JTCM 中医杂志 Journal of Traditional Chinese Medicine

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J Tradit Chin Med 2018 August 15; 38(4): 465-479
ISSN 0255-2922

SYSTEMATIC REVIEW

Meta-analysis on randomized controlled trials for scalp acupuncture treatment of stroke: A systematic review

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Supported by the Convergence of Conventional Medicine and Traditional Korean Medicine R & D Program Funded by the Ministry of Health & Welfare through the Korea Health Industry Development Institute (KHIDI) (No. HI14C0862)
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Accepted: February 19, 2017

Abstract

OBJECTIVE: To conduct a systematic review to assess the clinical effectiveness of scalp acupuncture (SA) for stroke.

METHODS: Literature searches were performed in 7 databases up to 16 August 2014, and all the randomized controlled trials (RCTs) in which SA therapy was administered to stroke patients were selected. Methodological quality was assessed using the Jadad score, the Cochrane risk of bias assessment, and the Standards for Reporting Interventions in Clinical Trials of Acupuncture.

RESULTS: Of a total of 2086 papers, 21 RCTs were selected. Meta-analysis revealed significant differences in the total efficacy rates of the SA group and the body acupuncture (BA) group *vs* the medication group ($P < 0.002$, $P < 0.000\ 001$, respectively), the SA plus BA group vs the BA group ($P < 0.001$); in the motor function of the SA plus BA group *vs* the BA group ($P = 0.077$); and in the nerve function of the SA group *vs* the SA plus BA group ($P < 0.0001$).

CONCLUSION: The results of our systematic review showed that SA therapy may exhibit effects in treatment efficacy and in the recovery of motor and nervous functions in patients with acute to chronic stroke. However, because of the lack of methodological quality, the thoroughly planned clinical studies are still required.

Keywords: Stroke; Review; Meta-analysis; Randomized controlled trial; Scalp acupuncture; Cochrane risk of bias; Jadad score

INTRODUCTION

Stroke is one of the three primary causes of death in Korea, and it has the next highest mortality rate after

malignant neoplasm (cancer) in both males (9.3%) and females (11.5%).[1] Stroke is a key cause of death not only in China,[2] but also in Western countries.[3] Risk factors for stroke include hypertension, myocardial infarction, atrial fibrillation, diabetes, hyperlipidemia, asymptomatic coronary artery disease, smoking, drinking alcohol, lack of exercise, oral contraceptives, and obesity.[4] After stroke, whether due to cerebral infarction or cerebral hemorrhage, the mortality rate is high, the possibility of a return to social life is low, and because stroke commonly occurs in individuals between the ages of 40 and 60 years, the socio-economic losses are large.[5]

Scalp acupuncture (SA), one of the therapies for stroke in Traditional Korean Medicine, involves inserting needles in parts of the scalp that correspond to functional principles of Western Medicine, where each cortical area is considered to be specialized for a distinct, characteristic function. The corresponding parts on the scalp areas are assigned as acupuncture stimulating zones for the motor zone, sensory zone, language zone, equilibrium zone, and reproductive zone, according to their corresponding locations on the cerebral cortex.

SA may exert therapeutic effects *via* such symptom-related areas, and many studies have been performed on the use of SA for diseases relating to the brain.[6] SA has been shown to be effective for quadriplegia, numbness, aphasia, blindness, and paresthesia, which are all the conditions that originate in the brain.[7] It has also been confirmed that acupuncture on the projection zone of the scalp corresponding to a particular functional region of the cerebral cortex is effective for treating some diseases of the central nervous system.[7] In addition to the standardized measures for acupuncture points of SA officially provided by WHO in November 1989, there are the other SA systems, e.g., Fang Yunpeng, Tang Songyan, and Jiao Shunfa.[8,9]

The effects of SA for central post-stroke pain,[10] hemiparalysis due to stroke,[11] dysphagia due to stroke,[12] and strokes per se [6,13] have been reported, which involve only individual cases, so making it difficult to access the overall efficacy. The systematic reviews of the use of SA for acute ischemic stroke[14] and the efficacy of SA on stroke recovery[15,16] have also been reported, but these studies admitted to a lack of high-quality clinical research due to the absence of descriptions for random allocation and blinded-testing methods.

In the present systematic review, we used domestic and overseas databases to find clinical studies on the use of SA for stroke, so as to investigate the efficacy of the treatment methods. It is suggested through qualitative assessment that SA can be clinically utilized for treatment of the sequelae of stroke, regardless of the time elapsed since stroke occurrence.

METHODS

Data sources and searches

We searched the published papers up to August 2014 and the databases registered with Korean Traditional Knowledge Portal (KTKP, http://www.koreantk.com), National Digital Science Library (NDSL, http://www.ndsl.kr), Korean Information Service System (KISS, http://kiss.kstudy.com), China National Knowledge Infrastructure (CNKI, www.cnki.co.kr), National Institute of Information Scholarly and Academic Information Navigator (CiNii, http://ci.nii.ac.jp), ScienceDirect (http://www.sciencedirect.com), and PubMed (http://www.ncbi.nlm.nih.gov/pubmed). The search words used were "stroke, hemiplegia, cerebral, infarction, cerebral infarction, cerebrovascular, apoplexy" and "acupuncture, scalp acupuncture, head acupuncture, skull acupuncture, brain acupuncture, cerebral acupuncture, cranial acupuncture". No limits were applied for language and country.

The search strategy for PubMed is as follows:

#1 "Acupuncture"[MeSH terms]
#2 "Scalp Acupuncture" [Title/Abstract]
#3 "Head Acupuncture" [Title/Abstract]
#4 "Stroke" [MeSH terms]
#5 "Cerebral Infarction" [MeSH terms]
#6 "Cerebral" [Title/Abstract]
#7 "Cerebrovascular" [Title/Abstract]
#8 #1 OR #2 OR #3
#9 #4 OR #5 OR #6 OR #7
#10 #8 AND #9

Literature selection/exclusion criteria

Among the papers published domestically and abroad, the randomized controlled trials (RCTs) were selected, in which SA was administrated to patients with stroke diagnosed through computed tomography (CT) or magnetic resonance imaging (MRI), regardless of age, sex, and other demographic factors. Studies that used invasive acupuncture methods, such as body acupuncture, pharmacopuncture, and electro-acupuncture, etc., were all included. Moreover, those that also used speech therapy, Western or Chinese Medicine, exercise treatment, and rehabilitation, as well as traditional Korean medical treatments, including moxibustion, cupping, and herbal medicine, were all included. RCTs that compared a control group implementing a placebo or sham treatment for stroke patients with a scalp acupuncture treatment group were included. In this study, both parallel and cross-over RCTs were included, but the non-randomized case reports and case-control studies were excluded. Only the papers with available full text were included in our study.

Data extraction and qualitative assessment

Data were extracted by concentrating on the time of onset, symptoms, the intervention therapy method, the duration and frequency (acupuncture criteria), the randomization method, the assessment tool, the control settings, the number of subjects, the therapeutic effectiveness, and the year of paper publication. As for methodological quality assessment tools, we used the Jadad score,[17] conceived in 1996 by Jadad *et al* as a

score to represent the quality of clinical trials based on the importance of randomization and blinding, as well as the Cochrane group's risk of bias (RoB).[18] Quality was measured by designating 'high', 'low', or 'uncertain' risk of bias, according to the 5 categories of bias, viz., selection bias, performance bias, result confirmation bias, elimination bias, and report bias. Moreover, the FEAS (the influencing factors that affect the effectiveness of acupuncture) rating scale was used to assess such factors as acupuncture rationale, methods of stimulation, treatment regimen, and practitioner background, in order to measure the quality of the clinical study.[19,20] These factors reflect the distinct characteristics of acupuncture based on the Standards for Reporting Interventions in Controlled Trials of Acupuncture 2010 (STRICTA) with recommendations prepared by the University of Exeter in England in 2001.

Comprehensive meta-analysis

Extracted data included the total efficacy rate of the disease, the National Institutes of Health Stroke Scale (NIHSS) score, the Modified Barthel Index (MBI) or Barthel Index (BI) score, the motor function and nervous function scores, the Functional Independence Measure (FIM) score, the Rankin scale score, etc. Using Comprehensive Meta-Analysis Ver.3.0 (Biostat, USA), risk ratios (*RR*) and 95% confidence intervals (*CI*) of the total efficacy rate were calculated for dichotomous data. For quantitative data, it was performed through determining weighted-mean difference (*WMD*) and 95% *CI*. Standard differences in the means (*SDM*) and 95% *CI* of motor function and nerve function were calculated for continuous data. Heterogeneity was analyzed through *q*-tests, and it was determined that when the *P*-value was above 0.1 and when I^2 was greater than 50%, the heterogeneity was high. Where possible, we assessed publication bias using a funnel plot. Post-hoc sensitivity analyses were performed to test the robustness of the overall effect.

RESULTS

Literature search and analysis

A total of 2086 papers were found in the 7 databases searched, of which 700 papers with duplicate titles or abstracts, 129 papers unrelated to stroke, 779 papers unrelated to SA, and 369 papers not involving humans were eliminated. Of the remaining 109 papers, 23 case studies, 17 systematic reviews, 12 narrative reviews, and 5 research articles were excluded, while those remaining papers with full text available were selected. Among the selected 40 RCTs, 8 papers with inappropriate control groups, 3 papers using mixed treatment for the treatment group, 5 papers with SA applied to both the control and treatment groups, and 2 papers that did not study the therapeutic efficacy of SA therapy were excluded. A total of 21 RCT papers were finally selected. The process used for the literature search for application in the systematic review is summarized in Figure 1.

Data extraction and analysis

Based on the 21 RCT papers finally selected, the number of subjects, gender, age, disease period, therapy, assessment method and the results in terms of stroke are summarized in Table 1; the SA therapy method, treatment period, follow-up period, and treatment site of each RCT are summarized in Table 2.

General characteristics of the subjects

Of the 21 RCT papers (2231 patients with stroke) included in the present study, there were 9 papers targeting patients with cerebral infarction (CI), 9 papers for patients with cerebral hemorrhage (CH) or CI, 2 papers for patients with CI and cerebral thrombosis (CB), and 1 paper for patients with CB, all published from 2001 to 2013. Among the total of 2231 subjects in these clinical studies, 737 males and 537 females participated, and although the age ranged from 24 to 83 years, 9 studies did not mention the gender and age.[21,23-26,28,34,37,38] The time elapsed since the stroke ranged from a minimum of 3 h to a maximum of 25 years, and there were 6 papers for acute cases, 2 papers for subacute cases, 1 paper for chronic cases, and 8 papers for a parallel study from acute to chronic; 1 RCT did not mention the disease period.[26] Assessment parameters for each treatment were the total efficiency rate (%), NIHSS, MBI, motor function, Activities of daily living (ADL), neuronal deficit score, FIM, and Rankin scale. Eleven papers assessed the total efficiency rate (%),[7,21,22,23-28,31,38,39] 3 papers assessed the motor function,[22,24,28] and 5 papers assessed the nerve function.[23,27,30,37,39] These characteristics are given in detail in Table 1.

There were 5 studies that used Zhu's SA system,[13,24,26,28,36] 9 studies used the standard SA,[7,22,23,27,30,31,33,37,38] 5 studies combined Zhu's SA with standard SA,[21,25,29,32,35] 1 study used Yamamoto's SA,[34] and 1 study used the anatomy-based SA.[39] The treatment methods used for the treatment group, the treatment period, follow-up period, and the site of SA are detailed in Table 2.

Qualitative research

For qualitative assessment of the 21 RCT papers, the Jadad score and the Cochrane risk of bias assessment were calculated. In terms of randomization methods, 4 papers used a method following diagnostic procedures,[13,22,24,36] 1 paper used an Excel random number producer,[21] 2 papers used a random number table in the SAS program,[22,35] 1 paper used block randomization in a computer program,[33] and 1 paper used a table of random numbers;[37] the other RCT papers did not mention randomization methods. In terms of blinding, 3 papers used single-blinding of the assessor,[13,26,34] 1 paper used single-blinding of the participants,[23] 1 paper used

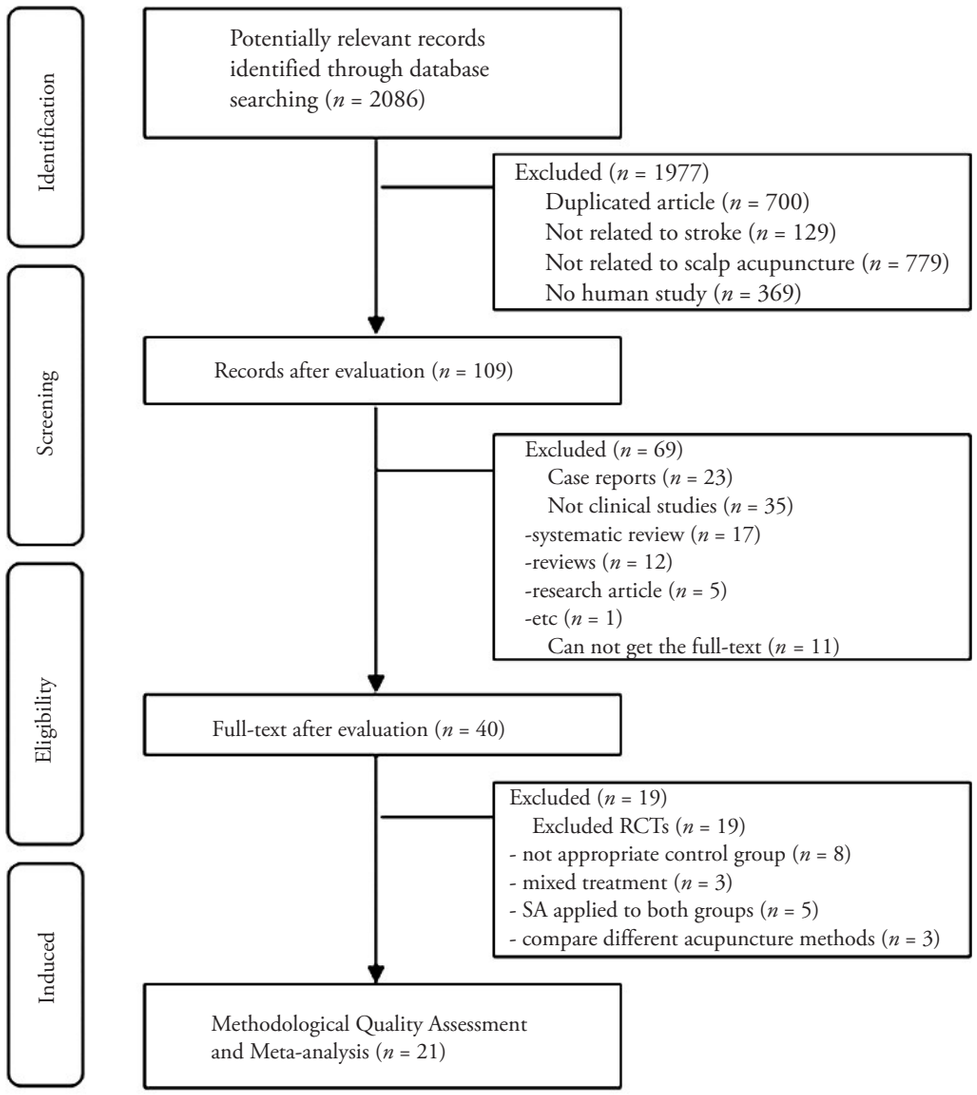

Figure 1 Flow diagram for literature search

single-blinding of the practitioner,[32] and 1 paper used double-blinding of the practitioner and evaluator;[27] the other RCT papers did not mention whether or not they used blinding. Out of the 3 RCT papers that reported whether there were any dropouts, 1 study reported no dropouts[32] and 2 studies reported dropouts.[13, 34] Therefore, 5 papers had Jadad scores that exceeded 3 points.[13,27,32-34] These results are summarized in Table 3.

The results of the Cochrane risk of bias assessment showed a high risk of randomization bias for 4 papers[13, 22,24,36] and low risk for 5 papers.[21,25,33,35,37] In terms of allocation concealment bias, 4 papers[21,25,33,35] showed a low risk of bias and 6 papers[13,22,24,34,36,37] showed a high risk of bias. For bias on subject blinding, 2 papers[27,32] showed a low risk of bias and 16 papers[21,22-25,28-31,33-39] showed a high risk of bias. For bias in terms of assessor blinding, 6 papers[13,27,29,32-34] showed a low risk of bias; and for bias regarding insufficient data, 1 paper[32] showed a low risk of bias while 2 papers[13, 24] showed a high risk of bias. In terms of bias on selective reporting, 8 papers[13,23,25,30,32-35] showed a low risk of bias while 7 papers[7,21,22,24,25,27,28] showed a high risk of bias. These results are summarized in Table 4.

Quality assessment was conducted using FEAS, which is designed to reflect the distinct characteristics of acupuncture. Regarding assessment criteria for the basis of acupuncture therapy, such as the presence or absence of a demonstration (1 point), the presence or absence of a basis for choosing meridian points of acupuncture therapy (2 points), and the presence or absence of the names of acupuncture points (3 points), all RCTs scored more than 4 points. In terms of assessment criteria for methods of stimulation, such as the presence or absence of de-*Qi* (1 point), the number of needles used (0.5 point), the depth of needle insertion (0.5 point), the duration of leaving needles in place (0.5 point), the type of needle used (0.5 point), the direction of needle placement (0.5 point), the position of the patient (0.5 point), and the method of needle stimulation (1 point), the RCTs scored from 1 to 4.5 points. Concern-

Table 1 Summary of the randomized control trials of SA for stroke included in this study

Study	Type of brain disease [sample size, male/female, average age (years)]	Average duration of disease	Intervention group [sample size, male/female, average age (years)]	Control group [sample size, male/female, average age (years)]	Outcome measure	Results
Cho *et al* 2003[13]	CH/CI (*n*=22, 8/14, 44-79, 65.8)	(A) 3.60±3.06 d (B) 3.33±2.77 d	(A) SA (B) (*n*=10, 3/7, 66.90±7.62)	(B) Conventional ba combined with medication and routine therapy (*n*=12, 5/7, 64.75±7.62)	NIHSS MBI	NIHSS was statistically significantly decreased after treatment, as compare with group B (P<0.05) MBI showed statistically significant increase after treatment, as compared with group B (P<0.05) No significant difference between the two groups after treatment
Ha *et al* 2001[6]	CH/CI (*n*=29, 8/21, 40-79)	1 week to > 6 months	(A) SA combined with (B) (*n*=14)	(B) BA combined with moxibustion, physiotherapy and chinese medicine (*n*=15)	Total efficacy rate (%) Motor function by Rankin	No significant difference between the two groups after treatment
Liu and Shi 2013[21]	CB/CH/CI (*n*=60)	(A) 15 d to 14 months (3.2±0.1 months) (B) 15 d to 13 months (3.0±0.2 months)	(A) SA combined with (B) (*n*=33, 19/14, 29-67, 55.0±3.5)	(B) Medication and rehabilitation (*n*=27, 18/9, 30-66, 53.0±4.9)	Total efficacy rate (%) Whole blood viscosity, plasma viscosity, hematocrit	Effective rate of group A>90.9%, compared to 70.4% in group B (P<0.05) Whole blood viscosity, plasma viscosity and hematocrit after treatment in group A were lower than those of group B (all P<0.05)
Qiu 2013[22]	CH/CI [(*n*=136, 70/66, 35-83, 63)	5-130 d (15.4 d)	(A) SA combined with rehabilitation (*n*=48) (B) rehabilitation with (C) (*n*=53)	(C) Medication (*n*=35)	Total efficiency rate Speech and limb function	Scores of consciousness, speech and limb functions more statistically significantly different in group A than in groups B and C (P< 0.01 and P<0.05) Total effective rate of group A was better than that of the other two groups (both P<0.01)
Shi and Zheng 2007[23]	CB (*n*=93)	(A) 31-69 d (37.98±4.96) (B) 31-67 d (37.24±5.15) (C) 31-67 d (38.72±5.22)	(A) SA (twirling method) combined with (B) (*n*=31, 21/10, 48-75, 68.93±4.71) (B)SA (drawing method) with (C) (*n*=31, 20/11, 49-75 (68.72±5.25)	(C) Routine medication (*n*=31, 22/9, 49-75, 68.24±5.92)	Score of neural motor function deficits (NFDS) of limbs ADL by BI	NDFS of limbs of group A was significantly lower than that of groups Band C (both P<0.01) ADL score was significantly higher in groups A (P<0.01) and B (P<0.05) than in group C (both P<0.01) Efficacy for improving ADL in group A was superior to that of group B (P<0.05)
Sun *et al* 2006[24]	CH/CI (*n*=120)	(A) 2-90 d (25.51±21.56 d) (B) 3-120 d (22.30±19.52) (C) 5-120 d (22.88±22.64 d)	(A) SA combined with consciousness-restoring resuscitation method (*n*=33, 17/16, 33-77, 62.21±10.31), (B) SA with (C) (*n*=60, 41/19, 30-80, 62.16±12.11)	(C) Traditional acupuncture (*n*=27, 14/13, 64.0±12.4)	Total efficacy rate Scores of manner, speech, motor function of limbs	The total efficiency rate of group C (66.7%) was significantly different from that of groups A (93.3%, P<0.001) and B (90.9%, P<0.05)

Table 1 Summary of the randomized control trials of SA for stroke included in this study (Continued)

Study	Type of brain disease [sample size, male/female, average age (years)]	Average duration of disease	Intervention group [sample size, male/female, average age (years)]	Control group [sample size, male/female, average age (years)]	Outcome measure	Results
Li *et al* 2006[25]	CH/CI (*n*=230)	-	SA combined with BA (*n*=67, 49/18, ≥40)	(B) SA (*n*=112, 68/44, ≥40) (C) BA (*n*=51, 34/17, ≥40)	Total efficacy rate (%)	Therapeutic effect in group A (98.5%) was higher than that in groups B (98.2%) and C (96%) (both *P*<0.01) Rankin score of group A was superior to that of both groups B and C (*P*<0.01) CT-absorption rates of hemorrhagic and infarct loci in group A were markedly higher than those of groups B and C (*P*<0.01)
Zhao and Mu 2005[26]	CH/CI (*n*=120)	(A) 6.3±3.8 d (B) 7.9±2.5 d	(A) SA combined (*n*=60, 36/24, 36-24, 63.0±9.3)	(B) simple sports therapy (*n*=60, 31/29, 67.4±5.7)	FMA and BI Movement function of limbs ADL	Movement function of limbs and ADL after treatment in group A improved significantly as compared with group B (*P*<0.01)
Zhou *et al* 2013[27]	CI (*n*=120, 64/56, 46-80)	6-48 h	(A) SA combined with Chinese and Western medication (*n*=60, 36/24, 65.5±7.38)	(B) Western medication (*n*=60, 28/32, 64.2±8.17)	CRP, FIB, UA, uric acid Nervous function The total efficacy	In group A, improvements in CRP, FIB, UA, uric acid, neurological function were better than those of group B (*P*<0.05) The total efficiency rate was higher than that in group B (*P*<0.05)
Bao *et al* 2008[28]	CI (*n*=42)	(A) 8.7±4.3 d (B) 10.3±3.0 d	(A) SA plus (B) (*n*=27, 16/11, 63.2±12.0)	(B) BA (*n*=15, 8/7, 62.1±11.8)	Comprehensive scores of mind, speech, limb motor function	After treatment, the cumulative scores in the two groups reduced significantly (both *P*<0.01)
Yu *et al* 2006[29]	CI (*n*=60, 39/21, 45-75)	Within 7 d (A) 4.90±1.83d (B) 4.60±1.82d (C) 5.10±1.52d	(A) Skull suture acupuncture combined with (C) (*n*=20, 12/8, 63.40±8.72) (B) SA combined with (C) (*n*=20, 13/7, 63.05±8.37)	(C) medication (*n*=20, 14/6, 62.60±9.83)	Serum vascular endothelial growth factor (VEGF) levels	After treatment, the serum VEGF level did not significantly change in group C (*P*<0.05), but significantly increased in groups A and B (*P*<0.01, *P*<0.05, respectively) Group A and B were significantly different with group C (*P*<0.05) There were no significant differences between group A and B (*P*<0.05)
Yu *et al* 2004[30]	CI (*n*=60, 37/23, 45-75, 53.41±10.72)	Within 7 d (5.58±1.34 d)	(A) SA combined with (B) (*n*=30, 19/11, 45-74)	(B) Routine medication (*n*=30, 18/12, 46-74) (C) Healthy subjects (*n*=30, 19/11, 45-75, 49.37±9.03)	serum MDA levels Nervous function ADL BI	After treatment, serum MDA levels and the scales of neurological deficits in both groups A and B decreased significantly (all *P*<0.01)
Wu *et al* 2001[31]	CI (*n*=100, 56/44, 38-75, 61.5)	2-15 d	(A) SEA (*n*=50)	(B) Medication (*n*=50)	Therapeutic effect	The therapeutic effect in group A (82%) was superior to that in group B (64%; *P*<0.01) In terms of integral values of physical signs, hemiplegia showed a statistical difference between the two groups (*P*<0.01), as did aphasia (*P*<0.05)

Table 1 Summary of the randomized control trials of SA for stroke included in this study (Continued)

Study	Type of brain disease [sample size, male/female, average age (years)]	Average duration of disease	Intervention group [sample size, male/female, average age (years)]	Control group [sample size, male/female, average age (years)]	Outcome measure	Results
Hsing *et al* 2012[32]	CI (*n*=62, 44/18, 24-65, 51.27±8.96)	1.5-16 years (7.88±4.35) (A) 2-25 years (8.06±4.56) (B) 1.5-16 years (7.65±4.15)	(A) SEA [*n*=35, 34-65 (50±9.1)]	(B) Sham-placebo SEA (*n*=27, 24-64, 52±7.65)	BI Rankin scale NIHSS	Significant difference in functional improvement between groups A and B as indexed by NIHSS scale (P<0.05) Rankin and Barthel scales not significantly different between the two treatment groups
Tang *et al* 2012[33]	CI (*n*=110, 57/53, 45-80)	15-30 d (A) 22.4±4.6 (B) 22.3±4.6	(A)SA combined with BA and (B) (*n*=55, 27/28, 62.8±8.2)	(B) Routine medication (*n*=55, 30/25, 64.3±7.7)	FMA NIHSS	FMA scores were increased and NIHSS scores decreased in both groups (both P<0.01) Therapeutic effect in group A were superior to that in group B (P<0.05) No significant differences between the two groups in the ratios of mortality/disability and recurrence rates at the end of 3 and 6 months' follow-up
Gabriella and Gyula 2012[34]	CH/CI (*n*=50)	Within 6 weeks	(A) YNSA combined with (B) (*n*=25, 8/17, 58.6±10.4)	(B) Rehabilitation therapy (*n*=25, 10/15, 59.8±9.6)	BI Rivermead scale index, VAS	Barthel index, Rivermead scale index, and Visual analogue scale of group A were higher than group B YNSA is a useful method to treat stroke patients and enhance their quality of life
Zhou *et al* 2009[35]	CI (*n*=222, 147/75, 4075)	14 days to 6 months (A) 64.58±11.54 d (B) 65.85±10.87 d	(A)SA combined with BA (*n*=133, 89/44, 62.73±6.25)	(B) BA (*n*=89, 58/31, 61.40±9.14)	FMA BI	After treatment, the FMA and Barthel index of group A were higher than those of group B (P<0.01)
Wang *et al* 2005[36]	CH/CI (*n*=59183, 112/71, 32-75, 59.55)	7-45 d (22.49 d) (A) 21.77±7.63 (B) 22.83±7.41 (C) 22.87±3.24	(A) (B) Combined with (C) (*n*=62, 36/26, 59.03±8.06)	(B) SA (*n*=60, 39/21, 59.40±7.93) (C) BA (*n*=61, 37/24, 60.23±8.08)	Total efficacy rate	Group A was improved better than group B or C (P<0.05) There was no difference between groups B and C in therapeutic effect
Tan and Li 2004[37]	CB/CH/CI (*n*=59)	(A) 3 h to 120 d (16.5 d) (B) 1 h to 160 d (15.7 d)	(A) SA (*n*=29, 19/10, 44-79, 64.8±9.35)	(B) BA (*n*=30, 22/8, 35-80, 64.1±8.7)	Nervous function FIM score	The score for degree of neurologic impairment was decreased and for FIM in the two groups was significantly increased, with significant differences between the two groups (P<0.05)

Table 1 Summary of the randomized control trials of SA for stroke included in this study (Continued)

Study	Type of brain disease [sample size, male/female, average age (years)]	Average duration of disease	Intervention group [sample size, male/female, average age (years)]	Control group [sample size, male/female, average age (years)]	Outcome measure	Results
Li and Chen 2001[38]	CH/CI (*n*=183)	Acute: 40 Convalescent: 47 Sequel: 6 (B) Acute: 37 Convalescent: 43 Sequel: 10	(A) SEA (*n*=93, 65/28, 56-72)	(B) BA (*n*=90, 59/31, 54-73)	Therapeutic effect 11 indexes of hemorheology (plasma viscosity, high sear rate, low shear rate of whole blood viscosity, ratio of whole blood viscosity, high shear reduced viscosity, low shear reduced viscosity, erythrocyte index of rigidity, red cell aggregation index, hematocrit, erythrocyte sedimentation rate, fibrinogen, and electrophoresis time of erythrocyte of the blood samples	Therapeutic effect of group A was better than that of group B (P<0.05) Group A was statistically significant in terms of reduction of plasma viscosity, high shear reduced viscosity, low shear reduced viscosity, erythrocyte sedimentation rate, hematocrit and fibrogen (P<0.01 to 0.05), but these indexes were not significant in group B
Yu *et al* 2004[39]	CI (*n*=60, 38/22, 50-75, 56.34±10.83)	Within 4 d (2.56±1.29) (A) 2.60±0.99 (B) 2.27±0.96	(A) Skull acupuncture (needling method) (*n*=30, 18/12, 53.28±11.37)	(B) Medication (*n*=30, 17/13, 53.84±10.82) (C) Healthy subject (*n*=30, 19/11, 45-65, 50.23±5.42)	Nervous function Granular membrane glycoprotein (GMP-140)	After treatment, group A showed significantly improved clinical nervous function (P<0.01) GMP-140 levels were superior to group A (P<0.05)

Notes: SA: scalp acupuncture; BA: body acupuncture; SIAN: Standard International Acupuncture Nomenclature proposed by World Health Organization; SEA: scalp electrical acupuncture; YNSA: Yamamoto's New SA; CB: cerebral thrombosis; CI: cerebral infarction; CH: cerebral hemorrhage; NIHSS: the National Institutes of Health Stroke Scale; MBI: Modified Bathel index score; BI: Bathel index score; ADL: activities of daily living; FMA: the Fugl-Meyer Assessment; VAS: Visual Analogue Scale; FIM: the Functional Independence Measure scale.

ing assessment criteria for treatment content, including the number of therapies (1 point), the frequency of treatment (1 point), and the treatment period (1 po-int), most RCTs scored 3 points, while 16 RCTs scored 3 points for the assessment of the practitioner's background. The combined FEAS score varied from 9 to 15.5 points. These results are summarized in Table 5.

Meta-analysis

The results of the meta-analysis on the efficacy of SA for stroke are summarized in Figure 2.

Total efficacy rate

Total efficacy rate was described in 11 of the RCT papers. The Meta-analysis results for the SA group and BA group[7,24,38] showed a significantly greater improvement in the SA group than in the BA group [n = 272, risk ratio (RR): 1.21; 95% CI (1.09, 1.31), P < 0.0002, = 0%]. The meta-analysis results for the SA group and the medication group[22,27,31,39] showed a significantly greater improvement in the SA group than in the medication group [n = 363, RR: 1.62; 95% CI (1.40, 1.87), P < 0.000 001, = 52%]. The meta-analysis results for the SA plus BA group and the BA group[21,24,25,28,36] showed a significantly greater improvement in the SA plus BA group than in the BA group [n = 430, RR: 1.12; 95% CI (1.05, 1.20), P < 0.001, = 78%].

Motor function

Motor function was assessed and described in 2 RCT papers.[22,24] The meta-analysis results for the

Table 2 SA methods used in randomized control trials in stroke

Study	SA method	Manipulation	Duration of treatment	Follow-up	Acupuncture points for SA	Adverse event
Cho *et al* 2003[13]	Dr. Zhu's SA	Once daily Rapidly twirling for 1 min and then retained for 30 min	2 weeks	0, 1, 2 weeks	Motor area, sensory area, Chorea and tremor control area (depending on the state)	4 drop-outs
Ha *et al* 2001[6]	SIAN	Once daily Quickly twisting every 1-3 min (200 spin/min) and then retained for 10-15 min	4 weeks	0, 4 weeks	MS 6, MS 7	n.r
Liu and Shi 2013[21]	SIAN with Dr. Zhu's SA	Once daily Twisted, lifted, and thrusted for 30 s and then retained for 30 min 4 weeks	4 courses	Before treatment, after final treatment	Baihui (GV 20), and Sìshéncōng (EX-HN 1), motor area, vascular dilation, and constriction area	n.r
Qiu 2013[22]	SIAN	Every other day Rapidly twirling for 1-2 min and then retained for 2 h 10 times	1 course	Before treatment, after final treatment	MS 6, MS 7	n.r
Shi and Zheng 2007[23]	SIAN	Every second day (3 times per week) Rapidly twirling for 5 min and then retained for 2 h	4 weeks	Before treatment, after final treatment	MS 5, MS 6	n.r
Sun *et al* 2006[24]	Dr. Zhu's SA	Every day Rapidly twirling for 1-2 min and then retained for 10-15 min Repeat 2-3 times more	(A) 10.45±7.78 times (B) 10.13±5.30 times (C) 9.85±4.71 times	Before treatment, after final treatment	Motor area, sensory area, speech #2 area, speech #3 area, balance area	n.r
Li *et al* 2006[25]	SIAN with Dr. Zhu's SA	Once daily in the 1st therapeutic course and once every other day in the 2nd course Rapidly twirling for 1 min (200 spin/min) and then retained for 5 min Repeated 1-3 times more 7-8 times/15 d	15 d	Before treatment, after final treatment	Motor area (MS 6), sensory area (MS 7), foot-motor sensory area (MS 8), speech area	n.r
Zhao and Mu 2005[26]	Dr. Zhu's SA	Once daily Rapidly twirling at 100 spin/min and then treated with electric current for 25-30 min	n.r	0, 1, 3 months	Motor area, balance area, foot-motor sensory area	n.r
Zhou *et al* 2013[27]	SIAN	Once daily Rapidly twirling for 5 min and then retained for 5 min Repeat 3 times	2 weeks	Before treatment, after final treatment	MS 6	n.r
Bao *et al* 2008[28]	Dr. Zhu's SA	5 d/week Rapidly twirling for 1-2 min and then retained for 30 min repeat 1-2 times	2 weeks	Before treatment, after final treatment	Motor area, sensory area, speech #2 area, speech #3area, balance area	n.r
Yu *et al* 2006[29]	Dr. Zhu's SA with SIAN	Once daily Rapidly twirling for 1-2 min (200 spin/min) twice (interval of 10 min) and then retained for 30 min 10 times	1 course	Before treatment, after final treatment	(A) coronal suture, sagittal suture, lambdoid suture, etc. (B) MS6, MS 7	n.r
Yu *et al* 2004[30]	SIAN	Once daily Rapidly twirling for 1-2 min (200-220 spin/min) and then retained for 30 min re-twirling 1-2 min after interval of 10 min	10 times	Before treatment, after final treatment	MS 5, MS 6, MS 7, MS 8	n.r
Wu *et al* 2001[31]	SIAN and applied SA	Once daily 1 mA, 100/50 Hz 14 d	2 courses (interval of 1 d)	Before treatment, after final treatment	MS5 (From GV 20 to GV 21), from GB 8 to GB 6	n.r

Table 2 SA methods used in randomized control trials in stroke (Continued)

Study	SA method	Manipulation	Duration of treatment	Follow-up	Acupuncture points for SA	Adverse event
Hsing *et al* 2012[32]	Dr. Zhu's SA with SIAN	Twice a week low-frequency electrical stimulation (2/100 Hz) for 30 min	5 weeks (10 sessions)	Before treatment, after final treatment	Motor, sensory, frontal, temporal associative area	No drop-outs
Tang *et al* 2012[33]	SIAN	Rapidly twirling for 2-3 min (200 spin/min) and then retained for 30 min Re-twirling 2-3 min after interval of 5 min 5 d	20 d (4 sessions)	Before treatment, after final treatment	MS 6	n.r
Gabriella and Gyula 2012[34]	YNSA	Dry needling method Once a month Inserted 12 needles Absorption for 4 weeks	24 months	0, 6, 12, 18, 24 months	Ypsilon points (LU, LI, KI, BL, HT, SI, LR, GB, PC, TB, SP, and ST)	3 drop-outs
Zhou *et al* 2009[35]	Dr. Zhu's SA with SIAN	Once daily 4-5 mA, 2/15 Hz for 30 min 5 times/week	5 weeks (25 times)	Before treatment, after final treatment; 1, 3 months	Motor area (MS 6)	n.r
Wang *et al* 2005[36]	Dr. Zhu's SA	Once a day retained 20-30 min and then twirling 1-2 min (150-300 spin/min) repeated 2-3 times	2 months	Before treatment, after final treatment	Motor area	n.r
Tan and Li 2004[37]	SIAN	Once daily Rapidly twirling at 200-300 spin/min and then retained for 30 min	28 d	Before treatment, after final treatment	MS 6, MS 7	n.r
Li and Chen 2001[38]	SIAN	Once daily (treated 6 d and then 1 day's rest) Lift, thrust, and rotate, followed by 6V 200-300 pulses/min for 30 min	30 sessions	Before treatment, after final treatment	MS6, MS 7, MS 8, MS 9	n.r
Yu *et al* 2004[39]	Skull acupuncture	Once daily Rapidly twirling for 1-2 min (200 spin/min) and then retained for 30 min Repeated twice	10 times	Before treatment, after final treatment	Coronal suture, sagittal suture, lambdoid suture, inferior temporal line, superior temporal line, parietal eminence	n.r

Notes: SA: scalp acupuncture; SIAN: standard international acupuncture nomenclature proposed by World Health Organization; YNSA: Yamamoto's New SA; n.r: not reported.

SA plus BA group and the BA group showed a significantly greater improvement in the SA plus BA group than in the BA group [n = 129, SDM = 0.33, 95% CI (− 0.04, 0.71), P = 0.077, = 0%].

Nerve function

Nerve function was assessed and described in 4 RCT papers[23,27,30,39]. The Meta-analysis for the SA group and the medication group was conducted. There was a significantly greater improvement in the SA group than in the medication group [n = 129, SDM = 0.52, 95% CI (0.29, 0.75), P < 0.0001, = 46.5%].

Publication bias

We assessed the publication bias using a funnel plot of the total efficacy rate, motor function, and nerve function. However, the low number of trials prevented them from assessment of the publication bias.

Adverse events

Of the 21 papers included, only 3 papers reported adverse reactions, of which 2 papers reported dropouts[13,34] and 1 paper described no adverse reactions.[32] However, the reasons for dropouts or symptoms of adverse reactions were not mentioned.

DISCUSSION

In this study, after searching a total of 7 databases up to August 2014, 21 RCT papers were ultimately selected; a systematic review of the clinical researches on SA for stroke was conducted, and a qualitative assessment of each study was performed.

In most RCT papers, it was difficult to identify techniques for the process of randomization and blinding. Only 9 papers[13,22-25,33,35-37] described the randomization methods, while only 6 papers[13,22,23,27,32,34] described blinding. Due to the consequent limitations on methodological quality, only 5 RCT papers had a Jadad score indicating high quality,[13,27,32-34] and the bias assessment also showed that the quality of clinical studies in RCT papers on SA

Table 3 Quality assessment of the randomized controlled trials by the modified Jadad score

Study	A	B	C	D	E	Total modified Jadad score
Cho *et al* 2003[13]	1	1	0	1	1	4
Ha *et al* 2001[6]	0	0	0	0	0	0
Liu and Shi 2013[21]	1	1	0	0	0	2
Qiu 2013[22]	1	1	0	0	0	2
Shi and Zheng 2007[23]	1	0	1	0	0	2
Sun *et al* 2006[24]	1	1	0	0	0	2
Li *et al* 2006[25]	1	1	0	0	0	2
Zhao and Mu 2005[26]	1	0	0	1	0	2
Zhou *et al* 2013[27]	1	0	1	1	0	3
Bao *et al* 2008[28]	0	0	0	0	0	0
Yu *et al* 2006[29]	0	0	0	0	0	0
Yu *et al* 2004[30]	1	0	0	0	0	1
Wu *et al* 2001[31]	1	0	0	0	0	1
Hsing *et al* 2012[32]	1	0	1	1	1	4
Tang *et al* 2012[33]	1	1	1	0	0	3
Gabriella and Gyula 2012[34]	1	0	1	1	1	4
Zhou *et al* 2009[35]	1	1	0	0	0	2
Wang *et al* 2005[36]	1	1	0	0	0	2
Tan and Li 2004[37]	1	1	0	0	0	2
Li and Chen 2001[38]	1	0	0	0	0	1
Yu *et al* 2004[39]	1	0	0	0	0	1

Notes: A: was the study described as randomized? B: the method of randomization was described in the paper, and that method was appropriate? C: were the patients blinded to the interventions? D: was the outcome assessor (evaluator) reported as blinded? E: was there a description of withdrawals and drop-outs?

for stroke was not particularly high. According to the FEAS scale assessment results, following the STRICTA recommendations, most studies showed high quality standards insertion. However, most studies did not thoroughly describe the presence or absence of De *Qi*, the number of needles, the depth of needle insertion, direction of the needles, or position of the patients. Our systematic review was based on participant screening, randomization, allocation concealment, and blindness assessment. Because of the limitations on methodological quality of the included studies, the lack of qualitatively outstanding RCTs made it difficult to draw accurate conclusions.

SA showed significantly better results in the meta-analysis on total efficacy rate, motor and neurological functions. According to the Meta-analysis results for total efficacy rate of the SA group *vs* the BA group, the SA group *vs* MD group, and the SA plus BA group *vs* BA group, SA showed significantly better therapeutic effects. Moreover, the meta-analysis also revealed significantly better improvement of stroke by SA, regarding not only motor function, but also neurological function (Figure 2).

The disease period investigated in the Meta-analysis varied from the acute to chronic. According to the analysis of the results of the SA group *vs* the BA group,[7,24,38] the SA group *vs* the medication group,[22,31] and the SA plus BA group *vs* the BA group,[21,24,28] SA had better effects on the total efficacy rate for acute to chronic stroke, as well as on the motor and neuronal functions. A previous study has shown the efficacy of SA in patients with acute and subacute stroke,[15] and a meta-analysis has been previously conducted on RCTs involving the use of SA in subacute ischemic stroke patients.[15]

Because the research design in terms of the control groups varies, in addition to variation in treatment endpoints, this Meta-analysis on the use of SA for stroke had some limitations. In particular, for research using ADL assessment through BI, the studies were designed to compare a SA group with a BA group,[35] a medication group,[23] a physical therapy group,[34] a simple exercise therapy group,[26] and a sham control group;[32] while in investigations using the Rankin scale, the studies were designed to compare a SA plus BA group with a BA group,[25] or a SA group with a sham control group.[32] Furthermore, because 2 RCT papers[33,35] described the FMA score using only a graph, the meta-analysis could

Table 4 Quality assessment of the randomized controlled trials by Cochrane risk of bias assessment

Study	Cochrane risk of bias						
	A	B	C	D	E	F	G
Cho *et al* 2003[13]	H	H	U	L	H	L	U
Ha *et al* 2001[6]	U	U	U	U	U	H	U
Liu and Shi 2013[21]	L	L	H	U	U	H	U
Qiu 2013[22]	H	H	H	U	U	H	U
Shi and Zheng 2007[23]	U	U	H	U	U	L	U
Sun *et al* 2006[24]	H	H	H	U	U	H	U
Li *et al* 2006[25]	L	L	H	U	U	H	U
Zhao and Mu 2005[26]	U	U	U	U	U	L	U
Zhou *et al* 2013[27]	U	U	L	L	U	H	U
Bao *et al* 2008[28]	U	U	H	U	U	H	U
Yu *et al* 2006[29]	U	U	H	L	U	U	U
Yu *et al* 2004[30]	U	U	H	U	U	L	U
Wu *et al* 2001[31]	U	U	H	U	U	U	U
Hsing *et al* 2012[32]	U	U	L	L	L	L	U
Tang *et al* 2012[33]	L	L	H	L	U	L	U
Gabriella and Gyula 2012[34]	L	H	H	L	H	L	U
Zhou *et al* 2009[35]	L	L	H	U	U	L	U
Wang *et al* 2005[36]	H	H	H	U	U	U	U
Tan and Li 2004[37]	L	H	H	U	U	U	U
Li and Chen 2001[38]	U	U	H	L	U	U	U
Yu *et al* 2004[39]	U	U	H	U	U	U	U
Sum of 'H'	6	4	2	6	1	8	0

Notes: A: random sequence generation; B: allocation concealment; C: patient blinding; D: assessor blinding; E: incomplete outcome data; F: selective reporting; G: other bias; L: low risk of bias; H: high risk of bias; U: unclear risk of bias.

not be conducted for this form of assessment; moreover, most papers showed a lack of objective assessment criteria.

There were only 4 papers reporting dropouts or adverse reactions to SA for patients with stroke; most papers did not mention this, which caused low qualitative assessment results by the Jadad score and the Cochrane risk of bias assessment.

In conclusion, our systematic review analyzed and assessed the results of research methods and the processes for clinical studies investigating the use of SA for treating stroke up to August 2014. We are able to confirm the significant improvements in the total efficacy rate, and in motor and neurological functions for patients with stroke treated by SA.

ACKNOWLEDGEMENTS

The authors would like to express sincere thanks to the colleagues and staffs from College of Korean Medicine of Dong-Shin University, from DongShin University Gwangju Oriental Hospital, and from Chonnam National University Medical School & Hospital for their support. This study was supported by the Convergence of Conventional Medicine and Traditional Korean Medicine R & D program funded by the Ministry of Health and Welfare through the korea Health Industry Development Institute (KHIDI) (HI14C0862)

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Table 5 Quality assessment of the randomized controlled trials by FEAS score

Study	A	B	C	D	FEAS score
Cho *et al* 2003[13]	4	1	3	3	11
Ha *et al* 2001[6]	4	3	2	3	12
Liu and Shi 2013[21]	4	2	2	3	11
Qiu 2013[22]	6	2.5	3	3	14.5
Shi and Zheng 2007[23]	6	2	3	3	14
Sun *et al* 2006[24]	6	2	3	3	14
Li *et al* 2006[25]	6	2	3	0	11
Zhao and Mu 2005[26]	4	2	3	0	9
Zhou *et al* 2013[27]	5	3.5	3	3	14.5
Bao *et al* 2008[28]	5	3	3	3	14
Yu *et al* 2006[29]	4	2	3	3	12
Yu *et al* 2004[30]	6	2	3	3	14
Wu *et al* 2001[31]	4	2.5	3	0	9.5
Hsing *et al* 2012[32]	6	3.5	3	3	15.5
Tang *et al* 2012[33]	6	2.5	3	0	11.5
Gabriella and Gyula 2012[34]	5	3.5	3	3	14.5
Zhou *et al* 2009[35]	6	2	3	0	11
Wang *et al* 2005[36]	4	3.5	3	0	10.5
Tan and Li 2004[37]	6	2	3	0	11
Li and Chen 2001[38]	4	3	2	3	12
Yu *et al* 2004[39]	6	2.5	3	3	14.5

Notes: A: acupuncture rationale; B: methods of stimulation; C: treatment regimen; D: practitioner background.

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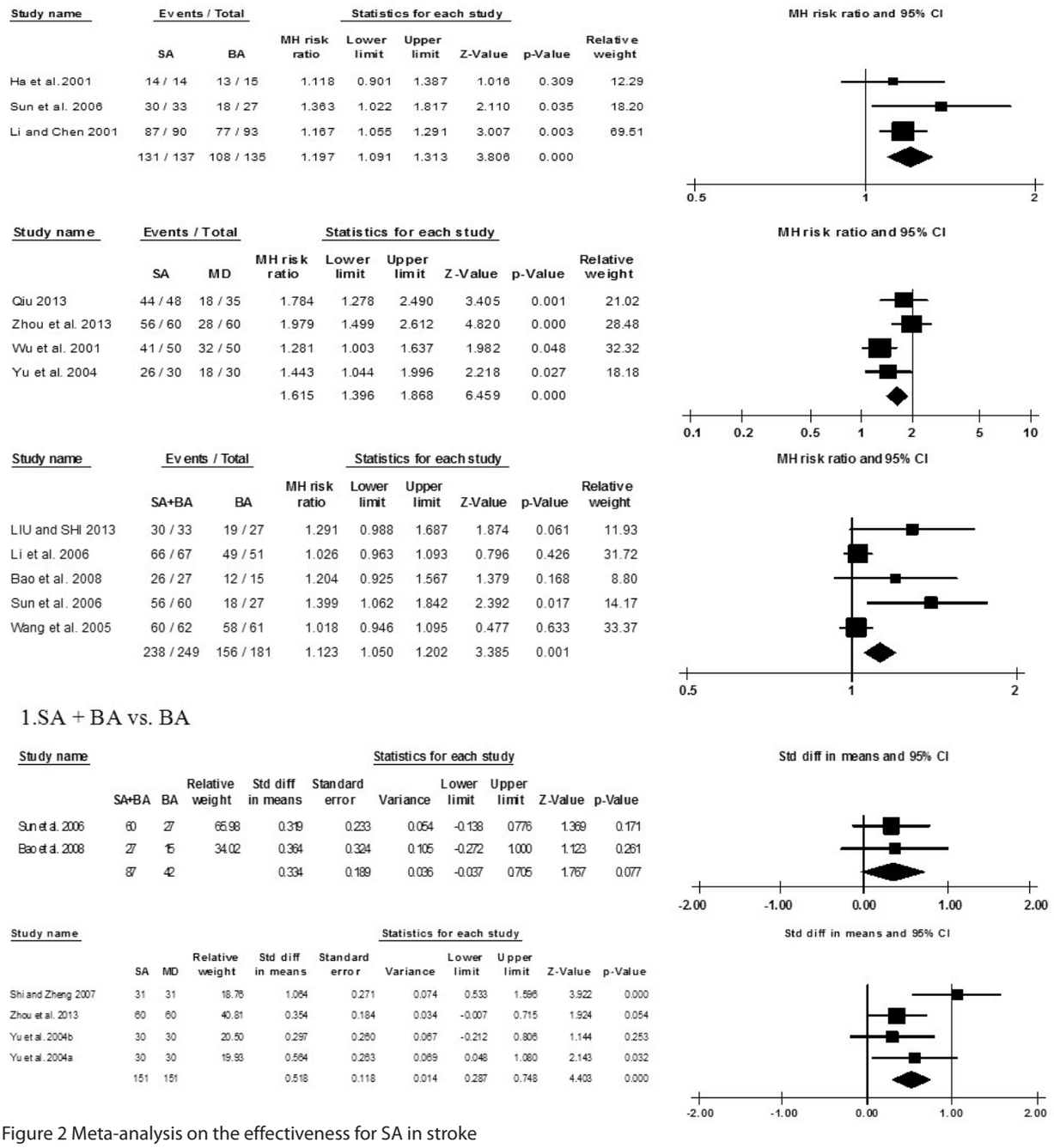

Figure 2 Meta-analysis on the effectiveness for SA in stroke
SA: Scalp acupuncture; BA: Body acupuncture; MD: medication; SA + BA: scalp acupuncture plus body acupuncture.

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