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Acupuncture for Post-stroke Shoulder-Hand Syndrome: A Systematic Review and Meta-Analysis

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Background: Shoulder-hand syndrome (SHS) is prevalent in hemiplegic patients after stroke. Potential benefits of acupuncture were shown in recent clinical trials. This systematic review aimed to comprehensively evaluate the safety and efficacy of acupuncture for SHS in stroke patients.

Methods: Five English databases (PubMed, Embase, CINAHL, CENTRAL, and AMED) and four Chinese databases (CBM, CNKI, CQVIP, and Wanfang) were searched from their inceptions to January 2019. Randomized, controlled trials that evaluated the add-on effects of acupuncture to rehabilitation for post-stroke SHS were identified.

Results: Thirty-eight studies involving 3,184 participants fulfilled the eligible criteria and were included in the review. The overall meta-analysis showed that acupuncture combined with rehabilitation significantly improved motor function (upper-limb Fugl-Meyer Assessment (FMA): 34 studies, mean difference (MD) 8.01, 95% confidence interval (CI) [6.69,9.33]), and reduced pain (visual analog scale (VAS): 25 studies, MD −1.59, 95%CI [−1.86,−1.32]). It also improved activities of daily living (ADL) when compared with rehabilitation alone (ADL: 11 studies, MD 9.99, 95%CI [5.91,14.06]). However, the certainty of evidence of all these outcomes was assessed as "low." Subgroup analyses of acupuncture stimulation types and treatment duration all showed significant add-on effects comparing with rehabilitation alone. The safety of acupuncture was unclear because there is a lack of detailed reporting of adverse events in most of the included studies.

Conclusions: Acupuncture therapy seems effective for motor function, pain relief and activities of daily living in stroke patients with mild SHS, when it is used in combination with rehabilitation. The low certainty of evidence downgrades our confidence in making recommendations to clinical practice.

Keywords: acupuncture, stroke, shoulder-hand syndrome, rehabilitation, systematic review

INTRODUCTION

Shoulder-hand syndrome (SHS) is a common condition among people who have had a stroke, with its reported prevalence ranging from 12% to 49% (1, 2). The main symptoms of SHS include pain, hyperalgesia, joint swelling and limitations in range of motion (ROM) (3). Post-stroke SHS is also named type I complex regional pain syndrome (CRPS) or reflex sympathetic dystrophy (4). The key to effectively treating SHS is believed to be an expert multidisciplinary team that provides individualized therapy (5). There is a wide range of treatment options available to help manage post-stroke SHS, including physical therapy, medications, regional anesthesia techniques and neuromodulation. However, there is insufficient evidence to support their efficacy (5).

Acupuncture, one of the most popular traditional Chinese medicine therapies, has been widely used in the clinical management of stroke (6). Several systematic reviews have assessed its efficacy for improving stroke rehabilitation using outcomes in motor function recovery and disability, but results are inconsistent (7–11). Three reviews published before 2010 showed acupuncture did not improve motor function or dependency outcomes after rehabilitation (8, 9, 11). However, two more recently published reviews suggested acupuncture might aid rehabilitation in several areas, including motor function recovery and pain relief (7, 10).

Three systematic reviews specifically evaluating acupuncture for post-stroke SHS have been published (12–14). Two of these were published before 2013 (12, 13), so they don't include recently published clinical evidence. Moreover, one review including three studies did not perform quantitative synthesis due to clinical heterogeneity (13). The third review (14) does not evaluate the effectiveness of electro-acupuncture, and only two of its included studies evaluated the effectiveness of acupuncture combined with routine care. Considering electro-acupuncture is commonly used in the clinical management of stroke complications, the implication of the review results (14) for clinical practice is limited. Therefore, we conducted this systematic review looking at the most recent evidence of acupuncture (including electro-acupuncture) as an additional therapy in the clinical management of post-stroke SHS.

METHODS

Study Design

This systematic review included randomized controlled trials (RCT) or quasi-RCTs that were published in English or Chinese and evaluated acupuncture's effects as an additional therapy for post-stroke SHS. Quasi-RCTs were evaluated using the same methods applied to RCTs.

We registered its protocol with the PROSPERO international prospective register of systematic reviews (CRD 42016050446).

Participants

We limited participants to people who were diagnosed with post-stroke SHS. The stroke (ischemic or hemorrhagic) diagnosis needed to be confirmed by computer tomography or magnetic resonance imaging. The SHS or CRPS type I diagnosis was based on clinical symptoms, including pain, motor disturbances and skin changes (3).

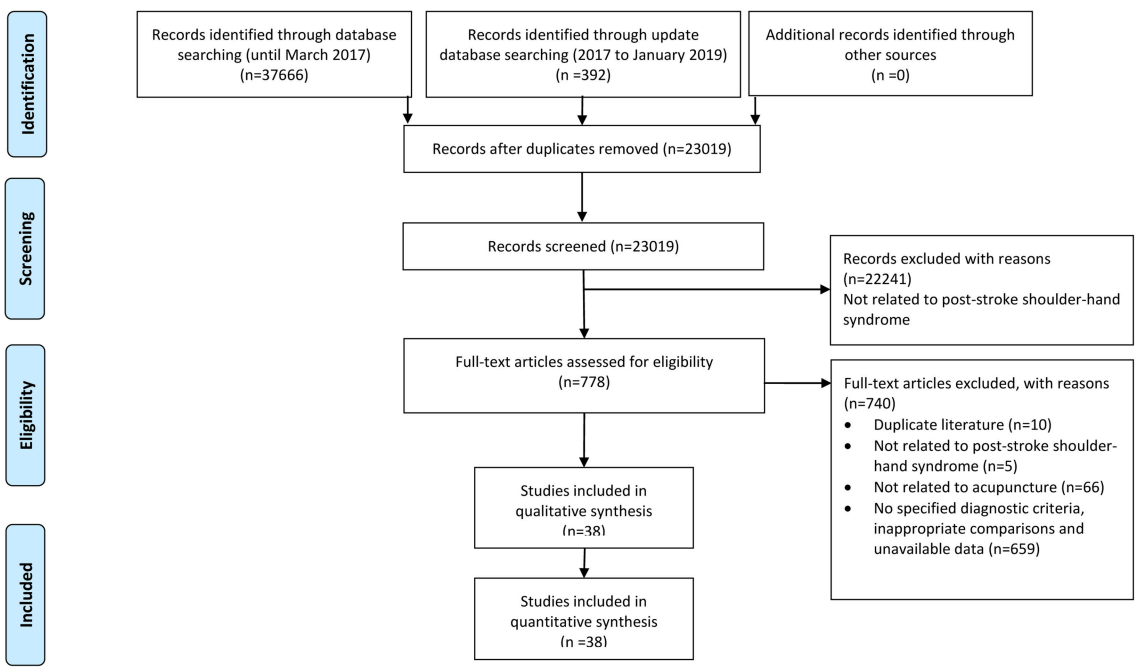

FIGURE 1 | PRISMA flow chart.

Intervention

We included RCTs or quasi-RCTs that evaluated the effects of manual or electro-acupuncture combined with routine care or rehabilitation as the experimental intervention in this review. Studies that assessed auricular acupuncture or other types of recently developed acupuncture forms, such as floating acupuncture, were excluded from this review.

The rehabilitation therapy used in RCTs or quasi-RCTs could be a combination of physiotherapy and occupational therapy, such as active ROM, passive ROM, mirror visual feedback, Bobath therapy, alternating heat and cold baths, and massage. The comparator was the same as the rehabilitation therapy used in the intervention group, but without acupuncture. Studies that used placebo or sham acupuncture and the same rehabilitation therapy in the control group were also eligible for inclusion.

Outcome

RCTs or quasi-RCTs that reported validated SHS outcome measures as below were considered for inclusion in this review.

Primary outcome measures: (1) motor function: Fugl-Meyer Assessment (FMA) upper limb; (2) pain assessment using visual analog scale (VAS) or numerical rating scale (NRS).

Secondary outcome measures: (1) Barthel Index (BI) or Modified Barthel Index (MBI), which is assessed for self-care and activities of daily living; (2) ROM; and (3) adverse events.

Literature Search

We searched nine databases, five in English, and four in Chinese languages, from their inceptions to January 2019. They are: PubMed, Embase, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Cochrane Central Register of Controlled Trials (CENTRAL), the Allied and Complementary Medicine Database (AMED), China BioMedical Literature (CBM), China National Knowledge Infrastructure (CNKI), Chonqing VIP (CQVIP), and Wanfang. We also searched clinical trial registration agencies, including the Chinese Clinical Trial Registry and National Institutes of Health Register (Clinical Trials.gov), and hand-searched references lists of included studies and relative systematic reviews. The search terms and search strategy we used are presented in **Appendix S1**.

Data Extraction

Two researchers (SL, YC) independently screened the titles, abstracts and full text of studies to assess eligibility. Any uncertainty was resolved through discussion with CZ. SL and YC developed a standardized data extraction file using Epidata software 3.1 (The EpiData Association, Odense, Denmark, 2003–2008). They also extracted data independently and cross-checked it for accuracy. Extracted data included: author, publication year, diagnostic criteria, duration of disease, sample size, participants' age, details of interventions and all clinical outcomes.

Risk of Bias and Certainty of Evidence Assessment

Two researchers (SL, YC) used the Cochrane risk of bias tool to assess the methodological quality of the included studies. They assessed seven items: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other sources of bias. The studies were judged as having a "low," "high," or "unclear" risk of bias. SL and YC resolved any difference in their assessment of a study by discussing it with a third researcher (CZ).

The Grading of Recommendations Assessment, Development and Evaluation Approach (GRADE) was used to evaluate the certainty of evidence. Five items involving risk of bias, inconsistency, imprecision, indirectness and publication bias were investigated for the clinical important outcomes.

Data Analysis

The included studies calculated acupuncture's safety and efficacy when combined with rehabilitation to treat SHS, compared to rehabilitation alone. Data analyses were performed in a random-effects model using the RevMan software (version 5.3). Dichotomous data was reported as relative risk (RR) with corresponding 95% confidence intervals (CI). For continuous data, the mean difference (MD) with 95% CI was calculated.

The following subgroup analyses were planned: (1) subgroups of manual or electro-acupuncture; (2) subgroups of treatment duration $\leq$4 or $>$4 weeks. Since an inappropriate randomization sequence generation was associated with biased intervention effects (15), we conducted a sensitivity analysis to check the robustness of the results by only including the RCTs that were assessed as "low" risk of bias for this item.

RESULTS

Descriptions of Studies

We identified 36 eligible studies (16–51) by searching Chinese and English databases up to March 2017. An updated search, including studies from 2017 to January 2019, located another two studies that met the inclusion criteria (52, 53). As a result, 38 RCTs involving 3,184 participants were included in this review (**Figure 1**).

As reported by the included studies, SHS occurred after ischemic stroke in four studies (40, 42, 44, 45), and after hemorrhagic or ischemic stroke in 23 studies. The remaining 11 studies (17–19, 23, 28, 30, 31, 41, 46, 47, 50) did not include information about the type of stroke. The duration of stroke ranged from 10 days (46) to 19 months (17). The severity of SHS was reported by 27 studies and divided into acute-hyperaemic (stage I), dystrophic-ischaemic (stage II) and atrophic (stage III) according to clinical symptoms (54). Twenty studies recruited participants at stage I with mild symptoms of $<$3 months of SHS. The remaining seven studies included participants with stage II or III.

All of the eligible trials compared body acupuncture plus routine rehabilitation with routine rehabilitation alone. Of all, 12 studies also applied electrical stimulation with acupuncture (16–18, 20, 21, 32, 34, 36–39, 46). The most commonly used acupuncture points were LI15 *Jianyu*, LI11 *Quchi*, TE5 *Waiguan*, LI4 *Hegu*, TE14 *Jianliao*, LI10 *Shousanli*, HT1 *Jiquan*, PC6 *Neiguan,* and SI9 *Jianzhen*. Routine rehabilitation included active ROM, passive ROM, mirror visual feedback, Bobath therapy,

TABLE 1 | Basic characteristics.

References	Sample size	Stroke type	SHS severity	Duration of condition	First stroke onset	Intervention	Comparisons	Acupoints	Acupuncture treatment details	Treatment duration	Outcome measures
Chen (32)	96/85	Cerebral infarction and hemorrhage	NS	NS	NS	EA + Rehab	Rehab	EX-B2, GB21, SI11, LI15, TE14, SI9, LI14, PC3, LU5, TE5, SI3, LI4, HT1	Once/d, 6 d/w	4 w	FMA
Chen et al. (51)	48/46	Cerebral infarction and hemorrhage	Stage I	I: 34.91 d; C: 35.41 d	Yes	Acupuncture + Rehab	Rehab	LI15, TE14, Jianqian, SI9, LI11, TE5, LI10, EX-UE9	30 min, once/d, 6 d/w	4 w	FMA, VAS, BI
Duan et al. (17)	60/60	NS	NS	14 d–19 m	NS	EA + Rehab	Rehab	SI11, SI9, SI10, LU2, LI11, LI10, HT3, Jianqian, Jianfeng, Ashi point	20 min, once/d, 5 d/w	8 w	FMA
Feng and Ma (50)	69/57	NS	Stage I	33.1 d	NS	Acupuncture + Rehab	Rehab	PC6, LI5, ST9, LU5, HT1	30 min, once/d	4 w	FMA, VAS, ROM
Gao et al. [2011[16]]	16/16	Cerebral infarction and hemorrhage	NS	48.5 d	NS	EA + Rehab	Rehab	LI15, TE14, LI14, LI11, TE5, TE4, KI15, EX-UE9	30 min, once/d	4 w	VAS, BI
He and Gao (49)	60/60	Cerebral infarction & hemorrhage	Stage I	I: 21.07 d; C: 20.32 d	NS	Acupuncture + Rehab	Rehab	CV12, CV4, ST24, ST26, Shangfengshidian, Shengfengshiwaidian	30 min, once/d	3 w	FMA, VAS, MBI
Hou (20)	30/30	Cerebral infarction and hemorrhage	Stage I	I: 29.8 d; C: 31.5 d	NS	EA + Rehab	Rehab	GV20, GV24, EX-HN3, LI11, TE5, LI4	50–100 Hz, 30 min, once/d, 5 d/w	4 w	FMA, VAS
Huang et al. (48)	30/30	Cerebral infarction and hemorrhage	Stage I	I: 46.8 d; C: 45.4 d	Yes	Acupuncture + Rehab	Rehab	EX-UE9, EX-UE8	20 min, once/d, 5 d/w	3 w	FMA
Jia et al. (21)	28/24	Cerebral infarction and hemorrhage	Stage I	I: 28.5 d; C: 31 d	NS	EA + Rehab	Rehab	GV20, GV24, EX-HN3, LI15, TE14, LI11, TE5, LI4	50–100 Hz, 30 min, once/d, 5 d/w	4 w	FMA, VAS
Li (18)	60/60	NS	NS	NS	NS	EA + Rehab	Rehab	LI1, LI2, LI3, LI5, LI11,	2–30 Hz, 15 min, once/d	14 d	FMA
Li and Tu (34)	45/45	Cerebral infarction and hemorrhage	Stage I	I: 4.29 m; C: 3.93 m	Yes	EA + Rehab	Rehab	LI10, LI15, LI15, LI11, PC6, TE5, LI4, Ashi point	50–100 Hz, 30 min, once/d, 5 d/w	6 w	FMA, VAS, MBI
Li et al. (47)	46/46	NS	NS	NS	NS	Acupuncture + Rehab	Rehab	LU9, ST36, LI11, LI10, LI15, GB39, BL62	30 min, once/d, 6 d/w	1 m	FMA
Liang and Liu (46)	42/42	NS	Stage I, II	I: 10 d–3 m; C: 15 d–3 m	NS	EA + Rehab	Rehab	GB21, LI15, SI9, TE14, LI14, SI11, LI11, TE5, SI3, PC8, LI4	30 min, once/ d	30 d	FMA, VAS
Liao (33)	45/45	Cerebral infarction and hemorrhage	NS	I: 48.6 d; C: 50.7 d	NS	Acupuncture + Rehab	Rehab	GV26, PC6, HT5, HT1, ST36, GB39, SP6,LI15, LI4, LI11, TE13, TE9	30 min, once/d	5 w	FMA, VAS, MBI
Lin et al. (30)	40/40	NS	Stage I	I: 29.3 d; C: 28.6 d	NS	Acupuncture + Rehab	Rehab	Piantan, Jiantong, Shengti, Jiansanzhen, Ashi point, HT1, PC6, LU5	30 min, once/d	4 w	FMA, VAS
Liu (23)	40/40	NS	NS	I: 36.25 d; C: 37.25 d	NS	Acupuncture + Rehab	Rehab	Jiantong	30 min, once/d, 5 d/w	40 d	FMA, VAS, ROM
Liu and Zhang (52)	49/49	Cerebral infarction and hemorrhage	NS	I: 48.18 d; C: 47.18 d	Yes	Acupuncture + Rehab	Rehab	LI15, LI11, TE5, LI4, SI3, TE3	20 min, once/d, 6 d/w	4 w	FMA, VAS
Qin et al. (27)	40/40	Cerebral infarction and hemorrhage	Stage I	I: 4 m; C: 4 m	Yes	Acupuncture + Rehab	Rehab	Four points in head	30 min, once/d, 6 d/w	NS	VAS

(Continued)

TABLE 1 | Continued

References	Sample size	Stroke type	SHS severity	Duration of condition	First stroke onset	Intervention	Comparisons	Acupoints	Acupuncture treatment details	Treatment duration	Outcome measures
Shang et al. (28)	40/40	NS	Stage I, II	I: 5.23 m; C: 5.02 m	NS	Acupuncture + Rehab	Rehab	LI15, Jianqian, TE14, HT1, LI14, LI11, PC6, LI4	40 min,2 times/d	30 d	FMA, ROM
Su et al. (24)	22/21	Cerebral infarction and hemorrhage	Stage I, II	I: 44.2 d; C: 43.7 d	NS	Acupuncture + Rehab	Rehab	Piantan, Jiantong, Shengti	once/d	2 w	FMA
Tang et al. (45)	30/30	Cerebral infarction	Stage I	I: 48.54 d; C: 49.12 d	NS	Acupuncture + Rehab	Rehab	SI11, LI15, LI14, Jianqian, KI15, SI3	40 min, 6 d/w	28 d	FMA, VAS
Wan et al. (25)	40/40	Cerebral infarction and hemorrhage	Stage I, II	I: 24.53 d; C: 24.4 d	NS	Acupuncture + Rehab	Rehab	Piantan, Jiantong, Bitong, Wantong	once/d, 5 d/w	4 w	FMA, MBI
Wan et al. (29)	60/60	Cerebral infarction and hemorrhage	Stage I, II	I: 38.4 d; C: 33.0 d	NS	Acupuncture + Rehab	Rehab	LU9, ST36, GB39, TE5, LI10, LI11, LI15	30 min, once/d	28 d	FMA
Wang et al. (31)	31/31	NS	NS	I: 10–26 d; C: 12–29 d	NS	Acupuncture + Rehab	Rehab	Ashi point, LI15, Jianqian, SI9, HT1, LU5, LI10, LI11, PC6, TE5, LI4	30 min, once/d, 5 d/w	5 w	MBI
Wang et al. (53)	71/71	Cerebral infarction and hemorrhage	Stagel, II, III	I: 66.8 d; C: 67.4 d	NS	Acupuncture + Rehab	Rehab	LI15, TE14, GB21, SI9, LI17, LI11, TE5, LI4, SI6, KI15, CV6, ST36	15 min, once/d	21 d	FMA, MBI
Wu (39)	30/30	Cerebral infarction and hemorrhage	Stage I	15 d–3 m	NS	EA + Rehab	Rehab	EX-B2, TE14, TE13, LI15, LI14, SI9, HT1, LI4, LI11, KI15, TE5, SI6, SI3	30 min, once/d, 6 d/w	4 w	ROM
Xie (40)	30/30	Cerebral infarction	NS	15 d–3 m	NS	Acupuncture + Rehab	Rehab	Tousanzhen, Jiansanzhen, HT1, LU5, PC6	once/d, 5 d/w	4 w	FMA, VAS, AE
Xu (36)	36/36	Cerebral infarction and hemorrhage	Stage I	I: 5–44 d; C: 4–47 d	NS	EA + Rehab	Rehab	LI1, LI2, LI3, LI5, LI11	30 min, once/d, 6 d/w	4 w	FMA, VAS, AE
Xu et al. (19)	42/40	NS	Stage I	I: 33.45 d; C: 27.14 d	NS	Acupuncture + Rehab	Rehab	Jiansanzhen, HT1, LU5, PC6	30 min, once/d, 6 d/w	5 w	VAS, FMA, ROM, AE
Xu et al. (44)	40/40	Cerebral infarction	Stage I	I: 47.2 d; C: 48.6 d	Yes	Acupuncture + Rehab	Rehab	LI15, LI14, HT1, Jianqian, Jianhou, KI15, SI3	40 min	14 d	FMA, VAS
Yang et al. (43)	40/40	Cerebral infarction and hemorrhage	Stage I	I: 87.93 d; C: 95.8 d	NS	Acupuncture + Rehab	Rehab	LI15, LI11, LI10, PC6, LI4	30 min, once/d	20 d	FMA, VAS
Yin et al. (26)	30/30	Cerebral infarction and hemorrhage	Stage I	I: 67.17 d; C: 67.10 d	NS	Acupuncture + Rehab	Rehab	Six meridians on hand, including LI15, LI11, TE14, GB21, etc.	20–30 min, once/d, 6 d/w	4 w	FMA, VAS
You (37)	31/31	Cerebral infarction and hemorrhage	Stage I, II, III	I: 31.89 d; C: 33.45 d	NS	EA + Rehab	Rehab	LI15, TE14, SI9, LI14, SI11, LI10, TE5, LI4, EX-UE9	30 min, once/d, 6 d/w	4 w	FMA, VAS, MBI, ROM
Zhang (38)	30/30	Cerebral infarction and hemorrhage	Stage I	I: 58.64 d; C: 54.97 d	NS	EA + Rehab	Rehab	LI15, LI11, LI4, TE5, LI10	30 min, once/d, 5 d/w	3 w	FMA, VAS, AE
Zhao (42)	24/23	Cerebral infarction	Stage I	I: 77.67 d; C: 65.65 d	Yes	Acupuncture + Rehab	Rehab	TE14, SI9, Jianqian, LI15, Ashi point, LI11, LI5, TE5	30 min, once/d, 6 d/w	28 d	FMA, VAS, MBI, AE
Zheng et al. (35)	39/38	Cerebral infarction and hemorrhage	Stage I	I: 41.72 d; C: 42.48 d	NS	Acupuncture + Rehab	Rehab	LI15, TE14, SI9, LI11, LI10, TE5, LI4, SI3	30 min, once/d, 5 d/w	4 w	FMA, VAS, BI
Zhong et al. (41)	30/30	NS	Stage I	I: 28.4 d; C: 29.2 d	NS	Acupuncture + Rehab	Rehab	Piantan, Jiantong, Shengti, Jiansanzhen, Ashi point, HT1, PC6, LU5	30 min, once/d	30 d	FMA, VAS
Zhou et al. (22)	45/45	Cerebral infarction and hemorrhage	NS	I: 55.13 d; C: 57.08 d	NS	Acupuncture + Rehab	Rehab	LI4, LU7, LI11, LI15, CV21, CV4	30 min, once/d, 6 d/w	1 m	FMA, VAS

All included articles were published in Chinese journals. AE, adverse events; BI, Barthel Index; C, comparison; d, day; EA, electroacupuncture; FMA, Fugl-Meyer Assessment (upper limb); I, intervention; m, month; MBI, Modified Barthel Index; NS, not specified; Rehab, rehabilitation; ROM, shoulder range of motion; VAS, visual analog scale; w, week; SHS, shoulder-hand syndrome.

alternating heat and cold baths, and massage. Treatment duration ranged from 2 to 8 weeks. None of the included studies involved a follow-up phase to investigate acupuncture's long-term effects.

Thirty-four studies used FMA to evaluate acupuncture's effects on upper limb motor function. Pain severity was assessed with VAS in 26 studies. None of the included studies reported NRS. For secondary outcomes, 11 studies reported BI or MBI, six studies reported ROM, and five studies reported adverse events (**Table 1**).

Risk of Bias of Included Studies

Seventeen studies (45%) were assessed as "low" risk of bias for sequence generation, and the remaining studies were assessed as "unclear" risk due to a lack of information. Only one study (38) used opaque envelopes to conceal the allocation procedure, so it was assessed as "low" risk of bias for this item. Blinding of participants and acupuncturists was not performed in any study. Blinding of outcome assessors was assessed as "unclear" risk of bias for all studies due to a lack

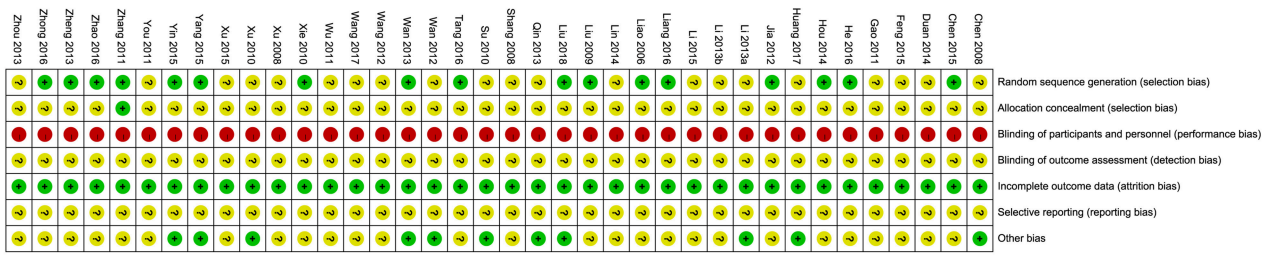

FIGURE 2 | Risk of bias of each study.

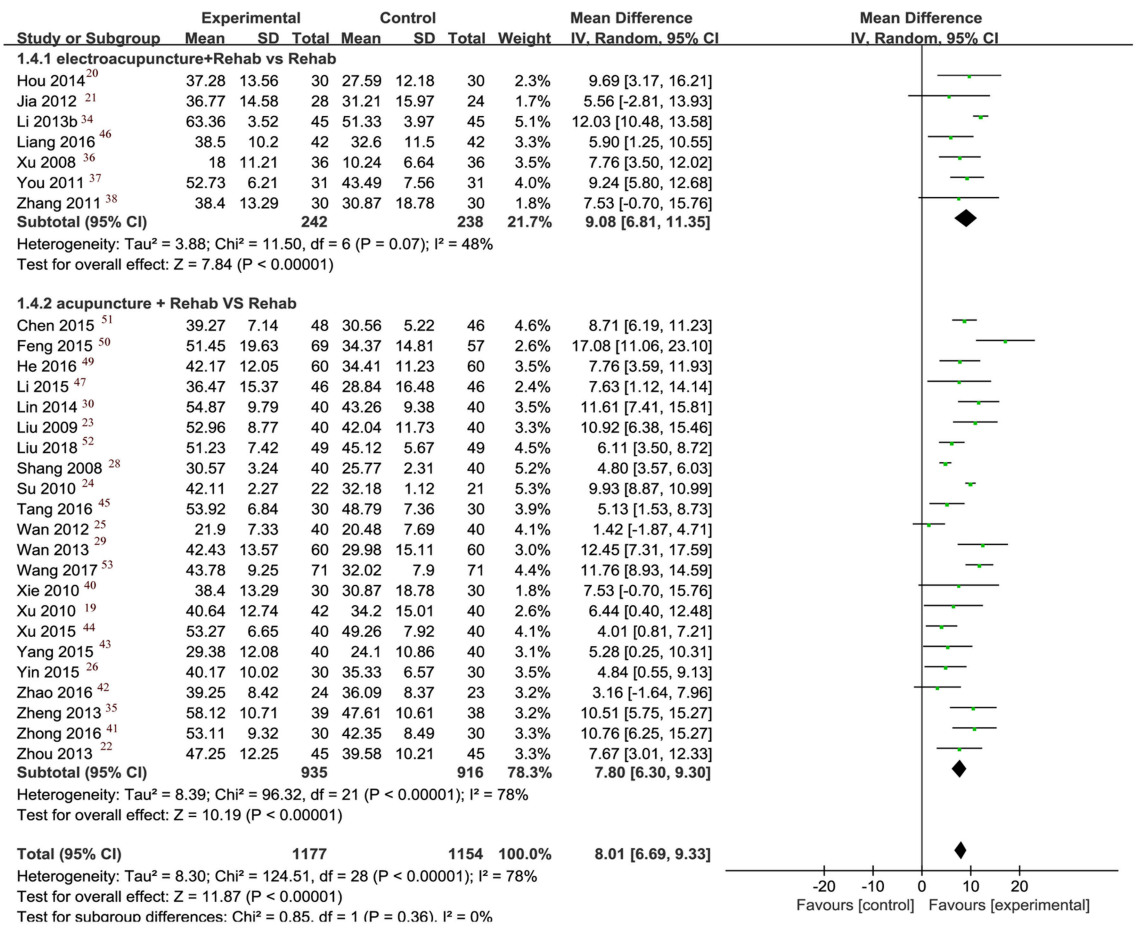

FIGURE 3 | Forest plot of FMA.

of information. We also assessed selective outcome reporting as "unclear" risk of bias for all studies, because none of the studies had published their protocols. For incomplete outcome data, we assessed all studies as "low" risk of bias because there was no missing outcome data. Eleven studies (18, 19, 24–27, 29, 32, 43, 48, 52) reported the funding source and showed balanced baseline data, so we assessed the relative other bias as "low" risk. Details are summarized in **Figure 2** and **Figure S1**.

Acupuncture's Effects on Post-stroke SHS

FMA (Upper Limb)

Thirty-four studies reported data on upper limb FMA scores when acupuncture was combined with rehabilitation compared to rehabilitation alone. Meta-analysis of 29 studies showed the combination therapy had a significant superior effect (MD: 8.01, 95% CI [6.69, 9.33]; $I^2 = 78\%$). We did not include the remaining five studies (17, 18, 32, 33, 48) in our analysis due to their inappropriate data reporting: three studies (18, 33, 48) only reported scores of certain items without the total score, one study (32) reported FMA as categorical data, and one study (17) did not report FMA data for the control group.

VAS

Compared with routine rehabilitation alone, acupuncture combined with routine rehabilitation showed superior effects on VAS scores in 25 studies (MD: −1.59, 95% CI [−1.86, −1.32]; $I^2 = 87\%$). We excluded one study (27) in the meta-analysis because its data was reported with median and interquartile ranges.

ADL

Eleven studies reported acupuncture's effects on ADL performance, as measured by the Barthel Index (BI) or Modified Barthel Index (MBI). Meta-analysis showed that acupuncture combined with routine rehabilitation enhanced ADL performance more than rehabilitation alone did (MD: 9.99, 95% CI [5.91, 14.06]; $I^2 = 86\%$).

ROM

Acupuncture combined with routine rehabilitation improved shoulder abduction by an average of 11.94 degrees (three studies (19, 23, 37): 95% CI [9.44, 14.45]; $I^2 = 0\%$), shoulder internal rotation by 18.72 degrees (one study (37): 95% CI [9.63, 27.81]), and shoulder external rotation by 15.73 degrees (one study (37): 95% CI [6.82, 24.64]), when compared with rehabilitation alone.

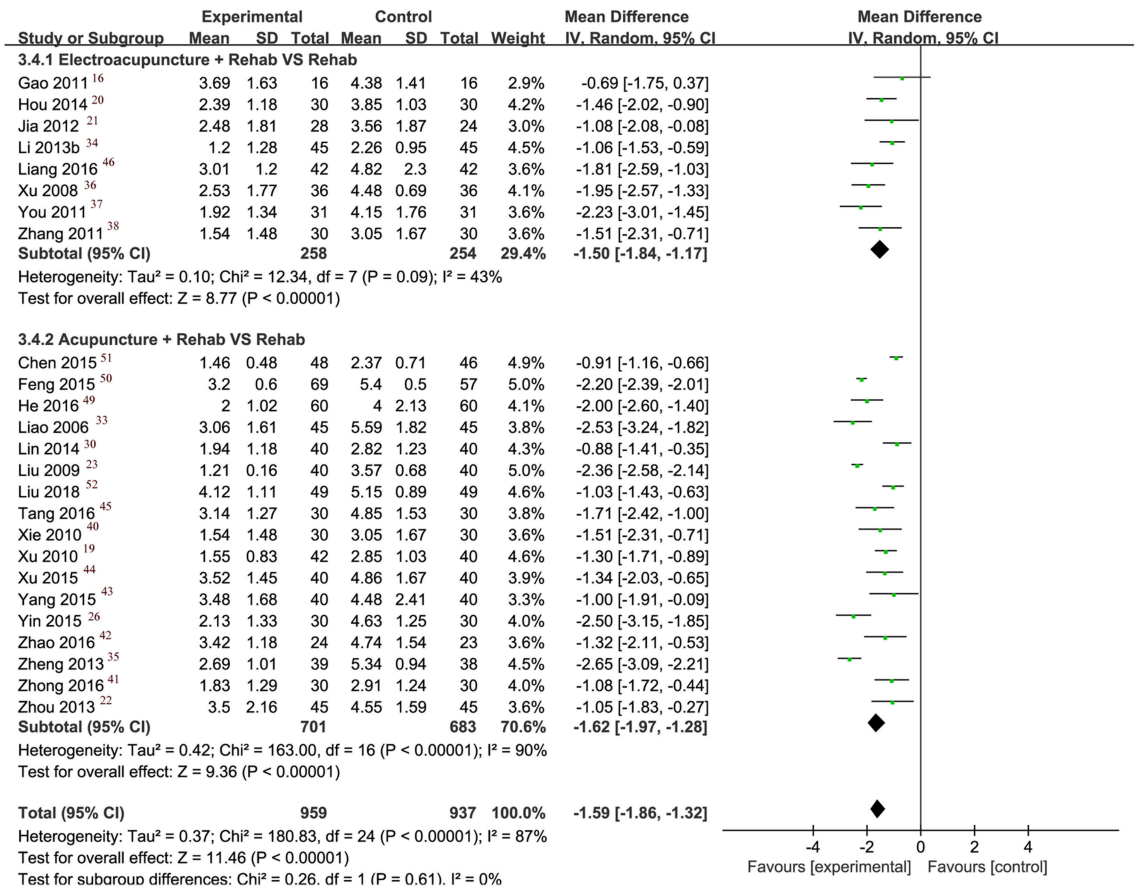

FIGURE 4 | Forest plot of VAS.

Subgroup Analysis and Sensitivity Analysis

Subgroup analysis was conducted to examine whether adding electrical stimulation to manual acupuncture will affect primary outcomes. Manual and electro-acupuncture combined with routine rehabilitation improved FMA and pain VAS outcomes more than rehabilitation alone did (**Figures 3**, **4**). The effect of electro-acupuncture (MD 9.08, 95% CI [6.81, 11.35]) seems greater in magnitude than manual acupuncture (MD 7.80, 95% CI [6.30, 9.30]) for improving upper limb motor function, however, there was not any direct analysis to compare electro-acupuncture with manual acupuncture in this research.

Further subgroup analyses in the manual or electro-acupuncture group looked at the impact of treatment duration on outcomes. We found that treatment duration ($\leq$4 weeks or $>$4 weeks) did not significantly change the outcome. However, the number of studies included in each subgroup was relatively small (**Table 2**).

Sensitivity analysis was performed by only including studies that reported appropriate randomization sequence generation methods. The results were similar to that of the overall pool, with lower heterogeneity. The results also showed that acupuncture combined with routine rehabilitation produces better outcomes for FMA and VAS than rehabilitation alone (**Table 2**).

Publication Bias

Publication bias was evaluated based on FMA and VAS, which were reported in 29 and 25 studies, respectively. Egger's test demonstrated there was no significant publication bias (FMA: $t = -0.39$, $P = 0.702$; VAS: $t = 1.50$, $P = 0.147$).

Adverse Events

Thirty-three studies did not mention adverse events. Four studies reported that no adverse event occurred during the trials (19, 36, 40, 42). One RCT (38) described that three participants in the intervention group and two in the control group reported bruising after treatment. These events were considered to be mild and did not require any medical management. The study did not explore the causality of these adverse events (38).

Assessment of Evidence

The evidence of all these outcomes was assessed as "low" certainty. The certainty of evidence was downgraded mainly due to the limitations in study design and inconsistency of results. The summary of finding table was presented in **Table 3**.

DISCUSSION

In this review, we identified 38 RCTs that evaluated the effects of adding acupuncture to routine rehabilitation to treat post-stroke SHS. Results showed that the combination of acupuncture and routine rehabilitation was superior to rehabilitation alone for improving motor function and ADL, and reducing pain. Manual and electro-acupuncture were both beneficial in the subgroup analysis. Further analysis of treatment duration did not indicate that treatment outcomes change with a long course of treatment (e.g., more than 4 weeks). The safety of acupuncture should be further validated, because most of the included studies did not mention adverse events. In addition, the overall "low" GRADE assessment results made our certainty in recommending this therapy to clinical practice as "low."

Manual and electro-acupuncture combined with routine rehabilitation improved FMA more than rehabilitation alone did. Moreover, the results reached the minimal clinical important difference (MCID) suggested by Page et al. (55) and Chen et al. (56) (5.2 and 4.58, respectively). Our results, based on 29 RCTs, confirmed the results of one previous systematic review (12) that evaluated FMA in six RCTs. Another previously published review (14) showed no benefit of acupuncture, however, the review only included two manual acupuncture RCTs in its meta-analysis. In contrast, our review included more studies with a larger sample size. It should also be noted that recent studies have sought to improve their methodology quality, with half of the included studies reporting appropriate randomization sequence generation. These will provide a greater certainty of the evidence of acupuncture's effect on motor function.

In terms of pain VAS, our review showed acupuncture combined with routine rehabilitation was much more effective

TABLE 2 | Subgroup analysis and sensitivity analysis.

Analysis	FMA (upper limb) (number of studies, number of participants in intervention/control group, mean difference, 95% CI, I^2)	VAS (number of studies, number of participants in intervention/control group, mean difference, 95% CI, I^2)
Acupuncture + rehabilitation vs. rehabilitation	22, 935/916, 7.80 [6.30, 9.30], 78%	17, 701/683, −1.62 [−1.97, −1.28], 90%
Treatment duration ≤ 4 weeks[a]	16, 692/675, 7.79 [6.02, 9.57], 77%	12, 499/483, −1.60 [−2.02, −1.17], 90%
Treatment duration > 4 weeks[a]	6, 243/241, 7.74 [5.04, 10.43], 62%	5, 202/200, −1.68 [−2.34, −1.03], 89%
Reported appropriate randomized allocation methods[b]	12, 480/476, 7.64 [6.09, 9.18], 40%	12, 465/461, −1.73 [−2.18, −1.27], 91%
Electroacupuncture + rehabilitation vs. rehabilitation	7, 242/238, 9.08 [6.81, 11.35], 48%	8, 258/254, −1.50 [−1.84, −1.17], 43%
Treatment duration ≤ 4 weeks[a]	5, 155/151, 8.46 [6.18, 10.75], 0%	6, 171/167, −1.57 [−1.97, −1.18], 37%
Treatment duration > 4 weeks[a]	2, 87/87, 9.37 [3.42, 15.33], 83%	2, 87/87, −1.37 [−2.09, −0.64], 61%
Reported appropriate randomized allocation methods[b]	4, 130/126, 7.00 [3.81, 10.18], 0%	4, 130/126, −1.50 [−1.87, −1.13], 0%

[a] *Subgroup analysis.*
[b] *Sensitivity analysis.*
FMA, Fugl-Meyer Assessment; VAS, Visual Analog Scale.

TABLE 3 | Certainty of evidence (GRADE).

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture + Rehab	Rehab	Relative (95% CI)	Absolute risk difference between two groups (95% CI)		
FMA UPPER LIMB												
29	Randomized trials	Serious[a]	Serious[b]	Not serious	Not serious	None	1,177	1,154	–	MD **8.01 higher** (6.69 higher to 9.33 higher)	⊕⊕◯◯ LOW	Critical
VAS												
25	Randomized trials	Serious[a]	Serious[b]	Not serious	Not serious	None	959	937	–	MD **1.59 lower** (1.86 lower to 1.32 lower)	⊕⊕◯◯ LOW	Critical
ADL												
11	Randomized trials	Serious[a]	Serious[b]	Not serious	Not serious	None	450	446	–	MD **9.99 higher** (5.91 higher to 14.06 higher)	⊕⊕◯◯ LOW	Important
ROM Abduction												
3	Randomized trials	Serious[a]	Not serious	Not serious	Serious[c]	None	113	111	–	MD **11.94 degree higher** (9.44 higher to 14.45 higher)	⊕⊕◯◯ LOW	Important

[a]*Lack of blinding of participants and personnel.*
[b]*Substantial statistical heterogeneity.*
[c]*Small sample size limits certainty of results.*
FMA, Fugl-Meyer Assessment; VAS, visual analog scale; ADL, activities of daily living; ROM, range of motion; Rehab, rehabilitation; CI, Confidence interval; MD, Mean difference; GRADE, The Grading of Recommendations Assessment, Development and Evaluation.

than rehabilitation alone at reducing pain. These results are consistent with a recent systematic review of acupuncture for post-stroke shoulder pain (57). Furthermore, our review showed that manual and electro-acupuncture both help to relieve pain when used in combination with routine rehabilitation. This could reinforce the evidence for acupuncture in reducing pain associated with post-stroke SHS (**Table 2**).

The mechanism of how acupuncture relieves pain has been extensively studied. Electro-acupuncture alleviates sensory and affective inflammatory pain by acting through bioactive chemicals, including opioids, serotonin, and norepinephrine; glutamate receptors and transporters; cytokines; and signal molecules (58–63). With regard to how acupuncture helps to improve motor function, experimental studies indicate it may work by enhancing the gamma-aminobutyric acid receptor expression or promoting angiogenesis (64, 65). Currently, there is no consensus on the mechanism of acupuncture for SHS or CRPS, so further research is needed to investigate how acupuncture influences sympathetic/somatic nervous system dysfunction.

Study Strengths and Limitations

Our systematic review has several strengths. First, we explored the effects of acupuncture for a specific complication (SHS) after stroke, rather than general motor function. Acupuncture points around the shoulder were the most frequently points used in treatment for SHS, which is consistent with two previous reviews (57, 66). These results may provide more focused evidence to improve clinical practice and health outcomes. Second, this systematic review was based on a comprehensive and up-to-date search of literature, with reliable evidence generated from analyses with large sample sizes. Third, subgroup analyses were conducted according to the type of acupuncture stimulation. Both electro-acupuncture and manual acupuncture were effective when they were used as add-on therapies. Fourth, validated outcome measures were selected to assess acupuncture's efficacy, which will also strengthen the reliability of our results.

However, some limitations of this review should be considered before its results can be translated to clinical practice. First, none of the studies used sham or placebo acupuncture in the control treatment. This means that the placebo effects of adding an intervention cannot be ruled out. In particular, Chinese populations usually have high expectations for acupuncture and this may have inflated treatment outcomes for the combined therapy. Second, the treatment duration and number of treatment sessions in the included studies varied greatly. Although we conducted a subgroup analysis based on treatment duration, the optimal duration, and number of treatment sessions are still unclear. Third, the included studies did not give enough information about the acupuncture parameters, such as depth of needle insertion and the acupuncturists' backgrounds. This may affect the clinical implications of this research. Fourth, few studies reported adverse events, making it difficult for us to provide a conclusion about acupuncture's safe use in the management of post-stroke SHS. Moreover, none of the studies performed a long-term follow-up investigation of acupuncture,

so it's unclear if acupuncture has a sustained effect on post-stroke SHS. Future clinical studies should include a sham/placebo control, a follow-up phase, and an in-depth data collection of adverse events.

Implication for Further Research

All of the studies included in this review were conducted on mainland China. Further studies should be done around the world to involve more ethnically and culturally diverse populations. The methodological quality of future clinical trials should also be improved. In particular, double-blinding should be used where possible to avoid RCT performance bias. While it's difficult to have genuine double-blinding in acupuncture trials because acupuncturists have to be aware of the participants' group allocation to treat them, participants can be blinded by using well-designed placebo acupuncture devices and sham acupuncture (67, 68). Outcome assessors can also be blinded. Finally, reports from future RCTs should follow the Consolidated Standards of Reporting Trials (CONSORT) statement and STRICTA checklists (69, 70).

CONCLUSION

This systematic review shows that adding acupuncture to routine rehabilitation can improve clinical outcomes (pain and motor function) for people with mild post-stroke SHS. However, the evidence was assessed as "low" by GRADE due to the methodological limitations and heterogeneity of included studies, which made our certainty in recommending acupuncture for this condition in clinical practice as "low." Well-designed placebo-controlled RCTs with a long treatment duration and follow up, as well as standardized reporting, are needed to support acupuncture's safe and effective use in the management of post-stroke SHS.

AUTHOR CONTRIBUTIONS

SL and CZ designed this study. SL, CZ, and YC performed data extraction and statistical analysis. SL, CZ, YC, XG, AZ, CX, and CL revised and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fneur.2019.00433/full#supplementary-material

Figure S1 | The summary of risk of bias graph.

Appendix S1 | Search strategy.

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