

**Evidence Reports of  
Japanese Acupuncture and Moxibustion 2011:  
53 Randomized Controlled Trials  
(EJAM 2011)**

**31 March 2012**



# **Project for Systematic Review of the Efficacy, Safety and Efficiency of Traditional East Asian Medicine**

## **Task Force for Evidence Reports of Japanese Acupuncture and Moxibustion**

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## Executive Summary

The final purpose of the project is to make a systematic review of traditional medicine in East Asia. The role of this taskforce was to make a systematic review focused on the clinical researches of acupuncture and moxibustion conducted in Japan. Special Committee for Evidence-based Medicine (EBM) The Japan Society for Oriental Medicine (JSOM) has conducted a project for making a systematic review of Kampo medicine and it was already published as a report of EKAT 2012 (Evidence reports of Kampo Medicine 2010). In this taskforce we used a similar protocol to that of EKAT project, and to make a structured abstracts of the RCTs of acupuncture and moxibustion conducted in Japan. They were translated in English and will be published in web or booklet. We hope they will promote the understanding of Japanese clinical trials of acupuncture and moxibustion.

The principle of this project was as follows:

- 1) RCT articles with high levels of evidence were exhaustively included for review.
- 2) The methods for literature search and review processes were specified to enhance accuracy and transparency.
- 3) The reports were presented in the form of structured abstracts consisting of 12 items adopted in the report of EKAT 2010 . They were objectives; design; setting; participants; intervention; main outcome measures; main results; conclusions; referral to acupuncture and moxibustion medicine; safety assessment in the article; abstractor's comments; and abstractor's name and date.
- 4) Excluded references were listed along with the reasons for their exclusion.

The inclusion criteria were RCT articles of acupuncture and moxibustion therapy, including acupressure and TENS, conducted in Japan. The data sources of searches were Ichushi Web Ver.4 from *Igaku Chuo Zasshi* (*Japana Centra Revuo Medicana* : JCRM) , The Cochrane Library CENTRAL, the JAM-RCT database developed by Tsutani and Suyama, JSAM-RDB (provisional name) developed by members of the Japan Society of Acupuncture and Moxibustion (JSAM). Hand search was also done based on the reference list of papers. The initial phase of this literature survey, all RCTs related acupuncture and moxibustion were searched, and it was found that many papers of basic research using normal subjects were included. As this project had limitation of period of 2 years, we made new inclusion criteria of the references that clinical research on the patients.

Finally, out of 243 references, 53 RCTs were prepared as structured abstracts. They were arranged in the order used in the International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD10). The 190 references not satisfying the inclusion criteria were listed as excluded references along with their bibliographic items and the reason for exclusion.

We would appreciate your comments on compilation method, the contents of the structured abstracts, information on references not included in the report compilations, if any, and other matters. Please send your comments to Kenji Kawakita. (k\_kawakita@meiji-u.ac.jp).



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## **1. Background**

Traditional medicine in East Asia, acupuncture and moxibustion therapy has long history and well developed in Japan and Korea as well as China. From view point of EBM, however, the majority of high quality and large-scale clinical trials of acupuncture therapy have been conducted in Western World. On the other hand, there are many clinical researches of acupuncture has been conducted in Japan and various interesting and unique evidence has been found. Unfortunately the majority of papers published were written in Japanese and published in Japanese journals, so the contents of Japanese acupuncture trials have not been well recognized in acupuncture researchers, clinicians and healthcare service organization in foreign countries. So in this study, we made structured abstracts of high quality clinical trials of acupuncture conducted in Japan and planned to publish them in web or booklet.

This study was conducted as a part of project “Systematic review of efficacy, safety and efficiency of traditional East Asian medicine” (Chief Investigator: Kiichiro TSUTANI, 2010-11, Health and Labour Sciences Research Grants), then similar procedures with the EKAT 2010 (Evidence reports of Kampo Medicine 2010) project, which was conducted by the Special Committee for Evidence-Based Medicine (EBM) of the Japan Society for Oriental Medicine (JSOM), were used

## **2. Purpose**

The purpose was to exhaustively gather and review reports of randomized controlled trials of acupuncture and moxibustion on the patients conducted in Japan, compile structured abstracts of them, and publish them on the web or in booklet.

## **3. Steps for development of structured abstracts**

### **(1) Criteria for reference selection**

References that satisfied all of the following 3 criteria were included:

- 1) References of trials of acupuncture and moxibustion therapy on the patients.
- 2) Randomized controlled trials (RCTs), quasi-randomized controlled trials (quasi-RCTs), and meta-analyses (including some with randomization procedure not fully indicated. Crossover trials are regarded as RCT)
- 3) Clinical trials conducted in Japan

### **(2) Search and screening**

Searches were performed using the 4 databases listed below. Screening was performed in 2 steps: firstly, the references overlapping among the databases and that obviously did not satisfy the criteria were excluded by the search staff. Secondly, the remaining references were reviewed in the process of preparation of structured abstracts described below to finally decide which to include or exclude.

In this study, similar searching procedures to those of EKAT project conducted by the Special EBM Committee of Japan Society for Oriental Medicine (JSOM) were used. 1) Ichushi Web Ver.4 (in Japanese). Ichushi is the abbreviation of *Igaku Chuo Zasshi (Japana Centra Revuo Medicana: JCRM)*; 2) The Cochrane Library CENTRAL which is worldwide RCT database developed by the Cochrane Collaboration and included in the Cochrane Library; 3) The JAC-RCT database developed by Tsutani and Suda, accessed at Japan Hand and Electric Search Society (JHES) website (<http://jhес.umin.ac.jp/JAC-RCT/menu.html>). 4) JSAM-RDB (provisional name) developed by members of the Japan Society of Acupuncture and Moxibustion (JSAM). Related papers were also checked by non-systematic hand-search procedure based on the citation of references.

## 1) Igaku Chuo Zasshi (I)

On 12 Feb 2011, RCTs of acupuncture and moxibustion therapies in Japan were searched by the following search formula using Ichushi Web Ver.4 without limitation of search period. Finally 207 references were found as the candidates of further screening. The results of search and search formula were shown in **Table 1**.

**Table 1 Search formula and results in Ichushi Web Ver. 4**

Date of search: Feb 12, 2011

No.	Search Formula	N
#1	鍼療法/TH	11,831
#2	灸療法/TH	4,544
#3	経絡/TH	5,848
#4	@鍼灸療法/TH	5,374
#5	鍼灸医学/TH	1,076
#6	経皮的電気刺激/TH	2,625
#7	#1 or #2 or #3 or #4 or #5 or #6	23,163
#8	鍼/AL or 灸/AL	24,376
#9	針療法/AL or はり療法/AL or 針治療/AL or はり治療/AL or もぐさ/AL or カッピング/AL or 針通電/AL or はり通電/AL or 経穴/AL or 経絡/AL	7,588
#10	経皮的末梢神経電気刺激/AL or 経皮的末梢神経刺激/AL or 経皮的電気の神経刺激/AL or 経皮的電気神経刺激/AL or 経皮的電気刺激/AL or 経皮的神経刺激/AL or 経皮的神経電気刺激/AL or 経皮末梢神経電気刺激/AL or 経皮末梢神経刺激/AL or 経皮電気の神経刺激/AL or 経皮電気神経刺激/AL or 経皮電気刺激/AL or 経皮神経刺激/AL or 経皮神経電気刺激/AL or "Transcutaneous Electrical Nerve Stimulation"/AL or "Transcutaneous Electric Nerve Stimulation"/AL or "Transcutaneous Electric Nervous Stimulation"/AL or TENS療法/AL or TENS治療/AL	1,010
#11	ツボ電気刺激/AL or ツボ電気療法/AL or ツボ療法/AL or ツボ表面刺激/AL or ツボ通電刺激/AL or 神経ツボ刺激/AL or つぼ電気刺激/AL or つぼ電気療法/AL or つぼ療法/AL or つぼ表面刺激/AL or つぼ通電刺激/AL or 神経つぼ刺激/AL or 経穴電気刺激/AL or 経穴電気療法/AL or 経穴表面刺激/AL or 経穴通電刺激/AL or "Transcutaneous electrical acupuncture"/AL or "Transcutaneous electric acupuncture"/AL or TEAS療法/AL or TEAS治療/AL	53
#12	SSP療法/AL or SSP治療/AL or "Silver Spike Point"/AL or シルバースパイクポイント/AL or "シルバースパイク・ポイント"/AL	173
#13	#1 or #2 or #3 or #4 or #5 or #6 or #8 or #9 or #10 or #11 or #12	27,972
#14	#13 and (RD=メタアナリシス,ランダム化比較試験,準ランダム化比較試験)	207
#15	#13 and 臨床試験/TH not #14	297
#16	#13 and RD=比較研究 not #14 not #15	366

## 2) The Cochrane Library (C)

RCTs of acupuncture and moxibustion therapy conducted in Japan were also searched using the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library. Since the CENTRAL covers all RCTs

in the Medline, searches using the Medline were not performed.

On 12 Feb 2011, searches were performed by the following search formula with no limitation of publications. (**Table 2**). As the results, 174 references were hit as Japanese acupuncture and moxibustion study, and 90 references were registered in CENTRAL. Of 90 search hit, 46 references were detected and 23 references were selected by the first visual inspection and finally 11 references satisfying the inclusion criteria and structured abstracts were made. Of 23 references of the CENTRAL search, 14 were overlapped with those of Ichushi Web Ver.4 search.

**Table 2 Search formula and results in Cochrane CENTRAL**

Date of search: Feb 21, 2010

No.	Search fomula	N
#1	MeSH descriptor Acupuncture Therapy explode all trees	2,135
#2	MeSH descriptor Acupuncture explode all trees	121
#3	MeSH descriptor Transcutaneous Electric Nerve Stimulation explode all trees	879
#4	(#1 OR #2 OR #3)	2,700
#5	acupunctur*	5,695
#6	moxibustion*	2,031
#7	moxa	31
#8	electroacupunctur*	751
#9	needl* NEXT therap*	53
#10	cupping NEXT therap*	23
#11	acupoint*	796
#12	transcutaneous NEXT electric* NEXT Nerve NEXT stimul*	955
#13	transcutaneous NEXT electric* NEXT Nervous NEXT stimul*	3
#14	transcutaneous NEXT electric* NEXT acupunctur*	0
#15	silver NEXT spike NEXT point*	1
#16	(#1 OR #2 OR #3 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15)	6,753
#17	japan* or nihon or nippon	17,636
#18	(#16 AND #17)	174
#19	#18 references included in Cochrane Central	90

### 3) JAC-RCT database (J), JSAM-RDB database (M) and handsearch (H).

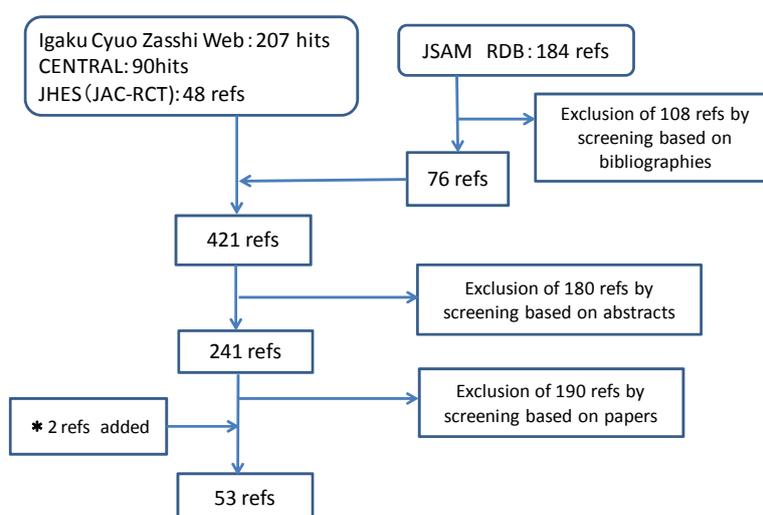
The JAC-RCT database (J) developed by Tsutani and Suyama, and reference list (tentatively named JSAM-RDB) (M) were also used as the source of search. Hand search (H) was also done based on the reference list of papers and two references were found, which were not found by databases search of Ichushi Web Ver.4 and Cochrane Library CENTRAL because of lack of registration to the databases. There were several overlapping among the data bases. Final results of search among the four data sources were shown in **Table 3**.

Screening in 3 steps were performed. 190 references were excluded step 3 screening, but were listed as excluded references along with bibliographic items and the reason for exclusion.

**Table 3 References of search hit and included**

Database	N	included	Inclusion rate (%)
Ichushi Web	216	36	16.7
Central	46	11	23.4
JHES (JAC-RCT)	41	4	9.8
JSAM-RDB	118	0	0
Handseach	2	2	100
total	423	53	12.3

Flow chart of search process of the included 53 references is shown as **Fig. 1**



**Fig. 1: Flow chart of search and screening**

\*indicates missing references in database which found by hand search.

### (3) Preparation of structured abstracts

The references satisfying the inclusion criteria were compiled as structured abstracts (SA). The 12 items of SA format used in the project of EKAT 2010 was adopted. They were: objectives; design; setting; participants; intervention; main outcome measures; main results; conclusions; acupuncture and moxibustion medicine perspective; safety assessment in the article; abstractor's comments; and abstractor's name and date.

Regarding item 9, acupuncture and moxibustion medicine perspective, no selection criteria based on the symptomatic diagnosis in this study, so the characteristics and/or significance of the study were included. Bibliographic items were indicated in the Vancouver style as a rule, with some modifications, including that the number of authors listed shall be up to 3 and that the name of a journal shall not be abbreviated. Structured abstracts were arranged in the order of ICD10 (Version 2003) code of diseases. Regarding excluded references, they included basic researches and normal subject studies, so the order did not precisely follow the order of diseases in ICD10 and related tissues and organs were also used for the arrangement. In preparing structured abstracts, to maintain the quality, a "Structured Abstract Preparation Manual" was prepared, distributed to Task Force members, and updated as appropriate.

#### 4. Included references and excluded references

##### (1) Studies compiled as structured abstracts

Fifty three studies were selected and their structured abstracts were prepared.

For studies compiled as structured abstracts, the following items were indicated in the structured abstract and included the reference list: 1) SA No. ; 2) ICD10 (2003 revision) code of disease; 3) research question; 4) intervention; 5) bibliographic items of the reference; 6) study design; and 7) search source.

**Table 4** summarizes the research designs of 53 references. One DB-RCT was performed by used of press tack needle and its sham. One crossover design is included in quasi-RCT.

**Table 4 Research design of references included**

Research Design	n
Double Blinded Randomized Controlled Trial (DBRCT)	1
Randomized Controlled Trial (RCT)	29
Randomized Controlled Trial envelop (RCT-envelop)	15
Quasi Randomized Controlled Trial (quasi- RCT)	3*
Cross-over Design (Crossover)	5

**Table 5 ICD-10 and disease classification of structured abstracts**

Chapter no.	ICD-10 code	Chapter title	Disease classification names in the EJAM	No. of structured abstract
1	A00-B99	Certain infectious and parasitic diseases	Infections (including viral hepatitis)	0
2	C00-D48	Neoplasms	Cancer (condition after cancer surgery and unspecified adverse drug reactions of anti-cancer drugs)	0
3	D50-D89	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	Blood diseases including anaemia	0
4	E00-E90	Endocrine, nutritional and metabolic diseases	Metabolism and endocrine diseases	4
5	F00-F99	Mental and behavioural disorders	Psychiatric/behavioral disorders	2
6	G00-G99	Diseases of the nervous system	Nervous system diseases (including Alzheimer's disease)	0
7	H00-H59	Diseases of the eye and adnexa	Eye diseases	1
8	H60-H95	Diseases of the ear and mastoid process	Ear diseases	0
9	I00-I99	Diseases of the circulatory system	Cardiovascular diseases	2
10	J00-J99	Diseases of the respiratory system	Respiratory diseases (including influenza and rhinitis)	1
11	K00-K93	Diseases of the digestive system	Gastrointestinal, hepato-biliary-pancreatic diseases	3
12	L00-L99	Diseases of the skin and subcutaneous tissue	Skin diseases	1
13	M00-M99	Diseases of the musculoskeletal system and connective tissue	Diseases of the musculoskeletal and connective tissue	33
14	N00-N99	Diseases of the genitourinary system	Genitourinary tract disorders (including climacteric disorders)	0
15	O00-O99	Pregnancy, childbirth and the puerperium	Ante/post-partum diseases	0
16	P00-P96	Certain conditions originating in the perinatal period	Certain conditions originating in the perinatal period	0
17	Q00-Q99	Congenital malformations, deformations and chromosomal abnormalities	Congenital malformations, deformations and chromosomal abnormalities	0
18	R00-R99	Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified	Symptoms and signs	4
19	S00-T98	Injury, poisoning and certain other consequences of external causes	Post-anesthesia and postoperative pain	1
20	V00-Y98	External causes of morbidity and mortality	External causes of morbidity and mortality	0
21	Z00-Z99	Factors influencing health status and contact with health services	Others	1
22	U00-U99	Codes for special purposes	Codes for special purposes	0

**Table 5** indicates classification of diseases in ICD-10 and those of EJAM and number of references included. Majority of diseases included in EJAM were those of pain in musculoskeletal and connective tissues, such as low back pain, osteoarthritis of the knee and neck pain.

**Table 6** summarizes the interventions used in included references. Except for usual acupuncture needling and electro-acupuncture to the acupuncture points, trigger points and tender points were frequently used. Cutaneous acupuncture needling methods such as press tack needle and intradermal needle which were rare in the foreign literature were also found.

**Table 6 Interventions used in the included references**

Intervention	N	Intervention	N
Acupuncture	35	Cutaneous acupuncture	10
Acupuncture	21	Press tack needle	4
Trigger point	9	Intradermal acupuncture	2
Electroacupuncture	4	Auricular acupuncture	4
Others	1	Indirect moxibustion	2
Heating acupuncture	1	Acupressure	2
		TENS, TEAS	3

About 20% of papers included were published in English Journals, and the rest of them were written in Japanese and published in Japanese Journals.

**(2) Preparation of excluded references list**

The references not compiled as structured abstracts but listed as excluded references along with bibliographic items and the reason for exclusion were:

- 1) Clinical articles but not RCTs or meta-analyses
- 2) Researches not related to acupuncture and moxibustion
- 3) Basic study and/or normal subjects
- 4) Review or report based on RCT studies.
- 5) Not conducted in Japan
- 6) Insufficient data for preparation of structured abstract.

Finally, 190 references were excluded, and their exclusion reasons were represented in the exclusion reference list.

**5. Conflict of interests**

None of the the members of the Task Force for Evidence Reports of Japanese Acupuncture and Moxibustion (JSAM) have COI during the period of the project (April 2010 –March 2012) .

## **6. Acknowledgements**

Special thanks to those involved in literature search in SunMedia Co. and staffs at Ichushi who provided advice in literature search.. This study was supported by Health and Labour Sciences Research Grants (fiscal year 2010-2011).

## **7. Contact point**

We would appreciate your comments on this report. Please send your comments to the address below. Comments from the authors of the included references would also be welcome. If you find that the references that should be included are not included, please inform us. We will reflect your comments in the report in future.

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## 8. Lists of Structured Abstracts (53 abstracts, 53 references)

As shown in the **Table 5**, Page X, regarding the ICD-10 disease classification with no RCTs found, we decided not to indicate the corresponding chapter numbers of ICD-10 and disease classification names in the list below.

Original English titles assigned by authors were used in this list and the structured abstracts. When references had no English titles, the Task Force translated the original Japanese titles into English ones.

Abbreviations: I: Ichushi Web Ver.4

C: The Cochrane Library CENTRAL

J: JAC-RCT developed by Tsutani and Suda

M: Reference List prepared by the member of the JSAM

### 4. Metabolism and Endocrine Diseases (4 abstracts, 4 references)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
E669	To evaluate the effects and the mechanism of ear needle treatment on obesity.	auricular acupuncture	Mukaino Y. Acupuncture therapy for obesity using ear needle treatment - analysis of effectiveness and mechanism. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 1981; 31(1): 67-74 (in Japanese with English abstract).	RCT	J	14
E669	To analyze whether electrodermal points in the ear are functional units.	auricular acupuncture	Mukaino Y, Tsuneya Y, Hattori T. Auricular acupuncture for obesity - Concerning the significance of dermal points. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 1983; 32(3): 226-32 (in Japanese with English abstract).	RCT	J	15
E669	To evaluate the effect of ear acupuncture on obese patients	auricular acupuncture	Mukaino Y, Arakawa K, Tsuneya Y. Comparison between cardia point and lung point on auricular acupuncture. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 1984; 33(3): 279-84 (in Japanese with English abstract).	RCT	I	16
E669	To evaluate the effect of ear acupuncture on taste	auricular acupuncture	Mukaino Y, Arakawa K. Change of taste by ear acupuncture in simple obese patients. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 1985; 34(3,4): 211-6 (in Japanese with English abstract).	RCT	I	17

### 5. Psychiatric/Behavioral Disorders (2 abstracts, 2 references)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
F03	To evaluate the effect of transcutaneous electrical acupuncture point stimulation (TEAS) on decreased intellectual function and activities of daily living in the elderly.	TEAS	Sawada T, Sawada C, Fukuda F, et al. Effect of TEAS (Transcutaneous Electrical Acupuncture Point Stimulation) on intellect and daily activity of the aged. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2001; 51(1): 69-80 (in Japanese with English abstract).	RCT-envelope	I	18
F459	To evaluate the objective effects of acupuncture and moxibustion on unidentified syndrome in a clinical trial using sequential testing.	needle + Garenical extract	Shichido T, Arichi S, Mori E, et al. The effect of acupuncture on unidentified syndrome - sequential medical trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 1982; 32(1): 33-43 (in Japanese with English abstract).	RCT	J	19

### 7. Eye Diseases (1 abstract, 1 reference)

ICD-10	Research question	Intervention	References	Study Design	Source	Page
H269	To evaluate the effects of acupuncture stimulation on the improvement of visual acuity in subjects without refractive change.	acupuncture	Fukuno A, Tsuru H, Kataoka K, et al. Acupuncture stimulation improves visual acuity without refractive change. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 2008; 58(2): 195-202 (in Japanese with English abstract).	RCT-cross over	I	20

### 9. Cardiovascular Diseases (2 abstracts, 2 references)

ICD-10	Research question	Intervention	Reference	Study Design	Source	Page
I10	To evaluate the depressor effect of acupuncture at the ST36 acupuncture point.	acupuncture	Kawase Y, Ishigami T, Hori S, et al. Effectiveness of the Zusanli (ST36) point for hypertension in acupuncture -Controlled clinical trials using the envelope method- <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2000; 50: 185-89 (in Japanese with English abstract).	RCT-envelope	I	21
I959	To determine the efficacy of transcutaneous electrical nerve stimulation (TENS) at the PC6 and PC5 acupoints for hypotension after spinal anaesthesia in Caesarean section patients.	TENS	Arai YCP, Kato N, Matsura M, et al. Transcutaneous electrical nerve stimulation at the PC-5 and PC-6 acupoints reduced the severity of hypotension after spinal anaesthesia in patients undergoing Caesarean section <i>British Journal of Anaesthesia</i> 2008;100 (1): 78-81.	RCT-envelope	C	22

### 10. Respiratory Diseases (including Influenza and Rhinitis) (1 abstract, 1 reference)

ICD-10	Research question	Intervention	Reference	Study Design	Source	Page
J00	To evaluate the preventative effects of acupuncture against common cold and its therapeutic effects after infection.	acupuncture	Isobe Y, Yu S, Inoue E. Common cold prevention and therapeutic effects of acupuncture in a randomized controlled trial*. <i>Toyo Ryohe Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2000; 24: 94-7 (in Japanese).	RCT	I	23

### 11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases (3 abstracts, 3 references)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
K590	To evaluate the effectiveness of acupressure point stimulation on defecation control in women recovering from childbirth.	acupressure	Kawano K, Tamura S, Inoue K. Effects of acupressure point stimulation on difficulty in defecating*. <i>Nihon Kango Gakkai Ronbunshu, Bosei Kango (Maternal Nursing)</i> 2007: 74-6 (in Japanese).	RCT	I	24
K910	To evaluate the efficacy of acupressure wrist bands for preventing postoperative nausea and vomiting.	acupressure	Kawauchi Y, Hayashida M, Takeuchi C, et al. Efficacy of acupressure on prevention of postoperative nausea and vomiting. <i>Rinsho Masui (Journal of Clinical Anesthesia [Japan])</i> 2000; 24(1): 21-4 (in Japanese with English abstract).	RCT	I	25
K910	To evaluate the effects of intradermal acupuncture on pain, nausea and vomiting after abdominal surgery.	intradermal acupuncture	Kotani N, Hashimoto H, Sato Y et al. Preoperative intradermal acupuncture reduces postoperative pain, nausea and vomiting, analgesic requirement, and sympathoadrenal responses <i>Anesthesiology</i> 2001; 95(2): 349-56.	RCT-envelope	C	26

### 12. Skin Diseases (1 abstract, 1 references)

ICD-10	Research question	Intervention	Reference	Study Design	Source	Page
L299	To evaluate the effectiveness of acupuncture for itching in hemodialysis patients.	intradermal acupuncture	Sakuraba H, Sawazaki K, Takeuchi H, et al. The effect of acupuncture in the improvement of hemodialysis patients' QOL: Practice of acupuncture treatment for itch. <i>Junzo (The Kidney)</i> 2007; 30(2): 167-74 (in Japanese).	quashi RCT-cross over	I	27

### 13. Diseases of the Musculoskeletal and Connective Tissue (33 abstracts, 33 references)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
M069	To examine the effectiveness of acupuncture and moxibustion for rheumatoid arthritis.	acupuncture	Kasuya D, Sawada T, Isobe H, et al. Multi-center randomized controlled trial of acupuncture and moxibustion for rheumatoid arthritis. <i>Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2005; 68(4): 193-202 (in English with Japanese abstract).	RCT	I	28
M179	To evaluate the clinical effect of remote acupuncture point treatment for symptoms of muscle meridian disease (defined as muscle stiffness, jerking, cramp, or pain during movement).	intradermal acupuncture	Shinohara S, Katsumi Y. Clinical effects of peripheral acupuncture point stimulation based on the concept of the muscle meridians for complaints during movements. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)</i> 2003; 53(1): 4-7 (in Japanese with English abstract).	RCT	I	29
M179	To evaluate the clinical effectiveness of acupuncture for knee osteoarthritis.	acupuncture	Ozawa N, Ogawa T, Nakagawa J, et al. The effects of acupuncture and moxibustion on anterior genicular osteoarthritis. <i>Shinkyu Osaka (Osaka Journal of Clinical Acupuncture &amp; Moxibustion)</i> 2002; 18(4): 393-6 (in Japanese).	RCT-envelope	I	30
M179	To evaluate the effects of TENS and acupuncture on pain in elderly patients with knee osteoarthritis.	acupuncture	Itoh K. Value of conservative therapy for chronic pain associated with locomotor disease - effects of TENS and acupuncture for knee osteoarthritis* - . <i>Mansei Totsu (The Journal of the Japanese Society for the Study of Chronic Pain)</i> 2005; 26: 143-8 (in Japanese with English abstract).	RCT	I	31
M179	To compare the effectiveness of trigger point and standard point acupuncture for treating knee osteoarthritis	acupuncture (TrP)	Itoh K, Hirota S, Katsumi Y, et al. Trigger point acupuncture for treatment of knee osteoarthritis - a preliminary RCT for a pragmatic trial <i>Acupuncture in Medicine</i> 2008; 26(1): 17-26.	RCT	C	32

ICD-10	Research question	Intervention	Reference	Study Design	Source	Page
M179	To evaluate the efficacy of acupuncture to different depths on motor function and pain in patients with osteoarthritis of the knee.	acupuncture	Miyamoto T, Itoh K, Ochi H, et al. The efficacy of acupuncture treatment on pain and ability with osteoarthritis of the knee. - Examination of the curative effect by the depth of an acupuncture needle -. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2009; 59(4): 384-94 (in Japanese with English abstract).	RCT	I	33
M179	To evaluate the clinical effects of acupuncture treatment for knee osteoarthritis (OA).	acupuncture	Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee 3 - a randomized, controlled trial. <i>Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)</i> 2009; 3: 36-40 (in Japanese with English abstract).	RCT	I	34
M179	To evaluate the effectiveness of acupuncture combined with therapeutic exercise for knee osteoarthritis.	acupuncture	Ochi H, Katsumi Y, Katayama K, et al. The effect of acupuncture with quadriceps exercise for the osteoarthritis of the knee joint - the importance of quadriceps exercise -. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 1993; 23(3): 136-42 (in Japanese with English abstract).	RCT	H	35
M179	To evaluate the effectiveness of acupuncture combined with therapeutic exercise for knee osteoarthritis.	acupuncture	Ochi H, Katsumi Y, Ikeuchi T, et al. A study of acupuncture for knee osteoarthritis - The importance of combined use with therapeutic exercise*. <i>Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 1995; 17: 7-14 (in Japanese).	RCT	H	36
M5422	To compare the effectiveness of acupuncture and local injection for neck pain.	acupuncture	Nakajima M, Inoue M, Itoi M, et al. A comparison of the effectiveness between acupuncture and local injection for neck pain: a randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2007; 57(4): 491-500 (in Japanese with English abstract).	RCT	I	37
M5422	To evaluate the effectiveness of trigger point acupuncture for chronic neck pain.	acupuncture (TrP)	Itoh K, Katsumi Y, Hirota S, et al. Randomised trial of trigger point acupuncture compared with other acupuncture for treatment of chronic neck pain. <i>Complementary Therapies in Medicine</i> 2007; 15: 172-9.	RCT	C	38
M543	To compare the effectiveness of paraneural and with that of non-paraneural acupuncture for sciatica.	acupuncture	Kinoshita H, Kinoshita N. Clinical research in the use of paraneural acupuncture for sciatica. <i>Nihon Shinkyu Chiryu Gakkaishi (The Journal of the Japan Acupuncture and Moxibustion Society)</i> . 1981; 30(1): 4-13 (in Japanese with English abstract).	RCT-cross over	J	39
M543	To evaluate the efficacy of electrothermal acupuncture for treating sciatica due to "cold-wetness evil."	electrothermal acupuncture	Yun X, Suzuki S, Urata S, et al. Therapeutic effect of the treatment of sciatica due to cold-wetness evil using an electro-warming needle. <i>Toho Igaku (Eastern Medicine)</i> 2005; 21(3): 25-7 (in Japanese with English abstract).	RCT	I	40
M545	To evaluate the efficacy and safety of low-frequency electro-acupuncture and transcutaneous electrical nerve stimulation (TENS) for low back pain.	acupuncture (electro-acupuncture)	Sakai T, Tsutani K, Tsukayama H, et al. Multi-center randomized controlled trial of acupuncture with electric stimulation and acupuncture-like transcutaneous electrical nerve stimulation for lumbago. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2001; 51(2): 175-84 (in Japanese with English abstract).	RCT-envelope	I	41
M545	To compare the effectiveness of electro-acupuncture with that of TENS in patients with low back pain	acupuncture (electro-acupuncture)	Tsukayama H, Yamashita H, Amagai H, et al. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: a preliminary study for a pragmatic trial <i>Acupuncture in Medicine</i> 2002; 20(4): 175-80.	RCT-envelope	C	42
M545	To evaluate the effect of acupuncture on pain intensity and QOL in patients with chronic low back pain.	acupuncture (TrP)	Itoh K, Katsumi Y, Kitakoji H. Trigger point acupuncture treatment of chronic low back pain in elderly patients—a blinded RCT <i>Acupuncture in Medicine</i> 2004; 22(4): 170-7.	RCT	C	43
M545	To compare the effect of acupuncture treatment at trigger points versus at acupuncture points in the back on chronic low back pain in the elderly.	acupuncture (TrP)	Itoh K. Effect of trigger point acupuncture treatment on chronic pain in the elderly - usefulness of acupuncture for treating chronic low back pain -*. <i>Mansei Totsu (The Journal of the Japanese Society for the Study of Chronic Pain)</i> 2004; 23(1): 83-8 (in Japanese with English abstract).	RCT-envelope	I	44
M545	Effectiveness of ah-shi (tender) point acupuncture therapy for chronic low back pain in elderly patients.	acupuncture	Katsumi Y, Itoi M, Kojima A, et al. Ah shi (tender) point acupuncture of chronic low back pain in aged patients*. <i>Rehabiritesyon Igaku (The Japanese Journal of Rehabilitation Medicine)</i> 2004; 41(12): 824-9 (in Japanese).	RCT-cross over	I	45
M545	To compare the effects of trigger point acupuncture versus sham acupuncture on pain and QOL in patients with chronic low back pain.	acupuncture (TrP)	Itoh K, Katsumi Y, Hirota S, et al. Effects of trigger point acupuncture on chronic low back pain in elderly patients—a sham-controlled randomised trial. <i>Acupuncture in Medicine</i> 2006; 24(1): 5-12.	RCT-cross over	C	46

ICD-10	Research question	Intervention	Reference	Study Design	Source	Page
M545	To compare the efficacy of taikyoku therapy and low-frequency electro-acupuncture for low back pain.	acupuncture (electro-acupuncture)	Kawase Y, Ishigami T, Nakamura H, et al. Acupuncture treatment for lower back pain - Multi-center randomized controlled trial using sham acupuncture as a control. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2006; 56(2): 140-9 (in Japanese with English abstract).	RCT	I	47
M545	To evaluate the efficacy of Silver Spike Point (SSP) therapy combined with far infrared irradiation for chronic low back pain.	SSP	Kawachi A, Kitade T, Kim M, et al. Combination of SSP therapy and far infrared irradiation for chronic low back pain. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2006; 36(1): 35-42 (in Japanese with English abstract).	RCT-envelope	I	48
M545	To compare the therapeutic effects of trigger point acupuncture with those of tender point acupuncture on chronic low back pain.	acupuncture (TrP)	Hirota S, Itoh K, Katsumi Y. A controlled clinical trial comparing trigger point acupuncture with tender point acupuncture treatments for chronic low back pain - a pilot study on 9 elderly patients - <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)</i> 2006; 56(1): 68-75 (in Japanese with English abstract).	quashi-RCT	I	49
M545	To evaluate the immediate effect of tender point acupuncture on low back pain.	acupuncture	Inoue M, Kitakoji H, Ishizaki N, et al. Relief of low back pain immediately after acupuncture treatment -a randomized, placebo controlled trial <i>Acupuncture in Medicine</i> 2006; 24(3): 103-8.	RCT	C	50
M545	To compare the effects of acupuncture at a trigger point and a tender point in elderly patients with chronic low back pain.	acupuncture (TrP)	Hirota S, Itoh K, Katsumi Y. Trigger point acupuncture treatment for chronic low back pain in elderly patients. <i>Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 2006; (38): 19-26.	RCT-cross over	I	51
M545	To compare the clinical effects of local injection and local acupuncture treatment for low back pain.	acupuncture	Inoue M, Nakajima M, Itoi M, et al. Comparison of the effectiveness of acupuncture treatment and local injection for low back pain A randomized controlled clinical trial - <i>Nihon Onsen Kikou Butsuri Igakukai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2008; 71(4): 211-20 (in Japanese with English abstract).	RCT	I	52
M545	To analyze the synergistic effects of acupuncture and transcutaneous electrical nerve stimulation (TENS) on chronic low back pain (LBP).	acupuncture	Itoh K, Itoh S, Katsumi Y, et al. A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat non-specific low back pain <i>Complementary Therapies in Clinical Practice</i> 2009; 15: 22-5.	RCT	C	53
M545	To evaluate the efficacy of press tack needle for low back pain.	press tack needle	Miyazaki S, Hagiwara A, Kanda R, et al. Applicability of press needles to a double-blind trial. A randomized, double-blind, placebo-controlled trial <i>Clinical Journal of Pain</i> 2009; 25(5): 438-44.	DB-RCT	C	54
M545	To evaluate the efficacy of trigger point acupuncture treatment for chronic low back pain in elderly people.	acupuncture (TrP)	Itoh S, Itoh K, Katsumi Y. Effect of trigger point acupuncture treatment in older patients with chronic low back pain: randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2009; 59(1): 13-21 (in Japanese with English abstract).	RCT	I	55
M6281	To investigate the problems associated with conducting clinical trials of acupuncture.	acupuncture	Nabeta T, Furuta T, Kitakouji H, et al. Randomized controlled pilot study of acupuncture on neck stiffness. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 1997; 47(3): 173-81 (in Japanese with English abstract).	RCT-envelope	I	56
M6281	To assess the relief of neck and shoulder pain and stiffness provided by treatment with real acupuncture to tender points.	acupuncture	Nabeta T, Kawakita K. Relief of chronic neck and shoulder pain by manual acupuncture to tender points-a sham-controlled randomized trial <i>Complementary Therapies in Medicine</i> 2002; 10: 217-22.	RCT	C	57
M6281	To evaluate the effect of press tack needle treatment on shoulder stiffness.	press tack needle	Furuya E, Nayuki T, Yakame M, et al. Effect of press tack needle treatment on shoulder stiffness. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2002; 52(5): 553-61 (in Japanese with English abstract).	RCT-envelope	I	58
M7919	To evaluate the efficacy of intradermal acupuncture based on the muscle meridians	intradermal acupuncture	Shinohara S. Clinical effects of acupuncture (intradermal needles) based on the muscle meridians for the complaints on the joints and muscles during movements. <i>Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 2000; 26: 65-80 (in Japanese with English abstract).	RCT-envelope	I	59
M7919	To evaluate the efficacy of trigger point acupuncture for chronic low back pain with aged patients.	acupuncture (TrP)	Ito K, Katsumi Y. Effect of acupuncture treatment on chronic low back pain with leg pain in aged patients - a controlled trial about short-term effects of trigger point acupuncture - <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2005; 55 (4): 530-37 (in Japanese with English abstract).	quashi-RCT	I	60

### 18. Symptoms and Signs (4 abstracts, 4 references)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
R35	To evaluate the effectiveness of moxibustion treatment for nocturia.	indirect moxibustion	Tomita K, Kitakoji H, Honjo H, et al. Effect of moxibustion treatment for nocturia: a randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)</i> 2009; 59(2): 116-24 (in Japanese with English abstract).	RCT	I	61
R391	To evaluate the effects on urinary dysfunction by acupuncture	acupuncture	Minagawa M, Ishigami T, Hori S, et al. Controlled clinical trials using the envelope method for urinary dysfunction - the effectiveness of the zhongji (cv-3). <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 1999; 49(3): 383-91 (in Japanese with English abstract).	RCT-envelope	I	62
R529	To evaluate the effectiveness of acupuncture for chronic fatigue	acupuncture	Yamazaki T, Fukuda F, Ishizaki N, et al. The effect of acupuncture on chronic fatigue in healthy subjects. <i>Nihon Mibyou Shisutemu Gakkai Zasshi (The Journal of Japan Mibyou System Association)</i> 2009; 15(2): 186-96 (in Japanese with English abstract).	RCT	I	63
R688	To evaluate the effect of acupuncture and moxibustion on sensitivity to cold.	acupuncture	Sakaguchi S, Kanai S, Toda S. A randomized controlled trial of the effect of acupuncture and moxibustion on sensitivity to cold*. <i>Kansai Iryou Daigaku Kiyou (The Bulletin of Kansai University of Health Sciences)</i> 2007; 1: 82-5 (in Japanese).	RCT	I	64

### 19. Post-anesthesia and Postoperative Pain (1 abstract, 1 reference)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
T888	To evaluate the effects of acupuncture analgesia on postoperative pain.	acupuncture (electro-acupuncture)	Ishimaru K, Sakita M. Effects of acupuncture analgesia on postoperative pain. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2002; 32(1-4): 10-18 (in Japanese with English abstract).	RCT-envelope	I	65

### 21. Others (1 abstract, 1 reference)

ICD-10	Research Question	Intervention	Reference	Study Design	Source	Page
	To evaluate the effectiveness of fireless moxibustion at home to maintain QOL for elderly people.	indirect moxibustion	Kuge H, Hatano Y, Mori H. Influence of fireless moxibustion on QOL (SF-36 $\delta$ ) in elderly people. <i>Nihon Onsen Kiko Bunsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2008; 71(3): 180-6 (in Japanese with English abstract).	RCT-envelope	I	66

## 9. Lists of Excluded References (190 references)

Original English titles assigned by authors were used in this list and the structured abstracts. When references had no English titles, the Task Force translated the original Japanese titles into English ones.

Abbreviations: I: Ichushi Web Ver.4  
 C: The Cochrane Library CENTRAL  
 J: JAC-RCT developed by Tsutani and Suda  
 M: Reference List prepared by the member of the JSAM

Reasons for exclusion were classified as follows:

- 1: Clinical articles but not RCTs or meta-analyses
- 2: Researches not related to acupuncture and moxibustion
- 3: Basic study and/or normal subjects
- 4: Review or report based on RCT studies
- 5: Not conducted in Japan
- 6: Insufficient data for preparation of structured abstract

### 3. Blood Diseases including Anaemia (2 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
D	Effects of pressure application on peripheral hemoglobin dynamics	Pressure	Matukuma H, Nakamura T. Effects of pressure stimulation at a site hemodynamically close to human forearms. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 2010; 60(1): 48-53 (in Japanese with English abstract).	3	I
D	Effects of acupuncture on blood cell responses induced by intense exercise.	acupuncture	Matsubara Y, Shimizu K, Miyamoto T, et al. Effects of acupuncture stimulation on the response of leukocyte and lymphocyte by high-intensity exercise. <i>Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2010; 73(2): 92-100 (in English with Japanese abstract).	3	I

### 4. Metabolism and Endocrine Diseases (2 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
E	Effects of auricular acupuncture on obesity	Auricular acupuncture	Mukaino Y.. Efficacy and mechanism of auricular acupuncture on obesity. <i>Ido no Nihon (The Japanese Journal of Acupuncture and Manual Therapies)</i> 1986; 45(10): 10-25 (in Japanese).	4	J
E	Effects of muscular acupuncture on the insulin resistance	electro-acupuncture	Kasuya D, Mine D, Koito Y, et al. Effects of electroacupuncture to skeletal muscle on the insulin resistance. <i>Gendai Shinkyu Gaku</i> 2008; 8(1): 9-19 (in Japanese).	3	I

### 5. Psychiatric/Behavioral Disorders (5 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
F	Effects of acupuncture on depression	acupuncture	Mukaino Y. The effectiveness of acupuncture for depression; a systematic review of randomized controlled trials. <i>Shinkyu Osaka (Osaka Journal of Clinical Acupuncture &amp; Moxibustion)</i> 2005; 21(3): 245-50 (in Japanese).	4	I
F	Comparison of efficacy of different acupuncture therapies on reduction of stress responses	acupuncture	Itou K, Kamizawa T. Effects of acupuncture in stress decreasing- Comparison between two acupuncture methods-. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2002; 30(1/2): 8-15 (in Japanese with English abstract).	3	I
F	Preventive effects of press tack needle on the stress induced by DVT work	press tack needle	Yamashita N, Miki M, Kitamura N, et al. Preventive effects of press tack needle on the stress by VDIwork -salivary amylase as an indicator-. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2007; 30: 74-7 (in Japanese).	3	I
F	Effects of acupuncture on the stress response induced by exercise loading	acupuncture	Tsutomino T, Taguchi T. Effects of acupuncture therapy on the stress induced by exercise loading. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2008; 31: 146-9 (in Japanese).	3	I
F	Effects of electroacupuncture on the patients of depression	electro-acupuncture	Luo H, Meng F, Jia Y, et al. Clinical research on the therapeutic effect of the electro-acupuncture treatment in patients with depression. <i>Psychiatry and Clinical Neurosciences</i> 1998; 52(Suppl.): S338-40.	1	I

### 6. Nervous System Diseases (including Alzheimer's disease) (1 reference)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
G	Methods of treatment with retaining acupuncture on the early stage of facial nerve paralysis	acupuncture	Okumura Y, Arai Y, Aramaki H, et al. Original method of facial palsy treatment by acupuncture during intravenous drip infusion of ATP. <i>Facial Nerve Research</i> 2000; 20: 123-5 (in Japanese with English abstract).	1	I

### 7. Eye Diseases (4 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
H	Comparison of efficacy of remote acupuncture points on blood circulation of the eye	acupuncture	Mizukami M, Yano T, Yamada J. Effects of acupuncture stimulation at distal meridian point on ocular circulation -The comparison between LI4, GB20, BL18, GE37 and LI11-. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2008; 58(4): 616-25.	3	I
H	Effects of acupuncture on the low leg on blood circulation of the eye	acupuncture	Mizukami M, Yano T, Yamada J. Effects of ocular circulation by acupuncture stimulation on the crus outside- The comparison of GB36, GB37, GB38, and non-meridian point- <i>Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2006; 69(3): 201-12 (in Japanese with English abstract).	3	I
H	Effects of acupuncture on the low leg on blood circulation of the eye	acupuncture	Mizukami M, Yano T, Yamada J. Effects of ocular circulation by acupuncture stimulation on Guangming (GB37). <i>Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2005; 68(4): 231-40 (in Japanese with English abstract).	3	I
H	Effects of electroacupuncture on the asthenopia	electro-acupuncture	Masuda K, Hanaoka H, Harada H, et al. Effects of electro-acupuncture to frontal notch (saichiku point) on asthenopia. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33 :155-8 (in Japanese).	3	I

### 9. Cardiovascular Diseases (11 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
I	Literature survey of efficacy of acupuncture on the high blood pressure patients	acupuncture & moxibustion	Hiro M, Takeda T, Yano T. Aconsideration of the effect of acupuncture on hypertension based on peer review and the subject in the future. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2003; 53(1): 55-61 (in Japanese with English abstract).	4	I
I	Effects of acupuncture on hypertension subjects	acupuncture	Kawase Y, Ishigami T. Effect of acupuncture therapy on hypertension. <i>Ido no nippon (The Japanese Journal of Acupuncture and Manual Therapies)</i> 2005; 64(6): 33-41 (in Japanese).	4	I
I	Effects of acupuncture on the autonomic function on the circulatory system	acupuncture	Taguchi K, Matsushima M, Ninagawa H, et al. Effects of acupuncture stimulation of the autonomic function of circulatory system Comparison of different methods of acupuncture. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2001; 24: 30-7 (in Japanese).	3	I
I	Effects of acupuncture on the circulatory response induced by mental stress	acupuncture	Yamamoto T, Kimura K, Sakaguchi S, et al. The effects of acupuncture stimulation at H7 on cardiovascular responses during mental arithmetic in humans. <i>Kansai Shinkyu Daigaku Kyo (The Bulletin of Kansai College of Oriental Medicine)</i> 2006; 3: 14-9 (in Japanese with English abstract).	3	I
I	Comparison of effects of acupuncture to the different acupuncture point on the elasticity of blood vessels	acupuncture	Iwamoto E, Murase K, Taninokuchi M, et al. Effects of acupuncture stimulation on the arterial compliance - A comparison between LI10, ST36, CV12 and non-stimulation-. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2010; 60(1): 54-63 (in Japanese with English abstract).	3	I
I	Effects of pressure application to the face on heart rate	pressure	Kinoshita S. Changes of the heart beat with supraorbital foramen stick. <i>Nihon Shinkyu Chiryō Gakkaishi (The Journal of the Japan Acupuncture and moxibustion Society)</i> 1975; 24(1): 22-6 (in Japanese).	3	I
I	Influence of posture on the transient depressor response induced by acupuncture	acupuncture	Imai K, Tawa M, Kitakoji H. Comparison of transient heart rate reduction associated with acupuncture stimulation in supine and sitting subjects. <i>Health Sciences</i> 2004; 21(1): 45-52 (in Japanese with English abstract).	3	I
I	Effects of moxibustion on the skin temperature	moxibustion	Tsutani K, Gunjji H, Tsukayama H. Randomized clinical trial with right left comparison Effects of moxibustion to Shou san li point on warmth of hand. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 1997; 47(1): 74. (in Japanese with English abstract).	3	J
I	Effect of acupuncture on hypertension by RCT envelop	acupuncture	Kawase Y, Ishigami T, Hori S, et al. Clinical trial of acupuncture on hypertension using envelop method Efficacy of Tsu-san-li points. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 1999; 49(1): 233. (in Japanese with English abstract).	6	J
I	Effects of Do-shi acupuncture to the on the blood pressure	acupuncture	Debata A. Utilization of "Do-shi" (puncture of the carotid sinus) to reduce the blood pressure. <i>Nihon Shinkyu Chiryō Gakkaishi (The Journal of the Japan Acupuncture and moxibustion Society)</i> 1970; 19(2): 26-8 (in Japanese).	1	J
I	Effects of acupuncture on the circulation of coronary artery	acupuncture	Kurono Y, Yano T, Shimoo K. The effect of acupuncture on the coronary arteries as evaluated by coronary angiography: a preliminary report. <i>The American Journal of Chinese Medicine</i> 2002; 30(2-3): 387-96	3	C

### 10. Respiratory Diseases (including Influenza and Rhinitis) (6 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
J	Effects of acupuncture on the symptoms of common cold	acupuncture	Kawakita K, Shichidou T, Inoue E, et al. Preventive and curative effects of acupuncture on the common cold: a multicentre randomized controlled trial in Japan. <i>Complementary Therapies in Medicine</i> 2004; 12(4): 181-8.	4	C

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
J	Effects of acupuncture on respiratory function	acupuncture	Harada K, Matsuo S, Uchimura R, et al. Effect of acupuncture on the respiratory functions. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 216-21 (in Japanese).	3	I
J	Effects of acupuncture on bronchodilation in the patients of asthma	acupuncture	Takishima T, Suetsugu M, Tamura G et al. The bronchodilating effect of acupuncture in patients with acute asthma. <i>Annals of Allergy</i> 1982; 48(1): 44-9.	1	A
J	Effects of indirect moxibustion on the symptoms of the aged subjects	Indirect moxibustion	Takahashi N, Tsuru H, Egawa M, et al. Effects of indirect moxibustion on common cold symptoms in elderly subjects lived in nursing home: single-case experimental design. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 2005; 55(5): 706-15 (in Japanese with English abstract).	1	I
J	Effects of acupuncture on the patients of COPD	acupuncture	Suzuki M, Namura K, Ohno Y, et al. The effect of acupuncture in the treatment of chronic obstructive pulmonary disease. <i>Journal of Alternative and Complementary Medicine</i> 2008; 14(9): 1097-105.	1	C
J	Effects of press tack needle on the symptom of pollinosis	press tack needle	Sumiya E, Inoue E, Umeda T, et al. Present status and issues of clinical research in Japan and Korea Multi-center pilot study on pollinosis by single subject randomized design (n-of-1 RCT). <i>Zen Nihon Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2006; 56(2): 130-3. (in Japanese with English abstract).	4	I

### 11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases (3 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
K	Effects of moxibustion on chronic hepatic diseases	acupuncture	Shichido T, Arichi S, Shigihara J, et al. The effect of moxibustion on chronic hepatopathy-Controlled clinical trial -. <i>Nihon Shinkyu Chiryu Gakkai Zasshi (The Journal of the Japan Acupuncture and Moxibustion Society)</i> 1980; 29(3): 56-73 (in Japanese with English abstract).	4	J
K	Effects of acupuncture on the stomach movement and filling sensation	electro-acupuncture	Sakano Y. Effects of electro-acupuncture to Tsu-san-li point on stomach filling sensation and index of gastric movement. <i>Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 2008; 41: 21-8. (in Japanese with English abstract).	3	I
K	Effects of acupuncture, moxibustion and acupressure on the constipation	acupuncture moxibustion acupressure	Arita T, Fujimoto S, Nose T, et al. Effects of treatment with three therapies on constipation. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 46-9 (in Japanese).	3	I

### 12. Skin Diseases (1 reference)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
L	Effects of acupuncture on the skin texture	none	Kagawa D. Effects of acupuncture on the nature of skin. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> 2009; 59(4): 347-52.	4	I

### 13. Diseases of the Musculoskeletal and Connective Tissue (59 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
M	Effects of acupuncture on the joint arthritis patients	acupuncture & moxibustion	Kasuya D, Etou H. Effects of acupuncture and moxibustion on joint arthritis QOL as an indicator. <i>Rehabilitatesyon Igaku (The Japanese Journal of Rehabilitation Medicine)</i> 2004; 41(12): 836-41 (in Japanese).	4	I
M	Study on the techniques of acupuncture needling for the sciatica patients	acupuncture	Kinoshita H. Study of the technique of acupuncture for sciatica. <i>Nihon Shinkyu Chiryu Gakkai Zasshi (The Journal of the Japan Acupuncture and Moxibustion Society)</i> 1962; 12(1): 17-24 (in Japanese).	4	J
M	Effects of acupuncture on the low back pain	acupuncture & moxibustion	Kurosu Y. Acupuncture and moxibustion for Lumbago (II)-Comparative experiment of the therapeutic effectiveness of acupuncture and garlic moxibustion-. <i>Nihon Shinkyu Chiryu Gakkai Zasshi (The Journal of the Japan Acupuncture and Moxibustion Society)</i> 1979; 28(2): 31-4 (in Japanese with English abstract).	4	J
M	Effects of press tack needle on the muscle power	press tack needle	Shimizu M, Tsuru M, Okamoto N, et al. Effects of press tack needle on the muscle power. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33:159-61 (in Japanese).	3	I
M	Effects of acupuncture on the dynamic muscle power	acupuncture	Kitayama K, Kawabara M, Utashiro Y, et al. Effects of acupuncture on the dynamic muscle power. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2002; 26: 69-72 (in Japanese).	3	I
M	Effects of acupuncture on the delayed onset muscle soreness	acupuncture	Takahashi H, Fujii M, Sugiyama T, et al. Effects of acupuncture on the muscle pain after eccentric exercise. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 26: 73-81 (in Japanese).	3	I
M	Effects of press tack needle on the reduction of muscle power after exercise	press tack needle	Sugiyama N, Miura Y, Sato R, et al. Effects of press tack needle on the reduction of muscle power after uniform motion exercise of knee flexion and extension. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 27: 35-9 (in Japanese).	3	I
M	Effects of press tack needle on the reduction of muscle power after repeated exercise	press tack needle	Egashira S, Goto M, Obashi T, et al. Effects of press tack needle on the reduction of muscle fatigue after isotonic exercise of knee flexion and extension. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2007; 30: 66-70 (in Japanese).	3	I
M	Effects of press tack needle on the muscle power	press tack needle	Tanba T, Morita Y. Effect of press tack needle on contraction power of the quadriceps muscle. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2007; 30: 71-3 (in Japanese).	3	I
M	Effects of press tack needle on the muscle power	press tack needle	Kobayashi H, Tanaka K, Ohe S, et al. Effect of press tack needle on the ability of vertical jumping. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2009; 32: 106-10 (in Japanese).	3	I

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
M	Effect of acupuncture to muscle hardness after exercise	acupuncture	Nishiwaki M, Kimura T, Kobayashi K, et al. Changes of hardness of the gastrocnemius muscle after exercise. Effect of acupuncture to chengjin point (needling prohibited point). <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2009; 32: 31-5 (in Japanese).	3	I
M	Effects of cupping on the muscle power	cupping	Marumo D, Utsuki T, Hirai K, et al. Effect of sui-kaku on the muscle power. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 138-40 (in Japanese).	3	I
M	Analysis of changes in flexibility of shoulder stiffness subjects	none	Uchimura R, Iwakawa H, Harada K, et al. Examination of flexibility in shoulder stiffness using movement of scapula. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 222-7 (in Japanese).	3	I
M	Effects of press tack needle on the muscle fatigue after exercise	press tack needle	Hamazaki G, Tanegashima E, Akiyama R, et al. Effects of press tack needle on the muscle fatigue after exercise of flexion and extension of elbow joint 30% of MVC loading. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 62-6 (in Japanese).	3	I
M	Effects of press tack needle on the muscle fatigue after exercise of flexion and extension of elbow joint 30% MVC loading	press tack needle	Mori H, Noguchi E, Kobayashi S, et al. <i>Nihon Onsen Kikou Butsuri Igakukai Zasshi (The Journal of the Japanese Society of Balneology, Climatolgy and Physical Medicine)</i> 1997; 61(1): 30 (in Japanese).	3	I
M	Preventive effects of press tack needle on muscle fatigue elicited by tolerance trainin	press tack needle	Kaneko Y, Nishizuka H, Inoue M, et al. Preventive effects of press tack needle on muscle fatigue elicited by total tolerance trainin-questionnaire survey on the triathletes -. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2000; 24:38-44 (in Japanese).	3	I
M	Effect of the press tack needle on recovery from muscle fatigue	press tack needle	Furuya E, Kaneko Y, Uehara A, et al. Effect of the press tack needle on recovery from muscle fatigue by randomized controlled trial -sham controlled study-. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2009; 59(4): 375-383 (in Japanese with English abstract).	3	I
M	Effects of press tack needle on the muscle pain and fatigue on the runner	press tack needle	Katayama K, Inoue M, Ishizaki N, et al. Effects of press tack needle on the muscle pain and fatigue on the runner evaluated by randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3):357. (in Japanese with English abstract).	3	I
M	Effects of press tack needle on the muscle pain and fatigue induced by long distance running	press tack needle	Katayama K, Inoue M, Ikeuchi T, et al. Effects of press tack needle on the muscle pain and fatigue induced by long distance running. <i>Kansai Rinsyo Supo-tsu I Kagaku Kenkyukai Shi (Journal of Kansai Clinical Sport Medical Science)</i> 2001; 10: 5-7 (in Japanese).	3	I
M	Effects of press tack needle on the time-devident changes of parameters during maximum exercise loading test	press tack needle	Kaneko Y, Ito H, Iida M, et al. Effects of press tack needle on the time-devident changes of parameters during maximum exercise loading test. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2002; 25: 85-93 (in Japanese).	3	I
M	Effect of acupuncture using press needle on muscle pain and stiffness after Marathon race-Double blind randomized control trial	press tack needle	Miyamoto T, Hamada J, Wada T, et al. Effect of acupuncture using press needle on muscle pain and stiffness after Marathon race-Double blind randomized control trial-. <i>Nihon Toyo Igakukai Zasshi (Kampo Medicine)</i> 2003; 54(5): 939-44 (in Japanese with English abstract).	3	I
M	Effect of acupuncture using press needle on muscle pain and stiffness after Marathon race-Double blind randomized control trial	press tack needle	Goto H, Iguchi Y, Ishikawa Y, et al. CEvaluation by changes in parameters during maximum exercise loading. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 26: 56-62 (in Japanese).	3	I
M	Effects of acupuncture on muscle pain after eccentric exercise	acupuncture	Tamura K, Asakawa M, Ishida M, et al. Effects of acupuncture on muscle pain after eccentric exercise (2nd report). <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 27: 40-5 (in Japanese).	3	I
M	Effect of press tack needle on the muscle power reduction induced by flexion-extension exercises of knee joint	press tack needle	Takahashi N, Komuro S, Aoyama T, et al. Effect of press tack needle on the muscle power reduction induced by flexion-extension exercises of knee joint (2nd report). Condition of high intensity and low cycle speed. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2004; 28: 103-7 (in Japanese).	3	I
M	Effects of acupuncture on delayed onset muscle soreness -Clinical trial of tender point acupuncture treatment	acupuncture	Itoh K, Kawamoto S, Fujiwara H, et al. Effects of acupuncture on delayed onset muscle soreness -Clinical trial of tender point acupuncture treatment-. <i>Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 2006; 37: 11-7 (in Japanese with English abstract).	3	I
M	The effect of trigger point acupuncture treatment on chronic neck and shoulder pain	acupuncture	Itoh K, Nanba T, Nishida A, et al. The effect of trigger point acupuncture treatment on chronic neck and shoulder pain -Questionnaire and acupuncture treatment for university students-. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2006; 56(2): 150-7 (in Japanese with English abstract).	3	I
M	Effect of press tack needle treatment on muscle soreness after triathlon race - Placebo-controlled stud	press tack needle	Kaneko Y, Furuya E, Sakamoto A. The effect of press tack needle treatment on muscle soreness after triathlon race - Placebo-controlled study-. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2006; 56(2): 158-65 (in Japanese with English abstract).	3	I
M	Effect of acupuncture and stretching in muscle fatigue of the boxers were compared	acupuncture & moxibustion	Izumi S, Miyamoto T, Hiura M, et al. The effect of acupuncture and stretching in muscle fatigue of the boxers were compared- the meridian test is used for evaluation-. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2007; 37(3-4): 61-9 (in Japanese with English abstract).	3	I
M	Effect of press tack needle on the muscle fatigue produced by isotonicexercise of elbow joint	press tack needle	Imokawa Y, Sawai M, Hayashi E, et al. Effect of press tack needle on the muscle fatigue produced by isotonicexercise of elbow joint. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2009; 32: 27-30 (in Japanese).	3	I
M	The effect continuing acupuncture treatment based on the M-test for collegiate rugby players	acupuncture	Okuma Y, Mukaino Y. The effect continuing acupuncture treatment based on the M-test for collegiate rugby players. <i>Nippon Rinsho Supotsu Igakkaishi (Japanese Journal of Clinical Sports Medicien)</i> 2010; 18(2): 264-273 (in Japanese with English abstract).	3	I

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
M	Effects of magnetic acupuncture to tsu san li point on the muscle fatigue recovery	magnetic acupuncture	Kitamura Y, Mukaino Y, Honda T. Effects of magnetic acupuncture to tsu san li point on the muscle fatigue recovery (double blinded study). <i>Tairyoku Kagaku (Japanese Journal of Physical Fitness and Sports Medicine)</i> 1993; 42(6): 810 (in Japanese).	3	J
M	. Effects of acupuncture on neck stiffness (kata kori)	acupuncture or sham	Nabeta T, Yoshida T, Kitakouji H, et al. Effects of acupuncture on neck stiffness (kata kori) evaluated by randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 1996; 46(3): 94.	3	J
M	Randomized controlled pilot study comparing acupuncture with sham acupuncture for lumbago	acupuncture or sham	Inoue M, Kitakouji H, Ikeuchi T, et al. Randomized controlled pilot study comparing acupuncture with sham acupuncture for lumbago. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2000; 50(2): 356.	6	J
M	Randomized controlled pilot study comparing manual acupuncture with sham acupuncture for lumbago	acupuncture or sham	Inoue M, Kitakouji H, Ikeuchi T, et al. Randomized controlled pilot study comparing manual acupuncture with sham acupuncture for lumbago (2nd report). <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3): 412.	6	J
M	Effect of press tack needle to the tenter points on shoulder stiffness	press tack needle	Furuya E, Nayuki T, Sakamoto A, et al. Effect of press tack needle to the tenter points on shoulder stiffness (kata kori) sensation. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3): 420.	6	J
M	Randomized controlled trial comparing the effect of manual acupuncture with sham acupuncture for acute low back pain.	acupuncture or sham	Araki S, Kawamura O, Mataka T, et al. Randomized controlled trial comparing the effect of manual acupuncture with sham acupuncture for acute low back pain. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3): 382. (in Japanese with English abstract).	6	J
M	Comparison of real and sham acupuncture on osteoarthritis of the knee using randomized controlled trial.	acupuncture or sham	Ogawa T, Nakagawa H, Sakuma M, et al. Comparison of real and sham acupuncture on medial type osteoarthritis of the knee using randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3): 381. (in Japanese with English abstract).	6	J
M	Randomized controlled trial comparing the effect of distal point needling with local point needling for low back pain.	acupuncture	Takeda H, Nabeta T. Randomized controlled trial comparing the effect of distal point needling with local point needling for low back pain. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3): 411. (in Japanese with English abstract).	6	J
M	Comparison of efficacy of real and sham acupuncture on the acute neck pain	acupuncture or sham	Tanabe K, Ozawa Y, Kotou S, et al. Comparison of efficacy of real and sham acupuncture on the acute neck pain by randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2001; 51(3): 381. (in Japanese with English abstract).	6	J
M	Effects of low frequency electro-acupuncture and TENS on the low back pain.	electro-acupuncture	Ikeuchi T, Nakamura T, Katsumi Y, et al. Effects of low frequency electro-acupuncture and TENS on the low back pain. Multicenter randomized controlled trial. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 1999; 49(1): 233. (in Japanese with English abstract).	6	J
M	Acupuncture and moxibustion treatment for chronic low back pain.	box moxibustion	Kawachi A, Kamei Y, Kim M, et al. Acupuncture and moxibustion treatment for chronic low back pain. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2005; 35(1/2): 14-7 (in Japanese with English abstract).	1	I
M	Clinical trial of spinex treatment for chronic low back pain	intradermal acupuncture	Sakaguchi S, Wakayama I, Tsukayama H. Clinical trial of spinex treatment for chronic low back pain -A research study for a pragmatic trial-. <i>Kansai Shinkyu Daigaku Kiyo (The Bulletin of Kansai College of Oriental Medicine)</i> 2006; 3: 20-5 (in Japanese with English abstract).	1	I
M	Effects of acupuncture and moxibustion on the sciatica syndrome.	acupuncture & moxibustion	Kinoshita H. Effects of acupuncture and moxibustion on the sciatica syndrome. <i>Proceeding of the Kokusai Shinkyu Gakkai (The proceeding of the International Acupuncture Conference)</i> 1965; 57.	1	J
M	Effects of acupuncture and moxibustion on the sciatica syndrome.	acupuncture & moxibustion	Kinoshita H. Effects of acupuncture and moxibustion on the sciatica syndrome. <i>Kokusai Shinkyu Gakkai Zasshi (The International Journal of Acupuncture)</i> 1966; 76-95. (in Japanese).	1	J
M	Effects of acupuncture and moxibustion on the sciatica syndrome.	acupuncture & moxibustion	Kinoshita H. Acupuncture and moxibustion therapy and Sciatica. <i>Ido no Nihon (The Japanese Journal of Acupuncture and Manual Therapies)</i> 1969; 126-48. (in Japanese).	1	J
M	Acupuncture and moxibustion therapy for the treatment on the sciatica.	acupuncture & moxibustion	Kinoshita H. Acupuncture and moxibustion therapy for the treatment on the sciatica. <i>Proceeding of the 2nd International conference of Acupuncture (Paris)</i> 1969;	1	J
M	Effect of acupuncture on scapulothoracic periarthritis	special treatment	Kinoshita H. Effect of acupuncture on scapulothoracic periarthritis. <i>Nihon Shinkyu Chiryō Gakkaiishi (The Journal of the Japan Acupuncture and moxibustion Society)</i> 1973; 22(1): 23-8 (in Japanese).	1	J
M	Comparative analysis of electrical acupuncture therapy for arthrosis of the knee.	current stimulation	Marumo A. Comparative analysis of electrical acupuncture therapy for arthrosis of the knee. <i>Nihon Shinkyu Chiryō Gakkaiishi (The Journal of the Japan Acupuncture and moxibustion Society)</i> 1976; 25(3): 52-4 (in Japanese with English abstract).	1	J
M	Clinical observation of paraneural acupuncture for cervico-brachial syndrome	acupuncture	Kinoshita H. Clinical observation of paraneural acupuncture for cervico-brachial syndrome. <i>Nihon Shinkyu Chiryō Gakkaiishi (The Journal of the Japan Acupuncture and moxibustion Society)</i> 1978; 27(1): 61-71 (in Japanese with English abstract).	1	J
M	Effectiveness of acupuncture and moxibustion therapy on the spinal canal stenosis	acupuncture & moxibustion	Fujinuki R. Research of effectiveness of acupuncture and moxibustion therapy on the spinal canal stenosis (1). <i>Ido no Nihon (The Japanese Journal of Acupuncture and Manual Therapies)</i> 1989; 48(10): 8-17 (in Japanese).	1	J
M	Comparison of the effects between low energy laser therapy and acupuncture in gonarthrosis	Laser	Tanimura H, Ono T, Sou H, et al. Comparison of the effects between low energy laser therapy and acupuncture in gonarthrosis. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 1990; 40(3): 243-6 (in Japanese with English abstract).	1	J
M	Clinical application of reihai yuketsu	acupuncture	Muto A, Kido Mn Mitsuzawa H, Clinical application of reihai yuketsu (2nd report) Focused on kneejoint pain. <i>Dento Igaku (Traditional Acupuncture and moxibustion)</i> 2010; 36(3): 134-9. (in Japanese).	1	I
M	Meta-analysis of acupuncture therapy for relieving low back pain on the visual analog scale	acupuncture	Zhu Y, Origasa H, Wang Q. Meta-analysis of acupuncture therapy for relieving low back pain on the visual analog scale. <i>Yakuri to Chiryō (Japanese Pharmacology and Therapeutics)</i> 2002; 30(12): 997-1002 (in Japanese with English abstract).	5	I

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
M	Acupuncture and sham acupuncture reduce muscle pain in myofascial pain patients.	acupuncture sham	Goddard G, Karibe H, McNeill C, et al. Acupuncture and sham acupuncture reduce muscle pain in myofascial pain patients. <i>Journal of Orofacial Pain</i> 2002; 16(1): 71-6.	5	C
M	Therapeutic effects of magnetic fields on frozen shoulder	magnetic device	Kanai S, Taniguchi N, Kawamoto M, et al. Therapeutic effects of magnetic fields on frozen shoulder. <i>Seikeigeka to Saigaigeka (Orthopedics and Traumatology)</i> 2001; 50(1): 241-4 (in Japanese with English abstract).	2	I
M	Perineural morphine in patients with chronic ischemic lower extremity pain	morphine	Keskinbora K, Aydinli I. Perineural morphine in patients with chronic ischemic lower extremity pain: efficacy and long-term results. <i>Journal of Anesthesia</i> 2009; 23(1): 11-8.	2	I
M	Studies on the effects of low energy laser irradiation therapy	Laser	Watsuji T, Ishimaru K, Shinohara S, et al. Studies on the effects of low energy laser irradiation therapy -The effects of Ga-Al-As diode laser therapy for low back pain-. <i>Nihon Toyo Igakukai Zasshi (Kampo Medicine)</i> 1991; 42(2): 259-64 (in Japanese).	2	I
M	The effect of acupuncture treatment for the low back pain patients with D-Phenylalanin (DPA) preadministration	acupuncture	Kawachi A, Toyoda S, Yamada Y, et al. The effect of acupuncture treatment for the low back pain patients with D-Phenylalanin (DPA) preadministration (II). <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 1984; 34(1): 28-31 (in Japanese with English abstract).	2	I
M	Literature survey of safety and efficacy of acupuncture on the low back pain and in pregnancy.	none	Mizumoto A, Minami K, Nakagomi S, et al. Literature survey of safety and efficacy of acupuncture on the low back pain and in pregnancy. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 198-202 (in Japanese). (in Japanese with English abstract).	4	I

#### 14. Genitourinary Tract Disorders (5 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
N	Effects of acupuncture and moxibustion on dysmenorrhea や menstrual cycle	acupuncture & moxibustion	Kobayashi H, Matsushita M, Shimizu N, et al. Effects of acupuncture and moxibustion on dysmenorrhea menstrual cycle Using basal body temperature of athletes as an index. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2008; 31: 25-8 (in Japanese).	3	I
N	Clinical trial of acupuncture on urination disorder by RCT envelope	acupuncture	Minagawa M, Ishigami T, Hori S, et al. Clinical trial of acupuncture on urinary disorder by RCT envelope -effectiveness of zhongji point (CV3) <i>Proceeding of 10th Cyubu Block Meeting of the Japan Society of Acupuncture and moxibustion</i> 1997; 13. (in Japanese).	6	I
N	Clinical trial of acupuncture on urinary disorder by RCT envelope	acupuncture	Minagawa M, Ishigami T, Hori S, et al. Clinical trial of acupuncture on urinary disorder by RCT envelope. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 1998; 48(1): 64.	6	J
N	Randomized controlled trial of acupuncture on urinary disorder	acupuncture	Kitakoji H, Sumiya E, Okamoto Y, et al. Randomized controlled trial of acupuncture on urinary disorder. Report of project of clinical division. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2000; 50(2): 343. (in Japanese with English abstract).	4	J
N	Present status and issues in clinical research in Japan and Korea, Clinical trial of acupuncture on premenstrual syndrome	acupuncture	Kim S C, Koo S T, Choi S M, et al. Present status and issues in clinical research in Japan and Korea, Clinical trial of acupuncture on premenstrual syndrome. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2006; 56(2): 135-8. (in Japanese with English abstract).	4	I

#### 19. Post-anesthesia and Postoperative Pain (10 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
S	Double blinded trials of acupuncture in treatment and rehabilitation on the injury of the ball game players in the university	acupuncture sham acupuncture	Nishizawa Y, Nagano T, Fushiki N, et al. Double blinded trials of acupuncture in treatment and rehabilitation on the injury of university ball players. <i>Kansai Rinsyo Supo-tsu Ikkagaku Kenkyukaiishi I (The Journal of Kansai Clinical Sport Medical Science Research Association)</i> 1999; 8: 57-9. (in Japanese).	3	I
T	Effect of D-phenylalanine on acupuncture analgesia	acupuncture	Kitade T, Morikawa K, Minamikawa M, et al. Studies on the enhanced effect of acupuncture analgesia and acupuncture anesthesia by D-phenylalanine (2nd report)-schedule of administration and clinical effects in low back pain and tooth extraction. <i>Acupuncture and electro-therapeutics Research</i> 1990; 15(2): 121-35.	1	C
T	Effects on acupuncture and moxibustion treatment of allergic diseases	acupuncture & moxibustion	Yano T, Egawa M, Yamamoto T, et al. Effects on acupuncture and moxibustion treatment of allergic diseases. <i>Toho Igaku (Eastern Medicine)</i> 2002; 18(2): 47-56 (in Japanese with English abstract).	4	I
T	Minute sphere acupressure does not reduce postoperative pain or morphine consumption	acupressure	Sakurai M, Suleman M-I, Morita N, et al. Minute sphere acupressure does not reduce postoperative pain or morphine consumption. <i>Anesthesia and Analgesia</i> 2003; 96(2): 493-7.	3	C
T	Uni-Laser acupuncture its analgesic effect on painful diseases.	laser acupuncture	Toyota S, Kawachi A, Matsuo I, et al. "Uni-Laser" acupuncture its analgesic effect on painful diseases. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 1985; 15(4): 173-177 (in Japanese).	1	I
T	The effect of acupuncture with DPA preadministration.	acupuncture	Kawachi A, Kitade T, Toyoda S, et al. The effect of acupuncture with DPA preadministration. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 1982; 32(2): 47-51 (in Japanese with English abstract).	2	I
T	Clinical study on various pains for therapeutic effectiveness with applications of static fields.	static fields	Kanai S, Kawamoto M, Endo H, et al. Clinical study on various pains for therapeutic effectiveness with applications of static fields. <i>Kansai Shinkyu Tanki Daigaku Nenpou (Annual Report of Kansai College of Oriental Medicine)</i> 2000; 15: 48-55 (in Japanese with English abstract).	2	I
T	Literature survey of effects of physical therapies on sprained ankle	none	Shiraiwa D, Wada T, Izumi S, et al. An investigation of the effects of physical therapies on sprained ankle -Comparison of cryotherapy, thermotherapy and acupuncture using MEDLINE and Japan Centra Revuo Medicina-. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2007; 37(1-2): 16-27 (in Japanese with English abstract).	4	I

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
T	Effect of SSP stimulation on the tooth extraction	SSP	Kawachi A, Kim M, Kuge H, et al. An experience of SSP anesthesia in teeth extraction. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2003; 32(1/4): 25-31 (in Japanese with English abstract).	3	I
T	Effects of acupuncture on the post tooth extraction pain	acupuncture	Kitade T, Ohyabu H. Analgesic effects of acupuncture on pain after mandibular wisdom tooth extraction. <i>Acupuncture and electro-therapeutics Research</i> 2000; 25(2): 109-15. (in Japanese).	1	C

## 21. Others (81 references)

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
O	Liver deficiency symptom and VAMFIT	none	Kido M, Samejima Y, Mitsuzawa H. Liver deficiency syndrome and VAMFIT. <i>Keiraku Chiryō (Meridian Therapy)</i> 2001; 145: 43-37. (in Japanese).	4	I
O	Comparative observation in Goshin-ho and Hinaishin-po.	acupuncture	Kinoshita H. Comparative observation in Goshin-ho and Hinaishin-po. <i>Nihon Shinkyū Chiryō Gakkaishi (The Journal of the Japan Acupuncture and moxibustion Society)</i> 1969; 18(2): 5-11 (in Japanese).	4	J
O	Importance of placebo and nocebo action in mechanisms of acupuncture effect.	none	Umlauf R. Importance of placebo and nocebo action in mechanisms of acupuncture effect. <i>Nihon Ryodoraku Jiritsushinkei Gakkai Zasshi (The Japanese Journal of Ryodoraku Medicine)</i> 1989; 34(11·12): 310-5. (in Japanese)	4	J
O	Studies on the methodologies of clinical research on acupuncture -Using a crossover design	none	Mori H, Nishijo K, Tsukayama H. Studies on the methodologies of clinical research on acupuncture -Using a crossover design-. <i>Biomedical Thermology</i> 1998; 18(2): 98-107 (in Japanese with English abstract).	4	I
O	Effect of polarized infra-red ray to acupuncture points on the peripheral blood flow.	infrared ray	Watanabe I, Mano Y, Jiang G, et al. Polarized infra-red light to acupuncture points improve peripheral blood flow. <i>Biomedical Thermology</i> 2000; 20(2): 53-8 (in Japanese with English abstract).	3	I
O	Examination of an eccentric contraction-induced trigger point model using human subjects	none	Itoh K, Okada K, Kawakita K. Examination of an eccentric contraction-induced trigger point model using human subjects. <i>Zen Nihon Shinkyū Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2001; 51(2): 81-90 (in Japanese).	3	I
O	Inhibitory effect of acupuncture on vibration-induced flexion reflex	acupuncture	Nishimura N, Chihara E, Shinbara H, et al. Inhibitory effect of acupuncture on vibration-induced flexion reflex and its removal by noaloxone. <i>Meiji Shinkyū Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 2002; 30: 31-40 (in Japanese with English abstract).	3	I
O	Effect of acupuncture with moxa heating at low back on the skin temperature of plantar	acupuncture with moxa heating	Teranishi H, Hakozaki M, Ogawa E, et al. Effect of acupuncture with moxa heating on the skin temperature of plantar (3rd report). <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 27: 83-7 (in Japanese).	3	I
O	Inhibitory effect of acupuncture on vibration-induced flexion reflex and its removal by noaloxone	acupuncture	Kawamoto M, Mutou I, Furuta T. T C <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 26: 82-6 (in Japanese).	3	I
O	Effect of painful TENS on vibration induced finger flexion reflex	TENS	Takakura N, Yajima H, Homma I. Inhibitory effect of pain-eliciting transcutaneous electrical stimulation on vibration-induced finger flexion reflex in the human upper limb. <i>Japanese Journal of Physiology</i> 2004; 54(3): 243-8.	3	I
O	Change of the plantar skin temperature induced by acupuncture stimulation to the low back	acupuncture	Matsuda I, Kato H, Morita T, et al. Immediate change of the plantar skin temperature induced by acupuncture stimulation to the low back (4th report) . <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2004; 28: 99-102 (in Japanese).	3	I
O	Changes of F wave induced by mental calculation stress and effect of acupuncture.	acupuncture	Shimizu Y, Yamana H, Kuroiwa M, et al. Changes of F wave induced by mental calculation stimulus and effect of acupuncture. <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2004; 28: 41-6 (in Japanese).	3	I
O	Study on change of cutaneous sensation produced by pressure application for discussion of the insertion pain.	Pressure	Nishibe T, Yoshida T. Study on change of cutaneous sensation produced by pressure application for discussion of the insertion pain. <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2004; 28: 63-6 (in Japanese).	3	I
O	The effect of electronic sheet to warm up body -To keep warmth during acupuncture treatment	electronic sheet	Tawa M, Yano T, Tuvo S. The effect of electronic sheet to warm up body -To keep warmth during acupuncture treatment-. <i>Health Sciences</i> 2004; 21(1): 147-53 (in Japanese with English abstract).	3	I
O	Influence on individual finger stalls in pain during acupuncture operation.	finger stall	Handa M, Tsunematsu R, Tokutake T, et al. Influence on individual finger stalls in pain during acupuncture operation. <i>Zen Nihon Shinkyū Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2004; 54(4): 627-35 (in Japanese with English abstract).	3	I
O	Effects of acupuncture and frolement on blood lactate concentration.	acupuncture frolement	Hayashi K, Fujinami K, Morita Y, et al. Effects of acupuncture and frolement on blood lactate concentration. <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2004; 28: 80-2 (in Japanese).	3	I
O	Effect of pressure stimulation to the plantar on the skin temperature of low back.	pressure	Wada T, usuda Y, Fukushima M, et al. Does pressure stimulation to the plantar increase the skin temperature of low back.? Comparison of stimulation to the plantar and low back. <i>Nihon Syūgiyōhō Gakkai Zasshi (The Journal of Japanese Association of Manual Therapy)</i> 2004; 15(1): 18-22 (in Japanese).	3	I
O	Evaluation of sham acupunctures for development of adequate one.	none	Sawamura J, Inazawa T, Inazawa Y, et al. Comparison and evaluation of sham acupuncture for development of adequate sham acupuncture. <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2004; 28: 67-72 (in Japanese).	3	I
O	Efficacy of low frequency SSP on the autonomic function	SSP	Sawada T, Takeuchi Y, Honjo H, et al. Efficacy of low frequency SSP on the function of autonomic system and lower limb blood flow. <i>Judo Seifuku Sekkō Igaku (Japanese Journal of Judo Therapy)</i> 2004; 13(2): 70-5 (in Japanese).	3	I
O	Application of fMRI to basic experiments of acupuncture	acupuncture	Ueda Y, Hayashi K, Kuriowa K. The application of fMRI to basic experiments in acupuncture. The effects of stimulus points and content on cerebral activities and responses. <i>IEEE Engineering in Medicine and Biology Magazine</i> 2005; 24(2): 47-51.	3	C
O	Effect of acupuncture on the changes of sensation of joint position after exercise	acupuncture	Ideta S, Miyamoto T, Shimazu D, et al. Effect of acupuncture on the changes of sensation of joint position by exercise. <i>Toyo Ryōho Gakko Kyōkai Zasshi (The Journal of Oriental Medicine College Association)</i> 2005; 29: 77-81 (in Japanese).	3	I

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
O	Change of skin temperature of the plantar induced by stimulation to low back	acupuncture	Yamamoto E, Aoki J, Sawahata Y, et al. Change of skin temperature of the plantar induced by stimulation to low back (5th report). <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2005; 29: 54-6 (in Japanese).	3	I
O	Effect of press tack needle on the reduction of muscle power after exercise	press tack needle	Aoyama T, Gowa N, Tsukahara Y, et al. Effect of press tack needle on the reduction of muscle power after flexion extension exercise (3rd report) Low intensity and high cycle with uniform motion. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2005; 29:73-6 (in Japanese).	3	I
O	Effect of low power Lasar application to acupunctue point.	laser	Ishimaru K, Chihara E. Effect of low power Lasar application to acupunctue point. <i>Nihon Re-za Chiryu Gakkaishi (The Journal of Japan Laser Therapy Society)</i> 2005;4(2):9-11	3	I
O	Compare the efficacy of superficial and deep acupuncture on neck and shoulder stiffness	acupuncture	Ohta K, Yano T. Comparison study between superficial and deep acupuncture on the neck and shoulder stiffness -As index of muscle hardness, surface EMG and deep hemodynamics-. <i>Nihon Onsen Kikou Butsuri Igakukai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2005; 68(2): 122-33 (in Japanese with English abstract).	3	I
O	Effects of press tack needle and magumatic therapeutic device on relaxation of muscle tension.	press tack needle magnetic particle	Nakamura M, Okumura E, Sato R, et al. Effects of press tack needle and magumatic therapeutic device on relaxation of muscle tension. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2005; 29: 69-72 (in Japanese).	3	I
O	Effct of moxibustion on the hemodynamics of cutaneous and subcutaneous tissue.	moxibustion	Tawa M, Kitakoji H, Yano T, et al. Effct of moxibustion on the hemodynamics of cutaneous and subcutaneous tissue. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2005; 55(4): 538-48 (in Japanese with English abstract).	3	I
O	Effect of local application of Linear polarizing near infrared rays on physiological function.	nea infrared ray	Watanabe K, Effect of local application of Linear plarizing near infrared rays on physiological function. <i>Biomedical Thermology</i> 2005; 25(2): 34-9.	3	I
O	Effects of acupuncture on the changes of evoked electromyogram induced by arm compression.	Pressure	Shimada S, Imamura K, Hashizume S, et al. Effects of acupuncture on the changes of evoked electromyogram induced by arm compression.. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2005; 29 :65-8 (in Japanese).	3	I
O	Effect of acupressure to plantar on the skin temperature	Pressure	Wada T, Usuda Y, Fukushima M, et al. Temperature change on the skin of lumber region observed with a thermography by acupressure stimulation to planter region -A comparison of the stimulus to planter and lumber region-. <i>Biomedical Thermology</i> 2005; 25(2): 45-51 (in Japanese with English abstract).	3	I
O	Evaluation of ionic effects of a metallic small prarticle pressed on sciatica zone of a human auricle	metal particle	Yoshida S, Kimura K, Sakaguchi S, et al. Evaluation of ionic effects of a metallic small prarticle pressed on sciatica zone of a human auricle -Using chaotic analysis of time series data of pulse waves-. <i>Kansai Shinkyu Daigaku Kiyo (The Bulletin of Kansai College of Oriental Medicine)</i> 2006; 3: 60-5 (in Japanese with English abstract).	3	I
O	Application of image analysis of skin temperature for evaluation	none	Tomura T, Sakaguchi S, Terada K. Exploratory study of apply image analysis method to thermogram, and evaluate an area of skin temperature. <i>Kansai Shinkyu Daigaku Kiyo (The Bulletin of Kansai College of Oriental Medicine)</i> 2006; 3: 31-4 (in Japanese with English abstract).	3	I
O	Relation between appeared leg length difference and maximum range of motion at spine position	none	Maekawa H, Matsuzawa T, Yamada E, et al. Relation between appeared difference of leg length and maximum range of motion at spine position. <i>Ido no Nihon (The Japanese Journal of Acupuncture and Manual Therapies)</i> 2006; 65(7): 105-9 (in Japanese).	3	I
O	Effects of application of soybean peptides after exercise loading	soybean peptide	Masuda K, Furukawa K, Fujiwara Y, et al. Effects of application of soybean peptides after exercise loading (2nd report) Growth hormone as an indicator. <i>Kansai Rinsyu Supoutsu Ikagaku Kenkyukaishi (The Journal of Kansai Clinical Sport Medical Science Research Association)</i> 2006; 15: 49-50. (in Japanese with English abstract).	3	I
O	Effect of high pressure oxygen bath on performance of exercise	oxgen bath	Hirano J, Ito Y, Hayashi T, et al. Effects of high pressure oxygen bath on performance of exercise (1st reort). <i>Toyo Igaku (Oriental Medicine)</i> 2006; 12(2): 19-23. (in Japanese).	3	I
O	Changes in skin temperature by acupressure stimulation	acupressure	Wada T, Usuda Y, Terada K. Changes in skin temperature by acupressure stimulation -A study of subjective and objective temperature changes-. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2006; 36(1-2): 10-8.	3	I
O	Effect of acupuncture on nitric oxide generation and local circulation.	acupuncture	Tsuchiya M, Sato E F, Inoue M, et al. Acupuncture enhances generation of nitric oxide and increases local circulation. <i>Anesthesia and Analgesia</i> 2007; 104(2): 301-7.	3	I
O	. Influences of acupuncture on the epidermal local oxidation-reduction potential	acupuncture	Watanabe K, Shinohara S. Influences of acupuncture on the epidermal local -Using the oxidation-reduction potential and hydrogen ion concentration as parameters-. <i>Jintai Kagaku (Journal of Mind-Body Science)</i> 2008; 17(1): 23-33 (in Japanese with English abstract).	3	I
O	Effect of electroacupuncture on exercise-induced oxidative stress.	electro-acupuncture	Fujimoto H, Katayama K, Hayashi T, et al. Effect of electroacupuncture on exercise-induced oxidative stress. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2008; 58(2): 203-12 (in Japanese with English abstract).	3	I
O	Effect of stretching and acupuncture manipulation of the FFD	acupuncture stretching	Ishida T, Matsuzawa T, Ishimaru K, et al. Effect of stretching and acupuncture manipulation of the FFD. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2009; 32: 80-3 (in Japanese).	3	I
O	Effects of moxibustion on peripheral cutaneous blood flow, heart rate and heart rate variability	moxibustion	Okubo J, Nakamura K, Miyakawa S, et al. Effects of direct moxibustion and indirect moxibustion on peripheral cutaneous blood flow, heart rate and high frequency part power of heart rate variability -from the viewpoint of stimulation pattern-. <i>Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)</i> 2009; 39(1-2): 31-47.	3	I
O	Effect of acupuncture and acupressure on equilibrium sensation	acupuncture acupressure	Nakura M, Miyamae K, Takaoka H, et al. Examination of effect of acupuncture and acupressure on equilibrium sensation. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2009; 32: 127-9 (in Japanese).	3	I
O	Effects of acupuncture and heating on blood volume and oxygen saturation of tendon	acupuncture	Kubo K, Yajima H, Takayama M, et al. Effects of acupuncture and heating on blood volume and oxygen saturation of human Achilles tendon in vivo. <i>European Journal of Applied Physiology</i> 2010; 109(3): 545-50.	3	C
O	Effect of acupuncture on salivary immunoglobulin A after a bout of intense exercis	acupuncture	Matsubara Y, Shimizu K, Tanimura Y, et al. Effect of acupuncture on salivary immunoglobulin A after a bout of intense exercise. <i>Acupuncture in Medicine</i> 2010; 28(1): 28-32.	3	C

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
O	The effects of acupuncture stimulation on the salivary secretory immunoglobulin a during training camp	acupuncture	Matsubara Y, Miyamoto T, Kono I. The effects of acupuncture stimulation on the salivary secretory immunoglobulin a during training camp. <i>Nihon Onsen Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)</i> 2010;73(3):191-201 (in Japanese with English abstract).	3	I
O	Effect of press tack needle on salibary amylase.	press tack needle	Nakabashi M, Ogura C, Nakazono T, et al. Effect of press tack needle on salibary amylase. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 56-8 (in Japanese).	3	I
O	Effect of press tack needle on electrically @roduced pain and two -point detection threshold..	Intradermal acupuncture	Hayashi K, Hikawa M. Effect of press tack needle on electrically induced pain and two -point detection threshold. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2010; 33: 180-3 (in Japanese).	3	I
O	A placebo method for evaluating the effect of ear acupuncture.	auricular acupuncture	Mukaino Y, Arakawa K, Kawano A, et al. A placebo method for evaluating the effect of ear acupuncture. <i>Gendai Toyo Igaku (The Journal of Traditional Sino-Japanese Medicine)</i> 1985; 6(4): 96-8 (in Japanese).	3	J
O	Experimental study on the augmentation effects of shakuyaku kanzo tou on acupuncture anesthesia.	acupuncture shakuyaku kanzo to	Kitade t, Jinno H, Hyoudou M, et al. Experimental study on the augmentation effects of shakuyaku kanzo tou on acupuncture anesthesia. <i>Kiso to Rinsyo (The Clinical Report)</i> 1986; 20(6): 3309-14 (in Japanese).	3	I
O	An evaluation of music-rhythm low-frequency electro-acupuncture.	acupuncture	Kawachi A, Toyoda S, Sakai Y, et al. An evaluation of music-rhythm low-frequency electro-acupuncture. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 1988; 38(3): 295-9 (in Japanese with English abstract).	3	I
O	The effect of auricular acupuncture on olfactory acuity.	Auricular acupuncture	Tanaka O, Mukaino Y. The effect of auricular acupuncture on olfactory acuity. <i>The American Journal of Chinese Medicine</i> 1999; 27(1): 19-24.	3	C
O	Effect of acupuncture on optokinetic motion sickness monitored by electrogastrograms	acupuncture	Shiomi M, Imai K, Sakita M. Effect of acupuncture stimulation on optokinetic motion sickness monitored by electrogastrograms. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> . 2003; 53(1): 71-80 (in Japanese with English abstract).	3	I
O	Effect of manual acupuncture on skin sympathetic nerve activities-microneurographic study	acupuncture	Kimura K, Masuda K, Wakayama I, Effect of manual acupuncture on skin sympathetic nerve activities-microneurographic study-. <i>Kansai Shinkyu Daigaku Kiyo (The Bulletin of Kansai College of Oriental Medicine)</i> 2004; 1: 20-4 (in Japanese).	3	I
O	Effect of moxibustion of the fatigue of thigh muscles.	moxibustion	Kashiuchi S, Ueno T, Hasaya K, et al. Effect of moxibustion of the fatigue of thigh muscles. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2000; 23: 22-4 (in Japanese).	3	I
O	Effects of acupuncture on muscle fatigue (2nd report). Comparison of different stimulation points.	acupuncture	Yamada N, Myoudai Y, Hasegawa K, et al. Effects of acupuncture on muscle fatigue (2nd report). Comparison of different stimulation points. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2002; 25: 35-42 (in Japanese).	3	I
O	Acupuncture and responses of immunologic and endocrine markers during competition	acupuncture	Akimoto T, Nakahori C, Aizawa K, et al. Acupuncture and responses of immunologic and endocrine markers during competition. <i>Medicine and Science in Sports and Exercise</i> 2003; 35(8): 1296-302..	3	C
O	Effects of acupuncture on CMI health questionnaire and basic temperature in female..	acupuncture	Inaba K, Kuroiwa T, Kuwayama M, et al. Effects of acupuncture on CMI health questionnaire and basic temperature curves in female. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 27: 63-7 (in Japanese).	3	I
O	Effect of acupuncture on alchol intake Using a device of alchol content in expiratory gas.	acupuncture	Honji T, Izumi K., Yonezawa N, et al. Effect of acupuncture on alchol intake Using a device of alchol content in expiratory gas. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2003; 26: 112-6 (in Japanese).	3	I
O	Factors that influence the applicability of sham needle in acupuncture trials	Sham acupuncture	Tsukayama H, Yamashita H, Kimura T, et al. Factors that influence the applicability of sham needle in acupuncture trials: two randomized, single-blind, crossover trials with acupuncture-experienced subjects. <i>The Clinical Journal of Pain</i> 2006; 22(4): 346-9.	3	C
O	MRI measurement of acupuncture's effect on gastric emptying in humans.	press tack needle	Arai N, Chihara E. MRI measurement of acupuncture's effect on gastric emptying in humans. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and moxibustion)</i> 2007; 57(4): 509-16 (in Japanese with English abstract).	3	I
O	Effect of acupressure on subjective and autonomic responses to needle insertion.	acupressure	Arai YC, Ushida T, Osuga T, et al. The effect of acupressure at the extra 1 point on subjective and autonomic responses to needle insertion. <i>Anesthesia and Analgesia</i> 2008; 107(2): 661-4.	3	C
O	Validation of a placebo acupuncture needle with potential for double blinding	placebo acupuncture	Takakura N, Yajima H. A placebo acupuncture needle with potential for double blinding - a validation study. <i>Acupuncture in Medicine</i> 2008; 26(4): 224-30.	3	C
O	Effect of press tack needle on muscle fatigue induced by flexion extension exercises on elbow joint-	press tack needle	Imokawa Y, Kitano Y, Nakamura Y. Effect of press tack needle on muscle fatigue induced by flexion extension exercises on elbow joint- a pilot study. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2008; 31: 82-6 (in Japanese).	3	I
O	Mubun method of abdominal palpation and the effects of acupuncture-moxibustion treatment	acupuncture & moxibustion	Matsumoto K. Importance of evaluating the degree of tension in the liver diagnostic areas using the Mubun method of abdominal palpation and the effects of acupuncture-moxibustion treatment physical at Goukoku (LI4) on performance. <i>Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)</i> 2008; 40: 15-27 (in Japanese with English abstract).	3	I
O	Effects of palm electrical stimulation on muscle atrophy by forearm immobilization.	TENS	Nakayama T, Takeuchi Y, Taguchi D, et al. Effects of palm electrical stimulation on muscle atrophy by forearm immobilization. <i>Judo Seifuku Sekkoku Igaku (Japanese Journal of Judo Therapy)</i> 2008; 16(3): 167-77.	3	I
O	Research on property of strongly reactive points and action mechanism of moxa-needle.	acupuncture with moxa heating	Watanabe K. Research on property of strongly reactive points and action mechanism of moxa-needle. <i>Nihon Tougou Iryou Gakkai Zasshi (Journal of Japanese Society for Integrative Medicine)</i> 2008; 1(2): 10-6 (in Japanese with English abstract).	3	I
O	Changes in blood flow of forebrain and autonomic function elicit by the stimulation with 1/f rhythm.	1/f rhythm	Demiya N. Changes in blood flow of forebrain and autonomic function elicit by the stimulation with 1/f fluctuation. <i>Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Science)</i> 2009; 3: 186-94 (in Japanese).	3	I
O	Effect of acupuncture to Nai kan point on the activity of salivary alfa amylase	acupuncture	Ohata T, Kadota T, Takano Y, et al. Effect of acupuncture to Nai kan point on the activity of salivary alfa amylase as a stress marker <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2009; 32: 96-100 (in Japanese).	3	I

ICD-10 Code	Research Question	Intervention	Reference	Reason for Exclusion	Source
O	Changes of hemoglobin by moxibustion before exercise.	moxibustion	Higuchi M. Changes of hemoglobin by moxibustion before exercise. Effect of moxibustion on DOMS (delayed onset muscle soreness) <i>Toyo Igaku (Oriental Medicine)</i> 2009; 15(3): 54-8. (in Japanese).	3	I
O	Clinical effectiveness of acupuncture applied to strongly reactive points	acupuncture	Watanabe K, Shinohara S. Clinical effectiveness of acupuncture applied to strongly reactive points: randomized controlled trial regarding clinical efficacy. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 2010; 60(1): 74-83 (in Japanese with English abstract).	3	I
O	Effectiveness of low frequency acupuncture combined with body sonic pad therapy.	electro-acupuncture	Kawachi A, Kadosaki K, Shinohara R, et al. Effectiveness of low frequency in situ needle acupuncture combined with body sonic pad therapy. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 1992; 42(2): 169-73 (in Japanese with English abstract).	3	I
O	Assessment of clinical usefulness of an aurora beamer used in combination with acupuncture	acupuncture aurora beamer	Kitade T, Hayashida I, Shinohara S, et al. Assessment of clinical usefulness of an aurora beamer used in combination with acupuncture: Using the AMI (apparatus for measuring the functioning of the meridians and their corresponding internal organs). <i>Nihon Shinkyu Ryodoraku Igakkai Zasshi (Journal of Japan Ryodoraku Medicine Society)</i> 1995; 23(4): 7-9. (in Japanese).	3	I
O	Acupuncture for gait disorders in the elderly	acupuncture	Seki T, Kurusu M, Arai H, et al. Acupuncture for gait disorders in the elderly. <i>Journal of the American Geriatrics Society</i> 2004; 52(4): 643-4.	1	C
O	Effect of press tack needle on smoking.	press tack needle	Ishibashi Y, Ono M, Kenmotsu T, et al. Effect of press tack needle on smoking. <i>Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)</i> 2008; 31: 113-7 (in Japanese).	1	I
O	Consideration of tonification and dispersion based upon clinical experiment.	acupuncture	Kinoshita H. Consideration of tonification and dispersion based upon clinical experiment. <i>Nihon Shinkyu Chiryō Gakkaishi (The Journal of the Japan Acupuncture and Moxibustion Society)</i> 1971; 20(3): 6-13. (in Japanese).	1	J
O	Intensity of acupuncture and its response, over dose of individuals.	acupuncture	Matsui Y, Okada T, Ogura C, et al. Intensity of acupuncture and its response, Over dose of individuals. <i>Do no Nihon (The Japanese Journal of Acupuncture and Manual Therapies)</i> 2004; 63(7): 86-95 (in Japanese).	4	I
O	Clinical significance of reihai transport point	none	Moto A, Kidi M, Mitsuzawa H, Clinical significance of rei-hai tranpost point. <i>Dento Shinkyu (Traditional Acupuncture and Moxibustion)</i> 2008; 35(1): 76-81. (in Japanese).	4	I
O	Current state of beauty acupuncture in Japan	none	Fujieda H, Suzuki S, Zhang W. Current state of beauty acupuncture in Japan. <i>Toho Igaku (Eastern Medicine)</i> 2009; 24(3): 1-12 (in Japanese with English abstract).	4	I
O	A research of literature on economic analysis of acupuncture	none	Iioka Y. A research of literature on economic analysis of acupuncture. <i>Nihon Kounenki Igakkai Zasshi (The Journal of the Japan Menopause Society)</i> 2009; 17(2): 179-89 (in Japanese with English abstract).	4	I
O	Effects of abdominal diagnosis on simulated patients on students	none	Okyno T, Taniguchi M. Effects of abdominal diagnosis on simulated patients on students of acupuncture and moxibustion school. (1st report) Communication ability of non blind students. <i>Shinkyu syugisyohou Kyōiku (Education of Acupuncture, moxibustion and Manual Therapies)</i> 2010; 6: 10-5. (in Japanese).	4	I
O	A research of literature on economic analysis of acupuncture	none	Iwa M, Urata S, Ono N, et al. A research of literature on economic analysis of acupuncture. <i>Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)</i> . 2003; 53(1): 62-70 (in Japanese).	4	I

## **10. Structured Abstracts**

### **(53 abstracts describing RCTs)**

Note: Original English titles assigned by authors were used in this list and the structured abstracts. When references had no English titles, the Task Force translated the original Japanese titles into English ones (\*).

Each bibliographic item is followed by its ID No. from a particular searched database



## 4. Metabolism and Endocrine Diseases

### Reference

Mukai Y. Acupuncture therapy for obesity using ear needle treatment – analysis of effectiveness and mechanism. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)*. 1981; 31(1): 67–74 (in Japanese with English abstract).

#### 1. Objectives

To evaluate the effects and the mechanism of ear needle treatment on obesity.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Internal Medicine, Chikko Hospital, Mie, Japan.

#### 4. Participants

Fifty outpatients with simple obesity (120% or more of ideal body weight; age range 18–45 years, mean age 32.2). Patients with symptomatic obesity, a past history of diabetes or currently receiving treatment, or fasting blood sugar in excess of 110 mg/dL were excluded.

#### 5. Intervention

Arm 1: Lung treatment group. Treatment for two weeks with intradermal needles. Two needles were inserted and retained at the respective locations on the ear flap, and replaced each week (n=25).

Arm 2: Shinmon (placebo) treatment group. Same as Arm 1 with different locations for insertion of the intradermal needles (n=25).

#### 6. Main outcome measures

Change in dietary intake, satiety, and hunger, and change in fasting blood sugar, free fatty acid, insulin, gastrin, secretin, and gastrin levels after intake of 300 mL of water (some cases).

#### 7. Main results

There was a significant difference ( $P<0.05$ ) between Arm 1 and Arm 2 in the percent of participants showing decreased dietary intake (56% vs 28%), satiety increased by 2.5 points or more (24% vs 4%), 2.0 points or more (52% vs 16%), 1.5 points or more (64% vs 36%), and decrease in hunger (36% vs 12%). Fasting blood sugar, free fatty acids, gastrin, and secretin level showed no significant change. Insulin level alone decreased significantly ( $P<0.05$ ) in Arm 1. Gastrin levels before and 10 minutes after intake of 300 mL of water showed gastrin secretion was promoted ( $P<0.05$ ) in Arm 1 only.

#### 8. Conclusions

Retaining intradermal needles at the Lung point in the cavum conchae of the ear in obese people decreases hunger sensation by promoting satiety, decreased dietary intake, decreased blood insulin levels, and increases gastrin secretion after oral intake of water.

#### 9. From acupuncture and moxibustion medicine perspective

Locations for retention of intradermal needles were selected from a neuroanatomy perspective, and determined by impedance measurements.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

Few researchers have scientifically investigated the mechanism involved in obesity treatment by insertion of ear needles. This study is of great interest because it investigates simple obesity treatment in a multi-faceted manner in outpatients of a medical institution. It is also commendable that the study included a control group. Regrettably, the authors do not describe details of the interventions, such as timing of blood tests for fasting blood sugar, free fatty acids, insulin, gastrin, secretin, and gastrin after intake of 300 mL of water. In addition, they include too many outcome measures to focus the point of conclusion. Double masking is not used in this trial: using fake needles for a double-mask trial would be preferable. Researchers have deduced a relationship between the hypothalamus, cavum conchae, and the pancreas, and infer that what connects them is the autonomic nerve system. Elucidating that relationship would be a major breakthrough for obesity treatment as well as acupuncture and moxibustion medicine. Verification through future research is anticipated.

#### 12. Abstractor and date

Okada A, Kaneko Y, 11 December 2010, Kawakita K, Takahashi N, 25 December 2010.

#### 4. Metabolism and Endocrine Diseases

##### Reference

Mukai Y, Tsuneya Y, Hattori T. Auricular acupuncture for obesity – Concerning the significance of dermal points. *Zen Nihon Shinkyu Gakkaishi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1983; 32(3): 226–32 (in Japanese with English abstract). Ichushi Web ID: 1984047876

##### 1. Objectives

To analyze whether electrodermal points in the ear are functional units.

##### 2. Design

Randomized controlled trial (RCT).

##### 3. Setting

Third Internal Medicine Department, Faculty of Medicine, Mie University, Mie, Japan.

##### 4. Participants

Fifty outpatients with simple obesity (120% or more of ideal weight). Patients with fasting blood sugar over 110 mg/dl, and patients receiving drug therapy for obesity complications were excluded.

##### 5. Intervention

Arm 1: Electrodermal point group. Two intradermal needles each were inserted to a depth of approximately 1 mm at two locations corresponding to electrodermal points (four needles in total), fixed in place with intradermal needle tape, and replaced every week. Treatment continued for 4 weeks (n=25).

Arm 2: Non-electrodermal point group. Same treatment as Arm 1, except the needle insertion points were non-electrodermal points (n=25).

##### 6. Main outcome measures

Changes in food intake, satiety, hunger sensation, and water intake, and changes in fasting blood sugar level, free fatty acids level, insulin level, serum Na level, and serum osmolality.

##### 7. Main results

In Arm 1, food intake decreased significantly ( $P<0.01$ ), satiety increased ( $P<0.05$ ), hunger decreased ( $P<0.05$ ), and water intake tended to decrease. In Arms 1 and 2, fasting blood sugar did decrease significantly at several time points. Insulin level, serum Na level ( $P<0.05$ ), and serum osmolality ( $P<0.005$ ) decreased significantly in Arm 1. The decrease in Na level and osmolality persisted into the fourth week. The mean difference in osmolality values showed a significant difference ( $P<0.05$ ). No significant changes were observed in Arm 2.

##### 8. Conclusions

Lung-area electrodermal points are functional units.

##### 9. From acupuncture and moxibustion medicine perspective

Locations for retention of intradermal needles were selected from a neuroanatomy perspective, and determined by impedance measurements.

##### 10. Safety assessment in the article

Not mentioned.

##### 11. Abstractor's comments

This is a clinical study of great interest. It verified that electrodermal points are functional units (acupuncture points) based on the differences in the effects of stimulation at electrodermal points and non-electrodermal points in a specific area (i.e., the lung area in the cavum conchae through which the vagus nerve passes). Notably, the study was conducted in clinic patients with obesity and outcome measures included objective measures as well as subjective measures. Table 2 shows the difference in free fatty acid values (one of the outcome measures); however, the authors do not mention this result in the body of the article. The study is multi-faceted, which complicates the data analysis. The study is not double masked. It would have been preferable to randomize in a double blind manner and include a sham needle treatment, although that may be difficult for intradermal needles. Of the 50 subjects, 44 were female and 6 male, so it is hoped that future studies investigate whether effects are gender neutral.

##### 12. Abstractor and date

Okada A, Kaneko Y, 12 December 2010, Kawakita K, Takahashi N, 25 December 2010.

## 4. Metabolism and Endocrine Diseases

### Reference

Mukaino Y, Arakawa K, Tsuneya Y. Comparison between cardia point and lung point on auricular acupuncture. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1984; 33(3): 279–84 (in Japanese with English abstract). Ichushi Web ID: 1985031761

#### 1. Objectives

To evaluate the comparative differences in appetite suppression and water metabolism between obese patients treated by ear acupuncture at either the cardia point or the lung point.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Second Department of Internal Medicine, Fukuoka University School of Medicine, Fukuoka, Japan.

#### 4. Participants

Forty-two outpatients aged 18 to 50 years with simple obesity (body weight, 110% or more of ideal weight). Patients with fasting blood sugar over 110 mg/dL or receiving drug therapy for symptomatic obesity or obesity complications were excluded.

#### 5. Intervention

Arm 1: Cardia point group. Two intradermal needles each were inserted to a depth of approximately 1 mm at the cardia point of each ear (four needles in total), and retained in place with sticking plaster. The needles were replaced every week. Treatment continued for 2 weeks (n=20).

Arm 2: Lung point group. The same treatment was given, at the lung point (n=22).

One participant dropped out of each arm.

#### 6. Main outcome measures

Changes in dietary intake, hunger, satiety, water intake, urine output and frequency, and pre- to post-treatment comparison of body mass, fasting blood sugar, serum Na, blood urea nitrogen (BUN), serum osmolality, and antidiuretic hormone (ADH). Blood samples were taken mornings after fasting from 10:00 p.m. the previous night.

#### 7. Main results

Dietary intake and hunger decreased, and satiety increased in both groups, but there was no significant difference between groups. Water intake decreased in many cases, but there was no difference between groups. There were many cases in Arm 2 of increased urine output, but there was no significant between-group difference. Many participants in Arm 2 showed a tendency toward increased urinary frequency ( $P<0.10$ ). Serum osmolality and ADH level ( $P<0.02$ ) were significantly decreased in Arm 2, but not significantly changed in Arm 1, and the between-group differences were not significant. Both groups had similar body mass, and levels of fasting blood sugar, serum Na, and BUN.

#### 8. Conclusions

Auricular acupuncture at the cardia point and the lung point have the same effect on appetite suppression and body mass decrease, but varied on water metabolism: the physiological significance of the cardia point and the lung point differ.

#### 9. From acupuncture and moxibustion medicine perspective

Intradermal needle retention points were determined from a neuroanatomical perspective.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study holds great interest for its comparison of the effects of the lung point and the cardia point (electrodermal points near the vagus nerve in the cavum conchae region, which when stimulated are thought to suppress appetite by regulation of the autonomic nervous system). The study suggests the lung point has a specific physiological significance. It can be surmised that the locations of the lung point and the cardia point were determined by dermatometer measurements, but the authors make no mention of this. Regrettably, data on measures mentioned in the abstract, namely hunger and satiety, are not included in the paper.

Serum osmolality decreased, however, water intake decreased, ADH decreased, and urine output increased. The authors account for this inconsistency in the negative feedback system by suggesting ear acupuncture resets the automatic fluid regulation mechanism. The explanation is, however, incomplete. A yet to be published study in obese rats hypothesizing that the hypothalamus is the destination of each acupoint stimulus found evidence to suggest that afferent stimulation at the ear (which results in efferent stimulation of peripheral organs) is mediated by the hypothalamus. This study and a series of studies investigating ear acupuncture outcomes are anticipated to elucidate the mechanisms involved.

The cardia point and the lung point are electrodermal points in the same region, the cavum conchae, and their appetite suppression effects are similar. However, this study has clinical significance because it suggests that the lung point specifically affects water metabolism.

#### 12. Abstractor and date

Okada A, Kaneko Y, 28 December 2010, Takahashi N, 11 January 2012.

## 4. Metabolism and Endocrine Diseases

### Reference

Mukai Y, Arakawa K. Change of taste by ear acupuncture in simple obese patients. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1985; 34(3,4): 211–6 (in Japanese with English abstract). Ichushi Web ID: 1986071708

#### 1. Objectives

To evaluate the effect of ear acupuncture on taste and the difference between the effects of left-side and right-side acupuncture.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Second Department of Internal Medicine, Fukuoka University School of Medicine, Fukuoka, Japan.

#### 4. Participants

Sixty-three outpatients aged 20–60 years with simple obesity (body weight, 110% of the ideal weight or more). Patients taking medications for obesity complications or with fasting blood sugar over 110 mg/dL and symptomatic obesity were excluded.

#### 5. Intervention

Method A Arm 1: Bilateral lung point group. Two intradermal needles were each inserted to a depth of approximately 1 mm at the lung point on both sides and retained in place with sticking plaster. The needles were replaced every week. Treatment continued for four weeks (n=19).

Arm 2: Right cardia/lung point group. Same treatment as Arm 1, at the right cardia point and right lung point (n=20).

Method B Arm 3: Right cardia/lung point group. Same treatment as Arm 1, at the right cardia point and right lung point (n=13).

Arm 4: Left cardia/lung point group. Same treatment as Arm 1, at the left cardia point and left lung point (n=11).

#### 6. Main outcome measures

Appetite suppression effects and changes in body weight and taste. (Dietary intake, appetite, and satiety were assessed by a daily questionnaire and rated on a 6–7-point scale. Body weight was measured every week. Taste was examined before treatment, and 1 and 4 weeks after treatment.)

#### 7. Main results

Method A: Appetite was suppressed in 47.4% of patients in Arm 1 and 25% of patients in Arm 2. Mean body weight decrease was greater in Arm 1 (1.7±0.2 kg compared to 1.5±0.3 kg), but there was no significant between-group difference. With the substantial appetite suppression effect and body weight decrease, salt-taste sensitivity increased in both Arm 1 and Arm 2.

Method B: There was a significant positive correlation ( $r=0.794$ ,  $P<0.01$ ) in Arm 3 between salt-taste threshold and body weight decrease. The same trend was observed in Arm 4 ( $r=0.536$ ,  $P<0.1$ ). There was a significant difference between the slopes of the regression lines in Arm 3 and Arm 4 but no difference in variance between the two groups. The mean body weight decrease for the four weeks was 1.3 kg in Arm 3 and 0.8 kg in Arm 4.

#### 8. Conclusions

Ear acupuncture increases salt-taste sensitivity. Right-side stimulation is more effective.

#### 9. From acupuncture and moxibustion medicine perspective

Locations for retention of intradermal needles were determined with an Ishikawa dermatometer (PD-1).

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study examined the effect of ear acupuncture on taste and the difference between the effects of left-side and right-side acupuncture. It infers a relationship between the afferent stimulation of ear acupuncture and the taste conduction pathway. It is hoped that further examination can clarify whether the glossopharyngeal, vagus, chorda tympani, and greater petrosal nerves, which conduct taste impulses, pass through the ear flap, and explain the relation between the afferent stimulation of ear acupuncture and the taste conduction pathway. While the study showed that right-side stimulation was effective, it goes no further than suggesting the possibility that the dominant hemisphere of the brain is involved, and does not explain that mechanism. This is a topic for future investigation, as the authors themselves mention. Neither of the subjects of investigation in this study have been investigated before and the results hold great interest; however, limiting the study to one subject (e.g. mechanism) might have given the study a clearer focus.

The paper also mentions the possibility of applying the treatment to various illnesses, besides obesity, such as hypertension, which are also strongly linked to salt intake. The study has great clinical significance.

#### 12. Abstractor and date

Okada A, Kaneko Y, 27 December 2010, Takahashi N, 11 January 2012.

## 5. Psychiatric/Behavioral Disorders

### Reference

Sawada T, Sawada C, Fukuda F, et al. Effect of TEAS (Transcutaneous Electrical Acupuncture Point Stimulation) on intellect and daily activity of the aged. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2001; 51(1): 69–80 (in Japanese with English abstract). Ichushi Web ID: 2001181197

#### 1. Objectives

To evaluate the effect of transcutaneous electrical acupuncture point stimulation (TEAS) on decreased intellectual function and activities of daily living in the elderly.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Nishikyoto Hospital, Kyoto, Japan.

#### 4. Participants

One hundred and five elderly inpatients aged 70 years or older; those with sequelae of stroke were excluded.

#### 5. Intervention

Arm 1: Exercise therapy + TEAS combination group. In addition to exercise therapy, electrical stimulation was applied to the left and right LI4 (合谷) – LI10 (手三里) acupuncture points at a frequency of 2 Hz for 15 minutes, 3 times a week for 8 weeks (n=49).

Arm 2: Exercise therapy alone group (n=44).

Of 105 patients, 12 discharged after the start of the study were excluded from the analysis.

#### 6. Main outcome measures

Revised version of Hasegawa Dementia Scale (HDS-R) and Dementia Behavior Disturbance Scale (DBD Scale).

Both scales were evaluated before and 4 and 8 weeks after the start of TEAS treatment.

#### 7. Main results

HDS-R score and DBD Scale score were significantly improved by 4 and 8 weeks after the start of the intervention in both arms ( $P<0.001$ ), but there was no significant between-arm difference. Subgroup analysis according to the pre-intervention HDS-R score or DBD Scale score revealed no significant difference.

#### 8. Conclusions

Exercise therapy improves intellectual and daily living functions in the elderly and the addition of TEAS treatment enhances this improvement.

#### 9. From acupuncture and moxibustion medicine perspective

The authors mentioned that increased cerebral blood flow may be the mechanism underlying the treatment effect of TEAS.

#### 10. Safety assessment in the article

None.

#### 11. Abstractor's comments

This valuable study determined how the addition of TEAS to the usual physical therapy could contribute to the improvement of intellectual and daily living functions in elderly inpatients. It is also appreciated that not only participants were stratified based on the HDS-R score, but also detailed analysis was accomplished by the stratification of patients according to the HDS-R score in addition to performing between-arm comparisons.

Although the authors concluded that TEAS improves intellectual and daily living functions in the elderly, the results showed improvement when pre- and post-intervention scores were compared within the each arm, but not when the combination was compared with physical therapy alone (between-arm comparison). In general, the post-intervention condition is affected by many factors besides the intervention itself. For example, spontaneous resolution or patient-specific fluctuation of symptoms may occur. In addition, various environmental factors and concomitant drugs may affect the condition. Therefore, the result of before-and-after comparison possibly involves some bias, and so further validation is needed.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

## 5. Psychiatric/Behavioral Disorders

### Reference

Shichido T, Arichi S, Mori E, et al. The effect of acupuncture on unidentified syndrome – sequential medical trial. *Zen Nihon Shinkyu Gakkaishi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1982; 32(1): 33–43 (in Japanese with English abstract). Ichushi Web ID: 1983164007

#### 1. Objectives

To evaluate the objective effects of acupuncture and moxibustion on unidentified syndrome in a clinical trial using sequential testing.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Arichi Internal Medicine Umeda Clinic, Osaka, Japan.

#### 4. Participants

Twenty pre-climacteric women 20 years or older complaining of unidentified syndrome. Matching was based on age and number of symptoms. Mean age in the two groups: 37.9±8.4 and 43.1±6.4.

#### 5. Intervention

Arm 1: Test group. Galenical extract plus acupuncture and moxibustion corresponding to the specific complaint (n=10).

Arm 2: Control group. Galenical extract only (n=10).

Approximately 20 minutes twice a week, for two weeks: total four times.

#### 6. Main outcome measures

Five-point self-evaluation (overall improvement, daily life difficulties, effects by symptom), and percentage change in  $\alpha$ ,  $\beta$ , and  $\theta$  waves recorded during the microvibration (MV) test.

#### 7. Main results

The percentage of participants subjectively benefiting from treatment was significantly higher in Arm 1 (60%) than Arm 2 (10%). A significantly more effective trend for shoulder stiffness in the second week was observed in Arm 1 than in Arm 2 ( $P=0.086$ ). Analysis of changes in wave energy between the first measurement and the second week showed that  $\theta$  waves increased significantly ( $P<0.05$ ) and  $\beta$  waves tended to decrease in Arm 1.

#### 8. Conclusions

Adding acupuncture and moxibustion to galenical treatment improves subjective symptoms of unidentified syndrome.

#### 9. From acupuncture and moxibustion medicine perspective

Acupuncture treatment locations depended on subjects' complaints, and treatment was aimed at muscle tenderness, induration, tension, etc.

#### 10. Safety assessment in the article

No adverse effect.

#### 11. Abstractor's comments

This controlled trial of acupuncture and moxibustion is thoroughly commendable for investigating unidentified syndrome, though most RCTs related to acupuncture and moxibustion focus on pain. As it was a clinical trial, the subjects were prescribed galenical extract to suit their various symptoms, acupuncture and moxibustion treatments were selected according to subjects' complaints, so treatment locations varied. Regrettably, it would be difficult to repeat the trial because the skill levels of the five therapists involved in the trial were not mentioned. While evaluating unidentified syndrome in a trial is difficult, this trial had a sequential design using matched pairs of patients, which increases the likelihood of arriving at outcomes even if the sample size is relatively small. Also the efficacy rate was calculated from patients' self-evaluation data, making for a very logical analysis. This study offers possibilities for future research.

#### 12. Abstractor and date

Kohashi T, 8 January 2011.

## 7. Eye Diseases

### Reference

Fukuno A, Tsuru H, Kataoka K, et al. Acupuncture stimulation improves visual acuity without refractive change. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)*. 2008; 58(2): 195–202 (in Japanese with English abstract). Ichushi web ID: 2008225957

#### 1. Objectives

To evaluate the effects of acupuncture stimulation on the improvement of visual acuity in subjects without refractive change.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Department of Ophthalmology, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Thirty patients (age  $73.0 \pm 1.4$  [mean  $\pm$  standard error]) randomly selected from patients who underwent phacoemulsification and intraocular lens implantation procedures between January and December 2005 and had no overall physical problems or ocular disorder, other than cataract (60 eyes; 16 males, 14 females). Eyes of one subject were allocated to test and control intervention.

#### Intervention

Arm 1: Trial group. Disposable stainless steel needles (0.16 $\times$ 30 mm, Seirin Co., Ltd.) were inserted and retained at the bilateral LI4 (合谷), Ex-HN5 (太陽), and Shang-jingming (上睛明穴, no WHO code) acupuncture points for 10 minutes while resting supine (n=30).

Arm 2: Control group. The same needles as Arm 1 were inserted and retained at the bilateral points one cm lateral from LI4 (合谷), Ex-HN5 (太陽), and a point one cm above the Shang-jingming (上睛明穴) for 10 minutes (n=30).

#### 5. Main outcome measures

Uncorrected visual acuity and corrected visual acuity before and after acupuncture stimulation.

#### 6. Main results

No significant difference in either change in uncorrected visual acuity or change in corrected visual acuity was observed between Arm 1 and Arm 2. No visual acuity enhancing effects were observed with acupuncture stimulation under drug-induced mydriasis.

#### 7. Conclusions

Acupuncture stimulation enhances visual acuity in elderly people who cannot regulate refraction. The results suggest that a pinhole effect from miosis caused by acupuncture stimulation may be involved.

#### 8. From acupuncture and moxibustion medicine perspective

The same results were observed in both the sham group and the acupuncture stimulation group in this experiment. That may be because LI4 (合谷), Ex-HN5 (太陽), and the Shang-jingming (上睛明穴) acupuncture points are locations identified on the basis of experience, and the results of this trial may be attributable to miotic reflex caused by trigeminal area stimulation.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

The mechanism of visual acuity improvement by acupuncture is not well known. This interesting paper examines the effectiveness of acupuncture in patients who received cataract surgery without refractive change, in order to elucidate that mechanism. The study is not an RCT with two or more groups, but rather a study with a crossover design. This design is not recommended by the WHO Clinical Research Methodology for Acupuncture because the results are difficult to interpret. The paper does not discuss the carry-over effect and the period effect, which are peculiar to this design. The study does not compare two independent groups; the interventions were carried out on a single eye in each subject, and the other eye was treated as the control. The sample size appears to be 60 (eyes), but the number of subjects was 30. This means that independence of measurement was not achieved, where one individual is treated as one individual, and subjects are randomly sampled. Therefore, statistical testing was not possible. Readers should be cautious. In addition, the control intervention (sham stimulation) involved needle retention, which would be expected to have a physiological effect. Further, it is premature to conclude that the improvement in visual acuity with acupuncture was due to the pinhole effect, as mentioned in the discussion. It is hoped that the authors will improve the design and evaluation methods of future studies, and pursue further research to find acupuncture and moxibustion applications for real ophthalmology disorders.

#### 11. Abstractor and date

Kaneko Y, 15 September 2010, Shichido T, 9 December 2010.

## 9. Cardiovascular Diseases

### Reference

Kawase Y, Ishigami T, Hori S, et al. Effectiveness of the Zusanli (ST36) point for hypertension in acupuncture -Controlled clinical trials using the envelope method- *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2000; 50: 185–89 (in Japanese with English abstract). Ichushi Web ID: 2000218637

#### 1. Objectives

To evaluate the depressor effect of acupuncture at the ST36 (足三里) acupuncture point.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Multicenter clinical trial in 10 clinics in Japan.

#### 4. Participants

Twenty four patients whose all three measurements of blood pressure met the criteria for hypertension, defined by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (USA).

#### 5. Intervention

Arm 1: Taikyoku therapy (太極療法, holistic approach to acupuncture and moxibustion treatment)+hyochiho (標治法, local or symptomatic treatment)+acupuncture at the ST36 (足三里) acupuncture point (n=12).

Arm 2: Taikyoku therapy+hyochiho (n=12).

Treatments were administered at least once weekly and at least 8 times during the study period.

Data for only 14 of the 24 participants with a diastolic pressure of 90 mmHg or higher and a systolic pressure of 140 mmHg or higher were reported.

#### 6. Main outcome measures

Diastolic and systolic blood pressures.

#### 7. Main results

Intragroup comparison revealed significant changes in systolic pressure only in Arm 2 ( $P<0.01$ , ANOVA). Diastolic pressure changed significantly in both Arms 1 and 2 ( $P<0.01$ ). There were, however, no significant between-arm differences.

#### 8. Conclusions

The ST36 (足三里) acupuncture point does not have a depressor effect in hypertensive patients.

#### 9. From acupuncture and moxibustion medicine perspective

Single acupuncture at the ST36 (足三里), in addition to taikyoku therapy and hyochiho, was administered to treat hypertension, but no clinical effect was identified.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This multicenter clinical trial in 10 acupuncture and moxibustion clinics was a meaningful attempt. It is, however, problematic that only 24 patients were enrolled and assigned treatment at each site. In addition, considering that the objective of the study was to evaluate the depressor effect of acupuncture at the ST36 (足三里) acupuncture point, there is strong doubt about the adequacy of the study design: stimulation of 13 acupuncture points, as taikyoku therapy, plus hyochiho were administered in both arms, and then single needling technique was applied at the ST36 (足三里) acupuncture point only in Arm 1. Results showed slight, but not significant, differences in reductions in blood pressure between the two Arms. The possibility of type II error cannot be ruled out because of the small number of patients included. It is also regrettable that outcomes of 10 out of 24 patients included were not described and no measurements at 3 months were reported. This article brings into question the design of clinical trials conducted in acupuncture and moxibustion clinics in Japan. Suggestions to resolve this issue are needed.

#### 12. Abstractor and date

Kawakita K, 9 September 2011.

## 9. Cardiovascular Diseases

### Reference

Arai YCP, Kato N, Matura M, et al. Transcutaneous electrical nerve stimulation at the PC-5 and PC-6 acupoints reduced the severity of hypotension after spinal anaesthesia in patients undergoing Caesarean section. *British Journal of Anaesthesia* 2008; 100 (1): 78–81. Pubmed ID: 17959591

#### 1. Objectives

To determine the efficacy of transcutaneous electrical nerve stimulation (TENS) at the PC6 (内関) and PC5 (間使) acupoints for hypotension after spinal anaesthesia in Caesarean section patients.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Not described.

#### 4. Participants

There were 36 singleton parturients (38–39 weeks). Patients with preeclampsia, hypertension, diabetes, or obesity were excluded.

#### 5. Intervention

Arm 1: Acupoint. TENS at the PC6 (内関) and PC5 (間使) acupoints of both arms (n=12).

Arm 2: Non-acupoint. TENS at non-acupoints of both shoulders (n=12).

Arm 3: Control. No treatment (n=12).

TENS was commenced immediately after patients entered the operating theatre. TENS was continued until delivery at 50 Hz with current intensity increased to the maximum tolerable level without causing muscle contraction or discomfort.

#### 6. Main outcome measures

Systolic BP, diastolic BP, heart rate, ephedrine dosage, and frequency.

#### 7. Main results

Minimal pressure, both systolic and diastolic, was significantly higher in Arm 1 ( $P=0.013$ ,  $<0.001$ ,  $0.001$ , respectively). Systolic pressure only was significantly higher in Arm 2 than Arm 3 ( $P<0.001$ ). There was no difference in heart rate among arms. Ephedrine dosage and frequency were significantly lower in Arm 1 ( $P=0.025$ ).

#### 8. Conclusions

TENS at the PC6 (内関) and PC5 (間使) acupoints reduces the severity of hypotension due to spinal anaesthesia in patients undergoing Caesarean section.

#### 9. From acupuncture and moxibustion medicine perspective

The fact that TENS at PC6 (内関) increases heart output and reduces hemorrhagic hypotension suggests the possibility that TENS at PC6 (内関) and PC5 (間使) augments sympathetic tone, increased cardiac function and vascular tone, and reduces hypotension.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

Vasopressor therapy has been heavily relied on for hypotension after spinal anaesthesia in patients undergoing Caesarean section. This is, therefore, a groundbreaking study in which an RCT was used to examine the effects of TENS. Although masking is not included in the design of this study, the measures are objective measures and enable impartial examination of the outcomes. The relationships between each individual measure and the objective are simple, so they are readily comprehensible. While this study does conclude that TENS at PC6 (内関) and PC5 (間使) acupoints is effective for hypotension, Caesarean section is major surgery that risks the life of both the mother and the fetus, so further vigorous work is anticipated to find the most appropriate frequency and to further increase the number of cases studied, with backup vasopressor drugs.

#### 12. Abstractor and date

Shimoichi Y, 11 September 2011.

## 10. Respiratory Diseases (including Influenza and Rhinitis)

### Reference

Isobe Y, Yu S, Inoue E. Common cold prevention and therapeutic effects of acupuncture in a randomized controlled trial\*. *Toyo Ryoho Gakko Kyokai Zasshi (The Journal of Oriental Medicine College Association)* 2000; 24: 94–7 (in Japanese). Ichushi Web ID: 2003049904.

#### 1. Objectives

To evaluate the preventative effects of acupuncture against common cold and its therapeutic effects after infection.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Morinomiya College of Medical Arts and Sciences, Osaka, Japan.

#### 4. Participants

Twenty-four healthy adult students and teachers recruited for the cold-prone winter period of 20 January to 19 February 2000.

#### 5. Intervention

Arm 1: Acupuncture treatment group. Acupuncture for 15 seconds at the ah-shi (tender) point(阿是穴) on both sides of the throat, above a point about 45 mm (1.5 cun) lateral to the laryngeal prominence, with 0.16 x 40 mm needles after obtained “acupuncture sensation (*hibiki*)” toward the back part of the throat as an indicator, twice a week for four weeks (1 month)(n=11).

Arm 2: Control group. No treatment (n=12).

One participant was dropped before allocation.

#### 6. Main outcome measures

Daily cold diary written by each subject noting the following: fit and well, normal, feels like cold coming on, severe cold (staying home and resting), number of days before catching cold, number of days sick with cold.

#### 7. Main results

The two groups were allocated almost evenly. The number of days until a cold was caught was greater in Arm 1 (second week). The number of occurrences of cold was the same in both groups. The median number of sick days was two days less in Arm 1.

#### 8. Conclusions

Intervention by acupuncture treatment delays the onset of cold, and decreases the number of sick days.

#### 9. From acupuncture and moxibustion medicine perspective

Treatment on “the *ah-shi* point located above a point about 45 mm lateral to the laryngeal prominence after obtained “acupuncture sensation (*hibiki*)” toward the back part of the throat as an indicator” is an empirical method. It is not the usual acupuncture point or an extra point.

#### 10. Safety assessment in the article

None.

#### 11. Abstractor’s comments

This study is of great interest since it focused on the preventative effects of acupuncture therapy against the common cold. The study was a pilot trial, as the authors mentioned, and there was no statistical analysis because the number of subject cases was small. This is problematic. The control group received no treatment: receiving some kind of sham treatment would be preferable. Another particular feature of the study was the selection of an atypical acupuncture point. Obtaining “acupuncture sensation (*hibiki*)” by manual insertion of a fine acupuncture needle, and using the “acupuncture sensation (*hibiki*)” as a guide, holds much interest since it is unique and characteristic method in Japanese acupuncture. It is anticipated that a future larger clinical trial based on this one will be designed with a suitable sample size.

#### 12. Abstractor and date

Shinohara S, 31 January 2011, Kawakita K, 3 December 2011.

## 11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

### Reference

Kono K, Tamura S, Inoue K. Effects of acupressure point stimulation on difficulty in defecating\*. *Nihon Kango Gakkai Ronbunshu, Bosei Kango (Maternal Nursing)* 2007: 74–6 (in Japanese). Ichushi Web ID: 2008110602

### 1. Objectives

To evaluate the effectiveness of acupressure point (ST36 [足三里] and SP6 [三陰交]) stimulation on defecation control in women recovering from childbirth.

### 2. Design

Randomized controlled trial (RCT).

### 3. Setting

Not described (the authors were affiliated with Saiseikai Kyoto Hospital).

### 4. Participants

Forty women recovering from childbirth after normal delivery between 2 August and 2 October 2006. Mean age in the two groups was, respectively, 29.1±4.81 and 30.9±5.22 years.

### 5. Intervention

Arm 1: Acupressure point stimulation group. The stimulus sites were the left and right ST36 (足三里) and SP6 (三陰交). Acupressure stimulation was applied to the sites for about one minute each twice a day for five days from the day after delivery. The acupressure stimulation was carried out at about 10 a.m. (by nurse or midwife) and about 9 p.m. (by self) (n=20).

Arm 2: Control group. No intervention (n=20).

### 6. Main outcome measures

Constipation assessment scale (CAS-long-term [LT]), and the number of women who used laxatives.

### 7. Main results

CAS scores were significantly lower in Arm 1 ( $P<0.05$ ). The number of women who used laxatives was significantly higher in Arm 2 ( $P<0.05$ ).

### 8. Conclusions

Acupressure point stimulation at ST36 (足三里) and SP6 (三陰交) is effective for defecation control in women recovering from childbirth.

### 9. From acupuncture and moxibustion medicine perspective

The paper suggests that the effective mechanism in acupressure point stimulation at ST36 (足三里) and SP6 (三陰交) involves stimulation of intestinal peristalsis.

### 10. Safety assessment in the article

Not mentioned.

### 11. Abstractor's comments

This clinical trial attempted to verify whether acupressure point stimulation can resolve constipation in women recovering from childbirth, without relying on drugs. The results suggest that acupressure point stimulation may be very helpful in the treatment of such women. However, the information given in the paper about recruitment, the setting, randomization method, allocation flow chart, etc. was not complete, leaving room for improvement. A more detailed report is anticipated.

### 12. Abstractor and date

Haruki J, 9 September 2011.

## 11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

### Reference

Kawauchi Y, Hayashida M, Takeuchi C, et al. Efficacy of acupressure on prevention of postoperative nausea and vomiting. *Rinsho Masui (Journal of Clinical Anesthesia [Japan])* 2000; 24(1): 21–4 (in Japanese with English abstract). Ichushi Web ID: 2000127596

### 1. Objectives

To evaluate the efficacy of acupressure wrist bands applied to the PC6 (内関) acupuncture point for preventing postoperative nausea and vomiting.

### 2. Design

Randomized controlled trial (RCT).

### 3. Setting

Department of Anesthesia, Tokyo Metropolitan Fuchu Hospital (current Tokyo Metropolitan Tama Medical Center), Tokyo, Japan.

### 4. Participants

One hundred and four patients with gynecological benign disease who were scheduled for laparotomy under general anesthesia between September 1997 and August 1998 (mean age for each group: 45, 46 years, respectively).

### 5. Intervention

Arm 1: Acupressure group: acupressure wrist bands (Sea band ® Sea Band UK Ltd.) were preoperatively applied at the bilateral PC6 (内関) acupuncture points (with a plastic ball under the band touching the acupuncture point). During the operation, the anesthesiologist pressed the point every 30 minutes and after the operation, each patient pressed the point on an as needed basis for 24 hours (n=52).

Arm 2: Control group: no intervention (n=52).

### 6. Main outcome measures

Presence or absence of nausea and vomiting (determined by interview) and usage of antiemetic infusion (obtained from nursing records).

### 7. Main results

Significantly fewer patients developed postoperative nausea or vomiting in Arm 1 compared with Arm 2 ( $P<0.05$  and  $P<0.001$ , respectively). The number of patients who used antiemetic infusion was also smaller, but not significantly, in Arm 1. Although the number of patients enrolled initially is not clear, patients whose acupressure ball had moved away from the PC6 (内関) acupuncture point were excluded from the analysis.

### 8. Conclusions

Acupressure at the PC6 (内関) acupuncture point is effective for preventing postoperative nausea and vomiting.

### 9. From acupuncture and moxibustion medicine perspective

The authors mentioned some reports on the mechanism underlying the treatment effects of acupuncture on nausea and vomiting, including acupuncture-induced secretion of neurochemical substances and increased gastric peristalsis.

### 10. Safety assessment in the article

Sixteen patients developed mild edema in the hands.

### 11. Abstractor's comments

This very simple clinical trial determined whether acupressure band application might have a preventive effect on postoperative nausea and vomiting and provided clear results. Some aspects of the trial may need improvement: 1) there is no detailed description about the method for random assignment; 2) there is no quantitative outcome measure; and 3) as the authors stated in the article, bias may have been introduced by telling patients about the antiemetic effect of the band before the bands were applied.

### 12. Abstractor and date

Wakayama I, 9 September 2011.

## 11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

### Reference

Kotani N, Hashimoto H, Sato Y, et al. Preoperative intradermal acupuncture reduces postoperative pain, nausea and vomiting, analgesic requirement, and sympathoadrenal responses. *Anesthesiology* 2001; 95(2): 349-56. Pubmed ID: 11506105

### 1. Objectives

To evaluate the effects of intradermal acupuncture on pain, nausea and vomiting, intravenous morphine consumption, and plasma cortisol and catecholamines after abdominal surgery.

### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

### 3. Setting

Department of Anesthesiology, School of Medicine, University of Hirosaki, Aomori, Japan.

### 4. Participants

One hundred and seven patients undergoing upper abdominal surgery and 82 undergoing lower abdominal surgery.

### 5. Intervention

Upper abdominal surgery group:

Arm 1: Intradermal acupuncture group: intradermal needles (5 mm in length and 0.16 mm in diameter) were inserted horizontally into the skin at the bilateral acupuncture points of BL18 (肝兪), BL19 (胆兪), BL20 (脾兪), BL21 (胃兪), BL22 (三焦兪), BL23 (腎兪), and BL24 (氣海兪), fixed with bandages, and retained until postoperative day 4 (n=54).

Arm 2: Control group: intradermal needles were put, without insertion, on the same sites as in Arm 1, fixed with bandages, and retained until postoperative day 4 (n=53).

Lower abdominal surgery group:

Arm 1: Intradermal acupuncture group: intradermal needles (5 mm in length and 0.16 mm in diameter) were inserted horizontally into the skin at the bilateral acupuncture points of BL20 (脾兪), BL21 (胃兪), BL22 (三焦兪), BL23 (腎兪), BL24 (氣海兪), BL25 (大腸兪), and BL26 (關元兪), fixed with bandages, and retained until postoperative day 4 (n=41).

Arm 2: Control group: intradermal needles were put, without insertion, on the same sites as in Arm 1, fixed with bandages, and retained until postoperative day 4 (n=41).

Nine and five patients in the upper and lower abdominal surgery groups, respectively, were excluded from the analysis due to postoperative complications.

### 6. Main outcome measures

Verbal rating scale (4-point scale from 0 to 3, with a lower score indicating less severity) scores for postoperative pain (incisional and deep visceral pain) and postoperative nausea and vomiting; daily consumption of intravenous morphine; and plasma concentrations of adrenal hormones (cortisol, adrenaline, noradrenaline, and dopamine).

### 7. Main results

In both upper and lower abdominal surgery groups, postoperative pain was significantly reduced in Arm 1 compared with Arm 2 ( $P<0.05$  for both). Morphine consumption decreased significantly over time ( $P<0.0001$ ). Daily consumption of morphine decreased significantly by up to 50% in Arm 1 compared with Arm 2 on postoperative days 1 to 4 ( $P<0.01$ ). The frequency of postoperative nausea and vomiting decreased significantly by up to 20–30% in Arm 1 compared with Arm 2 ( $P<0.05$  and  $P<0.01$ , respectively). Plasma concentrations of cortisol and epinephrine were up to 30–50% lower in Arm 1 than in Arm 2 on postoperative days 0 and 1 ( $P<0.01$ ).

### 8. Conclusions

Preoperative intradermal needle placement reduces pain, morphine consumption, morphine-induced nausea and vomiting, and sympathetic response after upper and lower abdominal surgery.

### 9. From acupuncture and moxibustion medicine perspective

The authors mentioned that preoperative acupuncture stimulation is important for obtaining relief of pain, nausea, and vomiting, and that acupuncture on the bladder meridian (gallbladder meridian) may be more useful for suppressing nausea and vomiting than acupuncture at the PC6 (内関).

### 10. Safety assessment in the article

Not mentioned.

### 11. Abstractor's comments

This is a very well-designed masked study (patients and evaluators were masked), providing reliable results and conclusions. It would be more complete if it included a flow chart of patient assignment, sample size calculation, intention-to-treat (ITT) analysis, and description of masking status.

### 12. Abstractor and date

Wakayama I, 9 September 2011.

## 12. Skin Diseases

### Reference

Sakuraba H, Sawazaki K, Takeuchi H, et al. The effect of acupuncture in the improvement of hemodialysis patients' QOL: Practice of acupuncture treatment for itch. *Jinzo (The Kidney)* 2007; 30(2): 167–74 (in Japanese). Ichushi Web ID: 2008091867

#### 1. Objectives

To evaluate the effectiveness of acupuncture for itching in hemodialysis patients.

#### 2. Design

Quasi-randomized controlled trial (Quasi-RCT - crossover).

#### 3. Setting

Hospital "T" (one author was affiliated with Takeuchi Hospital), Mie, Japan.

#### 4. Participants

Eighteen hemodialysis patients (7 males, 11 females, mean age 64.9±9.8 years).

#### 5. Intervention

Arm 1: Group A. Acupuncture (12 weeks), followed by washout (4 weeks), then no treatment (12 weeks).

A total of 24 Pyonex (0.6 mm, Seirin Co., Ltd.) press tack needles were applied, 12 by the acupuncturist and 12 by the patient. Application locations were determined by the Meridian Test. The authors mention that the treatment points for patients with strong itching were determined according to previous research, however, they do not mention the names or the number of these acupuncture points (n=10).

Arm 2: Group B. No treatment (12 weeks), followed by washout (4 weeks), then acupuncture (12 weeks). The acupuncture treatment was the same as in Arm 1 (n=8).

#### 6. Main outcome measures

Visual analogue scale (VAS) score for itchiness assessed before and after each treatment period, for a total of 4 times. Health Related Quality of Life (HRQOL) scale SF-8™ Health Survey Japanese edition (standard) assessed before and after each treatment period, for a total of 4 times. Original acupuncture treatment questionnaire completed only once, after acupuncture treatment was stopped.

#### 7. Main results

VAS scores in Arm 1 decreased significantly with acupuncture treatment ( $P<0.01$ ). SF-8™ scores increased during treatment in both groups, but showed no definite trend during the no-treatment period. The original questionnaire responses showed that itchiness, stiffness, dizziness, irritability, and sluggishness decreased in many patients. A plurality of patients (n=9) preferred a combination of self-treatment and treatment by an acupuncturist. The mean number of needles used was 26.8 per week (13.4 per treatment).

#### 8. Conclusions

Acupuncture for hemodialysis patients using press tack needles and self-treatment is effective for patient complaints, including itchiness.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Eight adverse events were reported including aggravation of symptoms (itch [2] and low back pain [1]), fatigue (2), residual acupuncture sensation (1), incrustation at the point of needle application (1), and bruising (1).

#### 11. Abstractor's comments

Regular long-term hemodialysis is a physical and mental burden on patients. It is important to find ways of improving the quality of life of such patients, even a little. This study is therefore very significant as it evaluates the efficacy of acupuncture for itching, including acupuncture administered by the patient at home on non-dialysis days. However, the paper does not clearly explain the link between Meridian Testing\* and itching, although the authors did use the test to select points for treatment. Neither do the authors describe the location, frequency, symptoms, or period of itching. Apparently when studying diseased patients in particular, and not just hemodialysis patients, researchers need to devise interventions suited to each patient's physical condition and stratify them. The authors reported eight safety-related incidents, however they completed the study with no dropouts by shortening the press tack needle application period. This is a significant clinical study of the complaints of hemodialysis patients: further research is anticipated.

\* The Meridian Test, also called the M-test, was devised by Mukaino Y. A pain or complaint that is induced by extension of a body part identifies the meridian that passes through the extended part requiring treatment.

#### 12. Abstractor and date

Shimoichi Y, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kasuya D, Sawada T, Isobe H, et al. Multi-center randomized controlled trial of acupuncture and moxibustion for rheumatoid arthritis. *Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)* 2005; 68(4): 193–202 (in English with Japanese abstract). Ichushi Web ID: 2005266317

#### 1. Objectives

To examine the effectiveness of acupuncture and moxibustion for rheumatoid arthritis (RA).

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Four medical institutions in Japan: Department of Allergy and Rheumatology, Graduate School of Medicine, the University of Tokyo Hospital (Tokyo); Tokyo Women's Medical University, Institute of Oriental Medicine (Tokyo); Department of Oriental Medicine, Saitama Medical School (Saitama); and Department of Oriental Medicine, Gifu Medical School (Gifu).

#### 4. Participants

Outpatients who received treatment for RA at the various medical institutions from 2001 to 2003 (n=178).

#### 5. Intervention

Arm 1: Drug therapy group (n=82).

Arm 2: Drug therapy plus acupuncture and moxibustion group. Acupuncture and moxibustion treatment was adapted to the RA severity and stage in each patient and was given for approximately one year once every one to two weeks (n=96).

Details of the treatment are not described.

Two patients were dropped from Arm 1, and six from Arm 2.

#### 6. Main outcome measures

The American College of Rheumatology (ACR) core set variables and AIMS-2 (Arthritis Impact Measurement Scales version 2). Both were evaluated at baseline and at 12 months of intervention.

#### 7. Main results

The number of patients who satisfied the ACR core set of improvement criteria was significantly greater in Arm 2 ( $P=0.04$ ). AIMS-2 scores were significantly lower (improved) in Arm 2 ( $P=0.01$ ).

#### 8. Conclusions

Combining acupuncture and moxibustion with drug therapy improves pain and activities of daily living in RA patients.

#### 9. From acupuncture and moxibustion medicine perspective

The paper mentions that a multi-center clinical trial of acupuncture and moxibustion has the advantage of less single-center bias but the disadvantage of more difficult treatment standardization. It also mentions the difficulty of acupuncture and moxibustion clinical research itself, as well as the difficulty of conducting clinical research into RA.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This important paper involves acupuncture and moxibustion as the intervention for the chronic disease (rheumatoid arthritis), and evaluates the course of treatment over a long period (about one year). The fact that the study was conducted at a number of centers reduces single-center bias, which (as the authors mention) is commendable. A number of issues arose from conducting a multi-center clinical trial, and this study offers a number of suggestions for future studies to deal with these issues. It is also very significant that the clinical study was conducted at four university hospitals that are leading centers of acupuncture and moxibustion as well as oriental medicine in Japan. However, patients were evaluated only at baseline and after one year, so we do not know what changes occurred in the intervening time period. Furthermore, the measures in this study (ACR core set and AIMS-2) are both summary measures based on multiple items, so no analysis identified factors that are beneficially affected by acupuncture. Apparently, the acupuncture treatments were adapted to the needs of each individual patient, however, the details are given in another paper. A broad description of the treatments should have been included in this paper.

#### 12. Abstractor and date

Haruki J, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Shinohara S, Katsumi Y. Clinical effects of peripheral acupuncture point stimulation based on the concept of the muscle meridians for complaints during movements. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)* 2003; 53(1): 4–7 (in Japanese with English abstract). IchushiWeb ID: 2003270662

#### 1. Objectives

To evaluate the clinical effect of remote acupuncture point treatment for symptoms of muscle meridian disease (経筋病, defined as muscle stiffness, jerking, cramp, or pain during movement).

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Center of Acupuncture Science. Outpatient Clinic of the Department of Orthopedics at Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

A total of 88 outpatients with complaints of knee joint pain and other problems associated with movement disability diagnosed as muscle meridian disease.

#### 5. Intervention

Arm 1: Real meridian treatment group. Intradermal needles were inserted to about a depth of 0.5 mm at the brook (榮穴) or stream (兪穴) acupuncture points on the muscle meridian related to pain, and fixed with bandages (n=30).

Arm 2: Sham treatment group. Only bandages were put on the same points as in Arm 1 (n=30).

Arm 3: Other meridian treatment group (n=28). Intradermal needles were inserted to a depth of about 0.5 mm near the brook (榮穴) or stream (兪穴) acupuncture points, and fixed with bandages (n=30).

#### 6. Main outcome measures

Visual analog scale (VAS) score for pain. The occurrence of tenderness at the brook and stream acupuncture points.

#### 7. Main results

Treatment in Arm 1 ( $P<0.0001$ ) and in Arm 2 ( $P=0.029$ ) significantly decreased pain. The decline in mean VAS score was greater in arm 1 than in Arm 2. Tenderness occurred very frequently at the brook and stream acupuncture points on the meridian related to knee pain.

#### 8. Conclusion

Contact stimulation of the brook and stream acupuncture points on the meridian related to knee pain significantly reduces pain. However, the decrease (therapeutic effect) is greater when needle insertion is to a depth of 0.5 mm. Tenderness at the brook and stream acupuncture points occurs very frequently in a large population of patients with knee joint pain, for which the large number of cases are known.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comment

In this interesting study, intradermal needling and contact stimulation at the brook and the stream acupuncture points decreased pain as measured on a VAS. The brook and stream acupuncture points related to knee pain are tender and this tenderness can be used to find the abnormal muscle meridian and to decide whether this treatment strategy is needed. However, complaints which lead to the diagnosis of muscle meridian disease were not described, and no analysis of intergroup differences was performed. The discussion should have focused on clarification of the protocol (i.e., description of the ratio of the numbers of stream and brook acupuncture points treated, method and duration of stimulation, and timing of the pain assessment). As pain is one of the most common indications for acupuncture and moxibustion treatment, its use for complaints other than knee pain should be investigated. Further studies on its merits and drawbacks are awaited.

#### 12. Abstractor and date

Furuhata T / Kaneko Y, 8 December 2010, Kawakita K, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Ozawa N, Ogawa T, Nakagawa J, et al. The effects of acupuncture and moxibustion on interior genicular osteoarthritis. *Shinkyu Osaka (Osaka Journal of Clinical Acupuncture & Moxibustion)* 2002; 18(4): 393–6 (in Japanese). Ichushi Web ID: 2003202117

#### 1. Objectives

To evaluate the clinical effectiveness of acupuncture for knee osteoarthritis.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Koto Orthopedic & Internal Clinic, Osaka, Japan.

#### 4. Participants

Sixty medial knee osteoarthritis patients who presented between September 2000 and November 2001 (mean age 64.9 years, range 45–89). Twenty-seven patients had experienced acupuncture previously and 33 had not.

#### 5. Intervention

Arm 1: Real acupuncture (experienced) group. Needle retained for 10 minutes after *de qi* (得気) sensation was achieved with sparrow pecking (n=15).

Arm 2: Sham acupuncture (experienced) group. Ten minutes rest after tapping with guide tubes (n=12).

Arm 3: Real acupuncture (not experienced) group. Needle retained for 10 minutes after *de qi* sensation was achieved with sparrow pecking (n=15).

Arm 4: Sham acupuncture (not experienced) group. Ten minutes rest after tapping with guide tubes (n=18). The same acupuncture points were treated in all groups: SP9 (陰陵泉), EX-LE 4 (内膝眼), SP10 (血海), and the point of maximum medial joint space tenderness. Stainless steel disposable needles (0.2×50 mm) were used.

#### 6. Main outcome measures

Evaluation on a visual analogue scale (VAS) of pain when ascending/descending stairs.

#### 7. Main results

The decrease in VAS score after treatment was significant in Arm 1 ( $P<0.05$ ), insignificant in Arm 2, and significant in both Arms 3 and 4 ( $P<0.05$ ).

#### 8. Conclusions

Real acupuncture is more effective than sham acupuncture immediately after treatment and the effectiveness depends on whether acupuncture has been previously experienced.

#### 9. From acupuncture and moxibustion medicine perspective

The paper mentions differences in the effects of acupuncture between patients who receive prior acupuncture treatment and those who do not receive prior acupuncture treatment.

#### 10. Safety assessment in the article

None.

#### 11. Abstractor's comments

This very interesting clinical trial stratifies knee osteoarthritis patients based on their history of acupuncture treatment and compares the effectiveness of acupuncture in those with and without prior acupuncture treatment in an RCT. However, the study should be improved in the following manner: the authors should describe the statistical methods, provide specific details of the randomization method (which is only described as the envelope method), and mention or compare ongoing effects (not simply the effects immediately after treatment). It is of great interest that the effectiveness of acupuncture depends on whether the patient has had prior experience with acupuncture. It will be very important to clarify whether masking with guide tube tapping accounts for this distinction. It is hoped that a larger scale clinical trial that includes more appropriate protocols will be carried out.

#### 12. Abstractor and date

Kawakita K, 30 January 2012.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K. Value of conservative therapy for chronic pain associated with locomotor disease - effects of TENS and acupuncture for knee osteoarthritis\* -. *Mansei Totsu (The Journal of the Japanese Society for the Study of Chronic Pain)* 2005; 26: 143–8 (in Japanese with English abstract). Ichushi Web ID: 2008144239

#### 1. Objectives

To evaluate the effects of transcutaneous electrical nerve stimulation (TENS) and acupuncture on pain in elderly patients with knee osteoarthritis.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Outpatient Clinic of Department of Orthopaedic Surgery and Center of Acupuncture Science, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine), Kyoto, Japan.

#### 4. Participants

Twenty-four elderly patients with a chief complaint of degenerative knee pain persisting for at least 6 months (6 males and 18 females).

#### 5. Intervention

Arm 1: Acupuncture group. Needles were inserted to a depth of 10 mm at tender points selected from among the SP6 (三陰交), GB34 (陽陵泉), SP10 (血海), ST34 (梁丘), ST36 (足三里), SP9 (陰陵泉) and BL40 (委中) acupuncture points, and retained for 10 minutes. Treatment was administered once weekly, a total of 5 times (n=6).

Arm 2: TENS group. TENS stimulation pads were put on the most tender point and the corresponding point on the contralateral side. Stimulation was applied for 10 minutes. Treatment was administered once weekly at the clinic and twice or more weekly at home, a total of at least 15 times (n=6).

Arm 3: Acupuncture+TENS group. As acupuncture treatment, needles were inserted to a depth of 10 mm at tender points selected from among the SP6 (三陰交), GB34 (陽陵泉), SP10 (血海), ST34 (梁丘), ST36 (足三里), SP9 (陰陵泉), and BL40 (委中) acupuncture points, and retained for 10 minutes. Acupuncture treatment was administered once weekly at the clinic, a total of 5 times. For TENS, stimulation pads were put on the most tender point and the corresponding point on the contralateral side. Stimulation was applied for 10 minutes. TENS treatment was administered 3 times or more weekly at home, a total of at least 15 times (n=6).

Arm 4: Control group. No intervention (n=6).

In all 4 arms, for patients who had received pharmacotherapy, the drug was concurrently administered with the above-mentioned treatment.

#### 6. Main outcome measures

Pain intensity measured on a visual analogue scale (VAS) 7 times overall: before the start of the treatment, 1 week after each of the 5 treatment sessions, and 1 month after the final treatment.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) measured 3 times overall: before the start of the treatment, and at 1 week and 1 month after the final treatment.

#### 7. Main results

VAS score decreased significantly after the treatment in Arm 3 compared with that in Arm 4 ( $P<0.01$ ). There was no significant change in WOMAC score in all arms.

#### 8. Conclusions

Acupuncture combined with TENS is effective treatment for pain in elderly patients with knee osteoarthritis.

#### 9. From acupuncture and moxibustion medicine perspective

The mechanism underlying the therapeutic effect of acupuncture may be similar to that described in previous reports, such as activation of the endogenous analgesic system and improved regional blood flow.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study explored various possibilities by employing TENS (which patients can easily self-apply at home) and acupuncture as interventions and by evaluating TENS and acupuncture not only separately but also combined. As the author stated in the Discussion, maintenance of quality of life may be essential for elderly people living in underpopulated areas with insufficient access to medical care. The value of this study lies in the consideration of self-care as one medical care option. In this study, however, patients' self-application of TENS at home precluded masking. Furthermore, differences in the frequency of treatment between arms may have resulted in bias. The quality of the article could be improved in several ways, such as preliminary calculation of sample size and accurate representation of resultant figures. This is a highly valuable report on an attempt to combine acupuncture with self-care to address the healthcare needs of an increasingly aging population.

#### 12. Abstractor and date

Shimoichi Y, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K, Hirota S, Katsumi Y, et al. Trigger point acupuncture for treatment of knee osteoarthritis - a preliminary RCT for a pragmatic trial. *Acupuncture in Medicine* 2008; 26(1): 17–26. CENTRAL ID: CN-00638475

#### 1. Objectives

To compare the effectiveness of trigger point acupuncture and standard point acupuncture for treating knee osteoarthritis in the elderly.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Thirty outpatients clinically and radiologically diagnosed with osteoarthritis of the knee according to the American College of Rheumatology criteria and with knee osteoarthritis pain for at least six months (3 males, 27 females; age 61–82).

#### 5. Intervention

Arm 1: Trigger point acupuncture group. Stainless steel needles (0.2×50 mm) were inserted into the muscle to a depth of between 10 and 30 mm. The sparrow pecking technique was used to elicit local muscle twitch, and the needles were left in place for 10 minutes (n=10).

Arm 2: Standard point acupuncture group. Stainless steel needles (0.2×40 mm, Seirin Co., Ltd.) were inserted into the muscle to a depth of 10 mm. The sparrow pecking technique was applied, and the needles were left in place for 10 minutes once the patient felt dull pain or the acupuncture sensation (de qi). The acupuncture points were 梁丘 (ST34), ST35 (犢鼻), ST36 (足三里), SP9 (陰陵泉), SP10 (血海), and GB34 (陽陵泉) (n=10).

Arm 3: Sham acupuncture group. Stainless steel needles (0.2×50 mm, with the tips cut off) were used. The treatment was applied at trigger points with the acupuncturist simulating insertion and sparrow pecking (needles were not actually inserted). Eye masks were used (n=10).

Treatment was given once a week on five occasions for Arms 1 to 3.

#### 6. Main outcome measures

- Pain intensity using a visual analogue scale (VAS) was assessed before the first treatment and then 1, 2, 3, 4, 5, 10, and 20 weeks after the first treatment (eight times).
- Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index was assessed before the first treatment and then 5, 10, and 20 weeks after the first treatment (four times).

#### 7. Main results

The mean VAS score was significantly lower in Arm 1 and Arm 2 than in Arm 3 ( $P<0.001$  and  $P=0.006$ , respectively). Comparison of area under the curve for the three groups showed that patients in Arm 1 had the lowest scores, confirming the significant difference in Arm 3 ( $P=0.025$ ).

The mean WOMAC index was significantly lower in Arms 1 and 2 than in Arm 3 ( $P<0.001$  and  $P<0.001$ , respectively). Comparison of area under the curve for the three groups showed that patients in Arm 1 had the lowest score, confirming the significant difference in Arm 3 ( $P=0.031$ ).

#### 8. Conclusions

Trigger point acupuncture is effective for knee osteoarthritis in elderly people.

#### 9. From acupuncture and moxibustion medicine perspective

Trigger points appear to be due to the heightening of sensitivity of nociceptors by a variety of factors and, acupuncture stimulation of these points affect nociceptors. On the other hand, the paper mentions that stimulation of acupuncture points does not necessarily affect nociceptors that have heightened sensitivity.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

The study compared the effects of differing acupuncture treatments, including sham acupuncture, for elderly people with knee osteoarthritis. The measures and the outcomes are clear and coherent. The quality of this RCT is high: it included randomization and masking procedures, and reports the outcomes. However, examination of the trigger points in Arm 2 and examination of the acupuncture points in Arm 1 clearly differed. If some participants had prior experience of acupuncture, then masking might have been inadequate. The study's clinical significance is great. Further development of this research is anticipated.

#### 12. Abstractor and date

Shimoichi Y, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Miyamoto T, Itoh K, Ochi H, et al. The efficacy of acupuncture treatment on pain and ability with osteoarthritis of the knee. - Examination of the curative effect by the depth of an acupuncture needle -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2009; 59(4): 384–94 (in Japanese with English abstract). Ichushi Web ID: 2009340447

#### 1. Objectives

To evaluate the efficacy of acupuncture to different depths on motor function and pain in patients with osteoarthritis of the knee.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopaedic Surgery, the Meiji University of Integrative Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Twenty-six outpatients with osteoarthritis of the knee who met certain inclusion criteria such as aged 45 years or older, disease duration for at least 6 months, and not treated knee pain with acupuncture within 6 months.

#### 5. Intervention

Arm 1: Superficial acupuncture group (n=13). Acupuncture needles were inserted about 3 mm into 10 tender points of the lower limb and retained for 10 minutes, once a week for 8 weeks.

Arm 2: Deep acupuncture group (n=13). Acupuncture needles were inserted about 10–20 mm into 10 tender points of the lower limb, with the same intervention duration and frequency as Arm 1.

Three subjects dropped out of the study.

#### 6. Main outcome measures

Knee pain intensity assessed on a visual analogue scale (VAS), performance time for the Timed Up and Go (TUG) Test, 20-m walking time, time for going up and down stairs, and Western Ontario and MacMaster Universities osteoarthritis index (WOMAC).

#### 7. Main results

Treatment significantly improved knee pain intensity (assessed by VAS) compared with baseline in both arms ( $P<0.05$ ). However, treatment improved TUG score, 20 m walking time, and time of going up and down stairs only in Arm 1 ( $P<0.05$ ). No significant change in WOMAC score was observed in either arm.

#### 8. Conclusion

Both deep and superficial acupuncture decrease knee pain intensity, but only superficial acupuncture improves motor function.

#### 9. From acupuncture and moxibustion medicine perspective

Ten tender points (in descending order according to pain intensity) in the femoral and leg region were selected for needling. Concordance rate of the tender points and acupuncture points was over 40% in both groups. High concordance rate tended to be observed in the medial part of the knee at points such as SP9 (陰陵泉), LR8 (曲泉), and LR7 (膝関), EX-LE4 (内膝眼).

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comment

This is the first study to compare the efficacy of acupuncture at two depths of needle penetration for pain intensity and motor function, and the result is interesting. By intention to treat (ITT) analysis including patients who dropped out of the trial, superficial acupuncture improved both pain intensity and motor function, which suggests that superficial acupuncture is therapeutically as effective as deep acupuncture. A previous study demonstrated that gentle stimulation (like superficial acupuncture) is more efficient than deep acupuncture in improving motor function, which clarifies the problem with many clinical trials that use minimal acupuncture as the sham acupuncture control. However, in this trial, the evaluation of motor function might have been biased because the person who provided treatment also performed the evaluation. Since no significant inter-group difference was observed, the authors suggest that it would be unwise to conclude the greater effectiveness of superficial acupuncture than deep acupuncture. Controlling for conditions such as masking and the grade of the osteoarthritis of the knee is anticipated to improve the study. In spite of some deficiencies, this study is highly regarded for its focus and demonstration of the possible efficacy of superficial acupuncture.

#### 12. Abstractor and date

Inoue E, 23 November 2010, Furuya E, 24 November 2010, Takahashi N, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### References

Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee 3 — a randomized, controlled trial. *Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)* 2009; 3: 36–40 (in Japanese with English abstract). Ichushi Web ID: 2010044483

Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee 2 — a randomized, controlled trial. *Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)* 2008; 2: 48–52 (in Japanese). Ichushi Web ID: 2008334853

Yamamoto H, Umeda T, Kibi N, et al. Clinical effects of acupuncture for osteoarthritis of the knee — a randomized, controlled trial. *Kansai Iryo Daigaku Kiyo (The Bulletin of Kansai University of Health Sciences)* 2007; 1: 41–5 (in Japanese). Ichushi Web ID: 2008048659

#### 1. Objectives

To evaluate the clinical effects of acupuncture treatment for knee osteoarthritis (OA).

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Acupuncture Clinic, Kansai University of Health Sciences, Osaka, Japan.

#### 4. Participants

Thirty-five patients aged at least 50 years and diagnosed with knee OA between October 2005 and July 2008.

#### 5. Intervention

Arm 1: Acupuncture group. Acupuncture treatment for one month after two weeks of no treatment (n=17).

Arm 2: Placebo acupuncture group. Simulated acupuncture treatment for one month after two weeks of no treatment (n=18).

In the acupuncture group, needles were retained at the SP10 (血海), LR8 (曲泉), SP9 (陰陵泉), ST34 (梁丘), ST36 (足三里), GB34 (陽陵泉), SP6 (三陰交), KI3 (太谿), GB39 (懸鐘), BL60 (崑崙) acupuncture points for 15 minutes twice a week. In the placebo acupuncture group, insertion of needles was simulated at the same acupuncture points as Arm 1, twice a week.

One patient dropped out in Arm 2.

#### 6. Main outcome measures

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

#### 7. Main results

The pre- to post-treatment decrease in WOMAC score was significant in Arm 1 (mean difference: -8.1, 95% CI, -3.1–-13.2,  $P=0.004$ ) and in Arm 2 (mean difference: -7.9, 95% CI, -3.2–-12.6,  $P=0.003$ ).

#### 8. Conclusions

Both acupuncture and placebo acupuncture are effective.

#### 9. From acupuncture and moxibustion medicine perspective

The acupuncture for knee osteoarthritis was performed using the Berman method (2004).

Reference: Berman BM, et al. *Ann Intern Med* 2004; 141(12): 901–10.

#### 10. Safety assessment in the article

The authors reported no adverse events.

#### 11. Abstractor's comments

The subject recruitment period and conditions of this study overlap with those in the preceding two studies (Yamamoto H, et al. 2007, Yamamoto H, et al. 2008), and the interventions and outcome measures are virtually identical, so they can be treated as a series of studies. The authors can be highly commended for using an RCT design; however, although the therapeutic effects in both groups were found to be significant, there was no significant between-group difference. This is not mentioned in the Results, but in the Discussion. It is possible that different sample size calculations may have resulted in different outcomes. Weaknesses of the study, including analysis of the success or failure of subject masking, should be improved. Future clinical studies by these authors will hopefully be larger and utilize more appropriate protocols.

#### 12. Abstractor and date

Takahashi N, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### References

Ochi H, Katsumi Y, Katayama K, et al. The effect of acupuncture with quadriceps exercise for the osteoarthritis of the knee joint — the importance of quadriceps exercise —. *Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)* 1993; 23(3): 136–42 (in Japanese with English abstract). Ichushi Web ID: 1994241815

Ochi H, Katayama K, Ikeuchi T, et al. Acupuncture with quadriceps exercise for osteoarthritis of the knee joint. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1990; 40(3): 247–53 (in Japanese with English abstract). Ichushi Web ID: 1991224289

#### 1. Objectives

To evaluate the effectiveness of acupuncture combined with therapeutic exercise for knee osteoarthritis.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopedic Surgery, Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Nineteen patients diagnosed with knee osteoarthritis.

#### 5. Intervention

Arm 1: Acupuncture, silver spike point (SSP) electro-therapy, and exercise group (n=6, mean age:59 years).

Arm 2: Acupuncture and SSP group (n=7, mean age: 51 years).

Arm 3: Therapeutic exercise group (n=6, mean age: 68 years).

Acupuncture: stainless steel disposable needles (0.18 mm×40 mm) were used to apply the sparrow pecking technique at 9 points in the thigh region and the GB31 (風市), ST36 (足三里), GB34 (陽陵泉), and SP9 (陰陵泉) acupuncture points once a week. SSP therapy: stimulation (compression wave, 10 minutes) was applied between the knee and the thigh. Therapeutic exercise: Participants did strengthening exercises at home for the muscles around the knee. The treatment period was one month.

#### 6. Main outcome measures

Score on a specially-designed evaluation (comprehensive evaluation of pain, activities of daily living, and physical findings) and muscle strength score.

#### 7. Main results

The comprehensive score increased significantly between the start of treatment and one month later ( $P<0.01$ ) in Arms 1 and 2 but not in Arm 3. The muscle strength score for knee extension increased significantly in Arms 1 and 3 ( $P<0.05$ ) but not in Arm 2.

#### 8. Conclusions

Combined use of acupuncture, SSP therapy, and therapeutic exercise is useful.

#### 9. From acupuncture and moxibustion medicine perspective

The paper mentions the risks of acupuncture to the joints, and uses SSP as an alternative therapy.

#### 10. Safety assessment in the article

None.

#### 11. Abstractor's comments

This valuable paper investigates the effectiveness of combining SSP therapy and therapeutic exercise with acupuncture treatment for knee OA, and it evaluates the differences between their effects. However, the authors should address issues such as the small group size (n=6 and 7), the lack of between-group comparison (only within-group comparison is reported), and the lack of analysis of any post-treatment effects. Yet, the study was designed to address real clinical issues and as such it has great significance. Hopefully, an even higher quality clinical trial that includes sample size calculations and WOMAC evaluation will be conducted. The authors' 1990 paper deals with the same matter: this abstract addresses the present paper only.

#### 12. Abstractor and date

Kawakita K, 30 January 2012.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Ochi H, Katsumi Y, Ikeuchi T, et al. A study of acupuncture for knee osteoarthritis — The importance of combined use with therapeutic exercise\*. *Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)* 1995; 17: 7–14 (in Japanese).

#### 1. Objectives

To evaluate the effectiveness of acupuncture combined with therapeutic exercise for knee osteoarthritis.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Forty-eight patients diagnosed with knee osteoarthritis (age range 53–77 years).

#### 5. Intervention

Arm 1: Acupuncture+silver spike point (SSP) electro-therapy group (n=18, mean age 62 years).

Arm 2: Acupuncture+SSP+therapeutic exercise group (n=20, mean age 63 years).

Arm 3: Therapeutic exercise group (n=10, mean age 67 years).

Acupuncture: stainless steel disposable needles (0.18 mm×40 mm) were used to apply the sparrow pecking technique at 9 points in the thigh region and the GB31 (風市), ST36 (足三里), GB34 (陽陵泉), and SP9 (陰陵泉) acupuncture points once or twice a week before applying SSP therapy (compression wave stimulation for 10 minutes between the knees and the thigh). Therapeutic exercise: Participants exercised mostly to strengthen the femoral quadriceps muscles, at least three times a day at home. The treatment period was one month.

Dropouts are mentioned, but the details are not reported in the original article.

#### 6. Main outcome measures

Japanese Orthopaedic Association score (JOA score) and muscle strength.

#### 7. Main results

JOA score tended to increase between the start of treatment and one month later in Arms 1 and 2 but not Arm 3. The differences between Arm 1 and Arm 3 ( $P<0.01$ ) and between Arm 2 and Arm 3 ( $P<0.05$ ) were significant. Follow up revealed a strong anesthetic effect in patients who continued to exercise. Scores for knee extension muscle strength showed significant increases in Arms 2 ( $P<0.01$ ) and 3 ( $P<0.05$ ).

#### 8. Conclusions

Combined use of acupuncture, SSP therapy, and therapeutic exercise is an effective conservative therapy for knee osteoarthritis.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This interesting study investigated the effects of combining acupuncture and SSP therapy with therapeutic exercise for knee OA. It revealed the significance of therapeutic exercise. SSP therapy is a form of transcutaneous electric nerve stimulation that uses spike-shaped surface electrodes. The authors have greatly improved the quality of the statistical analysis used in the present study from what it was in their previous work, but regrettably, they did not clearly describe their method of random allocation, and although dropouts are mentioned, this is not reflected in the analytical results. Further, the authors use the comprehensive JOA score as an outcome measure, yet analysis of the elements within that score, namely pain, functioning, joint range of motion, and swelling, would be worthwhile. This is a very valuable study in that it establishes a therapeutic method based on real clinical practice. Hopefully, the authors will conduct larger scale, more rigorously designed RCTs.

#### 12. Abstractor and date

Kawakita K, 3 February 2012.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Nakajima M, Inoue M, Itoi M, et al. A comparison of the effectiveness between acupuncture and local injection for neck pain: a randomized controlled trial. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2007; 57(4): 491–500 (in Japanese with English abstract). Ichushi Web ID: 2008024979

#### 1. Objectives

To compare the effectiveness of acupuncture and local injection for neck pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Thirty-three outpatients from the above orthopedic surgery department.

#### 5. Intervention

Arm 1: Acupuncture group. Stainless steel needles (0.18×40 mm, Seirin Co., Ltd.) were inserted to a depth of 10–20 mm, and the sparrow pecking technique (1 Hz, 20 seconds) applied after the *de qi* (得気) sensation was achieved (n=16).

Arm 2: Local injection group. A dibucaine hydrochloride formulation and Neurotropin were injected using a 25 G needle (0.5×25 mm, Terumo Corporation), and then the needle was withdrawn (n=17).

Treatment in both groups was directed to the most painful 3–5 points weekly for 4 weeks.

#### 6. Main outcome measures

Visual analogue scale (VAS) 6-point Neck Disability Index (NDI, Japanese edition) and standardized questionnaire of cervical root disease [developed by Tanaka et al] were measured. They were evaluated before treatment, and 0, 2 and 4 weeks after the end of treatment. Evaluation was masked.

#### 7. Main results

VAS was improved significantly in Arm 1 compared to Arm 2 ( $P<0.001$ ). Both NDI and standardized questionnaire showed significant improvement within group comparison ( $P<0.001$ ).

#### 8. Conclusions

Acupuncture is more useful than local injection for neck pain.

#### 9. From acupuncture and moxibustion medicine perspective

The most painful points were determined to be the treatment points.

#### 10. Safety assessment in the article

No adverse events were reported.

#### 11. Abstractor's comments

This study holds great interest for acupuncture therapists because it compares a Western medical treatment to acupuncture. It is highly commendable for having attempted a randomized controlled trial. However, the objective and the results are inconsistent because the research question is unclear. The quality of the study as an RCT is problematic. It lacks prior sample-size estimates, evaluation of internal validity (random allocation and masking success), and the statistics have not been analyzed appropriately. Within-group comparison and the necessary between-group comparison were made at the same time, which has the potential to give readers a mistaken impression of the results. Accordingly, the conclusions of the study should be recognized as having limitations. The objective of this study is important to clinical acupuncture, so it is hoped that the authors will improve on the points mentioned above by repeating the trial after preparing a thorough pre-trial plan, thereby contributing to the public good.

The material in this study is similar to that in Nakajima et al. Consideration of acupuncture and local injection for neck pain — A randomized controlled trial. *Ido-no Nippon (The Japanese Journal of Acupuncture & Manual Therapies)* 2008; 67(10): 116–125. JA0817, Ichushi Web ID: 2008373095 and Nakajima et al. A study of acupuncture and local injection for neck pain — A randomized controlled trial. *Nihon Seitai Denki Butsuri Shigeki Kenkyu Kaishi (The Journal of the Japanese Bio-Electrical and Physical Stimulation Research Society)* 2008; 22: 1–6. JA0818, Ichushi Web ID: 2009099691, so they are included in this structured abstract.

#### 12. Abstractor and date

Shichido T, 5 November 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K, Katsumi Y, Hirota S, et al. Randomised trial of trigger point acupuncture compared with other acupuncture for treatment of chronic neck pain. *Complementary Therapies in Medicine* 2007; 15: 172–9. Pubmed ID: 17709062

#### 1. Objectives

To evaluate the effectiveness of trigger point acupuncture for chronic neck pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

The Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Forty patients aged 45 years or more with neck pain for at least 6 months.

#### 5. Intervention

Arm1: Trigger point acupuncture group. Acupuncture at trigger points using disposable stainless steel needles (0.2×50 mm, Seirin Co., Ltd.) (n=10).

Arm 2: Standard acupuncture group. Disposable stainless steel needles (0.2×40 mm, Seirin Co., Ltd.) were inserted into muscle to 20 mm at the standard acupuncture points for neck pain, the GB20 (風池), GB21 (肩井), BL10 (天柱), BL11 (大杼), ST12 (缺盆), ST13 (氣戶), TE5 (外關), LI4 (合谷), and SI3 (後谿), and then the sparrow pecking technique was applied and the needles retained for 10 minutes after the *de qi* (得氣) sensation was achieved (n=10).

Arm 3: Non-trigger point acupuncture group. Disposable stainless steel needles (0.2×50 mm, Seirin Co., Ltd.) were used for acupuncture at non-tender points at least 50 mm away from trigger points in the same muscle (n=10).

Arm 4: Sham acupuncture group. Sham needles, stainless steel needles (0.2×50 mm) with the tips cut off, were used. The acupuncturist simulated insertion at trigger points, the sparrow pecking technique was applied, and then removal after 10 minutes (n=10).

Each group received two phases of acupuncture treatment, each phase comprising three treatments, one per week (3 weeks), with a 3-week period of no treatment between phases (total 13 weeks).

There were 2 dropouts each from Arms 1, 2, and 3, and 3 from Arm 4.

#### 6. Main outcome measures

Visual analogue scale (VAS) score for neck pain intensity before the first treatment, and 1, 2, 3, 6, 7, 8, 9, and 12 weeks after the first treatment (total 9 times). Neck Disability Index (NDI) score before the first treatment, and 3, 6, 9, and 12 weeks after the first treatment (total 5 times).

#### 7. Main results

VAS and NDI scores both improved significantly from baseline (pre-treatment) to 3 weeks after the first treatment in Arm 1 (both  $P<0.01$ ) and compared to the other three groups (both  $P<0.01$ ), after phase 2 treatment (9th week) in Arm 1.

#### 8. Conclusions

Trigger point acupuncture is more effective for chronic neck pain than standard acupuncture.

#### 9. From acupuncture and moxibustion medicine perspective

Treatment location, method, and stimulation intensity are three important factors in the effectiveness of acupuncture. Nociceptors with increased sensitivity are involved in the mechanism that makes trigger point treatment effective.

#### 10. Safety assessment in the article

Three of the participants who dropped out suffered symptom aggravation.

#### 11. Abstractor's comments

This study is highly commendable for its design and for having verified the effects of trigger point acupuncture by comparing it to standard acupuncture, non-trigger acupuncture, and sham acupuncture. The authors also report on sham acupuncture and the success of masking. Another aspect of this study is the interval between the two treatment phases and what follows. The authors touch on the time course after the interval, but this should have been described in greater detail, given that the question of whether the effects last is very important. Overall, it is a significant study based on an excellent design.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kinoshita H, Kinoshita N. Clinical research in the use of paraneural acupuncture for sciatica. *Nihon Shinkyu Chiryō Gakkaishi (The Journal of the Japan Acupuncture and Moxibustion Society)*. 1981; 30(1): 4–13 (in Japanese with English abstract).

#### 1. Objectives

To compare the effectiveness of paraneural and with that of non-paraneural acupuncture for sciatica.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Not described.

#### 4. Participants

Thirty sciatica patients (regardless of primary disease) enrolled from August 1979 to February 1980.

#### 5. Intervention

Arm 1: Paraneural acupuncture group. Stainless steel needles (0.2×50 mm) were inserted at the left and right BL23 (腎兪), healthy-side BL25 (大腸兪), affected-side Shangbaohuang (上胞育, no WHO code), Dianya (殿压, no WHO code), BL37 (殷門), Waichengjin (外承筋, no WHO code), and BL59 (附陽), depending on the case) acupuncture points, to 2.0 cm depth (haunches) or 1.5 cm (legs). Needles were inserted then immediately removed in lumbar locations, but retained (15 minutes) in the buttocks and lower extremities. In addition, five moxa cones (large rice-grain size) were burnt at the affected-side BL25 (大腸兪), Shangbaohuang (上胞育, no WHO code), Dianya (殿压, no WHO code), and Waichengjin (外承筋, no WHO code) points. Stainless steel needles (0.25×90 mm) were also inserted at the affected-side BL25 (大腸兪) point and the trochanter to a depth of 6.0 cm and retained for 15 minutes (n=30).

Arm 2: Non-paraneural acupuncture group. Same as paraneural acupuncture group, however, needles were retained at the affected-side BL25 (大腸兪) acupuncture point and the trochanter to a depth of 2.0 cm for 15 minutes (n=30).

Thirty patients were randomly allocated to two groups (A and B). Group A received paraneural acupuncture six times, then non-paraneural acupuncture six times. The order of treatment was reversed for group B.

Thirteen participants dropped out of Arm 1, and 12 from Arm 2.

#### 6. Main outcome measures

Amount of tenderness (kg) at the Dianya (殿压) and Waichengjin (外承筋) points, Lasègue's sign (patient experiences slight pain when raising the straight leg 30–70 degrees), and subjective symptoms (four-point scale: very good=2, good=1, no change=0, and bad=-1).

#### 7. Main results

Dianya (殿压) tenderness ( $P<0.01$ ), Waichengjin (外承筋) tenderness ( $P<0.05$ ), Lasègue's sign ( $P<0.01$ ), and subjective symptoms ( $P<0.01$ ) improved after six treatments in a significantly higher percentage of patients in Arm 1 than in Arm 2.

#### 8. Conclusions

Paraneural acupuncture is the more effective treatment for sciatica.

#### 9. From acupuncture and moxibustion medicine perspective

Acupuncture into the muscle located beside a nerve branch may relieve symptoms completely.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study was conducted in 1981, even before the acronym “EBM” had entered the Western medical lexicon. The authors used random allocation and crossover, which were absolutely cutting edge methods for the time, to compare the effectiveness of paraneural acupuncture to non-paraneural acupuncture for sciatica. It is truly a very important paper. The authors are to be congratulated for having conducted clinical research into acupuncture and moxibustion and achieved results using appropriate methods in that era. To their credit, they use quantitative outcome measures and classify participants according to sciatica type before allocating them randomly, which were both cutting-edge methods. The authors can also be commended for having their diagnoses checked by an orthopedic consultant.

Areas for improvement include the large participant drop-out rate, the lack of follow up of participants who dropped out, and the lack of an interval between the two interventions for washout.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Yun X, Suzuki S, Urata S, et al. Therapeutic effect of the treatment of sciatica due to cold-wetness evil using an electro-warming needle. *Toho Igaku (Eastern Medicine)* 2005; 21(3): 25–7 (in Japanese with English abstract). Ichushi Web ID: 2006072612

#### 1. Objectives

To evaluate the efficacy of electrothermal acupuncture for treating sciatica due to "cold-wetness evil (寒湿)."

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Not described.

#### 4. Participants

Sixty-four patients with sciatica due to "cold-wetness evil" (45 males and 19 females, mean age, 38.4 and 35.6 years for the two groups).

#### 5. Intervention

Arm 1: Electrothermal needle group. Using DZR-1-type electrothermal acupuncture apparatus, size 6 electrothermal needles were inserted perpendicularly to a depth of 1–1.5 cun at the main acupuncture points BL54 (秩边), BL37 (殷門) or GB31 (風市), BL40 (委中), BL57 (承山), or GB34 (陽陵泉) on the affected side, and stimulation with a current of 60–80 mA was applied. In addition, filiform needles were inserted perpendicularly at the adjunct acupuncture points BL25 (大腸俞) and BL26 (關元俞) bilaterally, and GB30 (環跳), GB31 (風市), or BL37 (殷門), GB34 (陽陵泉) or BL57 (承山), GB39 (懸鐘), GB40 (丘墟), BL60 (昆崙) on the affected side. A lifting and thrusting draining method was performed. The procedure was applied every 10 minutes. Needles were retained for 40 minutes (n=34).

Arm 2: Ordinary needle group. Filiform needles were inserted perpendicularly to a depth of 1–1.5 cun at the main acupuncture points, and a neutral supplementation and draining method was performed. Similar treatment was applied at the adjunct acupuncture points (n=30). ("Cun" used in this section is based on location of points by bone standard [骨度法] and is different from the linear measure "sun [3.03 cm]" [尺度法].)

#### 6. Main outcome measures

Therapeutic effects were determined on a 3-point scale: cure, response, and nonresponse.

#### 7. Main results

In Arm 1, cure was obtained in 23 patients and response in 9, resulting in an efficacy rate of 94.1%. In Arm 2, cure and response were obtained in 12 and 11 patients, respectively, resulting in an efficacy rate of 76.7%. When comparing the two arms, therapeutic effect was significantly superior in Arm 1 ( $P<0.05$ ).

#### 8. Conclusions

Electrothermal acupuncture is effective for treating sciatica due to "cold-wetness evil."

#### 9. From acupuncture and moxibustion medicine perspective

Electrothermal acupuncture was prescribed based on the traditional Chinese medical diagnosis, and administered using the traditional Chinese medical procedure. In the Discussion, fire needling was mentioned.

#### 10. Safety assessment in the article

Not described.

#### 11. Abstractor's comments

This study is highly appreciated for demonstrating the efficacy of treatment with electrothermal needles as compared with that of treatment with ordinary filiform needles. However, the treatment environment is not clear because the settings are not described. It is also unclear whether the study was an appropriate randomized controlled trial since the method for randomization was not reported. Detailed analysis of the assessment is also missing. Despite these omissions, this is a valuable study that may provide an opportunity for finding new therapies.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

## Diseases of the Musculoskeletal and Connective Tissue

### Reference

Sakai T, Tsutani K, Tsukayama H, et al. Multi-center randomized controlled trial of acupuncture with electric stimulation and acupuncture-like transcutaneous electrical nerve stimulation for lumbago. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2001; 51(2): 175–84 (in Japanese with English abstract). Ichushi Web ID: 2001280876

#### 1. Objectives

To evaluate the efficacy and safety of low-frequency electro-acupuncture and transcutaneous electrical nerve stimulation (TENS) for low back pain.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Four medical facilities in Japan (Meiji University of Oriental Medicine Hospital [current Meiji University of Integrative Medicine], Kyoto; Outpatient Clinics, Kansai College of Oriental Medicine [current Kansai University of Health Sciences], Osaka; Tsukuba College of Technology Clinic, Ibaraki; and Department of Medicine and Physical Therapy, Faculty of Medicine, University of Tokyo, Tokyo).

#### 4. Participants

A total of 70 male and female patients aged 20 years or older who had low back pain without leg pain and provided consent.

#### 5. Intervention

Arm 1: Low-frequency electro-acupuncture therapy group. Two points each for the left and right sides were selected from reactive points (taut, tender, or indurated) on the BL23(腎兪), BL25(大腸兪), and BL52(志室) acupuncture points, and electro-acupuncture was applied at a frequency of 1 Hz for 15 minutes using stainless steel needles (0.24×60 mm). Treatment was administered 5 times during a 2-week period (n=32).

Arm 2: TENS group. Sites, frequency, intensity, and duration of stimulation and frequency and number of treatment sessions were the same as those in Arm 1 (n=36).

There was a 1-week run-in period (patches were applied), during which 2 patients dropped out. Of the rest of 68, 4 patients dropped out of the study (1 in Arm 1, 3 in Arm 2).

#### 6. Main outcome measures

Change in pain intensity rated on a 5-point visual analogue scale (VAS) and using the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score).

#### 7. Main results

Among background factors, gender, history of acupuncture, and history of TENS were different between the two arms. There was no significant between-arm difference in pain relief and JOA score.

#### 8. Conclusions

Low-frequency electro-acupuncture and TENS have similar efficacy for low back pain.

#### 9. From acupuncture and moxibustion medicine perspective

None.

#### 10. Safety assessment in the article

In Arm 2, two patients complained of itching resulting from the application of electrodes.

#### 11. Abstractor's comments

In this ambitious RCT, the protocol, which is central to conducting a clinical trial, was developed over an extended period of time and the efficacy of acupuncture for low back pain, an important disorder in clinical practice of acupuncture and moxibustion, was evaluated in a multicenter setting. This study is regarded as an exploratory phase 2 trial, aiming to collect basic data for a phase 3 trial. Regrettably, TENS was used as the control treatment, but “no treatment” would have been a more desirable control. The study provides investigators who are planning RCTs with a lot of useful information, including issues concerning recruitment of subjects and selection of outcome measures.

#### 12. Abstractor and date

Takahashi N, 9 February 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Tsukayama H, Yamashita H, Amagai H, et al. Randomised controlled trial comparing the effectiveness of electroacupuncture and TENS for low back pain: a preliminary study for a pragmatic trial. *Acupuncture in Medicine* 2002; 20(4): 175–80. Pubmed ID: 12512791

#### 1. Objectives

To compare the effectiveness of electro-acupuncture with that of transcutaneous electrical nerve stimulation (TENS) in patients with low back pain in a pragmatic setting.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Tsukuba College of Technology Clinic, Tsukuba, Japan.

#### 4. Participants

Twenty patients aged 20 years or older with low back pain for at least 2 weeks.

#### 5. Intervention

Arm 1: Electro-acupuncture group. Electro-acupuncture was applied at 8 acupuncture points (4 acupuncture points each in the left and right) in the lower back down through the buttocks using disposable stainless steel needles (0.20×50 mm, 0.24×60 mm) in a pragmatic manner (standard practice at the Tsukuba College of Technology Clinic). The insertion depth was 20 mm and electro-stimulation was applied at a frequency of 1 Hz for 15 minutes. At the end of electro-stimulation, press tack needles were put on 4 out of the 8 points (n=10).

Arm 2: TENS group. Using gel-type disposable electrodes (20×30 mm), electro-stimulation was applied at the same 8 points under the same conditions as in Arm 1 (n=10).

One patient in Arm 1 dropped out due to influenza.

#### 6. Main outcome measures

Pain relief rated on a visual analogue scale (VAS) before and daily for 2 weeks after the intervention.

Score for the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score) obtained before and at 3 days after the intervention.

#### 7. Main results

VAS score was significantly lower at 2 weeks after the intervention and JOA score was more improved at 3 days after the intervention in Arm 1 than in Arm 2, but it was not statistically significant ( $P=0.24$ ).

#### 8. Conclusions

Electro-acupuncture is, in the short term, the more effective of the two techniques for low back pain.

#### 9. From acupuncture and moxibustion medicine perspective

The authors pointed out the importance of conducting a comparative trial that employs individualized treatment, which is a part of daily clinical practice in Japan.

#### 10. Safety assessment in the article

Mild adverse reactions were reported in 3 of 10 patients in Arm 1 (transient elevation of blood pressure, discomfort due to press tack needles, and mild subcutaneous bleeding) and 2 of 9 in Arm 2 (transient aggravation of low back pain, transient fatigue, and itching).

#### 11. Abstractor's comments

This article describes a very well-designed trial comparing standard electrical therapy with electro-acupuncture and demonstrating the efficacy of acupuncture. The effort to conduct a pragmatic clinical trial is also appreciated.

However, as the authors noted in the text, sample size was small and no follow-up was carried out. Further studies are needed to establish reliability and external validity. A detailed description of how the therapy was individualized is desirable. Although the patients were randomly assigned, the trial was conducted at a clinic affiliated with a college of acupuncture and moxibustion, and therefore a concern about potential selection bias exists.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh, K, Katsumi Y, Kitakoji H. Trigger point acupuncture treatment of chronic low back pain in elderly patients—a blinded RCT. *Acupuncture in Medicine* 2004; 22(4): 170–7 (in Japanese with English abstract). Pubmed ID: 15628774

#### 1. Objectives

To evaluate the effect of acupuncture on pain intensity and quality of life (QOL) in patients with chronic low back pain by comparing two types of trigger point acupuncture treatment and standard acupuncture treatment.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopaedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Thirty-five outpatients aged 65 years or older with low back pain for at least 6 months (10 males and 25 females, age range, 65–81 years).

#### 5. Intervention

Arm 1: Superficial needling to trigger points group. Stainless steel needles (0.2×50 mm) were inserted to a depth of 3 mm and the sparrow pecking technique was applied. After *de qi* (得氣) sensation was obtained, the needles were retained for 10 minutes (n=12).

Arm 2: Deep needling to trigger points group. Similar stainless steel needles were inserted to a depth of 20 mm and the sparrow pecking technique was applied. After the local muscle twitch response was observed, the needles were retained for 10 minutes (n=10).

Arm 3: Standard acupuncture group. Similar stainless steel needles were inserted to a depth of 20 mm at the BL23 (腎俞), BL25 (大腸俞), GB30 (環跳), BL40 (委中), BL60 (崑崙), and GB34 (陽陵泉) acupoints and up to 4 *ah-shi* points (阿是穴). The sparrow pecking technique was applied. After *de qi* sensation was obtained, the needles were retained for 10 minutes (n=13).

One session consisted of 3 once-weekly 30-minute acupuncture treatments and two sessions were performed with an interval between the sessions. Total treatment duration was 12 weeks.

Three patients in Arm 1, 1 in Arm 2, and 4 in Arm 3 dropped out.

#### 6. Main outcome measures

Pain intensity measured on a visual analogue scale (VAS), and QOL using the Roland Morris Disability Questionnaire (RMDQ).

#### 7. Main results

In Arm 2, VAS score after the treatment was significantly decreased compared with the pre-treatment value ( $P<0.01$ ), whereas in the other 2 arms, no significant change in the score was observed. Similar results were obtained for RMDQ scores.

#### 8. Conclusions

Deep needling to trigger points is more effective on low back pain in the elderly compared with superficial needling to trigger points or standard acupuncture.

#### 9. From acupuncture and moxibustion medicine perspective

None.

#### 10. Safety assessment in the article

Worsening of symptoms was observed in 1 patient in Arm 2.

#### 11. Abstractor's comments

This valuable study attempted to test the efficacy of three different acupuncture treatments. In particular, the authors' effort to demonstrate the importance of the depth of needle insertion in trigger point treatment is appreciated. It is also interesting that time series of outcome measures were observed by using the ABAB method.

The authors found significant pre- to post-treatment differences, but no difference among the three arms. Thus, although deep needling to trigger points may be superior to the other two treatments, further validation is needed. Also, sample size should be increased, and follow-up extended.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K. Effect of trigger point acupuncture treatment on chronic pain in the elderly - usefulness of acupuncture for treating chronic low back pain -\*. *Mansei Totsu (The Journal of the Japanese Society for the Study of Chronic Pain)* 2004; 23(1): 83–8 (in Japanese with English abstract). Ichushi Web ID: 2005066965

#### 1. Objectives

To compare the effect of acupuncture treatment at trigger points versus at acupuncture points in the back on chronic low back pain in the elderly.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Department of Orthopaedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Eighteen elderly patients aged 65 years or older with low back pain for at least 6 months.

#### 5. Intervention

Arm 1: Trigger point treatment group. Disposable stainless steel needles (0.16×40 mm, 0.18×50 mm) were inserted at up to 18 trigger points detected by palpation and retained for 10 minutes. One cycle consisted of 3 once-weekly treatments (3 weeks) followed by a 3-week wash out period; two cycles were administered overall (a total of 12 weeks) (n=9).

Arm 2: Acupuncture point treatment group. Disposable stainless steel needles (0.16×40 mm) were inserted at acupuncture points in the back, BL23 (腎兪), BL25 (大腸兪), GB30 (環跳), BL31 (上髎), BL33 (中髎), BL54 (秩辺), BL40 (委中), BL60 (崑崙), and GB34 (陽陵泉), and retained for 10 minutes. The frequency and duration of the treatment were the same as in Arm 1 (n=9).

#### 6. Main outcome measures

Low back and leg pain intensity rated on a visual analogue scale (VAS) at each of 9 time points: before the start of the treatment (once), one week after each treatment session (6 times), and at the end of each wash-out period (twice). Roland Morris Disability Questionnaire (RMDQ) score was recorded at each of 5 time points: before the start of the treatment (once), at the end of each treatment period (twice), and at the end of each wash-out period (twice).

#### 7. Main results

Improvement in VAS score was greater in Arm 1 than in Arm 2. In both arms, RMDQ scores were improved when compared with the pre-treatment values. The P value was not described in the original article.

#### 8. Conclusions

Trigger point acupuncture treatment reduces low back pain more effectively in the elderly compared with the standard acupuncture point treatment.

#### 9. From acupuncture and moxibustion medicine perspective

The author mentioned that the formation of trigger points may play a role in the development of low back and leg pain in the elderly.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study is interesting and appreciated in that it compares the efficacy of acupuncture point treatment with that of trigger point acupuncture treatment. However, the following points should have been included or discussed: 1) P values and a discussion of the statistical analyses of results; 2) the small sample size; and 3) no flow chart. This study seems valuable as it attempted to demonstrate the need for treatment of muscles, including trigger points, in the elderly.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Katsumi Y, Itoi M, Kojima A, et al. *Ah shi* (tender) point acupuncture of chronic low back pain in aged patients\*. *Rehabiritesyon Igaku (The Japanese Journal of Rehabilitation Medicine)* 2004; 41(12): 824–9 (in Japanese). Ichushi Web ID: 2005128701.

#### 1. Objectives

Effectiveness of ah-shi (tender) point acupuncture therapy for chronic low back pain in elderly patients.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Nine elderly people 65 years or over with low back and leg pain persisting for at least six months.

#### 5. Intervention

Arm 1: T-S group (Tender point acupuncture, then sham acupuncture). Disposable stainless steel needles (0.18 × 50 mm) were inserted for 10 minutes at up to 18 tender points detected by palpation. Tender point acupuncture occurred once a week for 3 weeks, then after a three-week washout period, sham acupuncture commenced (3 weeks), followed by a three-week washout period. In sham acupuncture, the guide tube was placed at the tender point and after employing the same technique as real needle insertion, the participant was told that the needle had been inserted and then was allowed to rest for 10 minutes (n=4).

Arm 2: S-T group (Sham acupuncture, then tender point acupuncture). The period of treatment was the same as in Arm 1, but the order of the treatments was reversed (n=5).

#### 6. Main outcome measures

Visual analogue scale (VAS) scores for intensity of low back and leg pain were recorded nine times: once before treatment commenced, one week after each treatment (six times), and at the end of each washout period (twice). The Roland Morris Disability Questionnaire (RMDQ) was given five times: once before treatment commenced, at the end of each treatment period (twice), and at the end of each washout period (twice).

#### 7. Main results

Tender point acupuncture led to greater VAS and RMDQ improvement. The P value was not reported.

#### 8. Conclusions

Tender point acupuncture therapy is effective for chronic low back and leg pain in the elderly.

#### 9. From acupuncture and moxibustion medicine perspective

The importance of *ah shi* (tender) point acupuncture was mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study seeks to validate the efficacy of tender point acupuncture for low back and leg pain in the elderly using a crossover within-group experimental design, however, no *P* value is mentioned in the results, and there is no statistical examination. Yet, meaningful evaluation can be made because the effects were compared with those of sham acupuncture. Further development including elaboration of the sham acupuncture method is anticipated.

#### 12. Abstractor and date

Hosaka M, 8 October 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh, K, Katsumi Y, Hirota S, et al. Effects of trigger point acupuncture on chronic low back pain in elderly patients--a sham-controlled randomised trial. *Acupuncture in Medicine* 2006; 24(1): 5–12. Pubmed ID: 16618043

#### 1. Objectives

To compare the effects of trigger point acupuncture versus sham acupuncture on pain and QOL in patients with chronic low back pain.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Twenty-six elderly patients aged 65 or older with chronic low back pain for at least 6 months (9 males and 17 females; age range, 65–91 years).

#### 5. Intervention

Arm 1: Group A. Trigger point acupuncture followed by sham acupuncture (n=13).

Arm 2: Group B. Sham acupuncture followed by trigger point acupuncture (n=13).

Trigger point acupuncture: Stainless steel needles (0.2×50 mm; Seirin Co., Ltd.) were inserted to a depth of 10–40 mm at trigger points, and sparrow pecking technique was applied. After the *de qi* (得氣) sensation was obtained, the needles were retained for 10 minutes. Sham acupuncture: Similar stainless steel needles (0.2×50 mm; Seirin Co., Ltd.), with blunt tips, were put on trigger points and stimulation was applied. To keep patients blinded, the acupuncturist pretended to insert the needle and to use sparrow pecking technique. After 10 minutes, needle extraction was simulated.

In both arms, one of the two acupuncture treatments (30 minutes) was administered 3 times with a frequency of once weekly (the first phase), followed by a 3-week washout period. Then the other treatment (30 minutes) was administered 3 times with a frequency of once weekly (the second phase), followed by a 3-week observation period. The overall study duration was 12 weeks.

Three patients in Arm 1 and 4 in Arm 2 dropped out.

#### 6. Main outcome measures

Visual Analogue Scale (VAS) score for pain intensity and Roland Morris Disability Questionnaire (RMDQ) score.

#### 7. Main results

Both VAS and RMDQ scores during the first phase were lower in Arm 1 ( $P<0.001$  and  $P<0.01$ , respectively). The within-group (before-and-after) comparison showed that both VAS and RMDQ scores decreased during the trigger point acupuncture phase ( $P<0.01$  for both), but remained unchanged during the sham acupuncture phase.

#### 8. Conclusions

Trigger point acupuncture is more effective than sham acupuncture on low back pain in the elderly in the short term.

#### 9. From acupuncture and moxibustion medicine perspective

Treatment at trigger points may be more effective than treatment at traditional acupuncture points on low back pain in the elderly.

#### 10. Safety assessment in the article

One patient experienced worsening of symptoms during the trigger point acupuncture in Arm 1.

#### 11. Abstractor's comments

This very well-designed crossover RCT demonstrated the efficacy of trigger point acupuncture, as compared with sham acupuncture, in the elderly patients with low back pain. Greater reliability and external validity of results would be obtained if the drop-out rate (one quarter in this study) is decreased and intention-to-treat (ITT) analysis is conducted.

#### 12. Abstractor and date

Wakayama I, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kawase Y, Ishigami T, Nakamura H, et al. Acupuncture treatment for lower back pain - Multi-center randomized controlled trial using sham acupuncture as a control. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2006; 56(2): 140–9 (in Japanese with English abstract). Ichushi Web ID: 2006225874

#### 1. Objectives

To compare the efficacy of taikyoku therapy and low-frequency electro-acupuncture for low back pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Eleven acupuncture and moxibustion clinics, Aichi and Gifu, Japan.

#### 4. Participants

Sixty-four patients who presented to the clinic for the first time with low back pain as a main complaint (36 males and 28 females).

#### 5. Intervention

Arm 1: Taikyoku therapy+electro-acupuncture. Treatments for Arm 2 and Arm 3 were combined (n=12).

Arm 2: Taikyoku therapy alone. Using disposable stainless steel needles (0.18×30 mm), single needling technique was applied at Kurono's basic meridian points for total body conditioning, CV12 (中脘), LR14 (期門), ST25 (天枢), CV6 (氣海), BL10 (天柱), GB20 (風池), BL11 (大杼), GB21 (肩井), BL13 (肺俞), BL14 (厥陰俞), BL20 (脾俞), BL23 (腎俞), and BL25 (大腸俞) (n=13).

Arm 3: Electro-acupuncture alone. Disposable stainless steel needles (0.2×30 mm) were inserted to a depth of 5–7 mm at the BL23 (腎俞) and BL40 (委中) acupuncture points. Electro-stimulation was applied for 5 minutes with a frequency of 5 Hz and a voltage of 2 V (n=20).

Arm 4: Sham acupuncture. Without using needles, guide tubes were tapped at the BL20 (脾俞), BL23 (腎俞), and BL25 (大腸俞) acupuncture points. Eventually, electro-acupuncture for Arm 2, taikyoku therapy for Arm 3, and electro-acupuncture+taikyoku therapy for Arm 4 were additionally administered (n=19).

#### 6. Main outcome measures

Visual Analog Scale (VAS) score for pain intensity and score for the Japanese Orthopaedic Association Back Pain Evaluation Questionnaire (JOA score); both scores were measured before the treatment, after the assigned treatment, and after the final treatment.

#### 7. Main results

When comparing pre- and post-treatment values, significant improvements in both VAS and JOA scores were observed in Arm 1, Arm 2, and Arm 3 ( $P<0.05$  for all), but not in Arm 4. Between-arm comparisons revealed significant improvements in Arm 1, Arm 2, and Arm 3 compared with Arm 4 ( $P<0.05$  for all).

#### 8. Conclusions

Taikyoku therapy and low-frequency electro-acupuncture are effective for low back pain.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

Although there is imbalance in the number of enrolled patients at each institution as well as the number of randomized patients in each arm, this study is highly appreciated for indicating future possibilities of conducting high quality multicenter RCT. In multicenter clinical studies, lack of the standardization of therapy makes an integrated evaluation difficult. In that regard, the technical gap among institutions was minimized by measures, including frequent training, in this study; the minimized gap also made the study meaningful.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Kawachi A, Kitade T, Kim M, et al. Combination of SSP therapy and far infrared irradiation for chronic low back pain. *Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)* 2006; 36(1): 35–42 (in Japanese with English abstract). Ichushi Web ID: 2007063453

#### 1. Objectives

To evaluate the efficacy of Silver Spike Point (SSP) therapy combined with far infrared irradiation for chronic low back pain.

#### 2. Design

Crossover randomized controlled trial (RCT cross-over).

#### 3. Setting

Not described.

#### 4. Participants

Sixty chronic low back pain patients.

#### 5. Intervention

Arm 1: SSP plus far infrared irradiation group. The same treatment as in Arm 1 plus far infrared ray irradiation at about 30 cm from the skin (n=30).

Arm 2: SSP group. Bilateral low frequency electrotherapy (3 Hz continuous waves for 15 minutes) at BL20 (脾俞) and BL23(腎俞) acupuncture points (n=30).

#### 6. Main outcome measures

Pain intensity after treatment (numerical scale), comfort during treatment (visual analogue scale [VAS] score).

#### 7. Main results

Intensity of chronic back pain after treatment was improved in 83% of patients in Arm 1 and 40% of patients in Arm 2. VAS scores for comfort during treatment were 8.4±0.9 mm for Arm 1, and 7.4±1.2 mm for Arm 2.

#### 8. Conclusions

The addition of far infrared irradiation to treatment with SSP further reduces pain and increases comfort in chronic back pain patients.

#### 9. From acupuncture and moxibustion medicine perspective

The paper mentions selection of acupuncture points from among those commonly used for chronic back pain clinically.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This trial compares SSP with SSP plus far infrared irradiation. The study measured skin temperature and deep tissue temperature, as well as tissue blood-flow volume, and investigated pain intensity and comfort in low back pain patients. It is of great interest that the study assessed both objective scores and subjective evaluations. However, temperature and blood flow were measured in one group, while clinical effects were examined in the other group, so there is a need for re-examination of the design. Acupuncture points were selected according to symptoms, but the relation between the type of low back pain and the selection of acupuncture points was not discussed. Such a discussion would improve clinical application.

#### 12. Abstractor and date

Furuhata T, Kaneko Y, 1 February 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Hirota S, Itoh K, Katsumi Y. A controlled clinical trial comparing trigger point acupuncture with tender point acupuncture treatments for chronic low back pain - a pilot study on 9 elderly patients -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)* 2006; 56(1): 68–75 (in Japanese with English abstract). Ichushi Web ID: 2006156313

#### 1. Objectives

To compare the therapeutic effects of trigger point acupuncture with those of tender point acupuncture on chronic low back pain.

#### 2. Design

Quasi-randomized controlled trial (quasi-RCT).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Twelve patients with chronic low back pain (mean age, 71.9 ±3.4 years; range, 66–77).

#### 5. Intervention

Arm 1: Trigger point acupuncture group (n=6). Needling to the trigger point of the muscle for a total of 5 times (once a week) .

Arm 2: Tender point acupuncture group (n=6). Needling to the tender point for a total of 5 times (once a week).

Three subjects dropped out during the study.

#### 6. Main outcome measures

Pain intensity (assessed using a visual analog scale: VAS) and functional disability (Roland-Morris Disability Questionnaire: RMDQ).

#### 7. Main results

At the end of the treatment course, VAS and RDQ values were significantly improved in Arm 1 ( $P<0.01$ ), whereas these values tended to be improved (but not significantly) in Arm 2. At one month follow-up, these improvements persisted and remained significant compared with baseline in Arm 1 ( $P<0.01$ ), but tended to decline and return to baseline in Arm 2.

#### 8. Conclusion

Trigger point acupuncture in contrast to tender point acupuncture appears to reduce pain intensity (VAS) and improve disability measures (RMDQ) after a few applications. The results suggest that these two techniques have different therapeutic effects.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comment

This study is a well-designed RCT with clear criteria for inclusion of the participants and sufficient follow-up duration. The difference in the therapeutic effects of the two acupuncture treatments, which are often confused, is of great interest. However, allocation of the patients in this study was dependent on the order of enrollment and therefore only quasi-randomized. Also as the authors mention, it is regrettable that the study design does not permit sufficient validation of masking and placebo effects. The results in this study are limited by the small number of the participants. Furthermore, the results of clinical application may vary depending on the operator's skill. Further studies concerning these issues are awaited to improve reproducibility in clinical practice.

#### 12. Abstractor and date

Matsumine R / Kaneko Y, 14 December 2010, Kawakita K / Takahashi N, 25 December 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Inoue M, Kitakoji H, Ishizaki N, et al. Relief of low back pain immediately after acupuncture treatment – a randomised, placebo controlled trial. *Acupuncture in Medicine*. 2006; 24(3): 103–8. Pubmed ID: 17013356

#### 1. Objectives

To evaluate the immediate effect of tender point acupuncture on low back pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Center of Acupuncture Science, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine), Kyoto, Japan.

#### 4. Participants

Thirty-one patients with low back pain who presented to the center between April 2003 and December 2004 (21 males and 10 females, mean age in the two groups: 68 and 70 years).

#### 5. Intervention

Arm 1: Acupuncture group. A stainless steel needle (Seirin Co., Ltd.; 0.18×40 mm) was inserted to a depth of 20 mm at the most tender point and sparrow pecking technique was applied for 20 seconds (n=15).

Arm 2: Sham acupuncture group. A guide tube was tapped at the most tender point, without using a needle (n=16).

#### 6. Main outcome measures

Visual Analog Scale (VAS) score for pain intensity and Schober test (a test of spinal mobility) score.

#### 7. Main results

Between-group comparison of the change from before to immediately after the treatment showed significant improvement in both VAS ( $P=0.020$ ) and Schober test ( $P<0.001$ ) scores in Arm 1.

#### 8. Conclusions

Acupuncture at the most tender point has an immediate relieving effect on low back pain.

#### 9. From acupuncture and moxibustion medicine perspective

The authors mentioned the descending inhibitory system or activation of spinal inhibitory system as a mechanism underlying the effect of tender point acupuncture.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study is highly appreciated for testing the effect of acupuncture in an evaluator- and patient-masked trial. The success of the masking was also described. Because the study objective was to examine the immediate relieving effect of acupuncture, no flow chart was presented and no follow-up was carried out, but the longer-term effect is a concern. If the sham acupuncture technique is modified, further development may be expected.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Hirota S, Itoh K, Katsumi Y. Trigger point acupuncture treatment for chronic low back pain in elderly patients. *Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)* 2006; (38): 19–26. Ichushi Web ID: 2008088212

#### 1. Objectives

To compare the effects of acupuncture at a trigger point (TrP) and a tender point of the same muscle in elderly patients with chronic low back pain.

#### 2. Design

Crossover Randomized controlled trial using sealed envelopes for allocation (RCT- envelope-crossover).

#### 3. Setting

Outpatient Clinic, Department of Orthopedic Surgery, Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Six elderly people with low back pain for at least 6 months and no abnormal findings on neurological tests, including tests of muscle strength and deep reflex (4 males, 2 females, mean age 66.3±7.9 years).

#### 5. Intervention

Arm 1: Group A. TrP treatment then tender point treatment (n=3).

Arm 2: Group B. Tender point treatment then TrP treatment (n=3).

A TrP was defined as the point in a muscle with cord-like induration that induced pain when the low back or hip joints were moved passively. A tender point was defined simply as a point felt tender in the affected muscle identified in similar way to a TrP. Each treatment was given weekly 3 times, for 2 weeks (total 6 times). In both treatments, stainless steel needles (0.16×40 mm) were inserted into muscle, and retained for 10 minutes, regardless of de qi sensation. In both arms, 8–12 points were stimulated.

#### 6. Main outcome measures

Pain evaluated on a Visual Analogue Scale (VAS) before treatment and one week after each treatment (total 7 times). Roland-Morris Disability Questionnaire (RMDQ) before treatment, and one week after the third and the sixth treatments.

#### 7. Main results

The pre- to post-treatment decrease in VAS pain score was larger in Arm 1, but there was no clear difference between the two treatments. RMDQ scores decreased in both groups, but there was no clear quality of life improvement.

#### 8. Conclusions

TrP and tender point acupuncture are both effective for chronic back pain in the elderly, but the difference in the effectiveness of these treatments was insignificant.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

The significance of this study lies in its comparison of TrP treatment with tender point treatment, both common clinical treatments for low back pain, which is the most frequent complaint in acupuncture practice. The study compared two different treatments for the same muscle using a crossover design, based on the design described in a previous study, Hirota S, et al. "A controlled clinical trial comparing trigger point acupuncture with tender point acupuncture for chronic low back pain - a pilot study on 9 elderly patients -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2006; (56): 68–75 (in Japanese with English abstract) JA0916". Deficiencies include the lack of information about the participant recruitment period, the period and length of the study, and the washout period. In addition, sample size was small, and effectiveness was not thoroughly analyzed statistically. Further, while on one hand the authors mention in the Discussion (and they include references in the bibliography) that a certain degree of practice is required to master trigger point acupuncture therapy, the sole acupuncturist in this study had only had one year of clinical experience. It is hoped that the authors rectify these deficiencies before carrying out further research.

#### 12. Abstractor and date

Shimoichi Y, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Inoue M, Nakajima M, Itoi M, et al. Comparison of the effectiveness of acupuncture treatment and local injection for low back pain - A randomized controlled clinical trial - *Nihon Onsen Kikou Butsuri Igakukai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)* 2008; 71(4): 211–20 (in Japanese with English abstract). Ichushi Web ID: 2008333712

#### 1. Objectives

To compare the clinical effects of local injection and local acupuncture treatment for low back pain.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Integrative Medicine Hospital, Kyoto, Japan

#### 4. Participants

Twenty-six outpatients who presented with low back pain between April 2006 and December 2007, received acupuncture therapy or local anesthetic injection for low back pain, and were suspected of suffering low back pain complications due to causes other than movement disorder were included, but not patients who received other treatment for low back pain within one month before commencement of the study (14 males; 12 females; average age in the two groups 70.8 and 73.6 years).

#### 5. Intervention

Arm 1: Acupuncture. Stainless steel needles (0.18 x 40 mm, Seirin Co., Ltd.) were inserted to a depth of 10–20 mm at the most painful points (two to five points) in each patient's lower back, then after the patient experienced *de qi* (得氣) sensation, sparrow pecking stimulation was applied (1 Hz, 20 s), and the needles were removed. Patients received treatment once a week on four occasions (n=13).

Arm 2: Local injection. 25 G hypodermic needles (0.5 x 25 mm, Terumo Corporation) were inserted to a depth of 10–20 mm at the most painful points (two to five points) in each patient's lower back and were removed after drug injection (NeoVitacain®, Neurotropin®). Patients received treatment once a week on four occasions (n=13).

#### 6. Main outcome measures

Pain was evaluated (on a visual analog scale [VAS]) before and after the initial treatment, before each subsequent treatment, and at two and four weeks after completion of the treatment. The Roland-Morris Disability Questionnaire (RMDQ) was used for evaluation before the initial treatment, at completion of treatment, and then at two and four weeks after completion of treatment. The Pain Disability Assessment Scale (PDAS) was used for evaluation before the initial treatment, at completion of treatment, and then two and four weeks after completion of treatment.

#### 7. Main results

Significant improvement in all measures in both Arm 1 and Arm 2 occurred over time (VAS:  $P<0.0001$ ,  $P=0.0156$ , respectively; RMDQ:  $P<0.0001$ ,  $P=0.0188$ , respectively; PDAS:  $P<0.0001$ ,  $P=0.0196$ , respectively). VAS scores improved significantly in both arms immediately after treatment ( $P<0.0001$ ,  $P=0.0428$ , respectively), but the size of the VAS change was significantly greater in Arm 1 ( $P=0.0348$ ). Continued treatment showed significantly greater change in VAS score (comparing the scores before the initial treatment and before the fourth treatment) in Arm 1 ( $P=0.0076$ ). The change in the RMDQ and the PDAS (comparing the scores before the initial treatment and after completion of the treatment) was also significantly greater in Arm 1 ( $P=0.0024$ ,  $P=0.0039$ , respectively).

#### 8. Conclusions

Acupuncture treatment is more effective than local injection for low back pain associated with degenerative change in elderly patients.

#### 9. From acupuncture and moxibustion medicine perspective

Acupuncture treatment uses physical stimulation alone, while local injection uses a combination of physical stimulation and anesthesia. The difference between the effects in the two groups could be due to the differences between the mechanisms of pain suppression and it is possible that physical stimulation alone is more effective, depending on the type and severity of the pain.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study is of great interest because it compares acupuncture with local injection, a Western medical therapy for low back pain. The measures used are highly reliable and the outcomes are appropriately described. The findings of the study do not apply to low back pain in all age groups, including low back pain for reasons other than degeneration, as the subjects of the study were 70 years or older. Improving the quality of the RCT including sample size precomputation and blinding of participants to the intervention is desirable, however, low back pain is one of the most common chief complaints in acupuncture therapy, so use of a variety of approaches for clinical study design is anticipated.

“Comparison of the effectiveness of local injection and acupuncture treatment for low back pain - A randomized controlled clinical trial. *Nihon Seitai Denki Butsuri Shigeki Kenkyu Kaishi (The Journal of the Japanese Bio-Electrical and Physical Stimulation Research Society)* (Inoue et al., 2008; 22:1-6. JA0806)” deals with the same topic as is dealt with in this structured abstract.

#### 12. Abstractor and date

Shichido T, Shimoichi Y, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh K, Itoh S, Katsumi Y, et al. A pilot study on using acupuncture and transcutaneous electrical nerve stimulation to treat chronic non-specific low back pain. *Complementary Therapies in Clinical Practice* 2009; 15: 22–5. CENTRAL ID: CN-00681603

#### 1. Objectives

To analyze the synergistic effects of acupuncture and transcutaneous electrical nerve stimulation (TENS) on chronic low back pain (LBP).

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

The Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Thirty-two LBP patients, 60 years or older, at least six months after onset (12 males, 20 females, ages 61 to 81).

#### 5. Intervention

Arm 1: Acupuncture group. Disposable stainless steel needles (0.2×40 mm, Seirin Co., Ltd.) were inserted into muscle to a depth of 10 mm using the sparrow pecking technique until the patient experienced the *de qi* (得氣) sensation, then retained for at least 10 minutes. The needles were inserted at BL23 (腎俞), BL25 (大腸俞), BL32 (次髎), BL40 (委中), BL60 (崑崙), GB30 (環跳), and GB34 (陽陵泉) acupuncture points. Treatment was given once a week for five weeks (n=8).

Arm 2: TENS group. Surface disposable electrodes (small and large) were placed at and near the most tender points; the pulse rate was set to 122 Hz and intensity was set to two to three times the patient's sensory threshold for 15 minutes. Treatment was given once a week for five weeks (n=8).

Arm 3: Acupuncture + TENS group. TENS was given for 15 minutes, and acupuncture treatment for 15 minutes. The respective treatments were the same as in Arms 1 and 2. Treatment was given once a week for five weeks (n=8).

Arm 4: Control group. Though nonspecific, treatment with topical poultices containing methylsalicylic acid was given, if required (n=8).

Two, one, two and one participants were dropped from Arms 1, 2, 3, and 4, respectively.

#### 6. Main outcome measures

Pain intensity (visual analogue scale [VAS]) score and Roland Morris (Roland-Morris Disability Questionnaire [RMDQ]) score for quality of life (QOL).

#### 7. Main results

The 4- and 5-week VAS scores for Arm 3 and the 5-week RMDQ score for Arm 3 were significantly lower than pre-treatment scores (before-after comparison) ( $P<0.008$ ). The mean 5-week VAS score for Arm 3 was significantly lower than the corresponding score for Arm 4 (comparison between groups). The RMDQ scores after 5 weeks of the treatment for Arm 3 decreased significantly compared to pre-treatment scores (before-after comparison) ( $P<0.008$ ).

#### 8. Conclusions

Acupuncture therapy combined with TENS alleviates pain and improves QOL in LBP patients.

#### 9. From acupuncture and moxibustion medicine perspective

“Gate control” is cited as the mechanism underlying the therapeutic effects of acupuncture with TENS. Since acupuncture excites small-diameter afferent fibers and TENS excites large-diameter afferent fibers, the authors surmise that their combined use is the reason for the effectiveness of the combined treatment against pain.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This is a very well designed RCT and an important study suggesting the effectiveness of the combined use of acupuncture with TENS. It is also commendable that patients were properly followed up until the fifth week. Interestingly, VAS scores improved about the same amount in the TENS group and the control group, but improved significantly more in the TENS + acupuncture group relative to the control group. This has clinical importance. However, there was no intention-to-treat (ITT) analysis and the results would have been more readily comprehensible if presented in graph form.

#### 12. Abstractor and date

Wakayama I, 23 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Miyazaki S, Hagihara A, Kanda R, et al. Applicability of press needles to a double-blind trial. A randomized, double-blind, placebo-controlled trial. *Clinical Journal of Pain* 2009; 25(5): 438–44. CENTRAL ID: CN-00706848

#### 1. Objectives

To evaluate the efficacy of press tack needle (円皮鍼) for low back pain.

#### 2. Design

Double blinded randomized controlled trial (DB-RCT).

#### 3. Setting

Faculty of Sports and Health Science, Fukuoka University, Fukuoka, Japan.

#### 4. Participants

Ninety university students with no experience of acupuncture treatment (recruited between 18 September and 31 October 2007).

#### 5. Intervention

Arm 1: Press tack needle (円皮鍼) group. Press tack needles (Pyonex, 0.2×0.6 mm, Seirin Co., Ltd.) were applied at the left BL23 (腎兪) acupuncture point (n=45).

Arm 2: Placebo group. Identical press tack needles, with only the needle element removed, were applied at the left BL23 (腎兪) acupuncture point (n=45).

Three participants dropped out of Arm 1 and six dropped out of Arm 2.

Participants were subdivided into healthy participants and low back pain participants. Low back pain participants were those with low back pain for several days, low back pain on examination before the intervention, or a six-month or greater history of low back pain. Therefore, Arm 1 (n=42) included nine low back pain participants and 33 healthy participants. Arm 2 included five low back pain participants and 34 healthy participants.

#### 6. Main outcome measures

Low back pain intensity rated on a visual analogue scale (VAS).

#### 7. Main results

Efficacy was greater for low back pain in Arm 1 than Arm 2 ( $P=0.03$ ). The reduction in subjective symptoms was greater among low back pain participants than healthy participants in Arm 1 ( $P<0.001$ ).

#### 8. Conclusions

Treatment with press tack needles is effective for low back pain.

#### 9. From acupuncture and moxibustion medicine perspective

While treatment at BL23 (腎兪) acupuncture point was effective for low back pain, not all treatment should be at this one acupuncture point: clinical therapists need to combine this acupuncture point with others in their treatment.

#### 10. Safety assessment in the article

Only one participant in Arm 1 complained of sleepiness.

#### 11. Abstractor's comments

This is a very well designed double-blind trial. The authors describe in detail how patients were successfully blinded to treatment allocation, inasmuch as the original purpose of the study was to determine whether press tack needle efficacy could be assessed in double-blind trials. It is also commendable that the sample size was calculated

However, the design was somewhat complex because of the subdivision of the two groups into healthy participants and low back pain participants. There was only one outcome measure (VAS score), so inclusion of another measure might have been beneficial. Unfortunately, as the authors mention, follow up ceased at 20 minutes after intervention, so any subsequent effects are unknown. Despite these issues, further development of this research offers promise.

#### 12. Abstractor and date

Wakayama I, 23 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Itoh S, Itoh K, Katsumi Y. Effect of trigger point acupuncture treatment in older patients with chronic low back pain: randomized controlled trial. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2009; 59(1): 13–21 (in Japanese with English abstract). Ichushi Web ID: 2009213798

#### 1. Objectives

To evaluate the efficacy of trigger point acupuncture treatment for chronic low back pain in elderly people.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Integrative Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Thirty-nine elderly outpatients with a six-month or greater history of chronic low back pain.

#### 5. Intervention

Arm 1: Trigger point group. Needles were inserted at  $9.4 \pm 2.3$  (mean  $\pm$  SD) locations per participant into the gluteus medius, lumbar quadratus, gluteus maximus, and iliopsoas muscles, and retained for 10 minutes. *De qi* (得氣) sensation and muscle contraction were not considered. Treatment was given once a week five times. Follow up continued until three months after treatment stopped (n=13).

Arm 2: Tender point group. Treatment was applied at tender points in the painful region. The examination to locate tender points took acupuncture points into account. Needles were inserted at  $9.7 \pm 2.3$  locations per participant at BL23 (腎兪), BL22 (三焦兪), BL25 (大腸兪), BL52 (志室), BL21 (胃兪), BL53 (胞兪), BL54 (秩辺), GB31 (風市), and EX-B7 (腰眼) acupuncture points to a depth of 10 to 20 mm and retained for 10 minutes. *De qi* sensation and muscle contraction were not considered. Treatment period and frequency were the same as in Arm 1 (n=13).

Arm 3: Sham group. Needles were inserted at  $9.0 \pm 2.2$  locations per participant at the same locations as in Arm 1. Treatment period and frequency were the same as in Arm 1 (n=13).

For a total of 5, 8, and 7 participants dropped out in Arms 1, 2, and 3, respectively.

#### 6. Main outcome measures

Low back and leg pain intensity rated on a visual analogue scale (VAS) before treatment, each treatment, and then one month and three months after treatment stopped. During the treatment period, post-treatment scores were the scores obtained before the subsequent treatment. Quality of life (QOL) scores using the Roland Morris Disability Questionnaire (RMDQ) were obtained before treatment started, after each of five treatments, and then one month and three months after treatment stopped.

#### 7. Main results

Low back and leg pain intensity changed significantly for Arm 1 compared to Arms 2 and 3 (Interaction,  $P < 0.05$ ). The decrease in pain intensity decreased from the first treatment (within-group comparison) ( $P < 0.01$ ) and persisted for three months after treatment stopped. Symptoms were not alleviated in either Arm 2 or 3.

No significant difference of QOL in three groups (group comparison). Scores improved greatly in Arm 1 (within-group comparison) but not in either Arm 2 or 3.

#### 8. Conclusions

VAS scores show that trigger point acupuncture is more effective than tender point treatment or sham treatment for chronic low back pain in elderly people. Pain is alleviated after one treatment. Trigger point acupuncture treatment of low back pain improves QOL.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This study compared trigger points and tender points as locations for acupuncture stimulation. The study compared a trigger point group, a tender point group, and a sham group, but it is regrettable that all the participants could not be retained, since some participants dropped out during the follow up. There was a significant change in the trigger point group compared to the other two groups by the end of treatment period, and clear effects could be inferred from the results of the within-group comparison. It is commendable that consideration was given to locating points with a certain level of tenderness for tender point identification. However, the method used by the authors' to locate stimulation sites raises some concern. For the sham group it was locating trigger point acupuncture sites only, for the trigger point acupuncture group it entailed examining the hip joint range of motion and locating sites, while for the tender point group it was locating the tender points in the low back and legs only. It is recommended that the effectiveness of trigger point acupuncture be verified by comparing it to the sham treatment. The researchers suggest that trigger points correspond to the pain relief points, so it may be possible to further improve the results of tender point treatment taking the classical acupuncture points into account, if it is possible to use trigger points properly. Recruitment and retention of subjects is a vital element of clinical research. It is hoped that the authors resolve this problem and move ahead with further research.

#### 12. Abstractor and date

Furuya E, 19 November 2010.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Nabeta T, Furuta T, Kitakouji H, et al. Randomized controlled pilot study of acupuncture on neck stiffness. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1997; 47(3): 173–81 (in Japanese with English abstract). Ichushi Web ID: 1998092691

#### 1. Objectives

To investigate the problems associated with conducting clinical trials of acupuncture.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT: envelope).

#### 3. Setting

Meiji School of Oriental Medicine, Osaka, Japan.

#### 4. Participants

Thirty-two student volunteers who were identified as having neck stiffness by questionnaire prior to the intervention, and who gave informed consent by signature (mean age in the two groups: 32.8 and 30.4 years).

#### 5. Intervention

Arm 1: Acupuncture group. A needle (0.2×50 mm) was inserted to a depth of 20 mm at the BL10 (天柱) point and was retained for 10 minutes after the sparrow-pecking technique was repeated 5 times (n=16).

Arm 2: Control group. A needle was used to pierce the skin at the BL10 (天柱) point but was removed after simulating insertion and sparrow pecking. Subsequent needle removal was also simulated (by deliberately making a sound when replacing the needle in the needle receptacle) (n=16).

The treatment period continued for three weeks. The volunteers received a weekly-intervention (3 in total). Two participants were dropped from Arm 1 (one due to herpes, and one due to needle pain), data were unavailable for four participants.

In Arm 2, data were unavailable for two participants (reasons unknown).

#### 6. Main outcome measures

Stiffness was measured on a visual analogue scale (VAS) before treatment, immediately after treatment, and 1, 3, 5, and 7 days after treatment. Participants were asked about neck stiffness in the stimulation region, and stiffness in the whole shoulder. Subjects were also asked after the trial what kind of acupuncture they received.

#### 7. Main results

There was no significant between-group difference in VAS change. In response to the question after the trial “What kind of acupuncture did you feel you received?,” 66.7% of participants in Arm 1 and 35.7% in Arm 2 replied “They inserted needles.” The difference was significant ( $\chi^2=7.843$ ,  $P=0.02$ ).

#### 8. Conclusions

Acupuncture has no effect on neck stiffness.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

One participant complained of needle pain in Arm 1.

#### 11. Abstractor’s comments

This study was intended to clarify the problems associated with the conduct of clinical trials of acupuncture and moxibustion by actually conducting an RCT of acupuncture. The aim of the study was not to evaluate the effect of acupuncture on neck stiffness. The authors mention that many problems result from the clinical trial design. Specifically, they discuss interventions, control group interventions, selection of disorders, recruitment bias, masking, statistical power, and intent-to-treat analysis. For researchers intending to conduct a study, the study has greater value as a reference for study design than as an evaluation of the therapeutic effect of acupuncture on neck stiffness. There were problems with the authors’ intentions and ethics, and the value of the study may have been increased by selection of a disorder and acupuncture intervention that could be applied in the clinic.

#### 12. Abstractor and date

Takahashi N, 6 December 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Nabeta T, Kawakita K. Relief of chronic neck and shoulder pain by manual acupuncture to tender points - a sham-controlled randomized trial. *Complement Ther Med*. 2002; 10:217–22. CENTRAL ID: CN-00736622.

#### 1. Objectives

To assess the relief of neck and shoulder pain and stiffness provided by treatment with real acupuncture to tender points.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

An acupuncture and moxibustion school, Osaka, Japan.

#### 4. Participants

Thirty-four staff and students from an acupuncture and moxibustion school who complained of chronic dull pain and stiffness in the neck and shoulders (20–63 years of age; average ages in the two groups: 34.2 and 30.8).

#### 5. Intervention

Arm 1: Acupuncture to tender points group. The stimulation points were all tender points in the left and right neck, shoulder, and back. Disposable needles (0.2 x 40 mm, Seirin Co., Ltd.) were inserted, then sparrow pecking technique was applied five times to elicit a *de qi* (得氣) sensation. Participants received treatment once a week for three weeks (n=17).

Arm 2: Control group. The stimulation points were all tender points in the left and right neck, shoulder, and back. Needles with rounded tips (sham needles) were used and insertion and sparrow pecking were simulated. Participants received the same number of treatments as in Arm 1 (n=17).

Two participants from Arm 1 and five from Arm 2 withdrew.

#### 6. Main outcome measures

The intensity of the pain in the neck, shoulders, and back, as well as the intensity of the stiffness in the shoulders was rated on a visual analogue scale (VAS). Pain intensities were rated before treatment (at six, four, two days, and immediately before), after each treatment (immediately, then at one, three, and five days after), and after the third treatment (at seven and nine days). Subjects were asked a question about their sensations during real and the sham acupuncture.

#### 7. Main results

VAS scores decreased significantly in Arm 1 immediately after each treatment and one day after each treatment (within the group,  $P < 0.01$ ). Scores subsequently tended to return to baseline level, but differences tended to last longer with successive treatments. Similar tendencies were observed in Arm 2, but they were not statistically significant. No significant differences were observed between the two groups at any point after treatment. Pressure pain thresholds tended to increase with real acupuncture, but not with sham acupuncture. The study managed to mask participants to the intervention.

#### 8. Conclusions

Acupuncture to tender points is effective for chronic neck and shoulder pain and stiffness for a short period.

#### 9. From acupuncture and moxibustion medicine perspective

There is a similarity between tender point sites and acupuncture points.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

The study is well designed. Worth particular mention is that the study compares the effectiveness of acupuncture therapy for neck and shoulder pain and stiffness with a sham acupuncture technique that simulates needle insertion. Also the study succeeded in blinding participants to the interventions.

A recent large-scale acupuncture clinical trial proposed 12 as the standard number of treatments, but there was no significant between-group difference in this study, which means the number of treatments was insufficient. Although the study also mentioned intention-to-treat (ITT) analysis, it is regrettable that the sample size was not designed to assure a particular power. However, using sham acupuncture as a control in clinical trials could be a model for future studies.

#### 12. Abstractor and date

Takahashi N, 3 December 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Furuya E, Nayuki T, Yakame M, et al. Effect of press tack needle treatment on shoulder stiffness. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2002; 52(5): 553–61 (in Japanese with English abstract). Ichushi Web ID: 2003144987

#### 1. Objectives

To evaluate the effect of press tack needle treatment on shoulder stiffness.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Tokyo Therapeutic Institute, Tokyo, Japan.

#### 4. Participants

A total of 53 teachers and students with awareness of (subjective) shoulder stiffness (15 males and 38 females).

#### 5. Intervention

Arm 1: Press tack needle group. Pyonex needles (Seirin Co., Ltd.; length 0.6 mm) were inserted at up to 4 tender points detected by palpation, and retained for 3 days (n=28).

Arm 2: Placebo press tack needle group. Needles with the same shape as Pyonex and tips removed were used. Stimulation was applied in the same manner as in Arm 1 (n=25).

#### 6. Main outcome measures

Visual analogue scale (VAS) score for shoulder stiffness (evaluated before, immediately after, and 3 days after the treatment) and the number of subjects with “awareness of shoulder stiffness” (based on the Hiro Jikaku-shojo Shirabe [questionnaire on subjective fatigue symptoms], developed by the Japan Society for Occupational Health; evaluated before and 3 days after the treatment).

#### 7. Main results

Comparison of pre- and post-treatment VAS scores revealed significant improvements immediately ( $P<0.05$ ) and 3 days ( $P<0.01$ ) after the treatment in Arm 1, but no significant change in Arm 2. The number of subjects with “awareness of shoulder stiffness” was significantly decreased in Arm 1 compared with Arm 2 ( $P<0.01$ ).

#### 8. Conclusions

Continuous retention of press tack needles improves shoulder stiffness.

#### 9. From acupuncture and moxibustion medicine perspective

The authors mentioned that press tack needle retention may enhance parasympathetic function, and that self-care with press tack needles might be a successful treatment for mibyō (presymptomatic disease).

#### 10. Safety assessment in the article

Adverse events occurred in 5 subjects in Arm 1 (itching in 4 and discomfort in 1) and 4 in Arm 2 (itching in 3 and discomfort in 1), but no one dropped out.

#### 11. Abstractor’s comments

This study is highly valued in that the effect of press tack needle treatment was evaluated in a double-masked trial. But, as all the subjects were teachers or students at the Tokyo Therapeutic Institute, who were likely able to distinguish press tack needles from placebo press tack needles, description about the success or failure of the double masking is needed. This revolutionary study attempted double masking (subject and practitioner masked), which is generally difficult in a clinical study of acupuncture. Future development of this type of study is anticipated.

#### 12. Abstractor and date

Hosaka M, 11 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Shinohara S. Clinical effects of acupuncture (intra-dermal needles) based on the muscle meridians for the complaints on the joints and muscles during movements. *Meiji Shinkyu Igaku (The Bulletin of Meiji University of Oriental Medicine)* 2000; 26: 65–80 (in Japanese with English abstract). Ichushi Web ID: 2001218258

#### 1. Objectives

To evaluate the efficacy of intra-dermal acupuncture based on the muscle meridians for relieving locomotor complaints (pain, stiffness, rigidity, and twitching during movement).

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Center of Acupuncture Science, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine); Outpatient Clinic of the Department of Orthopedic Surgery, the Meiji University of Oriental Medicine Hospital, Kyoto, Japan.

#### 4. Participants

Ninety patients with locomotor complaints. The mean ages for three groups were: 61.4, 63.9 and 62.4 years, respectively.

#### 5. Intervention

Arm 1: Real meridian treatment group: intra-dermal needle was inserted (transverse insertion, 0.2–0.5 mm) at the brook point (榮穴) on the periphery of the muscle meridian passing the site related to the complaints, and fixed with bandages (n=30).

Arm 2: Sham treatment group (n=30): at the same point as in Arm 1, intra-dermal needle was discarded just before the insertion and bandage fixation was applied.

Arm 3: Other meridian treatment group (n=30): intra-dermal needle was inserted (transverse insertion, 0.2–0.5 mm) at the brook point (榮穴) on the muscle meridian adjacent to that treated in Arm 1, and fixed with bandages (n=30).

Two patients in Arm 3 dropped out.

#### 6. Main outcome measures

Visual Analog Scale (VAS) score for pain during movement.

#### 7. Main results

VAS score improved significantly before and after the treatment in Arms 1 and 2 ( $P=0.0001$  and  $P=0.0287$ , respectively), whereas it did not change significantly in Arm 3. The greatest improvement in the score was seen in Arm 1. Also, reduction (“change” in the text) in VAS score was significantly greater in Arm 1 compared with Arm 2 ( $P<0.01$ ) and Arm 3 ( $P<0.001$ ).

#### 8. Conclusions

Intra-dermal acupuncture based on the muscle meridians is effective for relieving locomotor complaints.

#### 9. From acupuncture and moxibustion medicine perspective

The author mentioned that the muscle meridian, described in “Ling Shu (靈樞)”/Jing jin Muscle Regions Along Meridians (經筋篇) (No. 13), is a specific meridian system that controls functions of the locomotor system.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor’s comments

This article is valuable in that the authors described the significance of using muscle meridians for locomotor system control, based on the analysis of classic literature, and then attempted, in a clinical study, to prove a working hypothesis that muscle meridian-based treatment might contribute to the improvement of locomotor complaints. The author’s attempt to evaluate the original effects of intra-dermal acupuncture on locomotor complaints, rather than on disorders, is also appreciated. Some improvements may be needed in the following aspects: 1) the author did not mention sham needle when obtaining informed consent; 2) VAS was the only outcome measure; 3) only direct effects immediately after the treatment were evaluated and no follow-up was carried out; and 4) masking status was not evaluated. Further development of studies on the muscle meridians is anticipated.

#### 12. Abstractor and date

Wakayama I, 9 September 2011.

### 13. Diseases of the Musculoskeletal and Connective Tissue

#### Reference

Ito K, Katsumi Y. Effect of acupuncture treatment on chronic low back pain with leg pain in aged patients - a controlled trial about short-term effects of trigger point acupuncture -. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 2005; 55 (4): 530–37 (in Japanese with English abstract). Ichushi Web ID: 2005296314

#### 1. Objectives

To evaluate the efficacy of trigger point acupuncture treatment for chronic low back pain (LBP) with leg pain in aged patients.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Department of Orthopedic Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Forty-four outpatients (aged 65 years or older) with LBP and leg pain persisting for at least 6 months.

#### 5. Intervention

Arm 1: Standard acupuncture group (n=11), Standard acupuncture applied to traditional acupuncture points..

Arm 2: Superficial trigger point acupuncture group (n=11).

Arm 3: Deep trigger point acupuncture group (n=11).

Arm 4: Sham trigger point acupuncture group (n=11).

The intervention performed once a week for 3 weeks. Dropped out rate was 18% (8/44).

#### 6. Main outcome measures

The intensity of LBP with leg pain was assessed using a visual analog scale (VAS), and quality of life (QOL) was assessed using the Roland-Morris Disability Questionnaire (RDQ).

#### 7. Main results

At the end of the treatment period, pain intensity and QOL were significantly improved in Arm 3 alone compared with Arm 4 ( $P<0.01$ ). The effects persisted during the 3-week follow-up. Comparison of final values in Arm 2 with baseline values in each arm revealed a significant effect of superficial trigger point acupuncture.

#### 8. Conclusion

Trigger point acupuncture can be an effective treatment for chronic low back pain with leg pain in aged patients.

#### 9. From acupuncture and moxibustion medicine perspective

The observation that deep needling of the trigger points is more effective than standard acupuncture at traditional acupuncture points is interesting, as traditional acupuncture points and trigger points are closely related. However, this matter is not discussed.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comment

This is a well-designed clinical study with four parallel arms, and the trial and analyses were appropriately conducted. The report indicates that trigger point acupuncture treatment once a week for 3 weeks significantly improves chronic low back pain (with leg pain) in the elderly. On the other hand, the report showed that standard acupuncture at traditional acupuncture points and superficial needling of the trigger points are ineffective. Sham acupuncture (mimicked needling without insertion of the needle) was used successfully for single-masking. Pain intensity was rated on a VAS with 100 as the greatest pain ever experienced, which should have been the greatest pain imaginable. Also, methods other than the envelope method, such as assignment by a computer-generated randomization list, were attempted for appropriate randomization. Regrettably there is no description of adverse events. Anyhow, more high-quality studies like this one are indicated.

#### 12. Abstractor and date

Kawakita K, 15 December 2010.

## Symptoms and Signs

### Reference

Tomita K, Kitakoji H, Honjo H, et al. Effect of moxibustion treatment for nocturia: a randomized controlled trial. *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion: JJSAM)* 2009; 59(2): 116–24 (in Japanese with English abstract). Ichushi Web ID: 2009213798

### 1. Objectives

To evaluate the effectiveness of moxibustion treatment for nocturia.

### 2. Design

Randomized controlled trial (RCT).

### 3. Setting

Home and the Department of Urology, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

### 4. Participants

Forty eight outpatients with nocturia refractory to drug treatment who visited a department of urology.

### 5. Intervention

Arm 1: Moxibustion group (n=25). Indirect moxibustion applied to the CV3 (中極) acupuncture point, self-administered three times/day for one week.

Arm 2: Sham moxibustion group (n=23). Indirect moxibustion without adequate heating. Duration and frequency of the treatment were the same as in Arm 1.

Drop-out rate was 25% (12/48).

### 6. Main outcome measures

The number of nocturia events.

### 7. Main results

Treatment significantly decreased the average number of nocturia episodes in Arm 1 ( $P<0.01$ ), but not in Arm 2 ( $P=0.551$ ). There was no significant between-group difference in effectiveness ( $P=0.306$ ).

### 8. Conclusion

Indirect moxibustion may be able to improve nocturia.

### 9. From acupuncture and moxibustion medicine perspective

The CV3 (中極) acupuncture point was selected because it was 1) expected to affect bladder function regulation, and 2) be suitable for self-administration of moxibustion.

### 10. Safety assessment in the article

Second-degree burns were documented in 3 cases in Arm 1.

### 11. Abstractor's comment

Sham moxibustion (indirect moxibustion; application of insufficient heat) was used as control in this study, and validity of the sham moxibustion as control was also assessed. As there have been few RCT studies on moxibustion, this study should provide valuable information. Notably, the average number of nocturia events, the outcome measure of this trial, was significantly decreased in the treatment group. However, finding of no significant difference between arms was disappointing. The results were not assessed by ITT analysis even though some subjects withdrew from the study. Group allocation might have been biased by symptoms and underlying medical conditions. Indirect moxibustion performed at home might hamper recruitment of subjects and result in increased drop-out rate, but even so, these problems can be solved and lead to further progress in the studies.

### 12. Abstractor and date

Takahashi N, 10 August 2010, 21 August 2010.

## 18. Symptoms and Signs

### Reference

Minagawa M, Ishigami T, Hori S, et al. Controlled clinical trials using the envelope method for urinary dysfunction — the effectiveness of the zhongji (cv-3). *Zen Nihon Shinkyu Gakkai Zasshi (Journal of the Japan Society of Acupuncture and Moxibustion)* 1999; 49(3): 383–91 (in Japanese with English abstract). Ichushi Web ID: 2000067347

#### 1. Objectives

To evaluate the effects of treatment for urinary dysfunction as chief complaint, and treatment plus acupuncture at the CV3 (中極) acupuncture point.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Nine practicing acupuncture and moxibustion clinics, Japan.

#### 4. Participants

Ninety patients with urinary dysfunction symptoms identified by questionnaire (mean age in the two groups: 59.8 and 59.7 years).

#### 5. Intervention

Arm 1: CV3 (中極) group. Single needle treatment (5–7 mm) at the CV3 (中極) acupuncture point, in addition to treatment for the chief complaint (n=44).

Arm 2: Control group. Treatment for the chief complaint only (n=46).

Treatment in both groups at least once a week (three times in total).

#### 6. Main outcome measures

Evaluation of urinary dysfunction by questionnaire before each treatment and after the third treatment.

#### 7. Main results

No significant between-group and between-gender differences were observed in the change in overall urinary dysfunction score, frequency of nighttime urination, and daytime urination interval.

#### 8. Conclusions

Acupuncture stimulation at the CV3 (中極) acupuncture point has no effect on urinary dysfunction.

#### 9. From acupuncture and moxibustion medicine perspective

Not mentioned.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

The authors should be commended for having conducted a multi-center RCT with 90 urinary dysfunction patients. It is an important paper that demonstrates a study can be conducted at acupuncture and moxibustion clinics. Regrettably, the authors do not describe how they estimated sample size and how random allocation and masking were conducted. In addition, it is possible that the outcome was negative because the intervention was the usual treatment in the control group and only the usual treatment plus CV3 (中極) acupuncture in the intervention group. We anticipate further research that addresses those problems, since the authors did manage to conduct this multi-center randomized controlled trial.

#### 12. Abstractor and date

Shinohara S, 31 January 2011, Takahashi N, 11 January 2012.

## 18. Symptoms and Signs

### Reference

Yamazaki T, Fukuda F, Ishizaki N, et al. The effect of acupuncture on chronic fatigue in healthy subjects. *Nihon Mibyou Shisutemu Gakkai Zasshi (The Journal of Japan Mibyou System Association)* 2009; 15(2): 186–96 (in Japanese with English abstract). Ichushi Web ID: 2010161854

### 1. Objectives

To evaluate the effectiveness of acupuncture for chronic fatigue (*mibyou* [未病]; fatigue with no medical explanation).

### 2. Design

Randomized controlled trial (RCT).

### 3. Setting

Not described.

### 4. Participants

Nineteen workers from a firm in northern Kyoto prefecture who noticed persistent fatigue over the previous 6 months but no other related medical abnormality (age range, 25–65; mean age, 50.4 and 46.2 years, respectively).

### 5. Intervention

Arm 1: Acupuncture group. History taking (interview) and acupuncture treatment for fatigue twice a week for a total of 16 times (eight weeks). The basic acupuncture points were the LI4 (合谷), ST36 (足三里), KI3 (太谿), and BL23 (腎俞), and additional acupuncture points were selected for use in treatment according to the complaint location. Stainless steel needles (0.14×30 mm; Seirin Co., Ltd.) were used (n=9).

Arm 2: Control group. Interview conducted once a week (n=10).

One participant dropped out of Arm 2.

### 6. Main outcome measures

Subjective measures

Subjective physical fatigue and mental fatigue (visual analogue scale, VAS). General Health Questionnaire-12 (GHQ-12), and accumulated fatigue (Self-Diagnostic Checklists for Accumulated Fatigue, Ministry of Health, Labour, and Welfare).

Objective measures

Blood chemistry (ACTH, dopamine, adrenalin, noradrenalin, and cortisol), sleep efficiency scores (measured by actigraphy), and level of oxidative stress (8-hydroxy-2-deoxyguanosine [8-OHdG]) and potential antioxidant [PAO]).

### 7. Main results

All subjective measures improved significantly in Arm 1 compared to Arm 2 ( $P=0.001-0.034$ ). Differences in objective measures were not significant either before and after interventions, or between groups.

### 8. Conclusions

Acupuncture alleviates chronic fatigue with no medical explanation (*mibyo*).

### 9. From acupuncture an

### 10. d moxibustion medicine perspective

Fatigue is treated as a deficiency of the qi (気虚, *kikyo*) and blood (血虚, *kekkyo*). LI4 (合谷), ST36 (足三里), KI3 (太谿), and BL23 (腎俞) are considered the basic acupuncture points for treatment of those deficiencies.

### 11. Safety assessment in the article

No adverse event was developed.

### 12. Abstractor's comments

This study treats physical and mental fatigue as *mibyou*, and uses multiple measures to examine the effects of acupuncture in detail on this pathological condition. The authors properly present the baseline information for each group, the flowchart on allocation, and adverse event information. There were few participants (9 and 10 in the respective groups), and there was no follow up at the end of the 8-week study period. These are areas needing improvement. Focusing attention on *mibyou* is very significant for acupuncture and moxibustion. Expectations are great for future development in this area.

### 13. Abstractor and date

Haruki J, 9 September 2011.

## 18. Symptoms and Signs

### Reference

Sakaguchi S, Kanai S, Toda S. A randomized controlled trial of the effect of acupuncture and moxibustion on sensitivity to cold\*. *Kansai Iryou Daigaku Kiyou (The Bulletin of Kansai University of Health Sciences)* 2007; 1: 82–5 (in Japanese). Ichushi Web ID: 2008048658

#### 1. Objectives

To evaluate the effect of acupuncture and moxibustion on sensitivity to cold.

#### 2. Design

Randomized controlled trial (RCT).

#### 3. Setting

Kansai College of Oriental Medicine, Osaka, Japan.

#### 4. Participants

Nineteen volunteers with sensitivity to cold who: 1) responded to recruitment advertisements posted on the bulletin board in Kansai College of Oriental Medicine for approximately 2 weeks from the end of October 2005; and 2) provided written and oral informed consent (mean age, 20.5±3.2 years; range, 18–32 years).

#### 5. Intervention

Arm 1: Acupuncture group. In the supine position, disposable stainless steel needles (0.25×20 mm, Seirin Co., Ltd.) were inserted to a depth of 15 mm at the SP6 (三陰交) and ST36 (足三里) acupuncture points. Pre-cut moxa for heating (Hiei™, Senefa Corporation) was attached to the needle handle and burned. At the same time, warming moxibustion was applied around the CV4 (關元) acupuncture point by using 4 moxa rolls (Fukuju-koh™, Nippon Wakame Fukyu Kyokai) inserted in a guide tube for warm moxibustion (蓮台). Then, in the prone position, the moxibustion was applied around the BL32 (次髎) acupuncture point in the same manner as described above for CV4 (關元) while irradiating the lumbar area with infrared light (n=10).

Arm 2: Control group. No treatment during the intervention period (n=9).

One subject in Arm 1 with incomplete data was excluded from the analysis.

Treatment was administered taking into consideration each subject's menstrual cycle; once or twice per week, a total of 5 times, between the end of the menstrual period and the beginning of the next one.

#### 6. Main outcome measures

Degree of suffering from coldness assessed on a 6-point numerical rating scale (0–5; self-administered): 0=no cold feeling, 5=maximal coldness.

Score for static blood (瘀血, *oketsu*) measured by a masked evaluator before and after the intervention.

Peripheral blood hematocrit, remnant-like particles-cholesterol (RLP-C) level, and viscosity.

#### 7. Main results

Degree of suffering from coldness showed no interaction with treatment arms and no significant between-arm difference. Similarly, score for static blood showed no interaction with treatment arms and no significant between-arm difference. The three hematologic variables also showed no interaction and no significant between-arm difference.

#### 8. Conclusions

Acupuncture and moxibustion has no additional effect over that of control treatment on sensitivity to cold.

#### 9. From acupuncture and moxibustion medicine perspective

The authors linked the development of sensitivity to cold with static blood.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This valuable RCT evaluated the efficacy of acupuncture and moxibustion for reducing sensitivity to cold as compared with no treatment. Although the validity was not evaluated, the study is appreciated for seeking high-quality RCT by masking the evaluator of the static blood score. As a result, no effect of acupuncture and moxibustion was found, but it may become possible to detect a therapeutic effect on sensitivity to cold if sample size were predefined and outcome measures changed. The selection of treatment acupuncture points seems to have taken the link between sensitivity to cold and static blood into account, but the quantity and quality of the intervention should be discussed more extensively. Since sensitivity to cold is thought to occur over a wide age range, comparative trials including a wider range of age groups is desired.

#### 12. Abstractor and date

Takahashi N, 6 December 2011.

## 19. Post-anesthesia and Postoperative Pain

### Reference

Ishimaru K, Sakita M. Effects of acupuncture analgesia on postoperative pain. *Toyo Igaku to Pain Clinic (Oriental Medicine and the Pain Clinic)* 2002; 32(1-4): 10-18 (in Japanese with English abstract). Ichushi WEB ID: 2004115450.

#### 1. Objectives

To evaluate the effects of acupuncture analgesia on postoperative pain.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### 3. Setting

Department of Surgery, the Meiji University of Oriental Medicine (current Meiji University of Integrative Medicine) Hospital, Kyoto, Japan.

#### 4. Participants

Twenty-two outpatients who received abdominal surgery under general anaesthesia.

#### 5. Intervention

Arm 1: Electro-acupuncture group. Electro-acupuncture treatment (3 Hz) applied at the LI4 (合谷) and ST36 (足三里) acupuncture points was performed at three hours after surgery for three hours (n=11).

Arm 2: Non-energization group. No needle insertion or energization (n=11).

#### 6. Main outcome measures

$\beta$ -endorphin and adrenocorticotrophic hormone (ACTH) levels in peripheral blood, subjective pain evaluation.

#### 7. Main results

Post-operative  $\beta$ -endorphin levels were higher than pre-surgery levels in Arm 1 and although they had decreased by three hours after surgery (before electro-acupuncture commenced), they increased again immediately after electro-acupuncture. In contrast, while levels were higher than pre-surgery levels in Arm 2, they continued to decrease linearly with time. There was a significant difference ( $P<0.05$ ) between groups in the levels six hours after surgery (after completion of electro-acupuncture). The average ACTH levels in Arm 1 were  $42.8\pm 27.4$  pg/mL before surgery, and  $335.4\pm 205.7$  pg/mL one hour after surgery commenced. In Arm 2, the average ACTH levels were  $37.6\pm 19.2$  pg/mL before surgery, and  $237.1\pm 178.0$  pg/mL one hour after surgery commenced. This meant a significant increase ( $P<0.01$ ) from pre-surgery levels in both groups. ACTH levels continued to decrease in both groups after surgery, and no significant difference between groups was found. Painkillers were required for only one of the 11 participants in Arm 1, but they were required for 10 of the 11 participants in Arm 2.

#### 8. Conclusions

Post-operative electro-acupuncture decreases painkiller usage by raising  $\beta$ -endorphin levels.

#### 9. From acupuncture and moxibustion medicine perspective

The trial selected the LI4 (合谷) and ST36 (足三里) acupuncture points, which, as the basic data and the results of surgery during acupuncture anesthesia suggest, offer the most pain relief.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This interesting study compares the effects of acupuncture analgesia for post-operative pain using the time course of  $\beta$ -endorphin and ACTH levels in blood; it also evaluates painkiller dosage and mentions the mechanism of action of acupuncture analgesia as well as its effects. Unfortunately the envelope method was used for randomization. The control group was described as the "non-energization group," but in fact, no needles were inserted, so "no treatment group" would be a more apt description. This is an important study that suggests the clinical usefulness of acupuncture analgesia. Further examination is desirable.

#### 12. Abstractor and date

Inoue E, 27 January 2010.

## 21. Others

### Reference

Kuge H, Hatano Y, Mori H. Influence of fireless moxibustion on QOL (SF-36®) in elderly people. *Nihon Onsen Kiko Butsuri Igakkai Zasshi (The Journal of the Japanese Society of Balneology, Climatology and Physical Medicine)* 2008; 71(3): 180–6 (in Japanese with English abstract). Ichushi Web ID: 2008252546

#### 1. Objectives

To evaluate the effectiveness of fireless moxibustion at home to maintain QOL for elderly people.

#### 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

#### Setting

Subjects' homes, Japan.

#### 3. Participants

Twenty-seven elderly people living at home (10 males, 17 females, ages 66–94).

#### 4. Intervention

Arm 1: Fireless moxibustion group. Fireless moxibustion (Sennenkyu Taiyo®, Senefa Corporation) was used for about one hour each at the bilateral BL23 (腎兪) and ST36 (足三里) acupuncture points, every two days for a total of four treatments (n=11).

Arm 2: Sham fireless moxibustion group. Same treatment, but using Sennenkyu Taiyo® altered to give off no heat (n=16).

#### 5. Main outcome measures

SF-36™ Ver.2 acute Japanese version, evaluation on day 7, 14, and 21.

#### 6. Main results

Scores related to “bodily pain” in the SF-36 (questions seven and eight) improved significantly after treatment in Arm 1 ( $P<0.05$ ).

#### 7. Conclusions

Fireless moxibustion used at home relieves bodily pain in elderly people.

#### 8. From acupuncture and moxibustion medicine perspective

None.

#### 9. Safety assessment in the article

Not mentioned.

#### 10. Abstractor's comments

This study is of great significance for its focus on fireless moxibustion, which can be easily used at home to maintain or improve the QOL of elderly people, whose numbers continue to grow in Japan. The study evaluated low back and leg complaints; however, there was a pretreatment difference between the two groups. Therefore, the recruitment process might have been improved by stratifying participants by complaint after recruitment, or recruiting participants with low back and leg complaints. Masking subjects was difficult and bias might have been introduced as one type of moxa heated up to 50°C and the other did not heat up. It would be preferable to describe the timing of the trial and the success or failure of masking.

This therapy holds promise for elderly people trying to maintain or improve their QOL. Having a therapy that users can manage themselves, without frequent visits to a medical facility, is of great help to elderly people who live far from town or city centers. Further research is anticipated.

#### 11. Abstractor and date

Shimoichi Y, 11 September 2011.

