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Evidence-Based Integrative Medicine

Acupuncture Treatment for Post-Stroke Dysphagia: An Update Meta-Analysis of Randomized Controlled Trials*

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ABSTRACT **Objective**: To explore the effectiveness and safety of acupuncture in patients with post-stroke dysphagia by an update meta-analysis. **Methods**: Potentially eligible RCTs aimed to evaluate the effects of acupuncture *vs*. non-acupuncture treatments, such as rehabilitation training or routine medication on the swallowing difficulty after stroke were searched from PubMed, Cochrane Library, China National Knowledge Infrastructure, and other database from the earliest record to June 2016. Patient demographics, regimens for acupuncture, type of controls, methods of randomization, and measurements of the clinical symptoms of dysphagia were retrieved. The relative risk (RR) and 95% confidence interval (CI) of effective rate of dysphagia was calculated after intervention performed following admission. Subgroup analyses and a meta-regression analysis were performed to describe the heterogeneity. **Results**: Twenty-nine RCTs comprising 2,190 patients were included. The included studies had a medium quality grade based on the Consolidated Standards of Reporting Trials (CONSORT) and Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) checklist. Acupuncture therapy provided a higher effective rate compared with non-acupuncture treatments [RR=1.33, 95% confidence interval (CI), 1.25 to 1.43]. Subgroup and meta-regression analyses suggested that acupuncture intensity and measurement method were main sources of heterogeneity and resulted in a significant difference for pooled effect size. No severe adverse events were documented in these RCTs. **Conclusions**: Our meta-analysis provides a new evidence supporting the efficacy and safety of acupuncture in treatment to post-stroke dysphagia in short-term compared with rehabilitation or medication. More high-quality and large-scale research studies are needed.

KEYWORDS acupuncture, dysphagia, stroke, systematic review, meta-analysis, randomized controlled trials

Dysphagia is a common complication in patients with stroke and has an incidence rate of 45%–65% in stroke patients.[1] Dysphagia is characterized as being worse for liquids than solids,[2] and can lead to serious complications, including aspiration, pneumonia, and even death.[3,4] In addition, dysphagia is associated with social anxiety, withdrawal, and depression;[5,6] further, it may affect the activities of daily living, quality of life, and prognosis of stroke. The management of dysphagia in post-stroke patients including repetitive transcranial magnetic stimulation,[7,8] swallowing training,[9,10] speech and language therapy,[11] expiratory muscle strength training,[12,13] behavioral interventions,[14] dietary modification,[15] and neuromuscular electrical stimulation[16,17] only have a temporary and relatively limited effectiveness. Consequently, a multidisciplinary approach is essential to manage patients with post-stroke dysphagia.

Acupuncture is used routinely in stroke rehabilitation in China, and has been increasingly applied worldwide as an alternative treatment method. Furthermore, many studies suggested that acupuncture might be beneficial in the rehabilitation of patients with swallowing problems in post-stroke.[18-20] Particularly, a meta-analysis on acupuncture treatment for stroke indicated that acupuncture might be effective for treating post-stroke neurological impairments and dysfunctions such as dysphagia.[21] Several meta-analyses reported that there were limited and insufficient evidence on the therapeutic effect of acupuncture for dysphagia

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after stroke, and that large scale, high quality, and rigorously designed randomized controlled trials (RCTs) are required.[22-24] The present review analyzes the RCTs published to date and offers more rigorous and sufficient evidence of the effectiveness on acupuncture for post-stroke dysphagia rehabilitation.

METHODS

This review was conducted following the standard structure of a Cochrane systematic review. The assessment of methodological quality was performed according to the Consolidated Standards of Reporting Trials statement (CONSORT)[25] and Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) recommendations.[26]

Criteria for Selecting Studies

Types of Studies

Only RCTs published in English or Chinese, which aimed to evaluate the effects of acupuncture *vs*. non-acupuncture treatments, such as rehabilitation training or routine medication, on the swallowing difficulty after stroke were included. The RCTs were excluded if they did not clearly describe the generation of the random allocation sequence.

Types of Participants

Only those studies that recruited patients with similar characteristics were eligible: (1) the participants were clinically diagnosed with ischemic or hemorrhagic stroke by computerized tomography or magnetic resonance imaging, and in accordance with the criteria of the World Health Organization.[27] (2) dysphagia was diagnosed using a clinical bedside swallowing assessment, a video-fluoroscopic swallowing study (VFSS), or a fiberoptic endoscopic examination of swallowing (FEES).

Types of Interventions

Trials aimed at evaluating the effectiveness of acupuncture for post-stroke dysphagia were considered. RCTs were included if they compared classical acupuncture with non-acupuncture treatments (i.e., rehabilitation or routine medication treatment, meaning routine neurological treatment, including the reduction of intracranial pressure, platelet aggregation, maintenance of water and electrolyte balance, and nutritional support). Studies of acupuncture-related techniques that did not involve penetrating the needles into the skin were excluded, e.g., auricular seed therapy, laser acupuncture, point injection, acupoint-embedding, acupressure, tap-pricking, moxibustion, and cupping. Trials that compared different methods of acupuncture were also excluded. In all included RCTs of the current review, participants were individually randomized into intervention and control groups. The primary outcome measures and the events/no-events between treatment and control groups were collected and analyzed from each study. This approach follows the guidelines of the Cochrane Handbook for Systematic Reviews of Interventions.

Types of Outcome Measures

Several outcome measures were extracted from each included study. The primary outcomes included: (1) a bedside swallowing assessment, such as water swallowing test (WST);[28,29] (2) Kubota Toshio's Swallowing Ability Assessment (KSA);[30] (3) Fujishima Ichiro' s Dysphagia Scale (FDS);[31] (4) VFSS scores;[32] and (5) clinical symptoms assessment (CSA). The secondary outcomes included incidence of aspiration pneumonia, quality of life, length of the hospital stay, a nutritional measure, and adverse events. The clinical effect of treatment was determined using the following criteria: (1) recovery, i.e., the complete resolution of dysphagia and a level 1 WST score; (2) markedly improved, i.e., a nearly complete resolution of dysphagia and a WST score that improved through 2 levels; (3) improved, i.e., a partial resolution of dysphagia and WST score that improved through 1 level; (4) no improvement, i.e., a slight or no change in dysphagia and no change in the WST score. The effective rate of improvement in 2 treatment groups (acupuncture *vs*. non-acupuncture) was calculated using the following formula:[33] effective rate= (recovery + markedly improved + improved)/total number × 100%.

Search Methods for Identification of Studies

A comprehensive search was conducted using electronic databases, including PubMed, Cochrane Library, Web of Science, Elton B. Stephens Co. (EBSCO) Information Services, OVID, ScienceDirect, SpringerLink for English studies, China National Knowledge Infrastructure, China Biological Medicine Database, Wanfang Database, and China Science and Technology Journal (VIP) Database for Chinese studies. The databases were searched from their earliest inception through June 16, 2016, with restrictions on language in English or Chinese. In

addition, to search other source trials, a hand search of those references found in the selected articles was performed to identify all relevant studies. The keywords used in the search were "acupuncture/acupuncture therapy/acupuncture treatment and stroke/cerebrovascular accident/cerebral infarction/intracerebral hemorrhage/cerebral embolism and dysphagia/deglutition/swallow disorders and randomized controlled trials/randomized". The search strategy was designed and performed independently by 2 investigators (Li LX and Deng K). When discrepancies occurred, a third investigator (Qu Y) was consulted to reach a consensus. If multiple studies were identified from the same study group using the same database, we included only the most complete paper for analysis. Studies that did not focus on the clinical treatment efficacy of acupuncture were excluded.

Data Collection and Analysis

Data Extraction

Two investigators independently used a predefined extraction form to extract specific characteristics of the included eligible studies, including information about the author(s), year, age, sex, duration, acupoints, frequency, sessions, and outcomes. Additional information was sought from the principal investigators of the trials that appeared to meet the inclusion criteria when necessary. Disagreements were settled by discussion and consensus with a third author, and all review authors were blinded to the identity of the groups that published the studies.

Assessment of Methodological Quality in the Included Studies

Two reviewers (Li LX and Deng K) independently assessed the quality of the methodology of the included eligible studies using the CONSORT and STRICTA checklist. The methodological quality score of included studies were evaluated according to the following 2 criteria: clear explanation or not to need to explain(1); without clear explanation or not to mention(0). The maximum scores of both the CONSORT and STRICTA checklist are 53 and the minimum was 0. The higher the scores, the higher the methodological quality. Any disagreement in the selection of a study and discrepancies in their rating were resolved through discussion.

Measures of Treatment Effect

The relative risk (RR) with a 95% CI was calculated for dichotomous data, and the Statistics Data Analysis Special Edition software (Stata SE, version 12.0; Stata Corp LP, College Station, Texas, USA) was used in this systematic review.

Dealing with Missing Data

If the trial publication did not provide relevant data, we contacted the principle investigator in an effort to obtain the missing data. If the principle investigator did not respond, we excluded the trial from the analyses.

Assessment of Heterogeneity and Reporting Biases

The data was pooled across studies using random effects models if statistical heterogeneity was present. Statistical heterogeneity was assessed using the chi-square test and I^2 test, a $P<0.10$ and an $I^2>50\%$ represented substantial heterogeneity.[34] If any kind of heterogeneity was present, a subgroup analysis, sensitivity analysis, and meta-regression analysis was conducted for a more comprehensive understanding. A visual inspection of funnel plots and the Begg-Mazumdar Kendall's tau[35] and Egger bias test[36] were conducted to assess the potential publication bias when sufficient eligible randomized trials were included in this meta-analysis. Moreover, we conducted a trim and fill adjusted analysis[37] to fill-in the given unperformed studies, and recalculated the RR at each iteration until the funnel plot of the new RR was symmetric. Finally, the fail safe number (Nfs) of negative studies that would be required to nullify the RR (i.e., $P>0.05$) was calculated.[38]

RESULTS

Search Results

The searches resulted in 817 relevant references. After screening and assessment carefully, 29 RCTs[39-67] that met the criteria were identified (Appendix 1). The eligible cases of the included studies totaled 2,190 patients. The literature search process of this systematic review is summarized in Figure 1.

Characteristics of the Included RCTs

All of the included 29 RCTs were conducted in China, of which 27 and 2 RCTs were published in Chinese and English, respectively. These selected trials were reported from January 2004 to November 2016, and were entirely designed as a two-parallel-arm group. A total of 2,190 participants were included, of which 1,103 patients were in treatment group and 1,087 patients in control group. The outcome measures

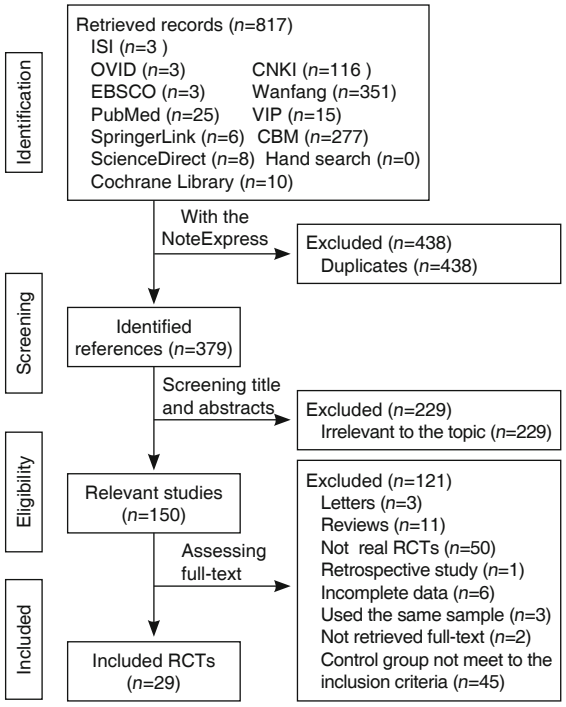

Figure 1. Flowchart of Literature Search

included scores for WST(23 studies),[41-47,50,52,54-67] KSA (1 study),[48] FDS (1 study),[51] VFSS (2 studies),[49,53] and CSA (2 studies).[39,40] The extracted characteristics of included studies are described in Appendix 1.

Study Quality

The quality of enrolled studies were evaluated using CONSORT and STRICTA checklist. The results indicated that most of the studies had a medium quality grade, with an average 38 scores out of a total 53 scores. Only 4 studies[41,44,52,57] were evaluated with a grade of more than 40, which indicated a medium or high risk of bias. No study reported how sample size was determined. No study evaluated the outcomes following an intention-to-treat principle. No study was registered in an international trial registry. The methodological quality of each study is summarized in Table 1.

Effective Rate of Acupuncture for Post-Stroke Dysphagia

Twenty-nine RCTs were included in this meta-analysis to investigate the efficacy of acupuncture treatment on dysphagia in stroke patients. The meta-analysis was conducted using a random effect model and the overall results show that the variations in RR were attributable to heterogeneity (I^2=64.2%, n=29, P<0.01). The estimate variance between studies indicated the presence of substantial heterogeneity(Tau^2=0.017). The results had a pooled RR of 1.33 (95% CI, 1.25 to 1.43) and a highly significant difference was found between the acupuncture group and non-acupuncture group (blank or rehabilitation control). The effect size of RR and 95% CI are shown in a forest plot (Figure 2).

Table 1. Methodological Quality of Included Studies

Study ID	CONSORT (36 scores)	STRICTA (17 scores)	Total (53 scores)
Han, et al 2004[39]	23	14	37
Yang, et al 2005[40]	19	12	31
Peng, et al 2006[41]	25	15	40
Wang, et al 2007[42]	23	14	37
Fan, et al 2007[43]	21	15	36
Zhou, et al 2007[44]	28	15	43
Lu, et al 2009[45]	24	15	39
Li, et al 2009[46]	22	16	38
Yan, et al 2009[47]	23	16	39
Zhang, et al 2009[48]	23	15	38
Li, et al 2010[49]	23	15	38
Su, et al 2010[50]	24	14	38
Su, et al 2011[51]	25	14	39
Xie, et al 2011[52]	28	16	44
Wang, et al 2011[53]	24	13	37
Huang, et al 2011[54]	23	14	37
Liu, et al 2012[55]	23	13	36
Zhen, et al 2012[56]	23	13	36
Wu, et al 2012[57]	30	16	46
Yu, et al 2012[58]	24	14	38
Cao, et al 2013[59]	23	14	37
Liu, et al 2014[60]	24	14	38
Wang, et al 2015[61]	24	14	38
Li, et al 2015[62]	23	14	37
Gao, et al 2015[63]	23	15	38
Zhang, et al 2015[64]	24	13	37
Li, et al 2015[65]	21	13	34
Liu, et al 2015[66]	21	14	35
Duan, et al 2016[67]	23	14	37

Subgroup and Meta-Regression Analyses

The results of subgroup analysis show that the effect size in all of the subgroups were above threshold. However, heterogeneity was observable in analysis of the subgroups, i.e., 2 studies[39,40] adopted the CSA score as primary outcome (I^2=99.1%, P<0.001). The results of other subgroups analysis included the cerebral ischemia group (RR=1.49, 95% CI, 1.15 to

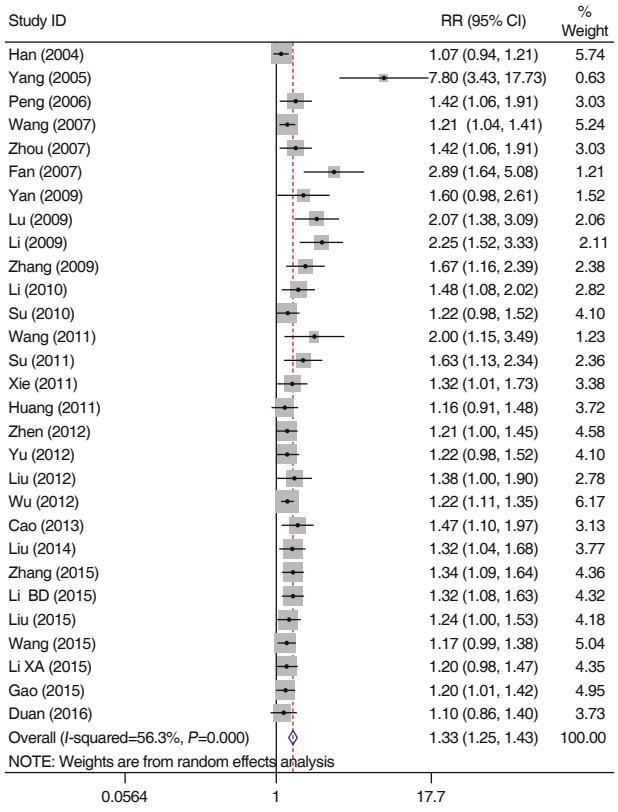

Figure 2. Forest Plot of Effective Rate

1.94), non-cerebral ischemia group (RR=1.33, 95% CI, 1.22 to 1.44), pseudo-bulbar palsy (PBP) group (RR = 1.48, 95% CI, 1.29 to 1.70), non-pseudo-bulbar palsy (non-PBP) group (RR=1.23, 95% CI, 1.14 to 1.32), duration ⩽30 d group (RR=1.27, 95% CI, 1.18 to 1.36), duration >30 d group (RR=1.46, 95% CI, 1. 26 to 1.70), high intensity acupuncture group meaning that the acupuncture protocol included electrical stimulation, more than 30 min of needle retainment, and more than 28 treatment sessions (RR=2.62, 95% CI, 0.87 to 7.86), low intensity acupuncture group meaning that the acupuncture protocol satisfied none, 1 or 2 of the 3 aforementioned high intensity criteria (RR=1.29, 95% CI, 1.21 to 1.37), blank or sham acupuncture control group (RR=1.40, 95% CI, 1.26 to 1.56), rehabilitation control group (RR=1.23, 95% CI, 1.13 to 1.34), subjective quantitative assessment group (included WST, KSA, FDS and VFSS scores; RR=1.32, 95% CI, 1.24 to 1.40), CSA group (RR=2.86, 95% CI, 0.03 to 224.97), moderate quality group (RR = 1.34, 95% CI, 1.01 to 1.77), and poor quality group (RR=1.36, 95% CI, 1.25 to 1.48). The results of 2 studies[39,40] with a CSA as the primary outcome (RR =2.86, 95% CI, 0.03 to 224.97), and 3 studies[40,47,50] that applied a high intensity acupuncture treatment (RR=2.62, 95% CI, 0.87 to 7.86) showed that acupuncture treatment was not effective for post-stroke dysphagia compared with non-acupuncture treatment. The results of meta-regression showed that the measurement method and acupuncture treatment intensity subgroups were the main sources of heterogeneity between the studies (P<0.01). The results of the subgroup and meta-regression analysis are shown in Table 2.

Meta-Influence Analysis

A sensitivity analysis was performed by selecting a different model and omitting the given study. The combined effect size of the included studies using a random effects model was similar to a fixed effect model (RR: 1.35, 95% CI: 1.25 to 1.46, P=0.000; RR: 1.39, 95% CI: 1.33 to 1.46, P=0.000, respectively). The meta-influence analysis showed the RR of 4 studies[39,40,47,50] in which the CSA was a primary outcome[39,40] and high intensity acupuncture was applied[40,47,50] were different from the combined RR, and might be the main influence of heterogeneity (Figure 3). Hence, we recalculated the effect size after removing the 2 studies and found that the heterogeneity observably reduced (I^2=67.4%, P<0.001; I^2=20.1%, P=0.183). The RR before and after removing the 4 studies were 1.35 (1.25 to 1.46, n=29, P=0.000) and 1.29 (1.22 to 1.36, n=25, P=0.000), respectively.

Assessment of Publication Bias

The possibility of publication bias was analyzed using funnel plots, Begg's test, Egger's test, trim and fill analysis, and Nfs. The funnel plot was not symmetric for the effect size of acupuncture on the clinical score of dysphagia, and showed an observable publication bias (Figure 4A). Begg's test, Egger's test also suggested the presence of a publication bias for all of the analyses(P=0.000, Figures 4 B and C). The trim and fill method was used to adjust the asymmetry of funnel plot. Using the Run method by random effects model after 6 iterations, which filled 12 studies, the results showed that the test for heterogeneity (Q=353.51, P=0.000; Q=726.17, P=0.000, respectively) and the pooled effect size (RR=1.29, 95% CI, 1.24 to 1.33; RR=1.21, 95% CI, 1.04 to 1.38, respectively) with the fixed/random effects model before and after trim and fill analysis did not observably change, and the filled funnel plot was approximately symmetric (Figure 4D). The fail-safe number ($Nfs_{0.05}$=2206.82; $Nfs_{0.01}$=1078.68) that was calculated using abovementioned formula.

Table 2. Subgroup and Meta Regression Analysis

Classification standard	RR	95% CI		Heterogeneity test		Meta-regression
				I^2	*P*	*P*
Stroke type						
1=CI	1.49	1.15	1.94	64.4%	0.000	0.947
2=Non-CI	1.33	1.22	1.44	81.3%	0.000	
Bulbar palsy type						
1=PBP	1.48	1.29	1.70	77.5%	0.000	0.192
2=Non-PBP	1.23	1.14	1.32	25.5%	0.186	
Duration						
1=≤30 d	1.27	1.18	1.36	30.1%	0.143	0.638
2=≥30 d	1.46	1.26	1.70	79.6%	0.000	
Acupuncture intensity						
1=low intensity acupuncture	1.29	1.21	1.37	44.4%	0.008	0.011
2=high intensity acupuncture	2.62	0.87	7.86	95.3%	0.000	
Control design						
1=blank or sham-acupuncture control	1.40	1.26	1.56	75.2%	0.000	0.420
2=rehabilitation control	1.23	1.13	1.34	7.4%	0.373	
Measurement						
1=subjective quantitative assessment	1.32	1.24	1.40	42.4%	0.011	0.001
2=subjective descriptive assessment	2.86	0.03	224.97	99.1%	0.000	
Quality grade						
1=total scores ≥40	1.34	1.01	1.77	59.3%	0.117	0.785
2=total scores <40	1.36	1.25	1.48	69.2%	0.000	
Overall	1.33	1.25	1.43	64.2%	0.000	

Notes: CI: cerebral ischemia; PBP: pseudo-bulbar palsy. High intensity acupuncture consists of 3 criteria including electrical stimulation, ≥30 min of needle retainment, and ≥28 sessions. Low intensity acupuncture consists of less than 3 or none of the 3 aforementioned criteria for high intensity acupuncture

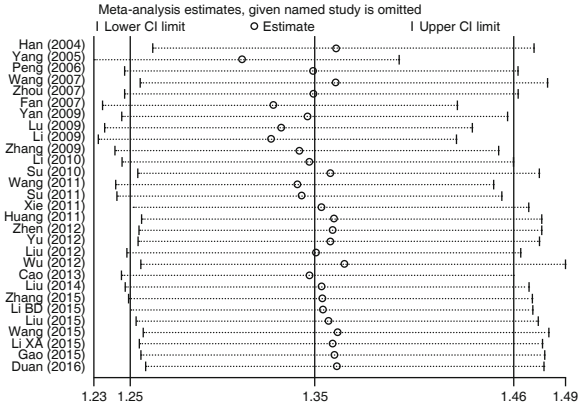

Figure 3. Meta-Influence Analysis

Adverse Events of Acupuncture

Five studies reported that no adverse events were caused by acupuncture treatment.[41,51,52,54,61] The other studies had no mention of the occurrence of adverse events.

DISCUSSION

The aim of our meta-analysis was to update the evidence of efficacy and safety of acupuncture for post-stroke treatment, and we considered the effective rate as a primary outcome in our review. Five systematic reviews related to acupuncture for dysphagia subsequent to stroke[19,20,22-24] were published before 2012, so we retrieve the latest RCTs about acupuncture for dysphagia subsequent to stroke aimed to provide more sufficient evidence for the use of alternative therapy. The primary outcome measures include subjective quantitative assessment scales, such as WST,[68] KSA, FDS, VFSS, and a non-quantitative CSA. All of these assessment tools were quantitative bedside swallowing assessments, except the last one. In the present review, the event and no-event counts of the treatment and control group were extracted to calculate the RR with a 95% CI for the effect size.

The strength of our study was that it involved the greatest number of updated RCTs and the rigorous inclusion criteria for the identificated RCTs. The main findings were that acupuncture was effective and safe

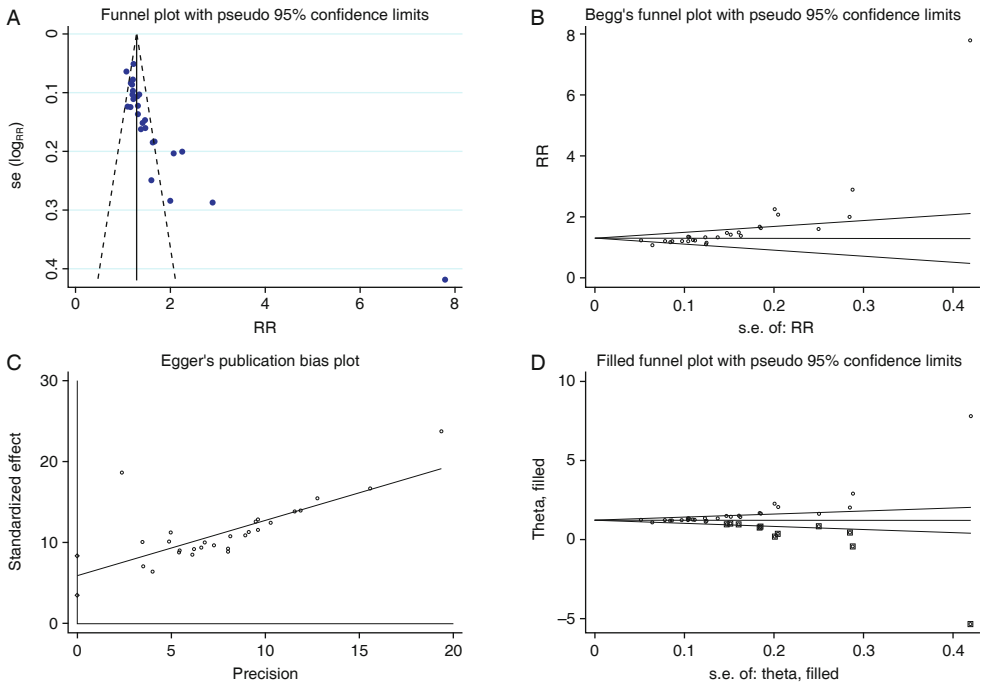

Figure 4. Assessment of Publication Bias

for improving clinical symptom scores of swallowing difficulties, and a significantly better clinical effective rate was observed for acupuncture treatment compared with no treatment or rehabilitation therapy. For subgroup analysis, compared with non-acupuncture treatment, acupuncture tended to be more effective in treatment of dysphagia in patients with ischemic stroke, PBP, and a long duration from stroke onset compared to those with non-ischemic stroke, non-pseudo-bulbar palsy, and a short duration from stroke onset. Moreover, high intensity acupuncture, i.e., electrical stimulation, a longer needle retainment time (≥30 min), and more treatment sessions (≥28 sessions) were more effective than low intensity acupuncture, i.e., manual stimulation, a shorter needle retainment time (<30 min), and fewer treatment sessions (<28 sessions).

According to the multivariate meta-regression, 29 studies included in the meta-analysis exhibited a significant heterogeneity in the dysphagia assessments. VFSS and FEES were regarded as the "gold standard" for diagnosing swallowing difficulties after stroke.[69,70] Due to the potential risk of aspiration, inconvenience of performance, and a consideration of cost-effectiveness,[71] other scales and questionnaires were more widely applied to evaluate the presence of dysphagia following stroke in clinical practice,[72] while the diagnostic accuracy varied due to the sensitivity and specificity of the bedside assessment tools and the subjective skills of the assessors. The scales of measurement that were used in the enrolled trials in our studies included WST, KSA, FDS, VFSS, and CSA, and all of them are subjective clinical assessment tools based on the observation of the assessors. The acupuncture treatment regimen was also diverse, including the acupoints, stimulation method, needle retainment time, and treatment sessions. Although some acupoints were more commonly used, the acupuncture treatment intensity greatly varied among included RCTs of the meta-analysis. The meta-regression analysis also demonstrated that the non-quantitative and symptom-descriptive measurement and the acupuncture treatment intensity were the main sources of heterogeneity in the present systematic review and meta-analysis.

The present systematic review provides inconclusive evidence for the consideration acupuncture as a routine treatment. However, our evidence is sufficient to regard acupuncture as an alternative approach to the current treatment strategies for post-stroke dysphagia, especially in the international background of an increasing application of acupuncture therapy.

There were some limitations in our study that may affect the interpretation of the results. First, the included trials were generally of poor methodological

quality. Insufficient or inexact reports on allocation concealment, blinding of performance, and assessment, especially non-quantitative instrumental evaluation of outcomes were found in most of included studies. The assessment of swallowing ability mainly included bedside and instrumental evaluation. The VFSS and FEES are the 2 instrumental evaluations for dysphagia that are considered the "gold standard" for swallowing evaluation. However, only 2 studies used VFSS in the reporting swallowing performance of the participants. In addition, the scale used was determining the clinical effective rate, which was classified as cured, markedly effective, effective, and ineffective, is not internationally recognized; hence, it may not be accurate for the assessment of the effect of treatment. Therefore, such analysis lowered the validity of the results. Second, the long-term effects could not be evaluated; this prevented us from reaching a robust conclusion with our meta-analysis. With the exception of one study[51] with a 3-month follow-up, most of the studies only reported the short-term effects of treatment. The outcomes were assessed before and immediately after the treatment sessions; thus, they could not reveal the long-term effects of acupuncture on dysphagia after stroke. Another limitation was the small sample sizes of the included studies. Only 1 trial in the review calculated the pretrial sample size using statistics. Finally, a language bias may exist because all of the included trials were conducted and published by Chinese investigators.

In conclusion, this systematic review and meta-analysis provides updated evidences to recommend acupuncture as an effective and safe alternative therapy for treatment to post-stroke dysphagia, although the beneficial effect from acupuncture is possibly overvalued due to the low methodology quality of the included RCTs. More high-quality and large-scale research studies are needed.

Conflict of Interest

The authors declare no competing interests.

Author Contributions

Qu Y designed the research; Li LX and Deng K performed the research; Deng K analyzed the data; and Li LX wrote the paper.

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