Postprint of Guidelines for the Prevention and Treatment of Stroke with Integrated Chinese-Western Medicine (2023 Edition)

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Abstract

In recent years, the disease burden of stroke in China has continued to grow, while much new clinical evidence has emerged in the field of integrated traditional Chinese and Western medicine for stroke treatment. To better guide clinical practice in the prevention and treatment of stroke with integrated traditional Chinese and Western medicine, this working group, based on the 'Evidence-based Practice Guideline for Stroke with Integrated Traditional Chinese and Western Medicine (2019)', conducted an assessment of the necessity for guideline updates and selection of clinical questions, identified 12 clinical questions requiring updates, and applied for project approval for the 'Guideline for Prevention and Treatment of Stroke with Integrated Traditional Chinese and Western Medicine' at the China Association of Chinese Medicine. Referencing the latest domestic and international clinical practice guidelines, based on systematic retrieval and objective evaluation of research evidence, combined with the experience of clinical experts in traditional Chinese and Western medicine in China, and through thorough discussions by the working group and extensive solicitation of opinions, 18 recommendations were finally formulated, with the aim of providing scientific and specific guidance for medical workers at all levels of medical institutions, promoting the standardized application of integrated traditional Chinese and Western medicine in stroke treatment, thereby reducing the mortality, recurrence rate, and disability rate of stroke.

Full Text

Clinical Practice Guideline for the Prevention and Treatment of Stroke with Integrated Traditional Chinese and Western Medicine (2023 Edition)

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Abstract

Stroke represents a major global public health challenge [1]. In recent years, China has achieved certain progress in stroke prevention and treatment, yet the disease burden continues to increase, characterized by persistent growth, rapid expansion among low-income populations, widening regional and urban-rural disparities, and a trend toward younger onset [2-4]. Consequently, China faces enormous challenges in stroke management that demand more effective prevention and treatment approaches.

Traditional Chinese Medicine (TCM) has a long history in stroke prevention and treatment and is widely applied in current clinical practice in China. In 2017, our working group developed an evidence-based practice guideline for integrated Chinese and Western medicine in stroke management, addressing 11 clinical questions related to the treatment of cerebral infarction, transient ischemic

attack, intracerebral hemorrhage, and stroke complications. This resulted in the *Evidence-based Practice Guideline on Integrative Medicine for Stroke (2019 Edition)* (hereinafter referred to as the "2019 Edition Guideline") [5], officially published in August 2020.

In recent years, evidence for TCM in stroke prevention and treatment has continued to accumulate, with clinical focus expanding beyond reducing motor and swallowing disabilities to improving post-stroke cognitive impairment and depressive symptoms [6]. The 2019 Edition Guideline can no longer provide optimal recommendations. To better guide clinical practice, our working group initiated an update of this guideline. After assessing the necessity for update and formulating new clinical questions, we applied for project approval for the *Clinical Practice Guideline for the Prevention and Treatment of Stroke with Integrated Traditional Chinese and Western Medicine* with the China Association of Chinese Medicine. Referencing the latest domestic and international clinical practice guidelines, and based on systematic literature retrieval and objective evaluation of research evidence combined with the experience of Chinese and Western medicine clinical experts in China, the working group engaged in thorough discussions and extensive consultation. The final *Clinical Practice Guideline for the Prevention and Treatment of Stroke with Integrated Traditional Chinese and Western Medicine* was published as a group standard by the China Association of Chinese Medicine in June 2023, comprising 18 recommendations to provide scientific and specific guidance for medical practitioners at all levels of healthcare institutions, promote standardized application of integrated Chinese and Western medicine in stroke treatment, and thereby reduce stroke mortality, recurrence rates, and disability rates.

Keywords: Stroke; Integrative medicine; Evidence-based practice guideline

1 Guideline Development Methods

The development process for this guideline referenced the *Technical Process and Specification for Development of Evidence-based Clinical Practice Guidelines in Traditional Chinese Medicine: T/CAM 1032—2017* [7], the *WHO Handbook for Guideline Development (2nd Edition)* [8], and the *Chinese Principles for Developing/Revising Clinical Diagnosis and Treatment Guidelines (2022 Edition)* [9]. The guideline was reported in accordance with the Reporting Items for Practice Guidelines in Healthcare (RIGHT) [10].

1.1 Initiating and Supporting Organizations

This guideline was led by the Guangdong Provincial Hospital of Chinese Medicine (The Second Affiliated Hospital of Guangzhou University of Chinese Medicine), the chair unit of the Stroke Branch of the China Association of Chinese Medicine, with methodological support provided by the Evidence-based

Medicine Center/GRADE Center of the School of Basic Medical Sciences at Lanzhou University.

1.2 Guideline Registration and Protocol Development

The guideline development strictly followed standardized procedures, with the update protocol registered on the International Practice Guideline Registry Platform (http://www.guidelines-registry.org) (Registration No.: IPGRP-2021CN388).

1.3 Target Users and Population

Target Population: Patients diagnosed with ischemic stroke, transient ischemic attack, intracerebral hemorrhage, or stroke complications. This document applies to clinicians including TCM physicians, integrated Chinese and Western medicine physicians, neurologists, rehabilitation physicians, acupuncturists, clinical pharmacists, and nursing staff in general internal medicine, neurology (encephalopathy), geriatrics, acupuncture, and rehabilitation departments at all levels of hospitals and rehabilitation institutions.

1.4 Guideline Working Group

Five main working groups were established: Guideline Update Necessity Assessment Expert Group, Guideline Consensus Expert Group, Guideline External Review Expert Group, Guideline Secretariat, and Guideline Evidence Evaluation Group. Members included experts from diverse disciplines such as TCM encephalopathy, integrated neurology, neurology, neurovascular intervention, neurosurgery, neurocritical care, neuroemergency, rehabilitation, acupuncture, nursing, pharmacy, guideline methodology, evidence-based medicine, TCM standardization, and health economics.

1.5 Conflict of Interest Declaration

All working group members completed conflict of interest declaration forms, stating no direct conflicts of interest related to this guideline.

1.6 Assessment of Update Necessity and Clinical Question Selection

Initially, based on the 11 clinical questions from the 2019 Edition Guideline, the working group used the UpPriority tool to evaluate existing guidelines, review recent research evidence, conduct expert questionnaires, and prioritize update questions [11], identifying 15 clinical questions requiring updates. During the review, correspondence review, and defense process for the group standard application with the China Association of Chinese Medicine in 2021, expert suggestions reduced the questions to 13. Finally, through Delphi expert surveys in 2022, importance assessment, face-to-face consensus meetings, and PICOS (Population,

Intervention, Comparison, Outcome, Study design) principle-based deconstruction, 12 clinical questions and 11 key outcome indicators were confirmed for inclusion.

1.7 Evidence Retrieval, Evaluation, and Grading

Given the large number and broad scope of systematic reviews/Meta-analyses on TCM for stroke prevention and treatment in recent years, the working group limited retrieval and evaluation to such evidence, with updates through August 2022. Building on the evidence base from the 2019 Edition Guideline, we searched CNKI, Wanfang Data, CBM, PubMed, Embase, and Cochrane Library. We also retrieved adverse reaction monitoring reports for Chinese medicines from the China National Medical Products Administration website and information on TCM prices and medical insurance reimbursement policies from the Ministry of Human Resources and Social Security and related websites.

The methodological quality of systematic reviews was assessed using A Measurement Tool to Assess Systematic Reviews 2 (AMSTAR-2) [12]. Evidence was selected based on AMSTAR-2 scores and relevance to clinical questions. Finally, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system [13] was used to grade evidence quality according to confidence in the proximity of predicted values to true values: high (A): very confident; moderate (B): moderately confident; low (C): limited confidence; very low (D): very little confidence. Evidence summary tables were produced.

1.8 Formulation of Guideline Recommendations

Recommendation strength grading referenced the GRADE system [13], classified according to confidence that benefits outweigh harms: strong (1): clear benefit or harm; weak (2): uncertain balance or equivalent benefits/harms regardless of evidence quality. Recommendation formulation involved three steps: (1) preliminary draft based on existing evidence, considering intervention costs, benefit-harm balance, accessibility, and patient preferences/values; (2) expert consensus using modified Delphi method to formulate recommendations for inclusion; (3) finalization through face-to-face expert discussions, resulting in 18 recommendations. For clinical questions lacking evidence support, good practice statements (GPS) [14] were developed based on expert clinical experience.

1.9 Guideline Manuscript Development and External Review

The guideline draft was prepared following RIGHT [10], with recommendations collected through internal and external expert review and public consultation, forming the final version after thorough revision.

1.10 Guideline Dissemination and Implementation

Following publication, the guideline working group will primarily disseminate and promote the guideline through: (1) interpretation at relevant academic conferences, such as activities of the Stroke Branch of the China Association of Chinese Medicine; (2) organized guideline lectures in selected Chinese provinces to ensure clinicians fully understand and correctly apply the guideline; (3) publication in academic journals and books; (4) promotion via WeChat and other media.

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2 Disease Diagnosis

This guideline references the *Diagnostic Points for Major Cerebrovascular Diseases in China 2019* [15] for disease diagnosis.

2.1 Ischemic Stroke

1. Acute onset focal neurological deficits, occasionally generalized deficits.
2. Brain imaging (CT/MRI) confirming corresponding infarct lesions, or symptoms/signs persisting >24 hours, or causing death within 24 hours.
3. Exclusion of non-ischemic etiologies.

2.2 Intracerebral Hemorrhage

1. Sudden focal neurological deficits or headache, vomiting, varying degrees of consciousness disturbance.
2. Brain imaging (CT/MRI) showing intracerebral hemorrhage lesions.
3. Exclusion of secondary or traumatic hemorrhage from other causes.

2.3 Transient Ischemic Attack

1. Sudden focal cerebral or retinal dysfunction consistent with carotid or vertebrobasilar system ischemia, typically resolving completely within 24 hours (mostly within 1 hour), with possible recurrent episodes.
2. No evidence of acute ischemic stroke on MRI diffusion-weighted imaging (DWI) for imaging-confirmed TIA; when DWI unavailable, conventional CT/MRI sequences without corresponding infarct can serve as clinical diagnostic basis; when imaging evidence unavailable, symptom/sign duration $ $24 hours remains the temporal criterion.
3. Exclusion of non-ischemic etiologies.

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3 Guideline Recommendations

The main recommendations are summarized in Table 1 .

3.1.1 Clinical Question 1: For ischemic stroke patients, what is the long-term efficacy and safety of Chinese medicine alone or combined with conventional therapy versus conventional therapy alone for secondary prevention?

Recommendation 1: For ischemic stroke patients, consider combined use of Chinese medicine with conventional secondary prevention strategies to reduce medium- to long-term stroke recurrence and mortality, though clinical application should consider specific patient conditions, personal preferences, and economic circumstances (2C). Referenced Chinese medicine: Dengzhan Shengmai Capsule.

Rationale: A 2021 systematic review [47 RCTs, 10,732 patients] showed Chinese medicine combined with conventional therapy further reduced stroke recurrence rates [16]. A 2022 systematic review [17] demonstrated Dengzhan Shengmai Capsule combined with conventional secondary prevention significantly reduced stroke recurrence (RR=0.57, 95%CI=0.44-0.73, 6 RCTs, 4,451 patients, I^2=44%) and all-cause mortality (RR=0.54, 95%CI=0.31-0.95, 4 RCTs, 4,221 patients, I^2=33%). Subgroup analyses for stroke recurrence showed patient age (<60 vs $ $60 years), treatment dose (low/medium vs high), and conventional therapy (with vs without statins) did not alter benefits. No serious adverse events were reported [16]; combined Dengzhan Shengmai did not significantly increase adverse events [17]. Insufficient evidence exists for Chinese medicine alone, hence no recommendation.

Recommendation 2: For minor stroke patients, consider Chinese medicine supplementation on top of conventional therapy for secondary prevention to reduce stroke recurrence (GPS).

Rationale: As minor stroke definitions remain inconsistent, this guideline adopts the definition from CHANCE (Clopidogrel in High-risk Patients with Acute Non-disabling Cerebrovascular Events): NIHSS score $ $3 [18-19]. No systematic reviews exist on TCM for minor stroke secondary prevention. Expert consensus suggests Chinese medicine supplementation on conventional therapy, formulated as GPS.

3.1.2 Clinical Question 2: For TIA patients, what is the long-term efficacy and safety of Chinese medicine alone or combined with conventional therapy versus conventional therapy alone for secondary prevention?

Recommendation 3: For TIA patients, consider Chinese medicine in addition to conventional secondary prevention to reduce TIA recurrence and new stroke events (2C).

Rationale: A 2021 systematic review [19 RCTs, 1,980 TIA patients] showed combined Chinese medicine versus conventional secondary prevention significantly reduced long-term ($ $3 months) new stroke risk ($RR =$

$0.37, 95^{\{2\}=0)}. Subgroup analyses by follow-up durations showed benefits at 3 months (RR = 0.34, 95\{2\}= 0), 6 months (RR = 0.13, 95^{\{2\}=0), and 1 year (RR = 0.47, 95\{2\}= 0). Combined therapy also improved long-term TIA recurrence risk (RR = 0.39, 95^\{2\}$=0). Eight studies evaluated safety without serious adverse events [20]. Insufficient evidence exists for Chinese medicine alone.

3.1.3 Clinical Question 3: For ischemic stroke patients, what is the effect of Chinese medicine combined with conventional therapy versus conventional therapy alone in improving neurological deficits?

Recommendation 4: For ischemic stroke patients, to better improve neurological deficits, consider Chinese medicine supplementation, particularly blood-activating and stasis-resolving formulas, on top of conventional therapy; treatment should begin early, at least during the acute phase, with duration of 3-30 days (2C). Referenced Chinese medicines include: Panax notoginseng preparations (Xueshuantong Injection, Xuesaitong Injection, Compound Xueshuantong Capsule, Sanqi Tongshu Capsule, Xuesaitong Dripping Pills), Ginkgo leaf injections (Ginkgolide Injection, Ginkgo Leaf Extract and Dipyridamole Injection), Shuxuetong Injection, Dengzhanxixin Injection, Huatuo Zaizao Pill, Maixuekang Capsule, and Buyang Huanwu Decoction.

Rationale: A 2020 overview of Cochrane reviews [21] included 8 Cochrane reviews (71 RCTs, 5,770 ischemic stroke patients) with average AMSTAR score of 10. All Cochrane reviews suggested potential benefits of Chinese herbs for improving neurological deficits (NIHSS scores), though high risk of bias in included RCTs precluded strong recommendations. Evidence showed combined Chinese medicine within 2 weeks of onset improved neurological deficits versus conventional therapy alone. Most formulas were blood-activating and stasis-resolving types with 3-30 day courses. Evidence supported improved NIHSS scores with: Panax notoginseng preparations [22] (MD=-2.27, 95%CI=-2.90 to -1.64, 3 RCTs, 323 patients, I^2=14%), Dengzhanxixin Injection [23] (MD=-2.83, 95%CI=-3.59 to -2.07, 35 RCTs, 4,379 patients, I^2=12%), Buyang Huanwu Decoction [24] (SMD=-1.07, 95%CI=-1.30 to -0.84, 34 RCTs, 3,188 patients, I^2=88%), Ginkgo leaf injections [25] (MD=-4.39, 95%CI=-5.47 to -3.32, 16 RCTs, 2,481 patients, I^2=96%), Shuxuetong Injection [26] (MD=-3.89, 95%CI=-4.34 to -3.43, 22 RCTs, 2,090 patients, I^2=72%), Maixuekang Capsule [27] (MD=-1.97, 95%CI=-2.91 to -1.03, 4 RCTs, 407 patients, I^2=90%), and Huatuo Zaizao Pill [28] (MD=-2.72, 95%CI=-3.72 to -1.73, 9 RCTs, 699 patients, I^2=74%).

3.1.4 Clinical Question 4: For acute ischemic stroke patients after thrombolysis, what is the optimal timing for combined Chinese medicine versus conventional therapy alone?

Recommendation 5: For acute ischemic stroke patients receiving intravenous thrombolysis within 4.5 hours, after strict bleeding risk assessment, consider

combined blood-activating and stasis-resolving Chinese medicine within 24 hours post-thrombolysis to better improve neurological deficits (2C).

Rationale: A 2022 systematic review [29] included 13 RCTs with 1,270 acute ischemic stroke patients receiving alteplase thrombolysis within 4.5 hours. Results showed alteplase combined with oral blood-activating Chinese patent medicine improved neurological deficits (NIHSS scores) versus conventional therapy (MD=-3.21, 95%CI=-4.02 to -2.40, 12 RCTs, 1,283 patients, I^2=85%), without increased bleeding events (RR=0.17, 95%CI=0.02-1.34, 4 RCTs, 324 patients, I^2=0). Subgroup analysis by timing showed better improvement when combined within 24 hours (MD=-4.23, 95%CI=-5.18 to -3.27, 6 RCTs, 646 patients, I^2=81%) versus after 24 hours (MD=-2.10, 95%CI=-2.93 to -1.28, 6 RCTs, 637 patients, I^2=58%). A 2021 systematic review [30] of 9 RCTs with 765 acute ischemic stroke patients within 4.5 hours showed Ginkgolide Injection combined with alteplase significantly improved neurological deficits (MD=-3.08, 95%CI=-3.74 to -2.43, 9 RCTs, 765 patients, I^2=86%) without increased adverse reactions (OR=0.76, 95%CI=0.42-1.40, 5 RCTs, 385 patients, I^2=33%). No specific Chinese medicine met preset consensus standards, hence no drug recommendation.

3.1.5 Clinical Question 5: For ischemic stroke patients with hemorrhagic transformation, does using blood-activating and stasis-resolving Chinese medicine increase additional risks?

Recommendation 6: For ischemic stroke patients with hemorrhagic transformation, after bleeding stabilization and exclusion of coagulation dysfunction, consider blood-activating Chinese medicine on top of conventional specialized treatment to improve neurological deficits (2C).

Rationale: A systematic review based on 2 RCTs [5] showed that for ischemic stroke with hemorrhagic transformation, blood-activating Chinese medicine combined with conventional treatment provided greater benefit in reducing neurological deficits (NIHSS scores) at day 7 (MD=-3.11, 95%CI=-4.84 to -1.39, 105 patients, I^2=0) and day 21 (MD=-3.70, 95%CI=-5.17 to -2.23, 105 patients, I^2=0), without increased adverse events. Current evidence does not specify optimal timing; expert consensus recommends use after bleeding stabilization. External experts suggested excluding coagulation dysfunction before use, leading to recommendation modification.

3.2.1 Clinical Question 6: For hypertensive intracerebral hemorrhage patients, what is the bleeding risk of blood-activating and stasis-resolving Chinese medicine after hemorrhage?

Recommendation 7: For hypertensive intracerebral hemorrhage patients not requiring surgical intervention, after strict contraindication screening, blood-activating Chinese medicine may be given on top of conventional hemorrhage treatment, with acute phase use requiring comprehensive assessment of

hematoma expansion and rebleeding risk (2C).

Rationale: Advanced age, hypertension, and deep hemorrhage are important risk factors for hypertensive intracerebral hemorrhage recurrence; blood pressure control is key to reducing rebleeding risk [31]. A systematic review of 9 RCTs [32] suggested that for patients within 72 hours of hypertensive intracerebral hemorrhage, combined blood-activating Chinese medicine more effectively reduced hematoma volume (MD=-2.72 mL, 95%CI=-4.12 to -1.32, 3 RCTs, 344 patients, I^2=77%) and perihematomal edema (MD=-5.84 mL, 95%CI=-8.62 to -3.06, 3 RCTs, 471 patients, I^2=95%), while also reducing 28-day neurological deficits (MD=-5.34, 95%CI=-7.14 to -3.53, 2 RCTs, 358 patients, I^2=92%) and mortality (RR=0.50, 95%CI=0.35-0.71, 7 RCTs, 699 patients, I^2=0), and improving independent living ability (Barthel Index) (MD=1.86, 95%CI=1.39-2.49, 2 RCTs, 131 patients, I^2=0). Existing evidence does not use rebleeding risk as an outcome, representing indirectness. No direct evidence shows blood-activating Chinese medicine increases rebleeding risk in hypertensive intracerebral hemorrhage. Considering high bleeding risk in the acute phase, expert consensus agreed that acute phase medication should comprehensively assess hematoma expansion and rebleeding risk.

3.2.2 Clinical Question 7: For postoperative hypertensive intracerebral hemorrhage patients, what is the optimal timing for blood-activating and stasis-resolving Chinese medicine versus conventional therapy?

Recommendation 8: For postoperative hypertensive intracerebral hemorrhage patients, blood-activating Chinese medicine on top of conventional postoperative treatment can reduce mortality, improve neurological function, and reduce hematoma volume; timing should comprehensively consider hematoma expansion and rebleeding risk (2C).

Rationale: Current clinical practice guidelines recommend surgical decisions for intracerebral hemorrhage based on individual bleeding volume, consciousness disturbance, and worsening neurological deficits [33]. A systematic review of 31 RCTs [34] showed that for postoperative hypertensive intracerebral hemorrhage patients, combined blood-activating Chinese medicine within 4 days post-surgery improved neurological deficits (MD=-3.81, 95%CI=-6.21 to -1.42, 535 patients, I^2=99%), reduced hematoma volume (MD=-4.42 mL, 95%CI=-4.85 to -3.99, 737 patients, I^2=75%), and improved independent living ability (MD=9.36, 95%CI=7.85-10.87, 294 patients, I^2=27%). Combined therapy also reduced mortality (RR=0.56, 95%CI=0.40-0.79, 1,538 patients, I^2=0). Pooled data showed no increased rebleeding risk (RR=0.57, 95%CI=0.26-1.28, 389 patients, I^2=0). No direct evidence on timing exists; expert consensus suggests timing should consider hematoma expansion and rebleeding risk.

3.3.1 Clinical Question 8: For early post-stroke consciousness disturbance, what is the efficacy of Chinese medicine-based consciousness-resuscitation therapy combined with conventional stroke treatment?

Recommendation 9: For acute intracerebral hemorrhage patients with consciousness disturbance and TCM "phlegm-heat obstructing the orifices" syndrome, consider immediate An Gong Niu Huang Wan on top of conventional stroke treatment to improve consciousness level (2C).

Rationale: TCM theory holds that "phlegm-heat obstructing the orifices" results from excessive phlegm-heat blocking the heart orifices and clouding consciousness, clinically characterized by sudden collapse, clenched jaw, gurgling phlegm, hemiplegia, or clouded consciousness with neck rigidity, red crimson tongue with yellow greasy coating, wiry slippery rapid pulse, possibly accompanied by fever and convulsions [35]. Consciousness-resuscitation therapy embodies TCM awakening methods, with traditional pill "An Gong Niu Huang Wan" and its derived injection "Xingnaojing Injection" as representative agents [36]. A 2021 systematic review [37] of 1,196 intracerebral hemorrhage patients showed combined An Gong Niu Huang Wan improved Glasgow Coma Scale (GCS) scores (MD=1.12, 95%CI=0.46-1.78, 3 RCTs, 153 patients, I^2=0). As An Gong Niu Huang Wan clears heat, resolves toxins, calms fright, and opens orifices—typical cold-natured Chinese medicine—its use requires TCM syndrome differentiation, reserved for phlegm-heat obstructing the orifices syndrome. Expert consensus noted treatment duration is influenced by multiple factors and should not be standardized.

Recommendation 10: For acute intracerebral hemorrhage patients with consciousness disturbance, after strict contraindication screening and fully informing patients (or families) of potential adverse reactions, consider Xingnaojing Injection supplementation to improve coma severity (2C).

Rationale: A 2017 systematic review [38] suggested Xingnaojing Injection combined with conventional treatment provided no additional benefit for ischemic stroke patients' coma severity (GCS score) (MD=1.00, 95%CI=-0.96 to 2.96, 2 RCTs, 140 patients, I^2=79%). However, another 2017 review [39] indicated combined Xingnaojing was superior for hemorrhagic stroke patients (MD=2.87, 95%CI=2.27-3.48, 6 RCTs, 536 patients, I^2=82%). National adverse drug reaction monitoring reports indicate numerous adverse events/reactions with Xingnaojing Injection, hence recommendation for use only after strict contraindication screening and full disclosure.

3.3.2 Clinical Question 9: For stroke patients, can combined Chinese medicine treatment better improve dysphagia compared with conventional care and rehabilitation?

Recommendation 11: For post-stroke dysphagia patients, consider acupuncture combined with basic nursing and rehabilitation (mainly swallowing training) to promote swallowing function recovery (2C). Acupuncture protocol: gen-

erally use regular acupuncture, 4-week course, main acupoints: Fengchi (GB20), Jinjin (EX-HN12), Yuye (EX-HN13), Lianquan (RN23), and Yifeng (SJ17).

Rationale: A 2021 systematic review [40] of 30 RCTs including 3,024 post-stroke dysphagia patients showed acupuncture combined with conventional medical or rehabilitation treatment significantly improved Kubota Water Swallowing Test (WST) grading (MD=-0.69, 95%CI=-0.78 to -0.60, 11 RCTs, 912 patients, I^2=0) and Standard Swallowing Assessment (SSA) scores (MD=-3.41, 95%CI=-3.98 to -2.84, 6 RCTs, 586 patients, I^2=0). Another 2021 review [41] of 35 RCTs with 3,024 patients showed acupuncture combined with conventional treatment was superior, reducing SSA scores (MD=-3.78, 95%CI=-4.64 to -2.91, 13 RCTs, 1,204 patients, I^2=80%) and WST grading (MD=-1.21, 95%CI=-1.85 to -0.57, 11 RCTs, 1,061 patients, I^2=99%). Analysis of acupoints showed Fengchi, Jinjin, Yuye, Lianquan, and Yifeng were most commonly used. A 2021 review [42] of 21 RCTs with 1,532 patients showed tongue-three-needle therapy combined with control groups significantly improved dysphagia severity (SSA score) (SMD=-2.18, 95%CI=-3.04 to -1.32, 5 RCTs, 292 patients, I^2=26%) and WST grading (SMD=-1.17, 95%CI=-1.29 to -1.04, 6 RCTs, 364 patients, I^2=18%).

Recommendation 12: For post-stroke dysphagia patients, consider Chinese medicine to assist swallowing function improvement (2C). Administration routes: oral, nasogastric, or external application.

Rationale: A 2021 systematic review [43] of 23 RCTs with 1,909 patients showed: (1) Chinese medicine combined with rehabilitation reduced WST grading more than rehabilitation alone (MD=-0.66, 95%CI=-0.86 to -0.46, 9 RCTs, 719 patients, I^2=86%); (2) improved Videofluoroscopic Swallowing Study (VFSS) scores (MD=1.59, 95%CI=1.04-2.13, 6 RCTs, 575 patients, I^2=81%); (3) reduced SSA scores more than placebo (MD=-1.33, 95%CI=-2.02 to -0.65, 3 RCTs, 244 patients, I^2=89%) and blank control (MD=-9.19, 95%CI=-10.17 to -8.21, 2 RCTs, 199 patients, I^2=0). Chinese medicine administration included oral, nasogastric, cold stimulation, spray, and fumigation. Considering aspiration risk in post-stroke dysphagia, external experts recommended nasogastric or external administration.

3.3.3 Clinical Question 10: For post-stroke depression patients, can Chinese medicine combined with antidepressants better relieve depressive symptoms than antidepressants alone?

Recommendation 13: For post-stroke depression patients, consider liver-soothing and depression-relieving Chinese medicine combined with antidepressants to better relieve depressive symptoms (2C). Referenced medicines include: Chaihu Shugan Powder, Xiaoyao Powder, Shugan Jieyu Decoction, Shugan Jieyu Capsule, Jieyu Pill, Jieyu Anshen Granules, and Wuling Capsule.

Rationale: A 2017 systematic review [44] suggested liver-soothing and depression-relieving Chinese medicine combined with antidepressants better reduced Hamilton Depression Scale (HAMD) scores. Subgroup analyses of

different formulas showed: Chaihu Shugan Powder (4 weeks: MD=-4.03, 95%CI=-5.21 to -2.84, 9 RCTs, 802 patients, I^2=84%; 8 weeks: MD=-3.78, 95%CI=-4.76 to -2.80, 8 RCTs, 623 patients, I^2=65%), Xiaoyao Powder (4 weeks: MD=-1.85, 95%CI=-2.86 to -0.84, 8 RCTs, 727 patients, I^2=86%; 8 weeks: MD=-5.25, 95%CI=-7.22 to -3.29, 4 RCTs, 279 patients, I^2=91%), Shugan Jieyu Decoction (4 weeks: MD=-4.14, 95%CI=-5.12 to -3.15, 3 RCTs, I^2=34%; 8 weeks: MD=-5.62, 95%CI=-6.85 to -4.40, 4 RCTs, 369 patients, I^2=55%), Shugan Jieyu Capsule (4 weeks: MD=-5.30, 95%CI=-6.52 to -4.08, 1 RCT, 90 patients, I^2=0; 8 weeks: MD=-5.27, 95%CI=-6.11 to -4.44, 2 RCTs, I^2=0). Results showed combined Wuling Capsule (MD=-2.97, 95%CI=-4.37 to -1.57, 5 RCTs, 436 patients, I^2=80%), Jieyu Pill (MD=-4.28, 95%CI=-4.92 to -3.63, 1 RCT, 98 patients, I^2=0), and Jieyu Anshen Granules (MD=-2.18, 95%CI=-2.92 to -1.43, 1 RCT, 94 patients, I^2=0) were superior to selective serotonin reuptake inhibitors (SSRIs) alone for improving HAMD-17 scores. Adverse events mainly included gastrointestinal reactions (nausea, vomiting, bloating, constipation) and neuropsychiatric symptoms (dizziness, headache, insomnia); no studies reported discontinuation due to safety events.

Recommendation 14: For post-stroke depression patients, consider acupuncture combined with antidepressants to better relieve depressive symptoms (2C).

Rationale: A 2021 systematic review [46] of 17 RCTs with 1,402 post-stroke depression patients showed acupuncture combined with conventional antidepressant treatment reduced HAMD-17 scores (MD=-5.08, 95%CI=-6.48 to -3.67, 3 RCTs, 252 patients, I^2=0) and HAMD-24 scores (MD=-9.72, 95%CI=-14.54 to -4.91, 2 RCTs, 123 patients, I^2=65%).

3.3.4 Clinical Question 11: For post-stroke cognitive impairment patients, can Chinese medicine combined with Western medicine better improve cognitive impairment than Western medicine alone?

Recommendation 15: For post-stroke cognitive impairment patients, consider Chinese medicine combined with Western medicine to better improve cognitive impairment (2C).

Rationale: A 2022 systematic review [47] of 34 RCTs with 2,900 patients showed Chinese medicine improved cognitive function. Using Montreal Cognitive Assessment (MoCA), combined therapy improved cognition at <3 months (MD=2.55, 95%CI=1.56-3.53, 8 RCTs, 600 patients, I^2=79%) and 3 months (MD=3.07, 95%CI=1.98-4.17, 11 RCTs, 1,459 patients, I^2=87%). Using Mini-Mental State Examination (MMSE), combined therapy improved cognition at <3 months (MD=2.55, 95%CI=1.99-3.10, 10 RCTs, 874 patients, I^2=53%), 3 months (MD=2.53, 95%CI=1.59-3.47, 11 RCTs, 833 patients, I^2=88%), 4 months (MD=2.91, 95%CI=1.26-4.56, 1 RCT, 80 patients, I^2=0), and 6 months (MD=3.11, 95%CI=-0.04 to 6.27, 3 RCTs, 232 patients, I^2=93%). Adverse events were mainly gastrointestinal discomfort without serious reactions.

Recommendation 16: For post-stroke cognitive impairment patients, con-

sider acupuncture combined with Western medicine to better improve cognitive impairment (2C).

Rationale: A 2020 systematic review [48] of 37 RCTs with 2,869 post-stroke cognitive impairment patients showed after 2-8 weeks of acupuncture, MMSE scores (MD=2.88, 95%CI=2.09-3.66, 31 RCTs, 2,349 patients, I^2=93%) and MoCA scores (MD=2.66, 95%CI=1.95-3.37, 14 RCTs, 1,129 patients, I^2=55%) significantly improved, suggesting acupuncture benefits post-stroke cognitive impairment without reported adverse events.

3.3.5 Clinical Question 12: For stroke patients, can acupuncture combined with rehabilitation better improve limb function than rehabilitation alone?

Recommendation 17: In stable patients, considering patient preferences and economic circumstances, acupuncture may be used on top of conventional rehabilitation to improve motor function (2C). Considered protocols: Jin's Three-Needle Therapy, abdominal acupuncture.

Rationale: A 2021 Meta-analysis [49] of 31 RCTs with 3,222 post-stroke hemiplegia patients showed Jin's Three-Needle Therapy combined with conventional rehabilitation improved Fugl-Meyer Motor Function Assessment (FMA) scores more than rehabilitation alone (MD=9.33, 95%CI=7.15-11.50, 19 RCTs, 2,060 patients, I^2=70%). Subgroup analyses by duration showed benefits at 14 days (MD=13.21, 95%CI=10.11-16.31, 4 RCTs, 349 patients, I^2=70%), 28 days (MD=9.32, 95%CI=7.24-11.40, 12 RCTs, 1,295 patients, I^2=0), and >28 days (MD=3.92, 95%CI=1.84-5.99, 2 RCTs, 147 patients, I^2=0). A 2021 systematic review [50] of 21 RCTs with 1,473 stroke patients showed abdominal acupuncture combined with non-abdominal acupuncture treatments (including conventional rehabilitation, body acupuncture, consciousness-resuscitation acupuncture) further improved motor function (MD=9.53, 95%CI=7.23-11.83, 13 RCTs, 967 patients, I^2=89%), upper limb function (MD=11.08, 95%CI=5.83-16.32, 6 RCTs, 411 patients, I^2=92%), and lower limb function (MD=5.57, 95%CI=2.61-8.54, 4 RCTs, 287 patients, I^2=96%).

Recommendation 18: Within 48 hours post-stroke is the optimal intervention window; hemodynamically stable stroke patients should receive acupuncture rehabilitation as early as possible for greater benefit (2C).

Rationale: A 2021 network Meta-analysis [51] comparing different acupuncture timing points for improving FMA scores ranked post-stroke within 48 hours as optimal, followed by 2-15 days post-stroke.

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4 Integrated Chinese and Western Medicine Stroke Prevention and Treatment Flowchart

The integrated Chinese and Western medicine stroke prevention and treatment flowchart developed by this guideline is detailed in Figure 1 [Figure 1: see original paper].

This guideline, after fully assessing the necessity for update, re-identified clinical questions requiring updates and formed a multidisciplinary expert working group. Based on systematic review/Meta-analysis evidence and using the GRADE approach, final recommendations were formulated. Methodologically, this guideline strictly followed internationally recognized standards; clinically, it aligns with current expert opinions and practice evidence.

Compared with the 2019 Edition Guideline, the 2023 Edition primarily adds: expert recommendations for secondary prevention of minor stroke with integrated medicine, acupuncture recommendations for post-stroke depression, clinical questions on integrated treatment for post-stroke cognitive impairment, and acupuncture-assisted limb function rehabilitation, providing more comprehensive coverage better aligned with current clinical needs in stroke prevention and treatment.

Despite strict adherence to evidence-based guideline development methods, several limitations exist. First, the clinical question of using Chinese medicine for secondary prevention in minor stroke lacks supporting evidence, with Recommendation 2 based solely on expert clinical experience—future research should address this gap. Second, due to insufficient evidence, Recommendations 3, 5, 6, 7, 8, 12, 14, 15, and 16 do not specify particular Chinese medicines or acupuncture protocols—future studies should focus on specific interventions. Additionally, high-quality clinical evidence has emerged in recent years, such as large clinical trials on Xuesaitong Soft Capsules [52], Ginkgo Diterpene Lactone Meglumine Injection [53], and Tongxinluo Capsules [54] for ischemic stroke—future updates should incorporate this evidence. Finally, this update did not conduct patient preference and values surveys for newly included clinical questions, which may affect final recommendations and strength grading [55]. The lengthy development period may also have altered supporting evidence and health economics—our working group will address these issues in future updates.

Declaration: The *Clinical Practice Guideline for the Prevention and Treatment of Stroke with Integrated Traditional Chinese and Western Medicine (2023 Edition)* was adapted from the China Association of Chinese Medicine group standard (T/CACM 1446-2023) and its development manual, following the Reporting Items for Practice Guidelines in Healthcare (RIGHT) and journal requirements.

This guideline was developed within the framework of current laws, regulations,

and mandatory standards, strictly adhering to existing international and national standards without conflict.

This guideline was proposed and is under the jurisdiction of the China Association of Chinese Medicine, led by the Guangdong Provincial Hospital of Chinese Medicine (The Second Affiliated Hospital of Guangzhou University of Chinese Medicine) as the chair unit of the Stroke Branch, with methodological support from the Evidence-based Medicine Center/GRADE Center of Lanzhou University. Based on evidence-based guideline development methods and the latest research evidence, multidisciplinary expert consensus was incorporated, though recommendations do not represent all participating institutions' views. This edition has shortcomings and deficiencies that we will continue to improve in future versions. We solemnly declare that views expressed in this guideline must not be used for commercial promotion or advertising.

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