## **Review Paper**





# Dysphagia Improvement Using Acupuncture Therapy: A Systematic Review

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#### **ABSTRACT**

**Background:** Dysphagia is a common complication in patients with stroke. Although the research on acupuncture treatment of dysphagia has stepped up, the results are still inconsistent. In this review, we intend to answer the potential of acupuncture in treating dysphagia in stroke patients and which acupuncture points are the most promising for treating dysphagia.

**Methods:** We used PRISMA (the preferred reporting items for systematic reviews and metaanalysis) 2020 guidelines in conducting this review. A literature search was performed in four databases (PubMed, ScienceDirect, Cochrane, and Willey online library) to find eligible randomized controlled studies that assessed the effect of acupuncture in post-stroke dysphagia. The search time is from 2010 to 2022. Study quality was assessed using the critical appraisal skills program (CASP), and the risk of bias was evaluated by the RoB software, version 2 (riskof-bias tool). The data were analyzed thematically.

**Results:** A systematic electronic search identified 1409 publications through forward and backward searching of relevant papers. The full-text screening was conducted on 777 articles. A total of 681 articles failed to meet eligibility criteria at this stage, and only 6 articles were finally eligible for further analysis. The results showed that compared with rehabilitation, acupuncture significantly improved dysphagia in post-stroke patients. Gallbladder (GB) 20 is often used as an acupoint. In addition, the frequency and duration of treatment also contributed to a more significant increase in dysphagia improvement.

**Conclusion:** Acupuncture could effectively improve dysphagia in post-stroke patients, and acupuncture combined with rehabilitation has a better effect.

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## **Highlights**

- Dysphagia is common among post-stroke patients due to neurological disorders.
- Dysphagia may lead to serious complications and even death.
- Acupuncture has been known as a therapy related to nerve points.
- Compared with rehabilitation, acupuncture had a significant effect on improving dysphagia in post-stroke patients.
- The gallbladder (GB) point is the most promising acupuncture location to treat dysphagia in post-stroke patients.

## Plain Language Summary

Dysphagia is a serious problem after a stroke. Apart from medical therapy, other therapies also provide evidence of high effectiveness. One of them is acupuncture therapy, originally from ancient traditional medicine in China. However, this study proves that acupuncture therapy will increase its effect when combined with other rehabilitative therapies.

## 1. Introduction

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ysphagia is prevalent in stroke survivors, with an incidence rate of 8.1% to 80%. Dysphagia was reported in 36.3% of post-stroke patients in Asia (Meng et al., 2020). Dysphagia worsens when swallowing liquids (Lancaster, 2015), causing

major problems such as aspiration, pneumonia, and even death (Calandra-Buonaura et al., 2021; Waters et al., 2022). Furthermore, dysphagia is associated with social anxiety, withdrawal, and depression (MacDonald et al., 2018; Olesen et al., 2021). It may also impact daily activities, quality of life, and stroke prognosis. Repetitive transcranial magnetic stimulation, swallowing training (Huang et al., 2014; Wen et al., 2022), transcutaneous and retropharyngeal electrical stimulation, non-invasive brain stimulation strategies, transcranial direct current stimulation (Marin et al., 2018), speech and language therapy (Brady et al., 2016), expiratory muscle strength training (Guillén-Solà et al., 2017; Park et al., 2016a), behavioral interventions (Speyer et al., 2022), dietary modification (Teuschl et al., 2018), and neuromuscular electrical stimulation (Chen et al., 2016; Park et al., 2016b). As a result, managing patients with post-stroke dysphagia requires a multidisciplinary approach (Song et al., 2015; Park et al., 2016b).

Acupuncture is a traditional Chinese medicine procedure in which acupuncturists insert needles through the skin to balance life energy, known as "qi." Over the past 1000 years, China has used acupuncture for stroke rehabilitation. Even the World Health Organization

(WHO) has acknowledged acupunctures as an alternative and complementary technique for stroke therapy and care (Chavez et al., 2017). Traditional manual acupuncture (TA), electroacupuncture (EA) (Lim et al., 2014; Yu et al., 2018), moxibustion acupuncture (MA), and scalp acupuncture (SA) are available modes for treating dysphagia following a stroke (Zhang et al., 2014). A series of trials in humans and investigations in animals have revealed that the acupuncture mechanism for stroke primarily includes neurotransmitter release regulation, cerebral microcirculation regulation, antiapoptosis, stimulation of neurogenesis and cell proliferation, and neuroplasticity regulation (Belskaya et al., 2020; Li & Wang, 2013).

Acupuncture's physiological influence on dysphagia after stroke has not been well researched. Previous studies show that acupuncture affects regional brain activity (Deng et al., 2016; Jia et al., 2015; Demao et al., 2016; Feng et al., 2016; Meng et al., 2016; Yu et al., 2018). Furthermore, acupuncture can aid in repairing and reconstructing swallowing function by forming new synaptic connections and hastening the restoration and reconstruction of the swallowing reflex arc (Li et al., 2018; Wu et al., 2019). Given the possible benefits of acupuncture for treating dysphagia after stroke, its use in dysphagia intervention has grown in popularity in China and worldwide.

According to a previous systematic review, acupuncture can lessen clinical symptoms such as trouble swallowing and lower the prevalence of dysphagia (Geeganage et al., 2012). It can also enhance patients' quality of

life. Acupuncture has been included in the most recent Cochrane study on swallowing therapy, although it did not significantly affect the outcomes of dependency/disability, misaspiration rate, or death (Bath et al., 2018).

Acupuncture research for dysphagia or swallowing disorders has risen, although the outcomes have been inconsistent (Chan et al., 2012; Feng et al., 2016; Xia et al., 2016; Chan et al., 2020). In a few systematic reviews, acupuncture has been utilized to treat dysphagia in stroke patients (Cai et al., 2015; Jiang et al., 2022; Li et al., 2018; Ye et al., 2017). However, a satisfactory conclusion would not be possible without higher-quality research. As a result, the inclusion and exclusion criteria were developed after incorporating previous relevant reports, and the studies using a single-blind approach were pooled to be examined independently. Furthermore, there is currently a lack of conclusive proof. Given the growing number of RCTs using acupuncture for dysphagia caused by a swallowing issue, this review study explored the potential of acupuncture in treating dysphagia in stroke patients and the most promising acupuncture points for treating dysphagia.

#### 2. Materials and Methods

## Study protocol

Following the preferred reporting items for systematic reviews and meta-analysis (PRISMA) 2020 recommendations (Page et al., 2021), we conducted a systematic evaluation of the literature comprising RCTs that documented the effectiveness of acupuncture therapy on dysphagia in post-stroke patients.

The population, intervention, comparison, outcome, and study design (PICOS) criteria outlined in Table 1 were used to select studies for inclusion in this review.

### Eligibility criteria

We removed articles uploaded to RefWorks, a web-based reference management software, and duplicates. It was then disseminated to the team members and continued by assigning to a single reviewer's initial review of the title and abstract. The next step was a full-text review executed by two reviewers. Additional reviewers were prepared for any disagreement to reach a consensus. Articles were included if the study subjects were >15 years old, >1 week post-stroke, the intervention of acupuncture or combined with other therapy, the study in a clinic or community, and the full text was available in English. Articles were excluded if the study was unavailable in

English version, observational studies, theses, conference abstracts, commentaries, and editorials; poster presentations were also excluded.

#### **Information source**

A database search was conducted in May 2022 by a medical librarian for articles published within the past 12 years, from 2010 to 2022. The databases searched were PubMed, ScienceDirect, Wiley Online Library, and Cochrane Library.

### Search strategy

The following search terms were used to build a comprehensive search strategy for each database: "Stroke," "hemorrhagic stroke," "cerebral hemorrhage," "ischemic stroke," "acupuncture," "impaired swallowing," AND "dysphagia" (Table 2). A review of references of all included studies was also performed.

#### **Data extraction**

Using the Cochrane data extraction and assessment form, two authors (HJS and LoA) independently extracted data from relevant studies. Disagreements between authors were resolved by consensus of all authors. The data extracted included the author(s), year of publication and country of origin, research design, sampling, assessment indicators, and main findings.

### **Quality assessment**

The quality of the studies was assessed by two authors independently using the critical appraisal skills program (CASP) for the randomized controlled trial (critical appraisal skills program (CASP), 2022). This tool consists of 11 questions which are divided into three sections with the choices of "yes," "no," and "can't tell" checklist columns. We categorize the quality of studies into high, medium, and low. In high-quality studies, the "yes" answers are 10–11; in medium-quality studies, the "yes" answers are 7–9; and in low-quality studies, the "yes" answers are <6.

## Risk of bias assessment

We assessed the risk of bias using the Cochrane RoB-2 (by using RoB (risk-of-bias tool) software, version 2 (Sterne et al., 2019), which uses the following 5 domains: Randomization process, deviation from intended interventions, missing outcome data, outcome measurement, and selection of the reported result. The overall risk of bias rating is derived from the 5 individual ratings

Table 1. Studies criteria based on PICOS

Criteria	Inclusion Criteria
Population	All cases included in the trial are patients with dysphagia after stroke, regardless of gender, educational level, citizenship, or outpatient or inpatient treatment. Specific criteria include:  1. Ischemic or hemorrhagic stroke confirmed by computerized tomography (CT) scan or magnetic resonance imaging (MRI)  2. Dysphagia confirmed by videofluoroscopic swallowing study (VFSS) and or mann assessment of swallowing ability (MASA)  Swallowing disorders caused by other neurological illnesses are excluded.
Intervention	We consider acupuncture and related therapies (acupoint-based therapy), regardless of needling techniques and stimulation methods, including traditional manual acupuncture (TA), electroacupuncture (EA), manual acupuncture (MA), scalp acupuncture (SA), moxibustion, catgut embedding, transcutaneous electrical acupoint stimulation, acupoint injection, medium-frequency electric stimulation, and so on. These interventions can be combined with conventional therapy (conventional treatment or rehabilitation training in the neurology department). Non-acupuncture-related treatments, such as medicine and transcranial electric/magnetic stimulation, will be excluded.
Comparisons	Controlled interventions will be limited to acupuncture, related therapies, placebo, or conventional therapy groups. Trials comparing two acupoint selections or acupuncture manipulations and rehabilitation therapy without acupuncture are excluded.
Outcomes	Swallowing disorder-specific quality of life score. Standardized swallowing assessment.
Study design	Randomized control trials

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and determined by the RoB-2 algorithm. Each domain's categorization of bias assessments includes high, moderate, and low. The bias assessment results are presented as a traffic light plot from the RoB visualization tool.

## 3. Results

## **Study selection**

The literature search results identified 1409 publications through the forward and backward search of relevant papers from the databases used. A complete screening was carried out on 777 articles. It was determined that 681 articles failed to meet the eligibility criteria at the full-text screening stage. At the end of the stage, only 6 articles were finally eligible for further analysis. Data were analyzed thematically. The search results follow the PRISMA 2020 flowchart (Figure 1).

Table 2. Search syntax in databases

Database	Keywords
PubMed	((((("stroke"[title/abstract]) OR ("hemorrhagic stroke"[title/abstract])) OR ("cerebral hemorrhage"[title/abstract])) OR ("ischemic stroke"[title/abstract])) AND ((("acupuncture"[title/abstract])) OR ("acupuncture acupoint"[title/abstract])) OR ("acupuncture administration"[title/abstract])) AND (((((("impaired swallowing"[title/abstract]))) OR ("impaired swallowing function"[title/abstract])) OR ("impaired swallowing ability"[title/abstract])) OR ("impaired swallowing function"[title/abstract])) OR ("impaired swallows"[title/abstract])) OR ("dysphagia"[title/abstract])) OR (dysphagia[title/abstract]))
ScienceDirect	Stroke OR hemorrhagic stroke OR ischemic stroke AND acupuncture OR acupuncture administration OR needling AND impaired swallowing OR swallowing disorder OR dysphagia
Wiley Online Library	Stroke OR hemorrhagic stroke OR ischemic stroke AND acupuncture OR needling AND impaired swallowing OR swallowing disorder OR dysphagia
Cochrane Library	((((("stroke"[title/abstract]) OR ("hemorrhagic stroke"[title/abstract])) OR ("cerebral hemorrhage"[title/abstract])) OR ("ischemic stroke"[title/abstract])) AND ((("acupuncture"[title/abstract])) OR ("acupuncture acupoint"[title/abstract])) OR ("acupuncture administration"[title/abstract]))) AND (((((("impaired swallowing"[title/abstract]))) OR ("impaired swallowing function"[title/abstract])) OR ("impaired swallowing ability"[title/abstract])) OR ("impaired swallowing function"[title/abstract])) OR ("impaired swallows"[title/abstract])) OR ("dysphagia"[title/abstract])) OR (dysphagia[title/abstract]))

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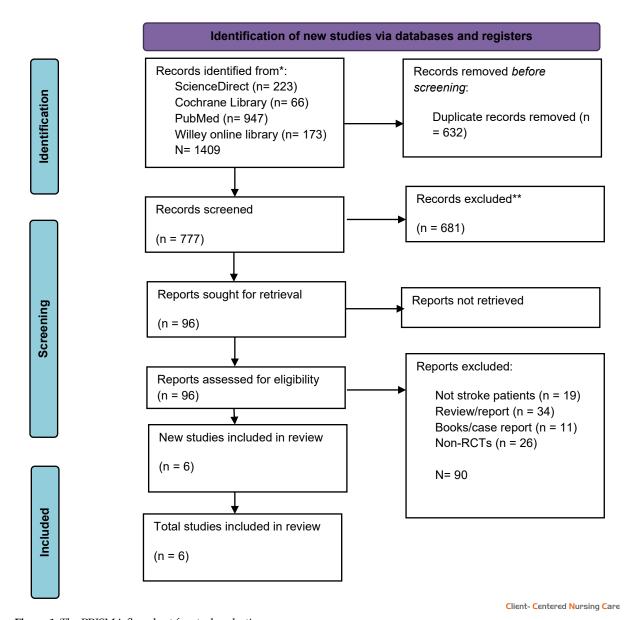


Figure 1. The PRISMA flowchart for study selection

## Results of study quality and bias assessment

Each study was screened against the 11 questions forming the CASP method. The screening result indicated that most eligible studies are high-quality, with "yes" answers between 10-11. Only one study was in the medium-quality category (8/11).

Based on the results of risk of bias analysis using the Cochrane RoB 2 tool (Sterne et al. 2019), 2 studies were found to be in the low risk of bias category, and the rest were in the status with some concerns (Figure 2).

## Characterization of included studies

Table 3 summarizes the features of all included trials investigating the therapeutic impact of acupuncture in persons with dysphagia after stroke (6 studies with 740 participants). For all trials, the median duration of symptoms was 6 months. Most participants (n=95) were older adults with an average age of 64 years. The average duration of the interventions implemented was 26 days. All the examined trials employed either single acupuncture or acupuncture paired with rehabilitation. The rehabilitation treatment methods included a swallowing therapy program, physical stimulation, physiotherapy, occupational therapy, and swallowing training. Instruments used to evaluate the effect of interventions, including

Table 3. The basic characteristics of the included studies								
Author(s), Year, Country	Participants	Post-stroke Duration	Intervention	Rehabilitative Treatment	Indicators of Evaluation	Adverse Ef- fects	Main Findings	Study Quality
Chan et al., 2020, China	n=26 Age: 46-89 Year old	Within 12 months	Acupuncture treatment was administered once every two days, three times a week, and the whole treatment period lasted for 2z months (8 weeks)	Swallowing therapy program and physi- cal stimulation	The Royal Brisbane hospital outcome measure for swallowing (RBHOMS)	None	A significant difference between baseline RBHOMS score and that after treatment (P=0.006)	Moderate
Chen et al., 2016, China	491 patients aged 35–80 years old	2–7 days	Acupuncture group (AG): Thirty minutes of acupuncture therapy as bedside treatment, six days per week for three weeks (eighteen total sessions)  No acupuncture group (NAG): Normal limb posture, passive motion with hemiplegia side, bedside rehabilitation (Bobath technique, overturning movement, bridge movement), neuromuscular electrical stimulation, and or swallowing training for dysphagia, and or cognitive training	Physiotherapy and occupational therapy	The bedside swallowing assessment (BSA) and the video fluoroscopic swallowing study (VFSS)	None	The VFSS score of AG was significantly higher than that of NAG (T=3.17, P=0.002)	High
Xía et al., 2016, China	Acupuncture=62 Control=62 Age: 40– 80 years old	4–12 days	AG: The nape, scalp, and tongue acupuncture is administered for 30 minutes per session. A training intervention consisted of 24 sessions six times a week for four weeks. Control group (CG): Only received swallowing training	Standard swallowing training	The standardized swallowing assessment (SSA), the dysphagia outcome severity scale (DOSS)	AG: Discomfort, hematoma, and severe pain, which were related to edema. CG: Discomfort related to swallowing training.	The SSA scores in the acupuncture group were significantly lower than those in the control group (P<0.01).	High
Feng et al., 2016, China	Observation group=30 Control group=30	<12 months	Observation group: Deep acupuncture at Lianquan (CV 23) and Yifeng (TE 17), once a day, 30 min per treatment, twice a day for 6 days of treatment as one session, and a total of 3 sessions were given with an interval of one day between sessions Control group: Swallowing training.	Swallowing training	The videofluoroscopic swallowing study (VFSS) dysphagia evaluation scale and Watian water swallow test (WWST)	None	The VFSS score in the observation group was significantly superior to that in the control group (P<0.01);  The WWST in the observation group was significantly superior to that in the control group (P<0.01).	High

Author(s), Year, Country	Participants	Post-stroke Duration	Intervention	Rehabilitative Treatment	Indicators of Evaluation	Adverse Ef- fects	Main Findings	Study Quality
Cai et al., 2015, China	Ninety in the tongue acupuncture group and 90 in the conventional acupuncture group.	Not reported	Acupuncture on the tongue for 1-2 minutes, 1 time daily, 5 times a week. The clinical efficacy was evaluated after 4 weeks of treatment.	None	The videofluoroscopic swallowing study (VFSS)	Not reported	VFSS scores were improved after treatment (P<0.05)	Moderate
Chan et al., 2012, China	Experimental group=20 Control group=67	<12 months	Experimental group: Sessions 1 to 10 were performed on consecutive days on subjects after baseline assessment.  sessions 11 to 20 were performed on alternate days  Each treatment session was 30 minutes in duration, with the subjects in the supine or sitting position.  Control group 1: Sham acupuncture that did not puncture true acupoints on a meridian.  Control group 2: No acupuncture treatment was administered to this group of subjects	Swallowing therapy	The royal brisbane hospital outcome measure for swallowing (RBHOMS)	Pain during puncturing or mild bleeding from the puncture points. A few cases reported petechia or slight dizziness	Statistically significant differences in the RBHOMS scores before and after 2 courses of treatment were found in the experimental group and control group (P<0.05)	High

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the Royal Brisbane Hospital outcome measure for swallowing (RBHOMS), standard swallowing function score (SSA), Dysphagia outcome severity scale (DOSS), videofluoroscopic swallow study (VFSS), and watian water swallow test (WWST).

## Efficacy of acupuncture

Based on the collected studies' results, the included studies showed great potential in improving the patient's swallowing condition, which can be seen in the statistical significance of acupuncture therapy on changes in the patient's swallowing score (P<0.001). The biggest

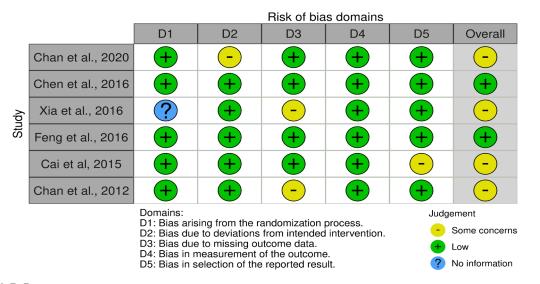


Figure 2. RoB assessment

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changes occurred in studies that provided acupuncture therapy more than once daily for 30 minutes per session.

No single study reveals the unsuccessful use of acupuncture therapy for dysphagia. However, acupuncture therapy will be more effective when combined with other therapies, such as a swallowing therapy program, physical stimulation (Chan et al., 2020; Chen et al., 2016; Xia et al., 2016), normal limb posture, passive motion with hemiplegic side, bedside rehabilitation (Bobath technique, overturning movement, bridge movement), neuromuscular electrical stimulation (Chen et al., 2016), oral motor exercises, different swallowing techniques, positioning and diet modification (Chan et al., 2012).

## **Acupuncture points**

There are different acupoints from the studies included in this review, including GB20 (Fengchi), EX-HN14 (Yiming), BL10 (Tianzhu), GV16 (Fengfu), Gongxue (1 cun below GB20-Cun is a traditional Chinese unit of length), and CV23 (Lianquan) (Chen et al., 2016), GB 12 (Wan Gu bilateral), GB20 (Feng Chi, bilateral), CV23 (Lian Quan), DU20 (Bai Hui), LI4 (He Gu, bilateral), HT5 (Tong Li, bilateral), Hang Sang, Shang Lian Quan (EX-HN20) (Chan et al., 2020), fengchi (GB 20, unilateral), jiaji (C2-C4) (EX-B2, bilateral), lianquan (CV23, unilateral), jiajianquan (left CV 23 and right CV 23, bilateral), and baihui (GV 20, unilateral) (Xia et al., 2016), Juanquan (EXHN10) (at the midpoint of dorsal raphe of the tongue) and Haiquan (EX-HN11) (Sublingual frenulum midpoint) (Cai et al., 2015). Acupoits on the body are Fengchi (GB20) and Neiguan (PC6) (Cai et al., 2015), angu (GB 12), Fengchi (GB 20) and Yifeng (SJ 17) (Chan et al., 2012).

## 4. Discussion

This systematic review evaluated 6 RCTs analyzing the efficacy of acupuncture compared with standard rehabilitation of dysphagia in stroke patients. Almost all relevant studies were conducted in China, given that acupuncture therapy is part of traditional Chinese medicine. There were few studies regarding acupuncture treatment for dysphagia in stroke patients that we could access; mainly, the available articles were in Chinese. In addition, the other studies were not RCTs, as we had defined them as inclusion criteria in the article search. Based on the accumulating evidence, acupuncture can significantly improve dysphagia in stroke cases. In addition, acupuncture combined with standard rehabilitation shows a better effect.

The study discovered that the therapeutic efficacy of acupuncture or acupuncture integrated with different interventions was superior to the control group. Meanwhile, the varied sources of instances may result in disparate statistical conclusions. Acupuncture, rehabilitation, and swallowing training were all linked to the practitioners' professional skills, just like the efficacy evaluation.

Acupuncture, alone or combined with other interventions, is frequently used in China to treat dysphagia following a stroke. Some evidence backs up that acupuncture can help with dysphagia after a stroke. Although one report (Ye et al., 2017) states that acupuncture improves dysphagia after stroke, this study does not provide a positive conclusion. According to one study (Meng et al., 2016), acupuncture simultaneous with swallowing rehabilitation training offers some benefits. According to Long and Wu, (2012), acupuncture may be effective for dysphagia, but more research is needed. The current study uses multiple inclusion and exclusion standards to estimate the efficacy of acupuncture in treating dysphagia after stroke and re-examined this efficacy, resulting in more powerful evidence. Most studies use the WWST, SSA, and other dysphagia outcome indicators. Three investigations used VFSS as a scoring indicator (Cai et al., 2015; Feng et al., 2016; Chen et al., 2016). The WWST was proposed by Toshio Watian from Japan and is used as an initial screening for dysphagia.

Meanwhile, depending on the patient's feelings and susceptibility level, it must be consistent with most clinical and laboratory examination results (Juan et al., 2016). However, everything is clearly labeled and easy to use. As a result, it has been used in numerous clinical studies (Zeng et al., 2015; Xia et al., 2016; Zhang et al., 2014). Hence, evaluating criteria in clinical trial design must be more rigorous and scientific. To improve dependability, high-level evaluators should be chosen to assess efficacy for dysphagia simultaneously. Acupoints, stimulation type, needle retention time, and treatment sessions were all different in the acupuncture therapy regimen. Although particular acupoints are more regularly employed, the intensity of acupuncture therapy varies substantially across included RCTs.

GB20 and CV23 are the acupoints that seem frequently in the studies. As a result, acupuncture at these two acupoints may aid in treating dysphagia following a stroke. The WHO conventional acupoints (WHO, 2007) place GB20 at the sub-occipital depression and the surrounding head clamp muscle, sternocleidomastoid muscle, trapezius muscle, and branches of the lesser occipital nerve.

CV23 can be found in Adam's tubercle, the anterior region of the cervical midline, and the depression of the superior margin of the hyoid bone. The suprahyoid muscle, hypoglossal, facial, glossopharyngeal, and vagus are among the surrounding anatomical tissues. According to studies, EA stimulation of CV23 triggered swallowing-related neurons in rats' ventrolateral medulla (VLM) and boosted swallowing activity. 5-Hydroxytryptamine may be essential in this excitatory effect (Ye et al., 2019; You et al., 2018).

This systematic review provides evidence to consider acupuncture as an alternative treatment for dysphagia but preferably in combination with standard post-stroke medical treatment for routine therapy, especially in the international background of an increasing application of acupuncture therapy.

Some limitations in this review include the small number of studies analyzed due to language limitations and access to certain databases. For this reason, the results of this study must be mentioned with caution. Besides, most trials were implemented in China, and it was hard to determine the efficacy of acupuncture in different countries and ethnic groups. Finally, since there were some concerns related to bias in most included studies, the findings should be interpreted with caution.

## 5. Conclusion

To summarize, acupuncture for dysphagia after stroke demonstrates therapeutic efficacy and is safe and reliable within a certain range. More stringent evaluation criteria and high-quality RCT designs are required to further examine acupuncture for treating dysphagia following stroke. Since no side effects were found from this acupuncture therapy, the duration of the intervention should have been longer, at least up to one year. Improving circulation and the affected nervous system in areas related to chewing and swallowing requires a longer recovery time, especially for older people.

## **Ethical Considerations**

## Compliance with ethical guidelines

All the authors have contributed to the design and conduct of the study. Duplicate publications were removed. Data were extracted independently by two authors, and disagreement between them were resolved by consensus after consulting with other researchers. Decisions on which data to include are also agreed upon by all authors.

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#### **Authors' contributions**

conceptualization and drafting the manuscript: Heriviyatno. J Siagian and Arimaswati Arimaswati; Data curation: Rusmimpong Rusmimpong and Sukurni Sukurni; Data analysis and interpretation: Heriviyatno. J Siagian and La Ode Alifariki; Critical revision of the article: Arimaswati Arimaswati; Final approval: All authors.

#### Conflict of interest

The authors declared no conflict of interest.

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