

The 2nd Korea-Japan Workshop on Acupuncture and EBM

第2回 韓・日 鍼灸 EBM 워크샵

Oct. 22, 2005, a.m. 10:00 ~ 12:00
Room No. 409, Daegu EXCO, Korea

Organized by KOMS(大韓韓醫學會), KAMS(大韓鍼灸學會) and JSAM(全日本鍼灸學會)

Congratulatory Address



Dong-Suk Park, O.M.D., Ph.D.
President
Korean Oriental Medical Society

It is my great honor to invite you and welcome you from Japan to discuss on acupuncture and EBM for the clinical research on acupuncture. We are expecting that this meeting will play an important role in improving the quality of clinical research on acupuncture and the globalization of the Oriental Medicine.

Acupuncture therapy has been highly recognized by the WHO for its effectiveness, and many profound research have been conducted on it in the United States and european countries since several decades ago. Oriental Medical doctors in Korea have reserved the knowledge about the unique acupoints and remarkable skills, and recently put their efforts on the clinical research.

I expect an excellent discussion in this meeting to contribute to the development of clinical research on acupuncture in the future. I would like to show my sincere respect to Dr. Jun-hyoun Jang and Kenji Kawakita for the preparation of this 2nd Korea-Japan Workshop on Acupuncture and EBM.

Lastly, I would like to invite you to the world-famous scenery of the beautiful autumn in Korea. My best wishes for your health and bless your work.

Thank you!

Congratulatory Address



Do-Young Choi, O.M.D., Ph.D.
President
Korean Acupuncture & Moxibustion Society

It is my honor to welcome you all to the 2nd Korea-Japan Workshop on Acupuncture and EBM.

The interest towards Oriental medicine is growing all over the world. Particularly acupuncture is receiving more spotlight because it is the most leading field of oriental medicine at the present.

Now we face a new task of "Evidence Based Medicine". The world science society requires us to show not only classical prescriptions and experiences but also scientific evidences. More and more scientists are interested in investigating the mechanism of acupuncture and moxibustion.

Korea and Japan share a long history and abundant experiences concerning acupuncture. We have been exchanging updated information through various meetings, formal and informal. I am sure that our efforts will be historically meaningful in developing traditional acupuncture into an evidence based future medicine.

Please enjoy the beautiful autumn of Daegu, and make yourselves at home.
Thank you very much.

C Contents

- Congratulatory Address Dong-Suk Park
- Congratulatory Address Do-Young Choi
- Comparison of Superficial and Deep Acupuncture in the Treatment of Ankle Sprain : A Randomized Controlled Trial
Seung-deok Lee (KAMS) 1
- A pilot study of acupuncture treatment for the degenerative knee arthritis on the Evidence Based Medicine
Sung-chul Kim (KAMS) 41
- Effect of indirect moxibustion on the elderly patients of osteoarthritis of the knee- sham controlled clinical trial
Kenji Kawakita (JSAM) 61
- Trigger-point acupuncture treatment of chronic low back pain in elderly patients
Kazunori Itoh (JSAM) 75

Comparison of Superficial and Deep Acupuncture in the Treatment of Ankle Sprain : A Randomized Controlled Trial



Seung-deok Lee, Jun-sung Park,
Woo-young Kim, Seung-Tae Baek, Kap-sung Kim

*Department of Acupuncture & Moxibustion, College of Oriental Medicine,
Dong-Guk University, Seoul, Korea*

Background and Aims : The aim of the study was to compare the therapeutic effect of the superficial and in-depth insertion of acupuncture needles in the treatment of patients with ankle sprain.

Materials and Methods : A prospective randomized single-blind study of superficial and deep acupuncture was conducted. The study was conducted in the Kang-nam Oriental Hosp. of Dong-Guk University. The study comprised 23 patients with ankle sprain who were divided into two groups (A and B).

In group A, the needle was introduced in the skin at a depth of 2mm, whereas in group B the needle was placed deeply into muscular tissue or the articular capsule at a depth more than 1.5cm. The treatment was planned for a duration of 1 week, 3 times. The intensity of pain was evaluated with the Ankle grade pain chart(AGPC) before and after treatment and at the 1-week follow-up examination. The AGPC includes Swelling, Tenderness, Exudation, Bruise, Medial/Lateral stability test, Anterior drawer test, Squeeze test, Bearing weight, Pressure Algometer, Walking state and Visual analogic scale(VAS).

Results : Although at the end of the treatment there was no evidence of significant statistical differences between the two different groups. Pain reduction(VAS) was greater in the group treated with deep acupuncture. A statistical difference existed between the two groups at the 1 week follow up, with a better result in the deeply stimulated group in VAS.

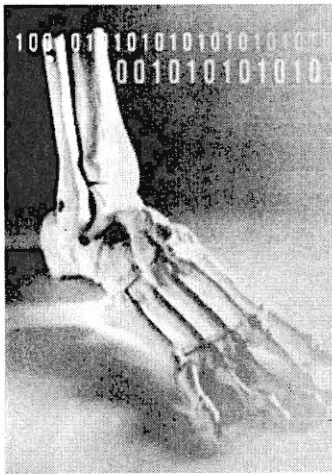
Conclusions : Clinical results show that deep stimulation has a better analgesic effect when compared with superficial stimulation in pain reduction(VAS).

E-mail: chuckman@dongguk.edu

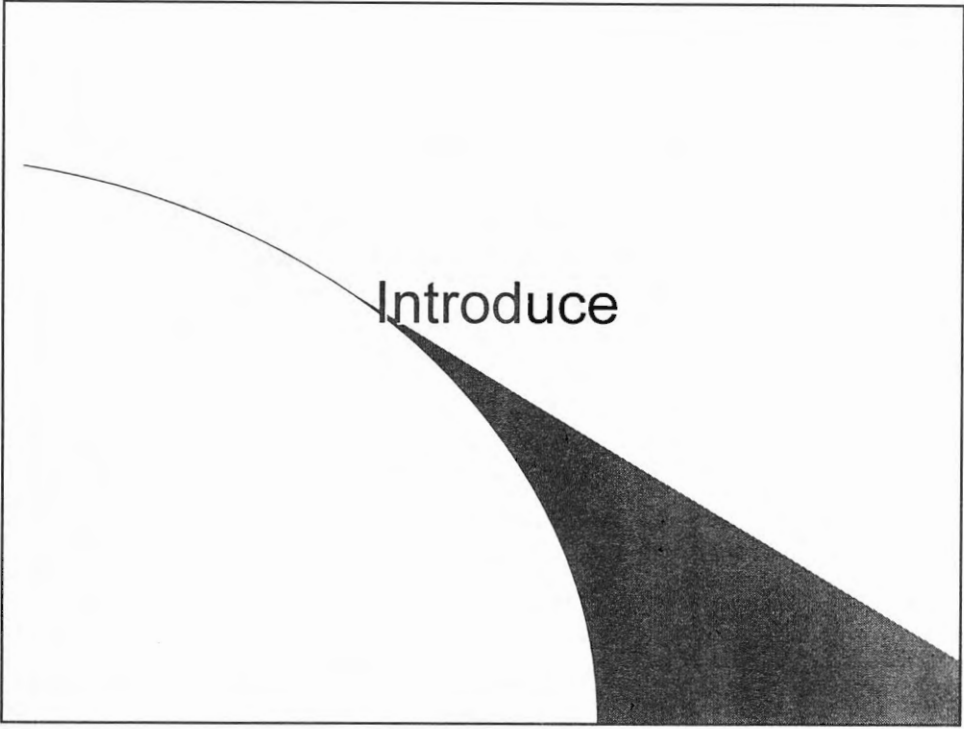
Comparison of superficial and deep acupuncture in the treatment of ankle sprain - pilot study -

- Lee Seung-deok, KMD, PhD,
- Assistant Professor of Acupuncture
& Moxibustion, Department of
Acupuncture & Moxibustion,
Dongguk University School of Korean
Medicine; Korea-medicine Hospital

Contents



- I. Introduce
- II. Background
- III. Design a clinical trial
- IV. Result
- V. Conclusion



Introduce

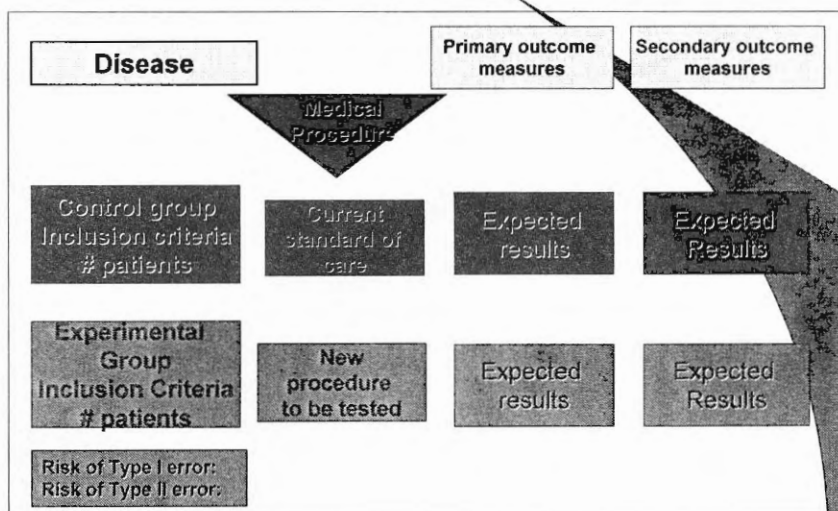
Definition of Clinical trial

- A prospective study
- Intervention
 - Comparing the effect and value
- Against a control
- Human subjects

Designing a clinical trial

- Goal:
 - Compare effectiveness of two different medical procedures
- Procedure:
 - Two groups of patients
 - each receives a different medical procedure
 - Observe clinical outcomes in the groups of patients
 - Primary outcome
 - most clinically important outcome
 - Secondary outcomes
 - other clinical results of interest

To design a clinical trial



Time course of clinical trial

- Define the purpose
 - Hypothesis
- Design the trial
 - Written protocol
- Conduct the trial
 - Good organization
- Analyze the data
- Draw conclusions
 - Publish results

Background

Sprain

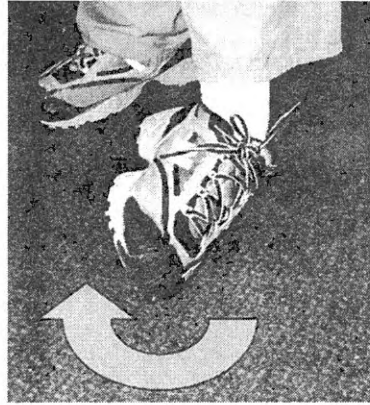
- Ligaments
 - Connection between bones
- Sprains
 - Injuries to the ligaments
 - Stretch or tear

Ankle sprains

- Ankle sprains
 - The most common injuries among all the sprain diseases
- Force around the ankle
 - Exceeds the tensile limits of the supportive ligaments
 - Less than break the ankle bones

Prevalence of ankle sprains

- 85% of all ankle injuries
 - Sprains
- 85% of ankle sprains
 - Lateral inversion
- 1/6 participation time lost
 - Ankle sprains
- Up to 40% of patients
 - Untreated or misdiagnosed

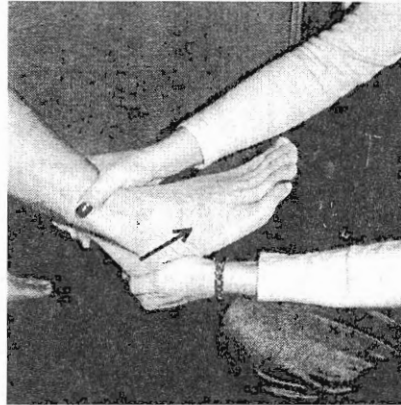


Physical examination

- | | |
|--|--|
| ● Observe <ul style="list-style-type: none">– Edema– Ecchymosis– Deformity | ● Assess <ul style="list-style-type: none">– Active and passive range of motion– Weight-bearing ability |
| ● Palpate <ul style="list-style-type: none">– Tenderness– Crepitant– Deformity | ● Special test <ul style="list-style-type: none">– Anterior drawer test– Talar tilt test– Squeeze test |

Anterior drawer test

- Assess the stability of the ATFL
- ATFL disruption
 - Translation of more than 10 mm
 - 3 mm difference between sides



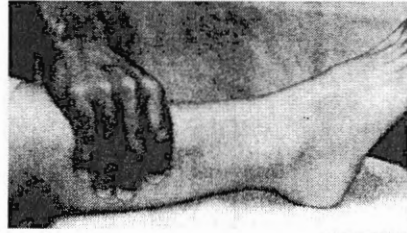
Talar tilt test

- Assess the stability of the ATFL and CFL
- If both the ATFL & CFL are ruptured
 - 3 degree ankle sprain
- If a firm endpoint cannot be felt
 - Damage to the CFL



Squeeze test

- Assess fractures of the tibial or fibular shafts
- Positive test result
 - Pain along the length of the fibula
- If this test increases pain
 - High level ankle sprain
 - Fracture of the proximal fibula

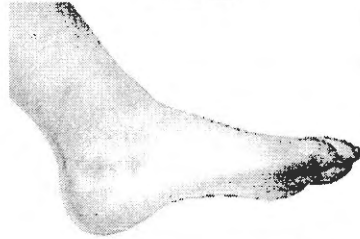


3 grades of ankle sprains

- Grade I
 - Microscopic but not macroscopic tearing
 - Little swelling
 - Little or no functional loss
 - No joint instability

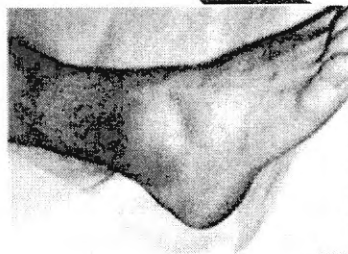
3 grades of ankle sprains

- Grade II
 - Partial tearing
 - Moderate-to-severe swelling
 - Ecchymosis
 - Moderate functional loss
 - Mild-to-moderate joint instability



3 grades of ankle sprains

- Grade III
 - Complete rupture of the ligament
 - Immediate and severe swelling
 - Ecchymosis
 - Inability to bear weight
 - Moderate-to-severe instability of the joint



3 grades of ankle sprains

Grade	Type of sprain	Sign & Symptom	Treatment
Grade 1	No tearing of ligament, no joint function is lost	Tenderness and slight swelling	Elastic band or taping soft exercise
Grade 2	A partial tear in the ligament	Obvious swelling , extensive bruising, difficulty bearing weight, and reduced function of the joint	Fixation of cast in 3 weeks
Grade 3	Complete tearing of the ligaments	Severe pain, loss of joint function, widespread swelling, bruising and inability to bear weight	Fixation of cast or surgery

Red flags/pearls sprains/tears

- Syndesmosis injury (high ankle sprain)
- TTP over navicular
- TTP over lateral process of talus
- TTP medial ankle and at proximal fibula
- TTP at 5th MT base
- TTP over talocrural joint

Ottawa ankle rules

- The Ottawa rules
 - Eliminate 30% of radiographs without missing clinically significant fractures
- Criteria for foregoing radiography
 - Younger than 55 years
 - Able to walk 4 steps
 - No tenderness over the posterior edge or malleolus

Design a clinical trial

Hypothesis

- Study population
 - Patient selection – eligibility
- Treatment
 - Intervention
- Endpoints
 - Outcome evaluation

Hypothesis

- Patient selection
 - Acute ankle sprain
- Intervention (treatment)
 - Deep acupuncture
- Endpoint (timeframe)
 - Pain relief
 - Stability

Hypothesis

- Deep acupuncture
 - Three times per week
 - For patients with ankle sprain has a beneficial effect on pain relief at one week
- What should be the control?
 - Superficial acupuncture

Study population - patient selection

- Unambiguous entry criteria
 - Inclusion
 - Exclusion
- Impact
 - Study design
 - Ability to generalize
 - Subject recruitment

Eligibility criteria

- Inclusion criteria
 - Roughly outline the intended patient population
- Exclusion criteria
 - Fine-tune the intended patient population
 - Safety
 - Feasibility
 - Practicality

Patient selection

- Inclusion
 - Acute ankle sprain
 - The age range was between 15 and 50 yr
- Exclusion
 - Pregnant
 - < 15 years
 - > 50 years
 - Onset > 2 weeks
 - High ankle sprain
 - Positive squeeze test
 - Ottawa ankle rules
 - Fracture in x-ray

Intervention

- Intervention
 - Preventative
 - Diagnostic
 - Screening
 - Drugs
 - Devices
 - Surgical procedures
 - Health service delivery

Intervention

- In-depth study about the method of the acupunctural needle insertion
- Deep vs superficial ?
 - Ankle sprain
 - Deep acupuncture
 - vs
 - Superficial acupuncture

Intervention

- Same condition
 - Without depth of needle insertion
 - Deep group
 - Superficial group

Intervention

- Depth of insertion
 - Superficial acupuncture
 - 2mm depth from the skin
 - Without strengthening-eliminating technique
 - 半刺 (Skin)
 - Deep acupuncture
 - 1.5cm or 2cm depth of joint and muscle
 - Without strengthening-eliminating technique
 - 關刺 (Ligament or Muscle)

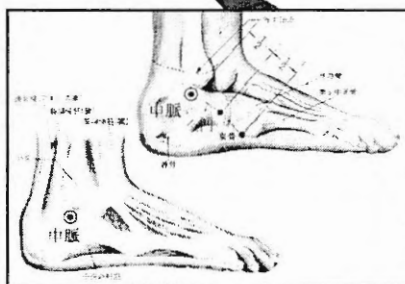
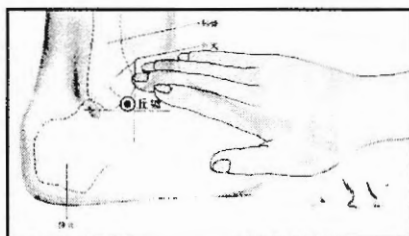
Acupuncture points

- Lateral injury
 - Local point (Pain side)
 - Qiuxu (G40)
 - Shenmai (B26)
 - Distant point (Healthy side)
 - Dicang (S4)
 - Yifeng (Te17)
 - Yanglingquan (G34)

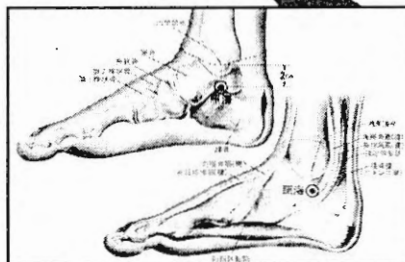
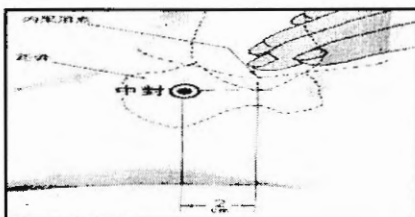
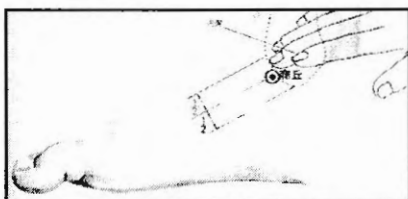
Acupuncture points

- Medial injury
 - Local point (Pain side)
 - Zhongfeng (Liv4)
 - Shangqiu (Sp5)
 - Zhaohai (K6)
 - Distant point (Healthy side)
 - Dicang (S4)
 - Yifeng (Te17)
 - Yinlingquan (Sp9)

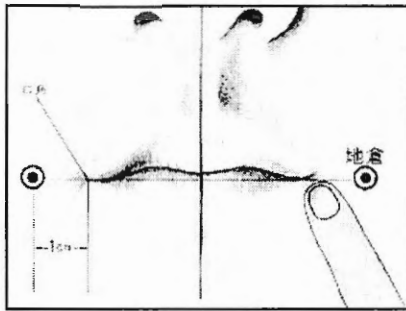
Acupuncture points - lateral injury -



Acupuncture points - medial injury -



Acupuncture points - distant point -



Technique of acupuncture

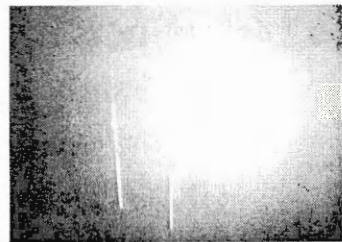
- Distant point (healthy side)
 - 半刺 (Skin)
 - 遠道刺 : yuandaoci
 - Distant road
 - 巨刺 : juci
 - Opposite needling

Technique of acupuncture

- Local point (pain side)
 - 關刺 (Ligament or Muscle)
 - 齊刺 : qici technique
 - One point : 3 needle
 - Balanced needling or triple needling
 - 揚刺 : yangci technique
 - One point : 5 needle
 - Scattered needling

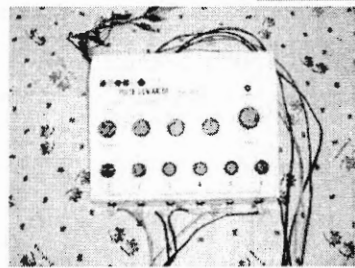
Intervention

- Types of needles
 - Stainless steel needle
 - Diameter
 - 0.30mm
 - Length
 - 40mm
 - Company
 - Dongbang acupuncture, INC, Korea
- Numbers of acupuncture needle
 - same numbers : 10



Intervention

- Needle stimulation
 - Needle insertion time
 - 20 minutes
 - During the treatment period
 - 9-V DC pulse generator device with 5mA mixed pulse
 - The degree of stimulation
 - The patients' tolerance



Intervention

- Co-intervention
 - During the needle insertion
 - Infrared rays
 - From the distance of pain side 40-50cm
 - The degree of 80-90

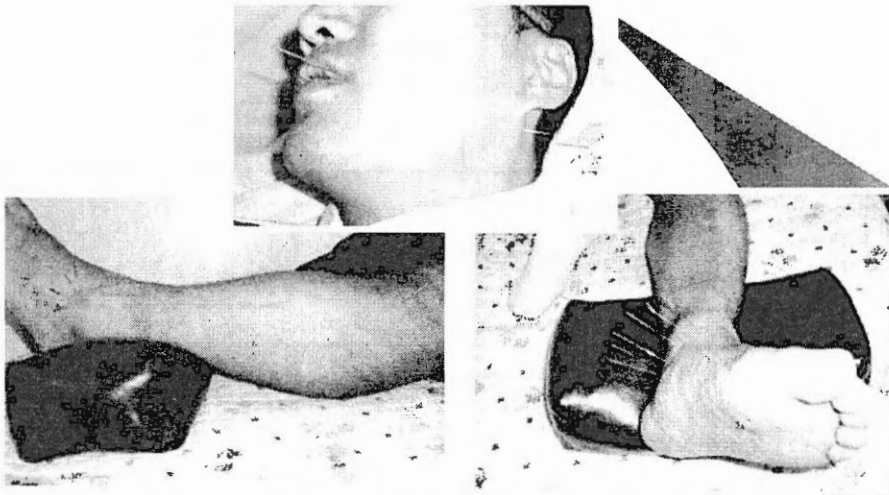
Intervention

- Frequency
 - Every other day
- Length of treatment
 - Three times a week in total

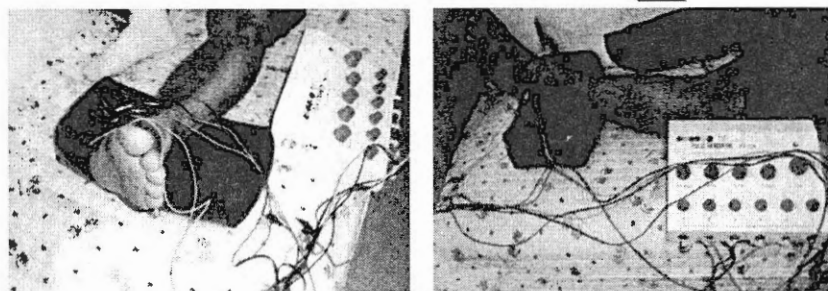
Intervention

- Acupuncturist
 - Same Korean traditional medical doctor
 - 2nd grade of Resident of department of acupuncture and moxibustion

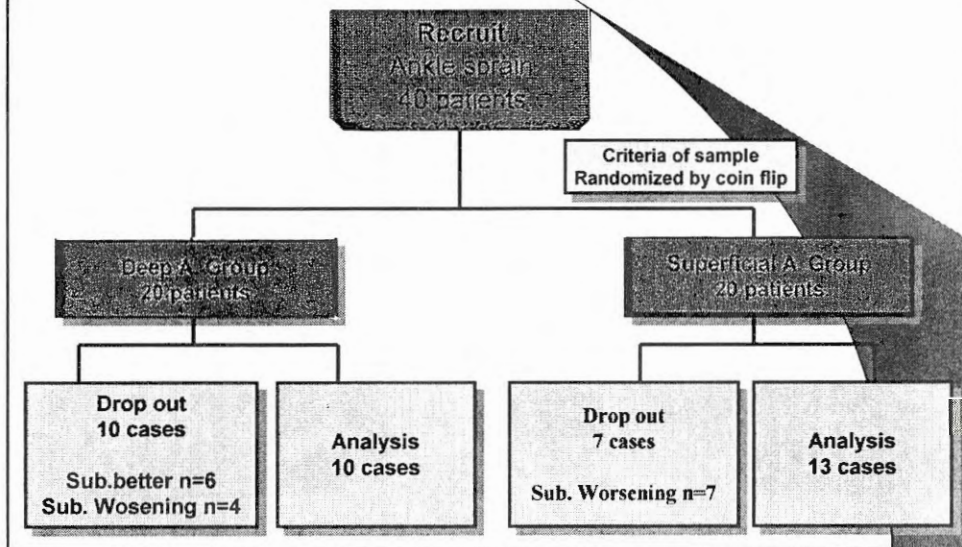
Treatment



Treatment



Trial profile



Randomization

- Basic Benefits of Randomization
 - Eliminates assignment bias
 - Tends to produce comparable groups
 - Produces valid statistical tests

Randomization

- Methods of Randomization
 - Flipping a coin
 - Rolling a die
 - From a dark bag
 - Random number tables
 - Computers

Kinds of Randomization

- Minimize differences
 - Number
 - Restricted (or block) randomization
 - Characteristics
 - Stratified randomization

Blinding (masking)

- Blindness (Masking)
 - unaware of treatment allocation
 - Single blinded
 - Participant
 - Double blinded
 - Participant
 - Clinician

The controlled trial

- The aim of a controlled trial
 - Ensure the comparisons
 - Precise
 - Informative
 - convincing as possible

Controls

- Placebo
- Standard treatment
- Usual care (best medical care)

Blindness/placebo

- Need placebo
 - If 'control' group is receiving no active treatment
 - Avoids biased evaluation
- Essential in studies involving patient self assessment

Blindness/placebo

- Pick best control group
 - Drugs
 - Placebos
 - Pills, injections, IV administration
 - Surgery
 - Sham surgery - ethical?
 - Behavioral
 - Not possible
 - Deception
 - Not ethical

Ethics and design: A question

Is it always ethical to have controls?

Or

Is it ever ethical not to have controls?

Issues in Clinical Trials: Use of Placebo Trials

- 1999 “Declaration of Helsinki”
 - Placebos not ethical in virtually all studies that involve diseases with PROVEN treatment
 - Remain ethical in trials where no proven treatment

Treatment sprains/tears

- Non-operative treatment is the mainstay
- RICE principles
- Early motion (P.T.)
- Short term immobilization and progression of weight bearing may be in order

What is the question?

- Primary question
 - Primary endpoint
- Secondary questions
 - Secondary endpoint
 - Subgroups
 - Alternative follow-up points

Endpoints Outcome : Response variable

- Typical endpoints
 - Mortality
 - Death from specific cause
 - Incidence of a disease
 - Symptomatic relief
 - Clinical finding
 - Laboratory measurement

Endpoints

Outcome : Response variable

- Pick one primary
- Specify secondary endpoints
- Type of data
 - Dichotomous
 - Yes or no (dead or alive, success or failure)
 - Continuous
 - Time to event (censoring)
 - Frequency of events

Good endpoints

- Primary response
 - Assessed in everyone
 - Minimize missing data
- Measured in the same way
- Uniform assessment
- Reliability
- When does participation end if achieve “endpoint”

Surrogate endpoints

- Motivation
 - Need for rapid reliable evaluation of promising new interventions
- Substitute for a clinically meaningful endpoint
 - (feel good, function better, live longer)
- A laboratory measurement or physical sign
- Cheaper, faster, easier
- Requirements
 - Correlate with true clinical outcome
 - Capture effect of treatment on clinical outcome

Ankle injury grade chart

- Swelling
- Tenderness
- Exudation
- Bruise
- Medial/lateral stability test
anterior drawer test
- Squeeze test
- Bearing weight
- Pressure algometer
- Walking state
- VAS (visual analogue scale)

<Ankle Injury Grade chart>
 No. 000 000/100
 O/S
 Made of O/S : Running, Walking, Sport, Rest, Other
 Pain score : Lat. part / Med. part / Lat. and Med. part
 / Lat. and Med. and distal (lateral) part
 Tenderness score : Ant. tibiofemoral lig / Collateral lig / Post. tibiofemoral lig
 / Distal lig / Medial lig / Medial lig / Med. lateral lig / Other

Grade	0	1	2	3	4	5	6	7	8	9	10
Swelling											
Tenderness											
Exudation											
Bruise											
Med. stability											
Lat. stability											
Ant. drawer											
Severest											
Bearing weight											
Pressure											
Algo meter											
Walking state											
VAS											
Load pain											
System											
Grade											

• 00 00 : 0000 / 00 / 00 / 00 / 00 / 00
 • 0000 : 0000 0000 00 00 00 00 00 00 00 00
 • Walking state : Control(V) Walking with Pain(V) Walking(V) Running with Pain(V)
 Running(V)

Statistical analysis

- Two samples Wilcoxon rank sum test
- The level of significance to test statistically significance was at 5 % level ($p < 0.05$)
- www.s-link.com

Sample Size Issues

- Fundamental Point
 - Trial must have sufficient statistical power to detect differences of clinical interest

Results

Demographic and clinical characteristics of subjects at baseline

Characteristics	Deep A. Group (n=10)	superficial A. Group (n=13)
Age (yr)	32.6 $\pm$ 9.99	30.53 $\pm$ 11.93
Female /Male	4/6	8/5
Grade	1.6 $\pm$ 0.51	1.23 $\pm$ 0.43
Duration (day)	1.4 $\pm$ 1.17	5.38 $\pm$ 5.67

Clinical manifestation of deep vs superficial acupuncture - visual analog sale-

	Deep A. Group (n=10)	Superficial A. Group (n=13)	P - value
1 trial	7.36 ± 0.78	6.94 ± 1.09	ns
2 trial	3.83 ± 1.05	5.22 ± 0.82	0.0047
3 trial	1.97 ± 0.79	4.53 ± 0.99	0.0001

Clinical manifestation of deep vs superficial acupuncture - bearing weight (open)-

	Deep A. Group (n=10)	Superficial A. Group (n=13)	P - value
1 trial	6.20 ± 8.01	10.07 ± 7.36	ns
2 trial	13.40 ± 10.42	11.96 ± 6.81	ns
3 trial	20.70 ± 9.34	14.69 ± 6.93	ns

Clinical manifestation of deep vs superficial acupuncture - pressure algometer-

	Deep A. Group (n=10)	Superficial A. Group (n=13)	<i>P - value</i>
1 trial	1.41 ± 0.57	1.86 ± 0.69	ns
2 trial	2.24 ± 0.50	2.26 ± 0.68	ns
3 trial	2.81 ± 0.55	2.53 ± 0.47	ns

Conclusion

Conclusion

- Superficial vs deep acupuncture
 - Deep acupuncture treatment
 - More effective improvement in VAS ($p < 0.001$)
- Not show statistical differences
 - Bearing weight
 - Pressure algometer

“Rules”

- Define the protocols for treatment and control
- Define the population, and sample it
- Define a response and how to measure it
- Randomize the sample to treatment and control
- Control for bias by ensuring objectivity or masked evaluation
- A priori rule as to what “proves” that treatment is better than control

Problems with the “rules”

- What is the appropriate control or comparison?
- When is a placebo control ethical?
- What is the appropriate population?
- Dropping subjects after randomization
- Analysis “by intention to treat.”
- What if you can’t mask and don’t have objective measures?
- What if you can’t randomize?
- “You can’t fix by analysis what you muddle by design.” Light et al.

Thank you for
your attention

A pilot study of acupuncture treatment for the degenerative knee arthritis on the evidence based medicine



Sung-chul Kim, Sung-tae Koo,
Sun-mi Choi, Sung-nam Kim, Jeong-a Lim, Sung-yong Lee

*Department of Acupuncture & Moxibustion, College of Oriental Medicine,
Won-kwang University, Iksan, Korea*

Background and Aims : To determine whether the pragmatic acupuncture treatment provides more effective pain relief than treatment using the same acupuncture point to the all patients.

Protocol Design: pragmatic randomized controlled trial

Setting: One outpatient clinics (acupuncture clinic) located in hospital of oriental medicine, Wonkwang University.

Patients: 40 patients (age 50years or older) with a diagnosis of degenerative osteoarthritis of the knee based on radiographic evidence of at least 1 osteophyte at the tibiofemoral joint (kellgren-Lawrence grade ≥ 2).

We recruited patients through the local newspaper and radio advertisements.

Method: We randomly allocated participants to 2 groups. The group 1 is the pragmatic acupuncture treatment group and the group 2 is the standardization acupuncture treatment group.

Group 1: We used 3 liver meridian points (LI 3,4,7) for the patients with medial knee joint pain, 2 stomach meridian points(ST 35,36) for the patients with middle knee joint pain, and 3 gall bladder meridian points(GB 33, 34, 43) for the patients with lateral knee joint pain, we added to LI 2 point using reduction method if patients have knee edema. Group 2: we used the acupuncture points of B34, SP9, ST35, S36, BL60, GB39, SP6, and KI3 using the reinforcement-reduction method.

Measurements: Primary outcomes were changes in the Western Ontario and McMaster Universities Osteoarthritis index (WOMAC) pain and function scores at 4, 8, and 14 weeks. Secondary outcomes were consisted of 100mm VAS(Visual Analog Scale), SF-36(physical health scores of the 36-item Short-Form Health Survey), ROM (Range of Motion) using Goniometer, and pain threshold using pressure algometer.

Results: We will continue to investigate the clinical study based on the protocol described above.

E-mail: kscndl@hanmail.net

* This study was supported by the Korea Institute of Oriental Medicine.

**A pilot study of acupuncture treatment
for osteoarthritis of the knee joint
on the EBM
(Evidence Basement Medicine)**

*Sung Chul Kim
School of Oriental Medicine, Wonkwang University*

**Domestic acupuncture study on O.A of
the knee joint**

- The effect of common acupuncture on O.A of the knee joint : 55.0%, 66%, 68%
- The effect of Aqua-Acupuncture on O.A of knee :
- 1) Cerui Cornu Paruum Aqua-Acupuncture: 73.2%
- 2) Bee venom Aqua-Acupuncture: 89.5%, 82.5%, 88%
- For the present, Bee venom Aqua-Acupuncture is superior to Cerui Cornu Paruum Aqua-Acupuncture and common acupuncture on the clinical study of O.A of knee joint

Abroad acupuncture study on O.A of the knee joint

- The Clinical Study of Brian m. Berman in the United States (supported by NIH, broadcasted in the CNN) : Recently the largest scale RCT
- Result: After 14 weeks, pain decrease . After 8 weeks, improvement of the quality of life

Abroad acupuncture study on O.A of knee joint

- The problem is treatment without liver channel acu-point
:“ the knee is warehouse of liver”
- Taking simple analgesic, NSAIDS, COX-2, opioid at one's convenience
- Using electroacupuncture
- Insufficiency of establishing specificity in acu-point : treatment around the diseased part

The object

- **To observe pain decrease and improvement of quality of life on senescent person (>50 years old) with osteoarthritis of knee joint under the acupuncture treatments according to meridian**
- **(based on Dong-Eui-Bo-Kham)**

Subjects

- **Patients (>50 years old) with osteoarthritis of the knee joint**
- **Just, the weight must be regular before and after treatment (Excluding Weight loss patient over 3Kg after treatment)**

(Jorge Vas, Camila Mendez, Emilio Perea-Milla, Evelia Vega, Maria Dolores Panadero, Jose Maria Leon, Miguel Angel Borge, Olga Gaspar, Francisco Sanchez-Rodriguez, Inmaculada Aguilar and Rosario Jurado. Acupuncture as a complementary therapy to the pharmacological treatment of osteoarthritis of the knee. BMJ. 2004;329:1216-.)

Inclusion

- Satisfied with 4 lists what is mentioned below
- Diagnosed (> 50 years old) as osteoarthritis at the hospital
- Knee pain daily during this one month
- More than one osteophyte at tibiofemoral joint (kellgren-Lawrence grade ≥ 2)
- Voluntary participation will

Exclusion

1. A person with serious disease not to participate in clinical trial (ex, hemophilic disease)
2. Interarticular injection within 3 months (ex . Steroid)
3. Past history with acupuncture therapy within 1 month.
4. Plan for total knee replacement within 26 weeks.
5. R.A or gout
6. Cancer

- 7. pain caused by trauma indirectly (ex. T.A)**
- 8. poor communications (Dementia, Psychosis etc.)**
- 9. Taking simple analgesic, NSAIDS, COX-2, opioid etc. (or planning to take)**
- 10. Taking a herb medicine of knee pain (or planning to take)**
- 11. Arrhythmia (The pulse is over 100)**
- 12. A heart disease or taking a heart medicine**

- 13. Fasting blood sugar >180u (Among Insulin dependent diabetes patients)**
- 14. Visual disturbance, foot necrosis, peripheral neuropathy caused by diabetes taking s herb medicine of knee pain(or planning to take)**
- 15. Past history of stroke or hemiplegia under medical care**
- 16. Under the care of hypertension, diabetes and hyperlipoidemia all together**
- 17. Tuberculosis**
- 18. Asthma**

19. Legal communicable disease (ex. typhoid, AIDS)

20. Infectious hepatitis or liver cirrhosis

21. Planning operation (within 12months)

22. Forecasting absence over 14 weeks

23. Patients forecasting absence over 7 days in first one month can be treated three times before and after absent week

Just, Prohibit continual treatment for 2 days and treatment over 4 times for a week

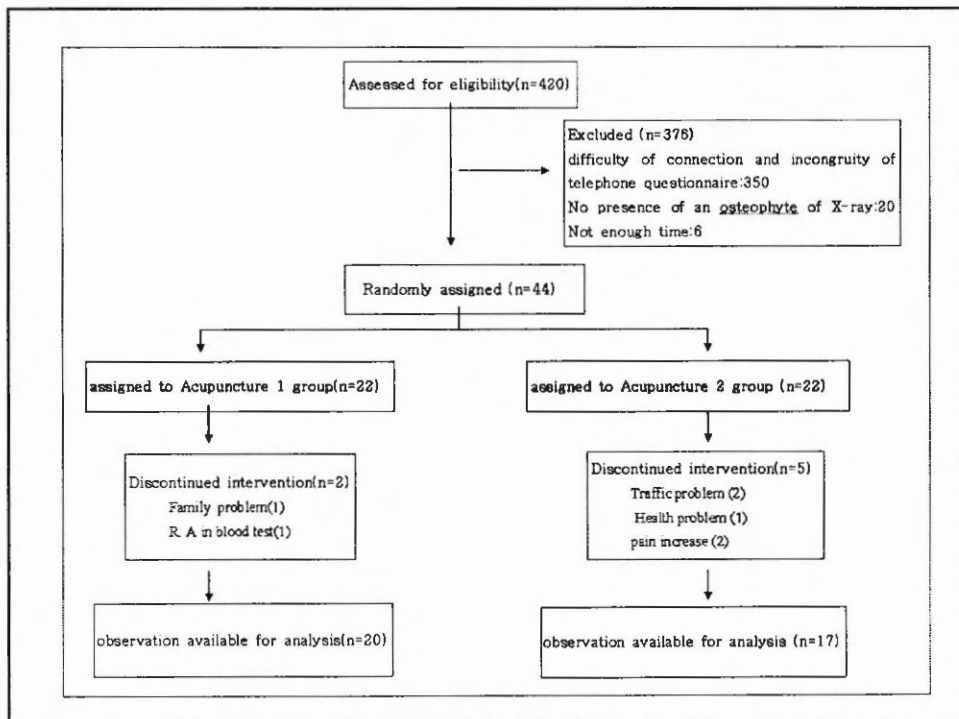
The study hypothesis

Personalized acupuncture treatment on O.A of the knee joint is more effective than electro-acupuncture treatment around the diseased part in Brian m. Berman's Study

(Effectiveness of Acupuncture as Adjunctive Therapy in Osteoarthritis. Annals of internal Medicine. 2004.)

Registration

- The first clinical volunteer : 420 persons
(Radio advertisement : 70, newspaper advertisement : 80, Public relations at the hospital : 40, Subjects taking part in the study of diagnosis agreement: 120, The participant of filial piety campaign: 80, From married women meetings: 30)
- The second clinical volunteer : 70 persons for X-ray (through telephone questionnaire)



We made a Classified table of meridian muscle disease [figure. 1]
and choose a acu-point to use in treatment
(in association with a statistician)



We made a Classified table of deficiency and excess on meridian
to classify deficiency and excess using it. [figure. 2]



Many oriental medicine doctor diagnosed same patients
using differentiation of symptoms and signs.
Then a significance test was performed by the statistician



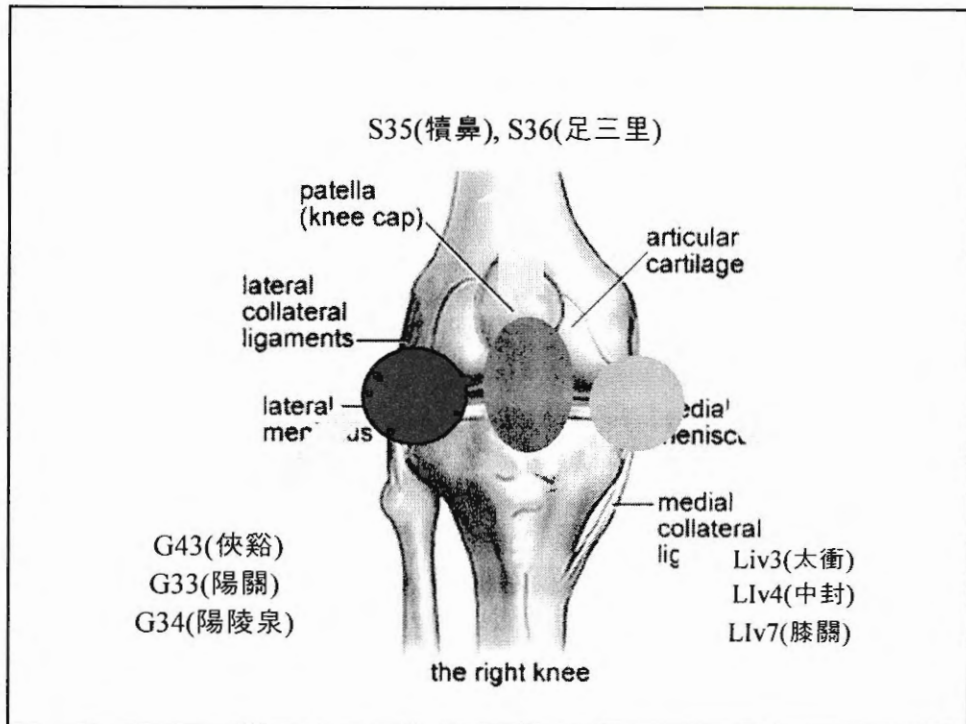
To improve the degree of consensus on diagnosis
acupuncturist had a diagnosis education.
Then a significance test was performed
until the degree of consensus is above 85%

Classified table of meridian muscle disease and acu-point

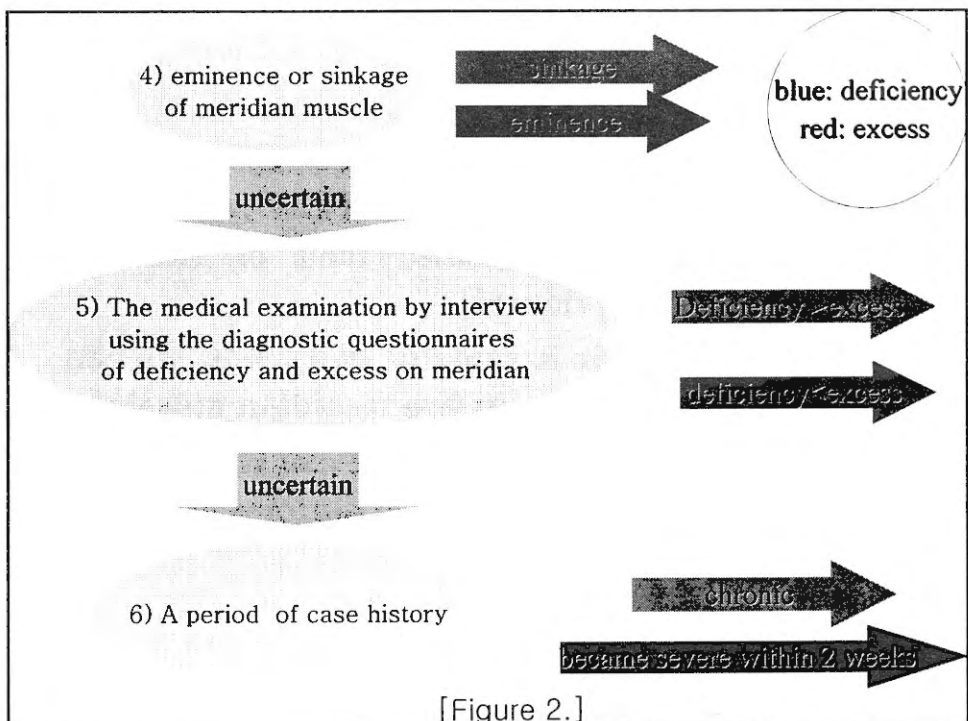
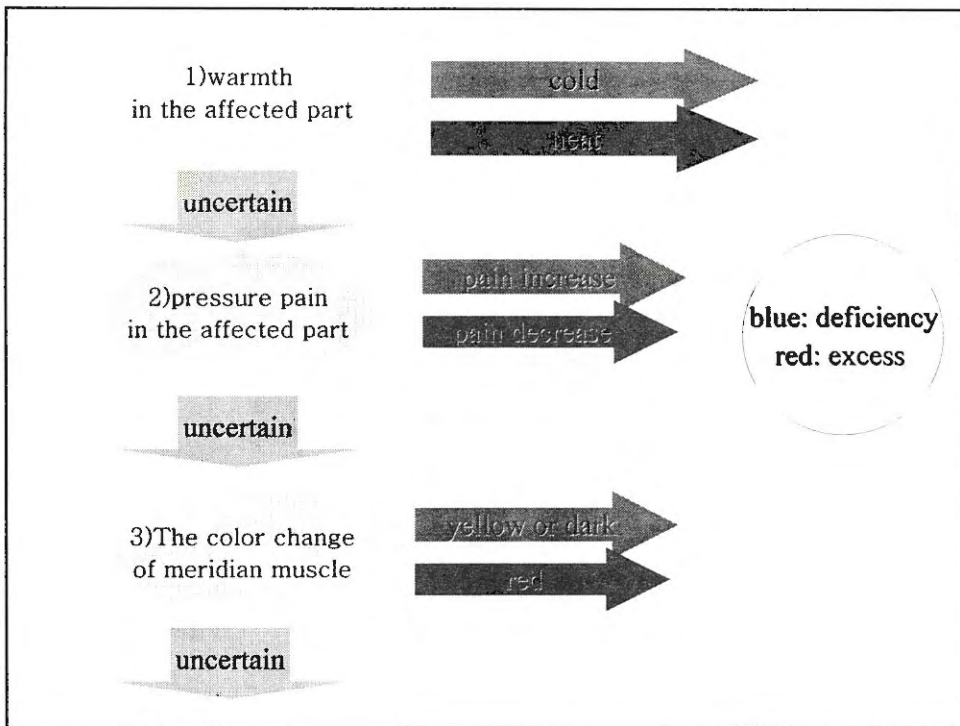
- 1) Classification based on Dong-Eui-Bo-Kham
- 2) Because the posterior knee pain is absence, We add it.
- 3) We divide into four classes and regard Swelling of the knee as accessory symptom.

Medial knee pain(liver channel) ㄱ
Liy3(太衝), Liy4(中封), Liy7(膝關) ㄱ
Middle knee pain(Stomach channel) ㄱ
S35(犢鼻), S36(足三里) ㄱ
Lateral knee pain(gallbladder channel) ㄱ
G43(俠谿), G33(陽關), G34(陽陵泉) ㄱ
Posterior knee pain(urinary bladder channel) ㄱ
B40(委中), B60(崑崙) ㄱ
Knee swelling (liver channel) ㄱ
Liy2(行間) : reduction method ㄱ

Figure 1.



- If painful part is more than two, we choice the most painful place. Then we apply acupuncture as classified table of meridian muscle disease.[Figure1]
- If painful grade is same in two parts, we can apply acupuncture in two meridian muscle.
- If painful part is changed, we can change acupoint as differentiation of symptoms and sign. Then, we record it.



Treatment schedule

week	Acupuncture	Body composition	D.I.T.I	pain threshold	questionnaire	VAS	ROM	T.C thermometer	medicine investigation
1	two times								
2	two times								
3	two times								
4	two times								
5	two times								
6	two times								
7	two times								
8	two times								
9	one time								
10	one time								
11	one time								
12									
13	one time								
14									

Research Randomizer Results

Acupuncture 1 group:

revision:2, 4, 6, 7, 9, 11, 17, 20, 23, 26, 27, 28, 29, 31, 32, 33, 34, 36, 38, 40 ,42,44

Acupuncture 2 group:

revision:1, 3, 5, 8, 10, 12, 13, 14, 15, 16, 18, 19, 21, 22, 24, 25, 30, 35, 37, 39 ,41,43

Acupuncture 1 group (n=22) (*De-qi* and manipulation)

- Needling : 0.3*4mm Dongbang Co. (korea)
- Depth: 0.8-2.5cm insertion
- Maintaining time: 30 minutes
- Contralateral insertion
- Distal or proximal acupuncture
- Lifting and thrusting method with short thrust needling
- Green dragon shaking tail method
- White tiger shaking head method
- Flexion and extension of knee

Deficiency

- Transformation of green dragon shaking tail method

Straight insertion in healthy part (until De-qi)

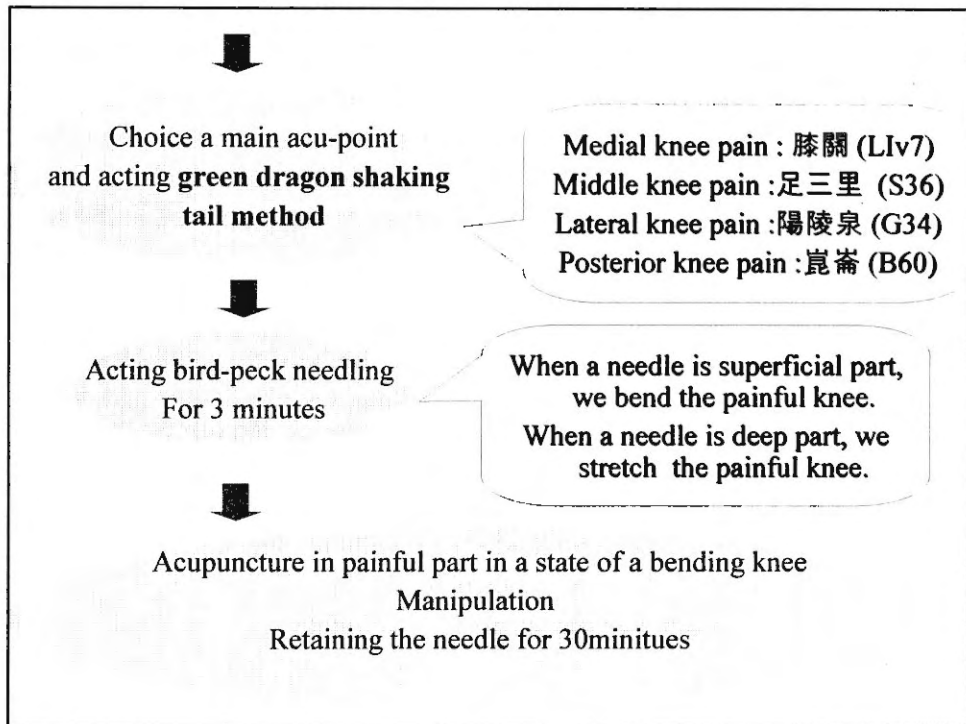


Lay down the handle of needle in the opposite direction of the knee



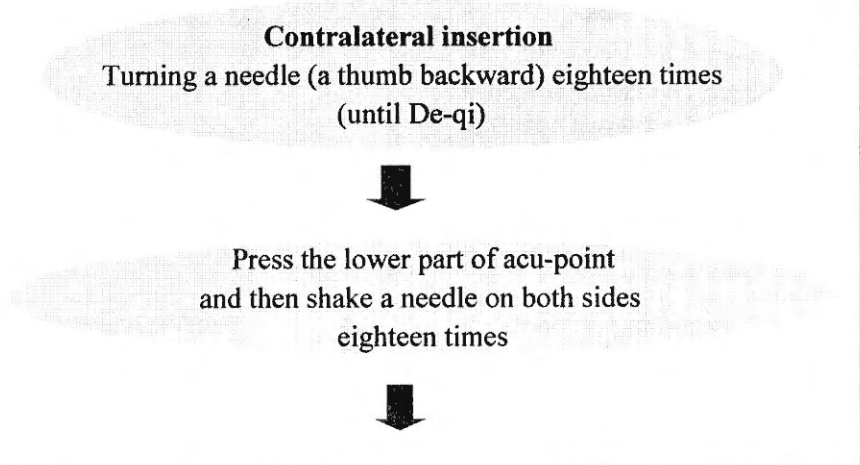
Turning a needle like Rowing a boat
(Forwarding a thumb)
twenty-seven times

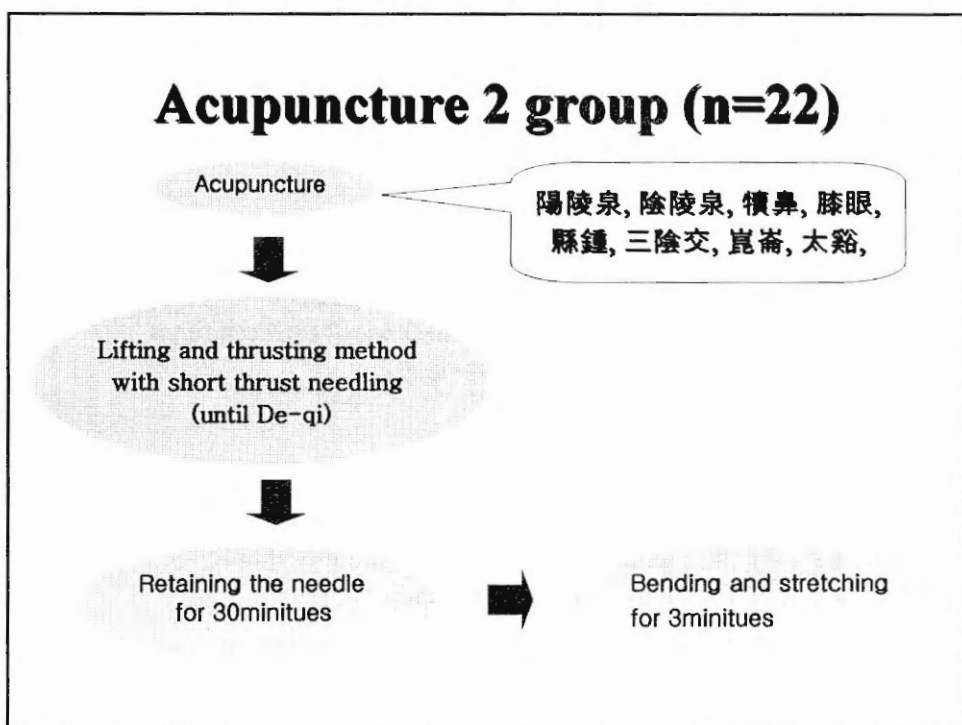
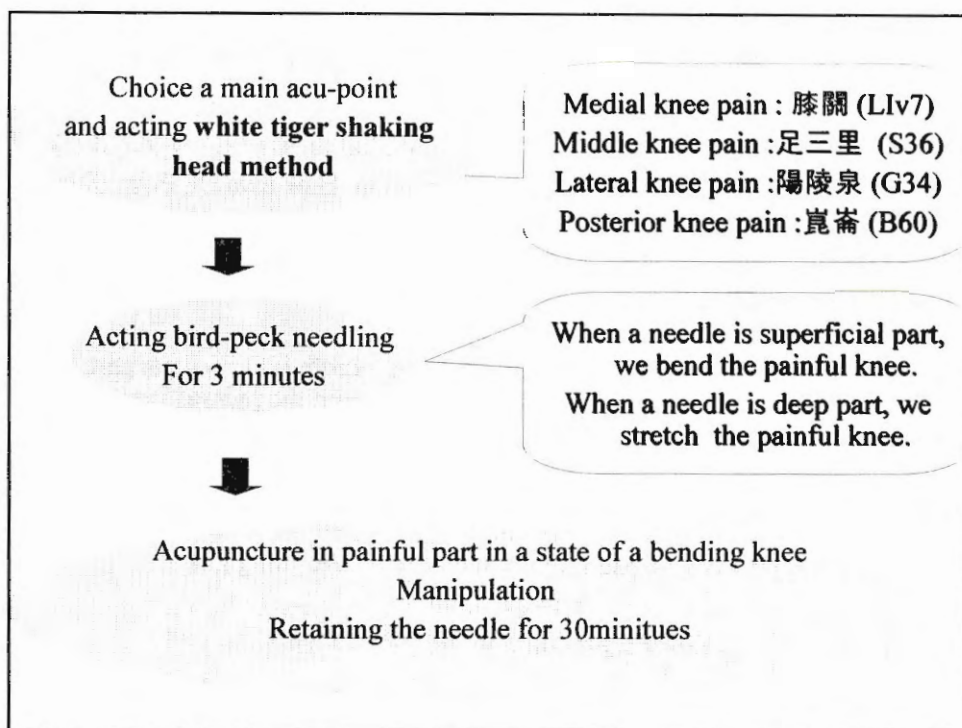




Excess

■ Transformation of white tiger shaking head method





Outcome Measures

- 1. Primary outcome:
- WOMAC (Western Ontario and McMaster universities)
- 2. Secondary outcomes:
- 2-1. 100mm VAS (Visual Analog Scale)
- 2-2. SF-36(physical health scores of the 36-Item Short-Form Health Survey)
- 2-3. pain threshold (with Algometer)
- 2-4. D.I.T.I

Result

<Table 1> The change of a pain threshold before and after treatment
(paired t-test)

variable	before treatment (n=37)	after treatment (n=37)	t(p)
	$\bar{x} \pm S.D.$	$\bar{x} \pm S.D.$	
pain threshold	2.98 ± .471	2.52 ± .430	-4.985 (.000)***

- This table shows pain threshold changed before and after of treatment with significance ($t=-4.985$, $p=.000$). But, pain threshold decreased. So, treatment didn't help the increase of pain threshold [Table.1]

Result

<Table 2> The change of a pain threshold as treatment method

	Acupuncture		t(p)
	1 group	2 group	
	(n=20)	(n=17)	
	$\bar{x} \pm S, D,$	$\bar{x} \pm S, D,$	
The change of pain threshold	$-.45 \pm .395$	$-.46 \pm .711$	.046 (.964)

- This table shows two treatment group didn't have difference in the change of a pain threshold ($t=.046$, $p=.964$). [Table 2]

Result

<Table 3> The change of ROM (Extension) before and after treatment (paired t-test)

Variable	before treatment	after treatment	t(p)
	(n=37)	(n=37)	
	$\bar{x} \pm S, D,$	$\bar{x} \pm S, D,$	
ROM(Extension)	4.73 ± 4.85	1.35 ± 3.47	-3.632 (.001)**

- This table shows ROM (extension) changed before and after of treatment with significance ($t=-3.632$, $p=.001$). So, treatment has an effect on ROM of the knee extension [Table.3]

Result

<Table 4> The change of ROM (Extension) as treatment method

Variable	Acupuncture 1 group (n=20)	Acupuncture 2 group (n=17)	t(p)
	$\bar{x} \pm S, D,$	$\bar{x} \pm S, D,$	
The change of ROM(Extension)	4.50 $\pm$ 5.826	2.06 $\pm$ 5.321	1.321 (.195)

- This table shows two treatment group didn't have difference in the change of ROM of the knee extension (t=1.321, p=.195). [Table 4]

Result

<Table 5> The change of ROM (Flexion) before and after treatment
(paired t-test)

variable	before treatment (n=37)	after treatment (n=37)	t(p)
	$\bar{x} \pm S, D,$	$\bar{x} \pm S, D,$	
ROM(flexion)	144.05 $\pm$ 6.44	149.46 $\pm$ 11.29	2.935 (.006)**

- This table shows ROM (flexion) changed before and after of treatment with significance (t=2.935, p=.006). So, treatment has an effect on ROM of the knee flexion. [Table.5]

Result

<Table 6> The change of ROM (Flexion) as treatment method

variable	Acupuncture	Acupuncture	t(p)
	1 group	2 group	
	(n=20)	(n=17)	
	$\bar{x} \pm S, D,$	$\bar{x} \pm S, D,$	
The change of ROM(flexion)	7.50±11.642	2.94±10.467	1.243 (.222)

- This table shows two treatment group didn't have difference in the change of ROM of the knee flexion (t=1.243, p=.222). [Table 6]

Effect of indirect moxibustion on the elderly patients of osteoarthritis of the knee- sham controlled clinical trial-



Kenji Kawakita¹, Noriko Uryu¹, Kaoru Okada¹,
Kazunori Itoh², Megumi Itoi³ and Yasukazu Katsumi³

¹*Department of Physiology,* ²*Department of Clinical Acupuncture,* ³*Department of Orthopaedic Surgery, Meiji University of Oriental Medicine, Kyoto, Japan*

Background and Aims: There is few clinical research of moxibustion on the symptoms of osteoarthritis (OA). The aim of this study was to evaluate the effects of moxibustion on the symptoms of OA of the knee.

Materials and Methods: Thirty patients (14 men, 16 women, 74+/-3 years) with diagnosis of OA of the knee by the X-ray photograph were allocated to real indirect moxibustion group (9 men, 7 women) or sham group (low temperature moxibustion; 5 men, 9 women) group. Moxibustion treatments were done two times per week for three weeks. Acupuncture points around the knee joint bilaterally (ST-34, SP-9, SP-10, GB-33, LV-8) were used. Outcome measures were VAS of knee pain, WOMAC scores and physical symptoms around the knee joint.

Results: Baseline scores of VAS and WOMAC were similar in two groups. Both VAS and WOMAC scores showed improvement in both groups, but a significant reduction was found only in real group. Physical symptoms were not changed in both groups.

Conclusion: These data demonstrate the real moxibustion is more effective than sham intervention for the pain relief of OA of the knee. The importance of heat-sensitive afferent inputs in both acupuncture and moxibustion treatment is suggested.

E-mail: k_kawakita@mx.meiji-u.ac.jp

Effect of indirect moxibustion on the elderly patients of osteoarthritis of the knee –sham controlled clinical trial–

**Kawakita K, Uryu N, Okada K, Itoh K ¹
Itoi M² and Katsumi Y².**

*Department of Physiology, Department of Clinical Acupuncture¹
and Department of Orthopedics²
Meiji University of Oriental Medicine,
Kyoto, Japan*

Background

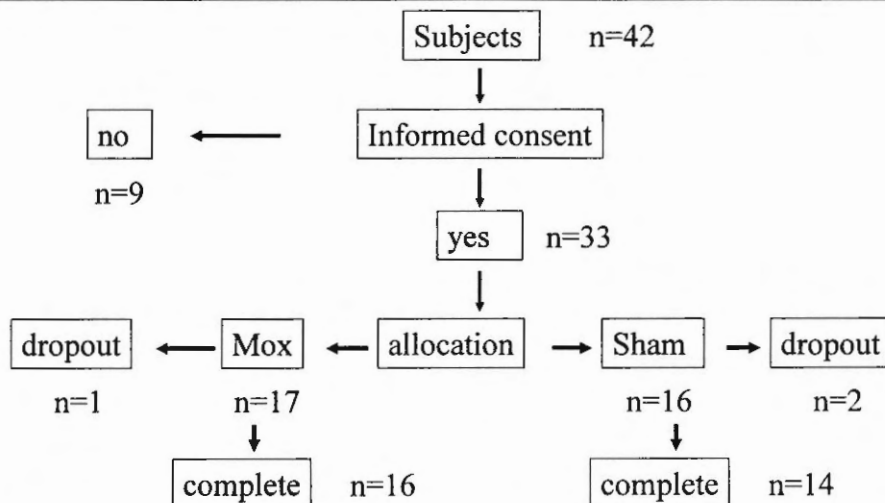
1. Positive effects of acupuncture on the osteoarthritis of the knee (Knee OA) have been demonstrated by well-conducted RCT
2. Moxibustion is the origin of the traditional Chinese medicine but no clinical study has done using sham controlled randomized trial.

Purpose

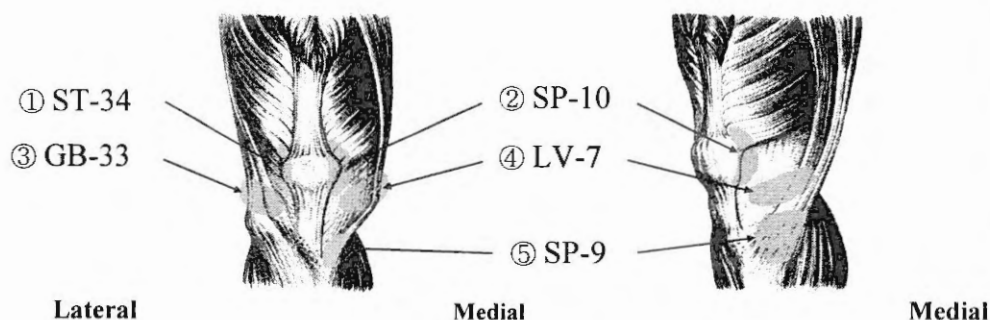
To evaluate the efficacy of warm moxibustion on the pain and physical ability of the patients of osteoarthritis of the knee using special designed sham moxibustion.

Subjects

Out patients of the MUOM hospital. The main symptom was the knee pain and diagnosed as the Primary osteoarthritis of the knee



Sites of treatment



Method of Mox : Two indirect-moxibustion to the bilateral sites

Sites of Mox : ST-34、SP-10、GB-33、LV-7、SP-9

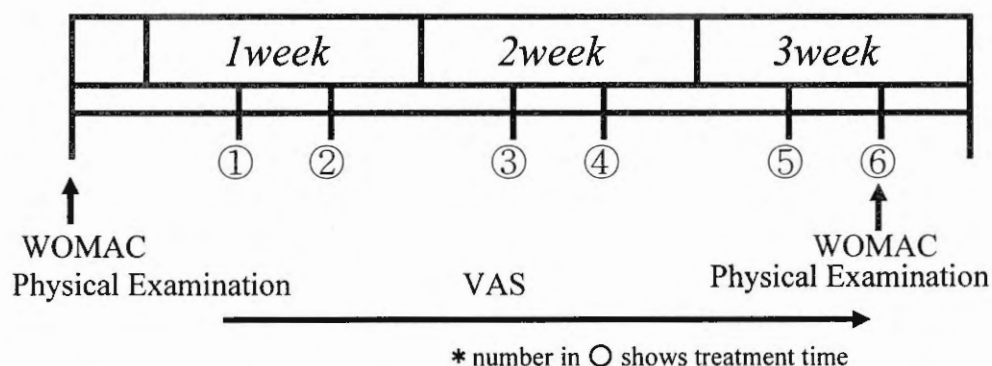
Duration : Three weeks, twice a week

Moxibustion: Indirect moxibustion → Kamaya-mini (Soft)

Sham moxibustion → Long outer-tubed one

Evaluation

- Pain Assesment (Visual Analogue Scale : VAS)
- Western Ontario and McMaster Universities Osteoarthritis Index : WOMAC
- Physical Examinations (excursion, heat, ballottement of patella)



WOMAC Scale (Japanese version)

○ Pain

- 1.Walking on a flat surface.
- 2.Going up or down stairs.
- 3.At night while in bed.
- 4.Sitting or lying.
- 5.Standing upright.

- 1.non
- 2.slight
- 3.moderate
- 4.very
- 5.extreme importance

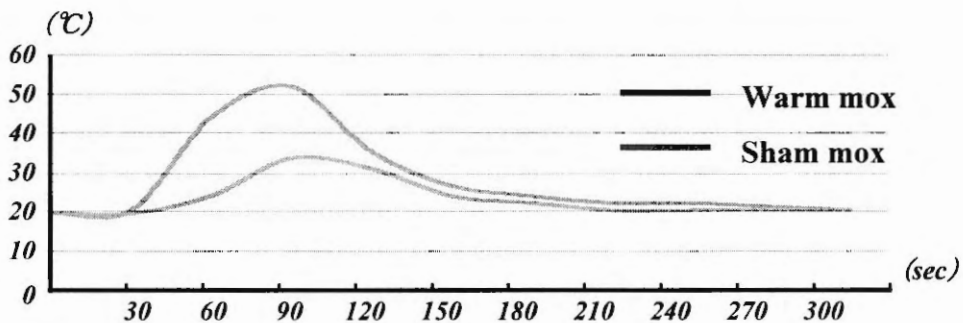
○ Physical Function

- | | |
|------------------------|---------------------------|
| 1.Descending stairs. | 10.Rising from bed. |
| 2.Ascending stairs. | 11.Taking off socks. |
| 3.Rising from sitting. | 12.Lying in bed. |
| 4.Standing. | 13.Getting on/off bath. |
| 5.Bending to floor. | 14.Sitting. |
| 6.Walking on flat. | 15.Getting on/off toilet. |
| 7.Getting in/out car. | 16.Heavy domestic duties. |
| 8.Going shopping. | 17.Light domestic duties. |
| 9.Putting on socks. | |

- 1.non
- 2.slight
- 3.moderate
- 4.very
- 5.extreme importance

* Total scores of pain and physical function are adjusted its maximum to 100 (best). The worst is zero.

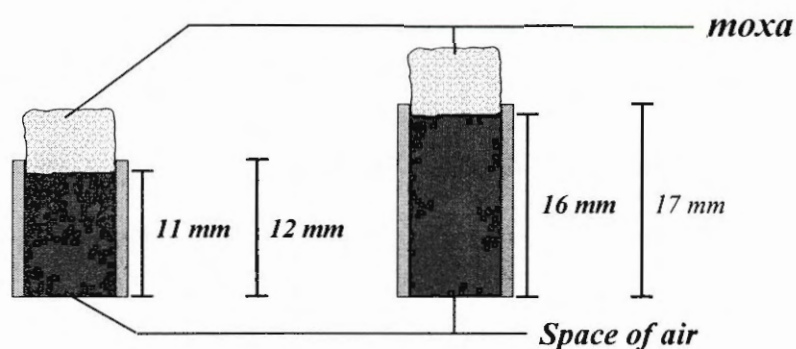
Pattern of Heat Stimulation (Real and Sham mox)



* Measured on a board 10 times

	Real	Sham
Max Temp (°C)	51.2 ± 1.6	35.4 ± 2.6
Time to peak (sec)	102.5 ± 8.5	107.8 ± 10.5

Warm and sham moxibustion devices



Warm moxibustion

Sham moxibustion

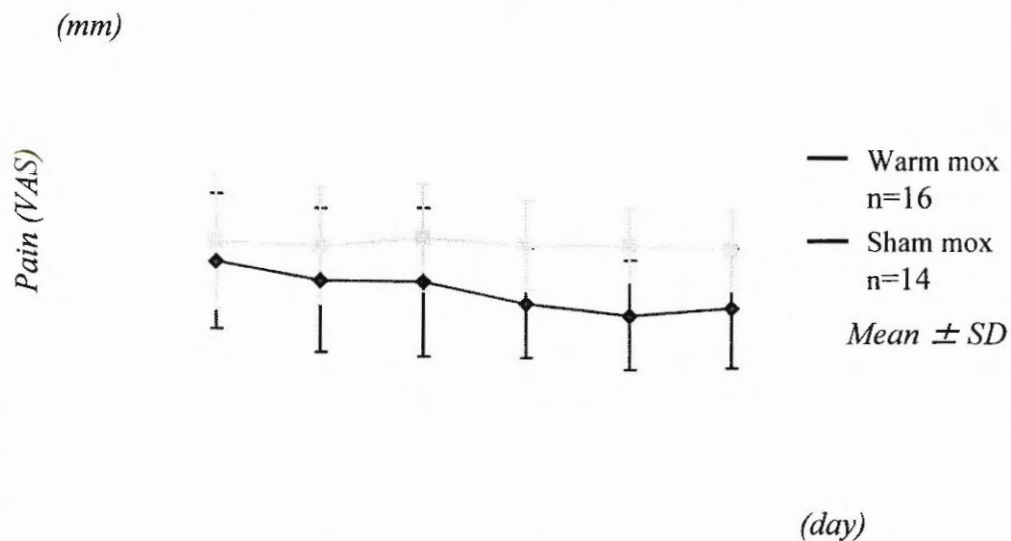
Background factors of two groups

	Warm mox	Sham mox	p - value
Subjects (n)	16	14	0.20
(male / female)	(9 / 7)	(5 / 9)	(ratio)
Grade(I : II : III : IV)	8 : 18 : 4 : 2	6 : 7 : 11 : 1	0.35
Average year	73 +/- 7	72 +/- 7	0.97
Average events	no	no	-
Symptoms	Spondylosis def : n=5	Spondylosis def : n=5	-
VAS (mm) pain	52 +/- 17	57 +/- 17	0.49
WOMAC(score) pain	77 +/- 24	75 +/- 22	0.08
Physical Function	73 +/- 20	79 +/- 16	0.99

* 評価項目は初診時のMean ± SD

Results 1

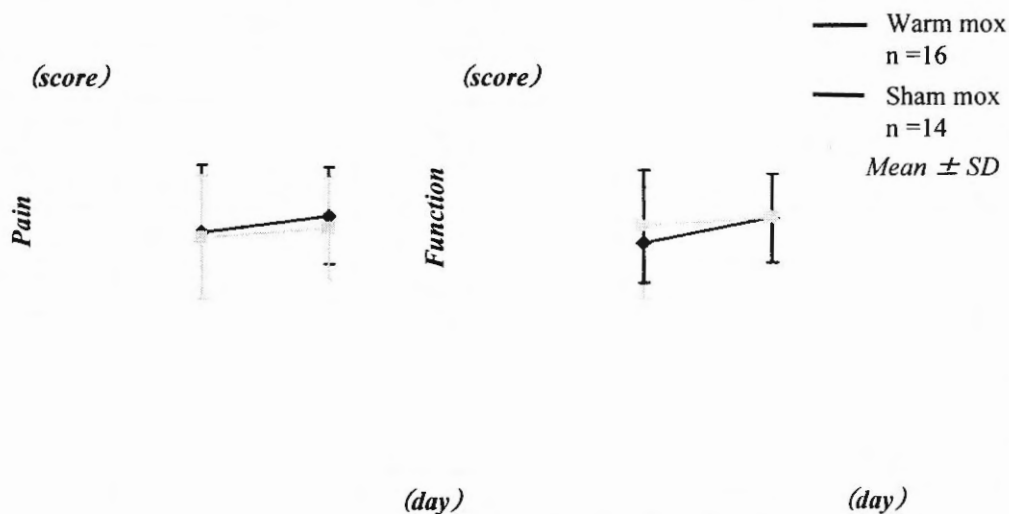
Time course of pain magnitude



Repeated measures ANOVA, Interaction $p < 0.05$

Results 2

Changes in WOMAC scores



Wilcoxon signed rank test

* $p < 0.05$

Kellgren - Lawrence Grade Classification

0. No osteophytes

1. Doubtful osteophytes
2. Minimal osteophytes, possibly with narrowing, cysts and sclerosis
3. Moderate or definite osteophytes with moderate joint space narrowing
4. Severe with large osteophytes and definite joint space narrowing

⇒ Subjects of grade 1-4 were included.

* Patients in grade 1 who have pain symptoms were adopted.

Results 3

Changes in physical examination

Warm moxibustion (n = 32)

Sham moxibustion n = 26 (TKA : 2)

	Warm moxibustion			Sham moxibustion			p value
	improve	no change	worse	improve	no change	worse	
excursion (flexion)	6	20	6	6	17	3	0.54
excursion (extension)	0	31	1	0	26	0	0.84
heat	3	27	2	0	23	3	0.84
ballottement of patella	3	25	4	0	24	2	0.84

Changes in excursion

improve : over +5° , worse : less than -5°

Mann - Whitney U test

Discussion 1

Warm moxibustion

Reduction of Pain
Improvement of QOL

Sham moxibustion

No pain relief

Analgesic effects of warm moxibustion
was confirmed



**Temperature of warm moxibustion is
essential for the analgesic effect**

Discussion 2

Can the warm moxibustion change the excursion of
knee joints, heat and ballottement of patella



No apparent difference between the warm and
sham moxibustion on the results of physical examination

We could not make a conclusion from the present data

Reasons

1. Assessment in categorical scales (improve, no change and worse).
was not so sensitive. Quantitative evaluation will be required.
2. The experimental period might be too short to make a conclusion

Conclusion

Sham controlled quasi RCT was conducted to evaluate the effects of warm moxibustion on the osteoarthritis of the knee.

VAS was reduced accompanied with time in both two groups, but only warm moxibustion was significant (compared to the baseline)

Significant increase of WOMAC score was observed only in the warm moxibustion group.

No change was observed in physical examination in both groups

It is concluded that warm moxibustion is useful method of pain relief of the osteoarthritis patients.

**We need more
basic and clinical researches
on Moxibustion.**

Because

**Meridian phenomena were discovered
by the clinical experiences of moxibustion,
not by acupuncture.**

Ancient medical literatures were found in Mawangdui (馬王堆),
which describes only eleven moxibustion meridians (十一脈灸經)

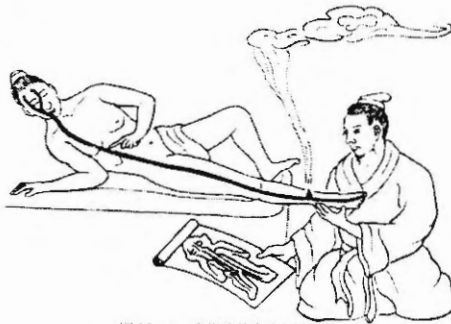


图 17-1 俞樾秋均灸病而定冠帽

朱兵編著：針灸的科學基礎，1998

**Polymodal receptors are
the most possible candidates for
moxibustion and *acupuncture* stimuli**

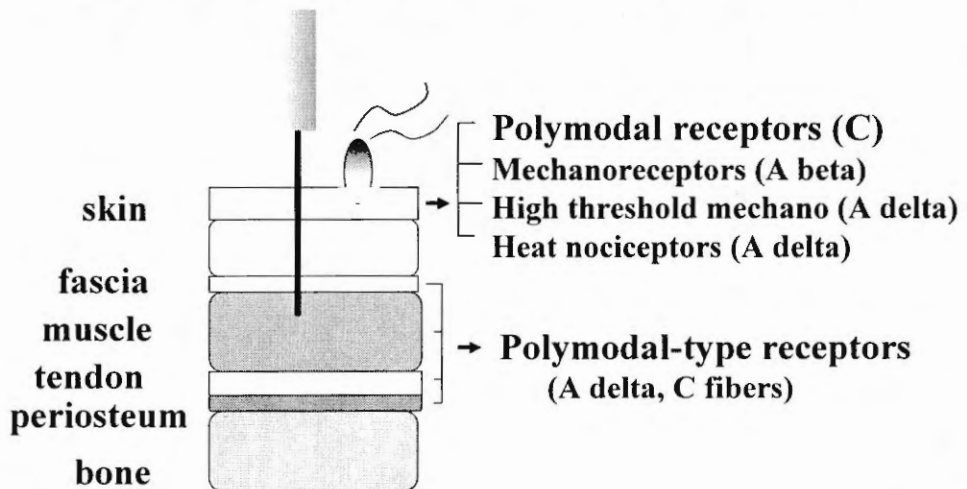
*** *A kind of nociceptor***

• *Responsive to poly=multiple stimuli*

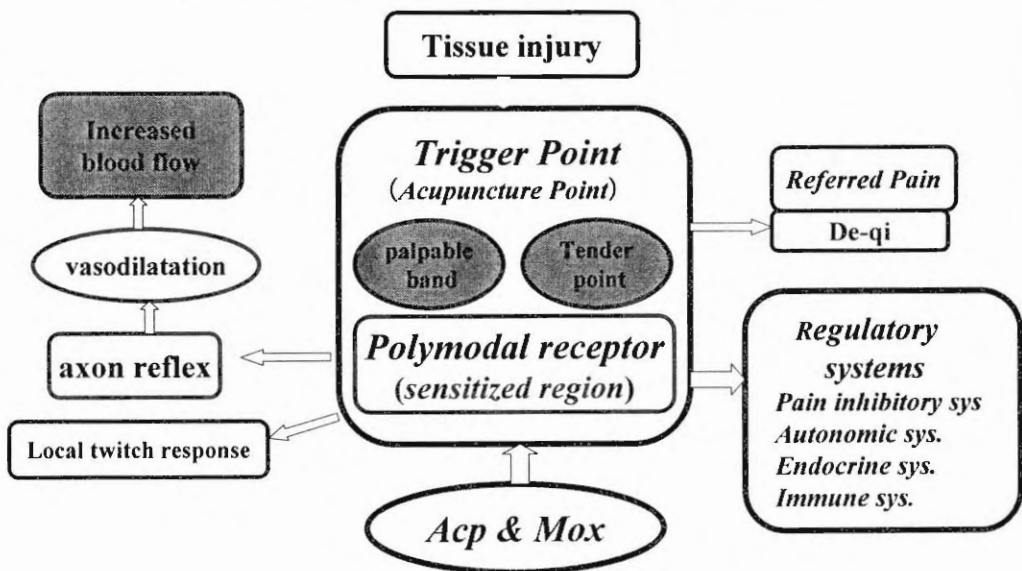
- 1. *thermal (moxibustion)***
- 2. *mechanical (acupuncture)***
- 3. *chemical (moxibustion & acupuncture)***

*** *Effector function (secretion of SP and CGRP)***

Receptors responsive to Acp & Mox



Acupuncture Points and Trigger Points





Trigger-point acupuncture treatment of chronic low back pain in elderly patients



Kazunori Itoh¹, Yasukazu Katsumi², Satoko Hirota²,
Megumi Itoi², Akiyoshi Kojima²,
Shougo Toyama², Hiroshi Kitakoji¹, Kenji Kawakita³

¹Department of Clinical Acupuncture, ²Department of Orthopaedic Surgery, ³Department of Physiology, Meiji University of Oriental Medicine, Kyoto, Japan

Background and Aims: Our objective was to evaluate the effects of two different modes of trigger-point acupuncture on pain and quality of life in chronic low back pain patients compared to standard acupuncture.

Materials and Method: Thirty five consecutive out-patients (age range: 65-81 years), with non-radiating low back pain for at least six months, were randomised to one of three groups over 12 weeks. Each group received two phases of acupuncture with an interval between them. The standard acupuncture group received treatment at traditional acupuncture points, while the other acupuncture groups received superficial or deep treatments on trigger-points. Outcome measures were VAS pain intensity and Roland Morris Questionnaire.

Results: After treatment, the deep needling to trigger-points reported less pain intensity and improved quality of life compared to the standard acupuncture or the superficial needling to trigger-points, but the differences were not statistically significant. There was a significant reduction in pain intensity between the treatment and interval in the deep needling to trigger-points, but not in the standard acupuncture or the superficial needling to trigger-points.

Conclusion: These results suggest that deep needling to trigger-points may be more effective in the treatment of low back pain in elderly patients.

E-mail: k_ito@uom.meiji-u.ac.jp

Trigger point acupuncture treatment of chronic low back pain in elderly patients

*Department of Orthopaedic Surgery¹,
Clinical Acupuncture², Physiology³*

Meiji University of Oriental Medicine,

Hiyoshi, Funai, Kyoto, 629-0392, JAPAN

***Katsumi Y¹, ITOH K², Hirota S¹, Itoi M¹,
Kojima A¹, Toyama S¹, Kitakoji H², Kawakita K³***

Background

Acupuncture has been frequently used on chronic low back pain (LBP) and chronic neck pain (CNP) patients. A number of randomized controlled trials (RCTs) have already been published. However, recent systematic reviews have pointed out the lack of adequate design, methodology and quality of the administered acupuncture.

The method of point selection in the previous trials seemed to be too simple and formal. The more precise selection of stimulating points are required.

Aim of Investigation 1

Our main aim in this study was to compare the efficacy of acupuncture to trigger points on the chronic low back pain in the elderly to those of acupuncture to widely-used acupoints.

Methods

Subjects

Eighteen patients (10 women, 8 men; age range: 65-81 years) of Meiji University of Oriental Medicine Hospital with no-radiating low back pain for at least 6 months and normal neurological examination.

Design & Treatment

The standard acupuncture group (SA, n=9) received treatment at traditional acupoints for low back pain, the other acupuncture groups received on trigger points (TrP, n=9) .

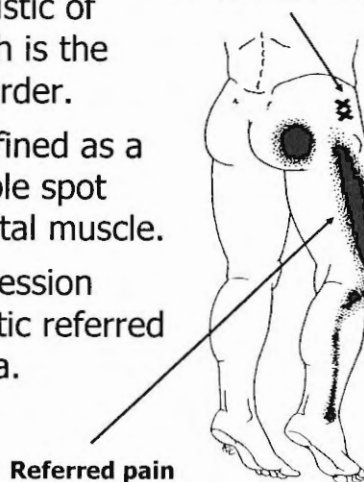
Outcome Measures

- **Pain intensity : VAS** (0 - 100 mm)
- **QOL measure : RMQ**
(Roland Morris Questionnaire: range 24)

What is Trigger Point ?

- **The trigger point** is characteristic of myofascial pain syndrome which is the most common muscle pain disorder.
- **The trigger point** has been defined as a highly localized and hyperirritable spot in a palpable taut band of skeletal muscle.
- **The spots** are painful on compression and can give rise to characteristic referred pain and autonomic phenomena.

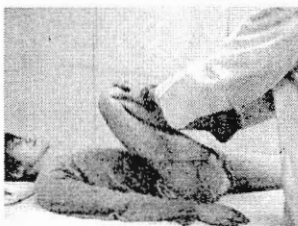
Trigger point of
M. Gluteus Minimus



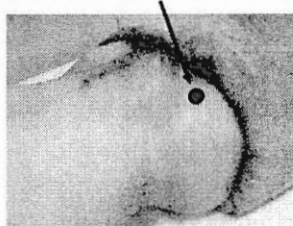
Detection of Trigger Point

1. Full-stretch range of motion (ROM) of the affected muscle was restricted by pain. Therefore, therapist was measured ROM of patients and determined as the affected muscle. (a)
2. The affected muscle was carefully palpated.
3. The localized sensitive region was detected on a palpable taut band in the affected muscle.
4. If trigger points were located, the pressure on localized sensitive region induced some of the pain of which the patient complains. (b)

a. Flexion of hip joint

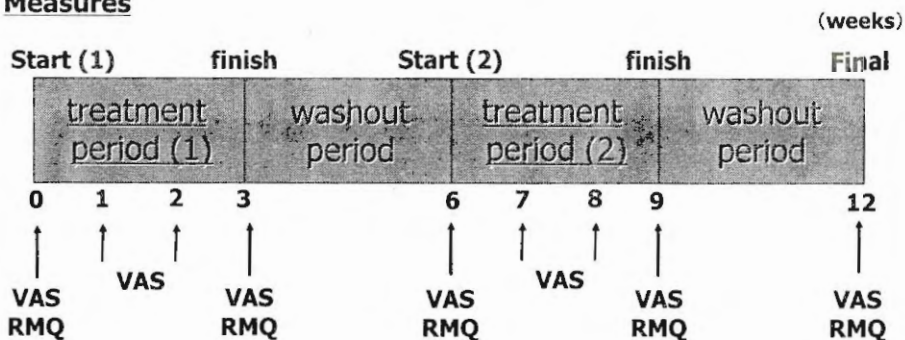


b. Trigger Point of M. Iliopsoas



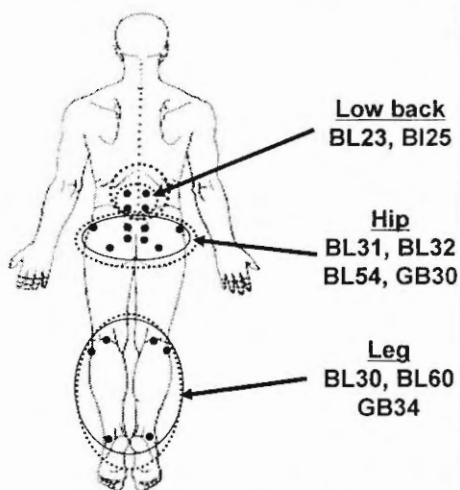
Design 1

Measures



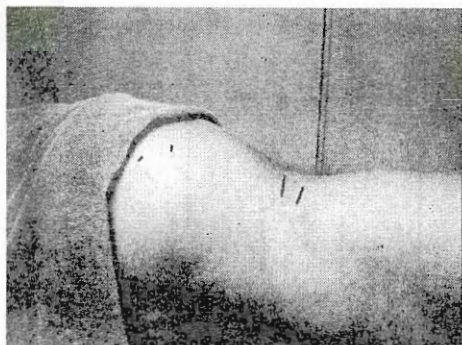
RDQ: Roland –Morriss Disability Questionnaire

Treatment Points of the Standard Acupuncture (SA) Group



Total: 18 points

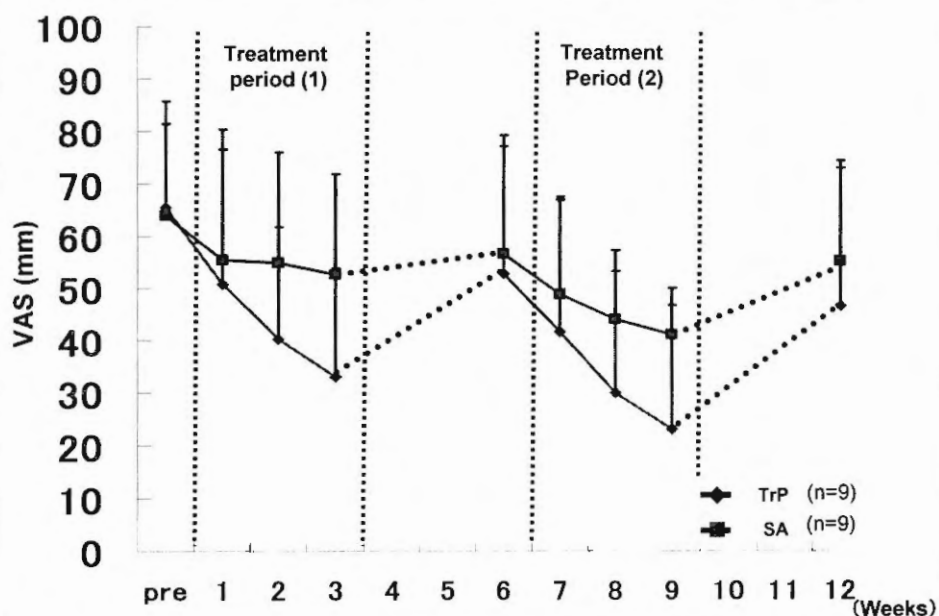
Treatment Points of the Trigger Point (TrP) Group

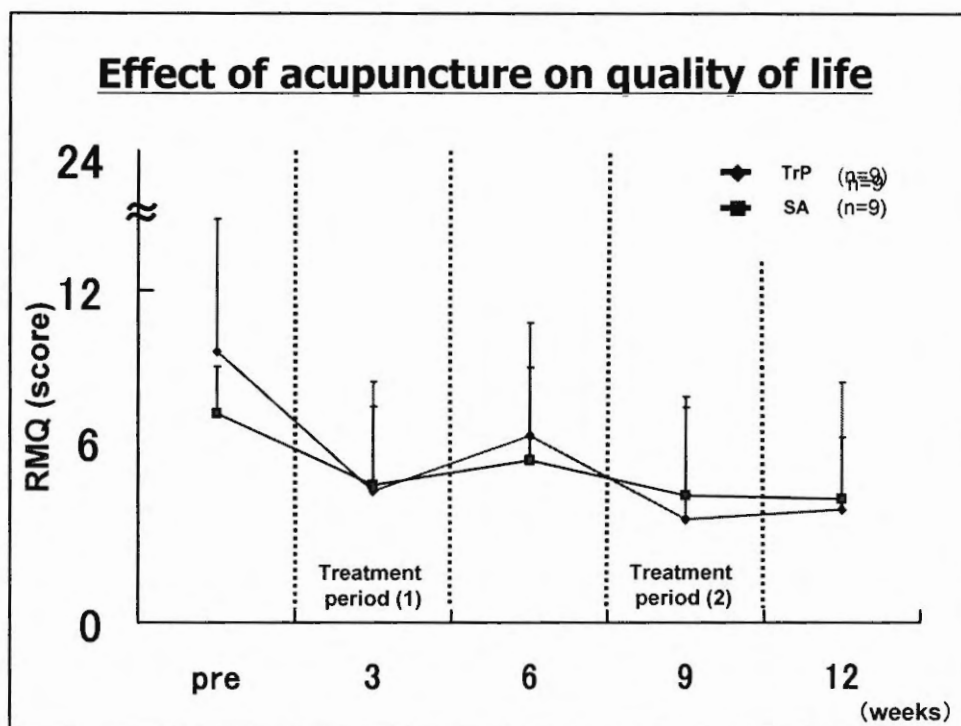


**Trigger point of
M. Quadratus Lumborum
and
M. Gluteus Medius.**

<i>muscle</i>	<i>number</i>
M. Quadratus Lumborum	5
M. Iliopsoas	4
M. Piriformis	4
M. Gluteus Maximus	3
M. Iliocostalis Lumborum	3
M. Gluteus Medius	2
M. Gluteus Minimus	1
Mean Number	2.4

Effect of acupuncture on low back pain





Aim of Investigation 2

Our main aim in this study was to compare the efficacy of acupuncture to trigger points on the chronic neck pain in the elderly to those of acupuncture to widely-used acupoints.

Methods

Subjects

Twenty patients (13 women, 7 men; age range: 56-81 years) of Meiji University of Oriental Medicine Hospital with no-radiating neck pain for at least 6 months and normal neurological examination.

Design & Treatment

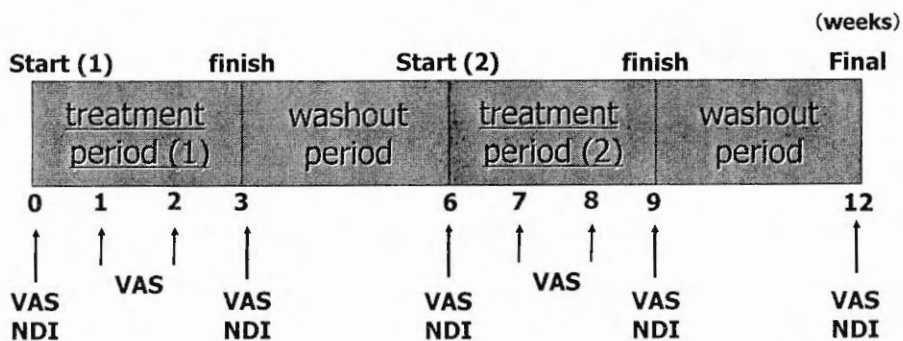
The standard acupuncture group (SA, n=10) received treatment at traditional acupoints for low back pain, the other acupuncture groups received on trigger points (TrP, n=10).

Outcome Measures

- **Pain intensity : VAS** (0 - 100 mm)
- **QOL measure : NDI**
(Neck Disability Index: range 60)

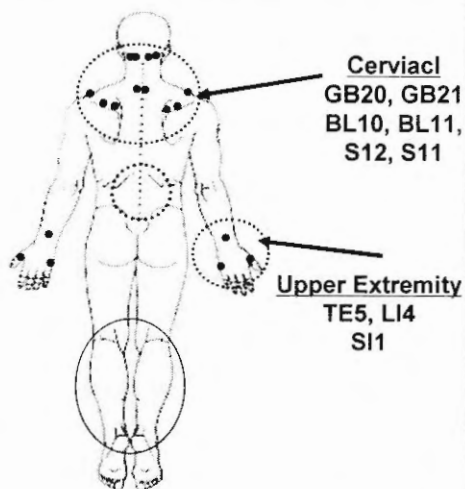
Design 2

Measures



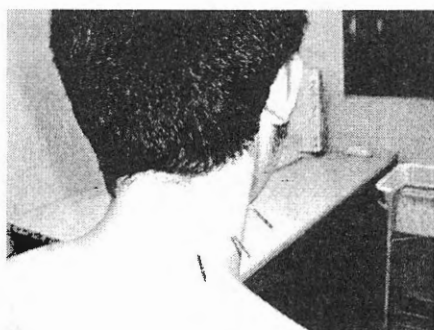
NDI: Neck Disability Index

Treatment Points of the Standard Acupuncture (SA) Group



Total: 18 points

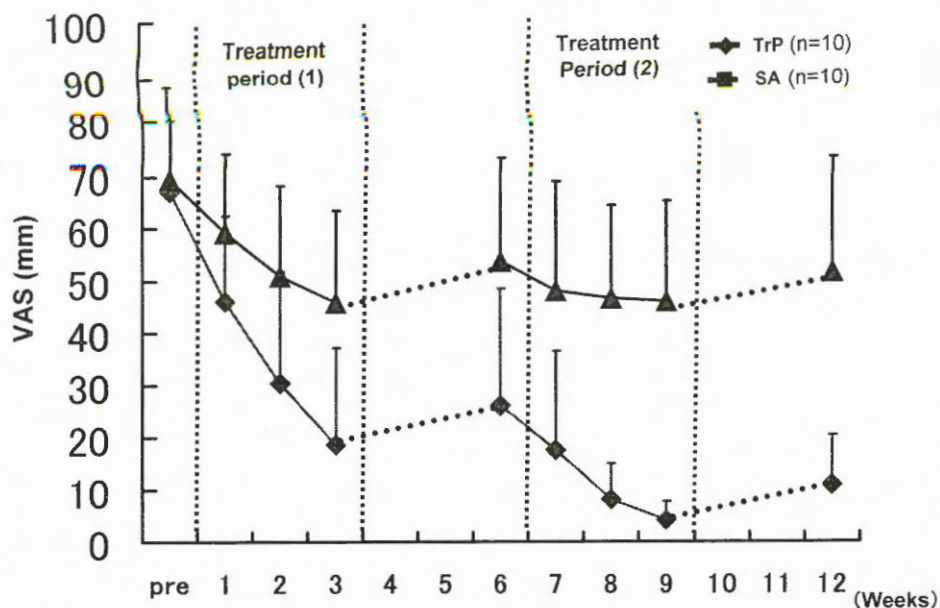
Treatment Points of the Trigger Point (TrP) Group



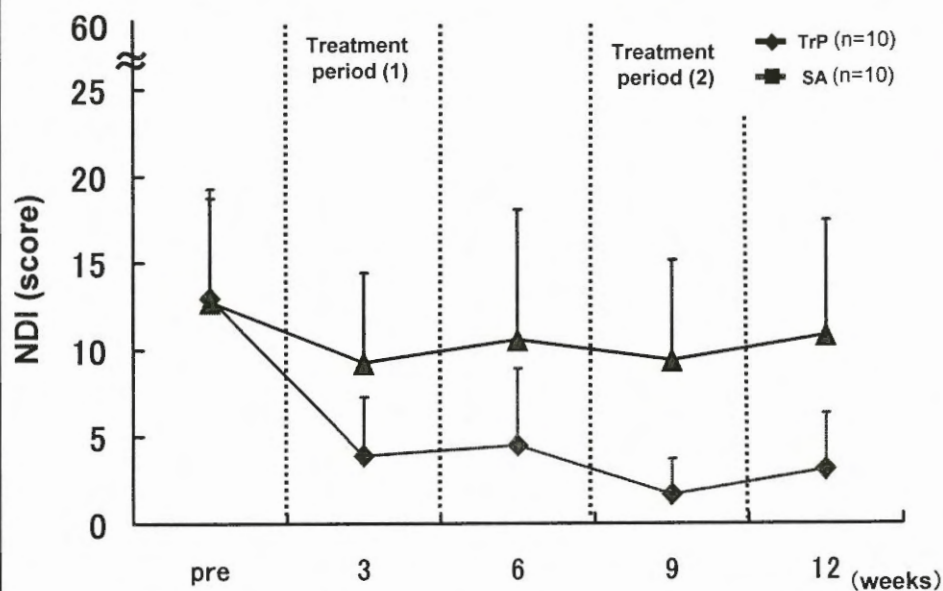
**Trigger point of
M. Sternocleidom, M. Scenus
and
M. Levator Scapulae.**

<i>muscle</i>	<i>number</i>
M. Splenius Capitis	3
M. Trapezius	5
M. Sternocleidom	3
M. Scalenus	4
M. Levator Scapulae	3
Paravert M.	2
M. Suboccipitales	1
Mean Number	2.1

Effect of acupuncture on neck pain



Effect of acupuncture on quality of life



Conclusion

The trigger point acupuncture therapy is more effective than the standard acupuncture therapy on chronic low back pain and neck pain in the aged patients .