1. In case of deterioration, pattern identification according to meridians and collaterals is most commonly utilized. 2. Most important diagnostic standards include patient's complaints such as description of pain and its location, as well asmedical history. Also, swelling and degree of change of the knee joint, color change, ROM of the knee, patient's sensation on heat and cold, improvement and exacerbation factors of pain, pulse feeling and palpitation, information according to one of the four methods of diagnosis, and patient's normal factors are heavily considered. 3. Frequently used acupuncture techniques include Sa-am chipbeop, Ashi point, acupuncture technique based on anatomical structures (muscle, ligament, joint cavity) and five Su points. 4. Both the normal, and the ill side of the patient are mix treated. 5. Depth of needling should be 5 pun to 1 chon; thickness of the needle should be 0.25mm; and length of the needle should be 40mm. In case of the patient's position, laying down position looking at a ceiling is most commonly used. 6. De-qi and purgation were most frequently used, and for the retaining time, 15 to 20 minutes were frequently utilized. 7. In case of treatment cycle, 3 times per week were utilized most frequently. Treatment periods for acute and chronic (over 3 months) knee pain were applied for less than three weeks and three weeks to five weeks, respectively.	Evidience level : C(Consensus)