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Meta-analysis of Traditional Chinese Medicine Syndrome Differentiation in Carotid Atherosclerotic Plaque

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 5 July 2026 and was last updated on 5 July 2026.

INTRODUCTION

Review question / Objective This systematic review and meta-analysis aims to investigate the distribution characteristics and composition ratio of Traditional Chinese Medicine (TCM) syndromes in patients with carotid atherosclerotic plaque.P - Patients diagnosed with carotid atherosclerotic plaque by ultrasound or other imaging methods.I (Interest factor/Exposure) - TCM syndrome differentiation and syndrome types (e.g., Phlegm-stasis互结, Qi stagnation and blood stasis, Yang deficiency, etc.) reported in the included studies.C - Not applicable (this is a descriptive systematic review focusing on syndrome distribution; no comparison group is required).O - Primary outcomes: the frequency and constituent ratio of each TCM syndrome type. Secondary outcomes: the distribution of syndrome elements (e.g., blood stasis, phlegm, deficiency) if available.S - Cross-sectional studies, cohort studies, or observational studies that reported TCM syndrome classifications.

Rationale Carotid atherosclerotic plaque (CAP) is a major risk factor for ischemic stroke, posing a significant threat to global public health. Traditional Chinese Medicine (TCM) is widely used in the adjuvant treatment of cardiovascular diseases in China. TCM syndrome differentiation is the core principle of personalized TCM treatment; however, the distribution characteristics of TCM syndromes in CAP patients remain inconsistent across individual studies due to small sample sizes and regional differences. To date, there is a lack of a comprehensive systematic review and meta-analysis that systematically summarizes the overall constituent ratio and distribution rules of TCM syndromes in CAP patients. Therefore, this systematic review and meta-analysis aims to synthesize the available cross-sectional and observational studies to clarify the TCM syndrome distribution patterns in CAP patients, thereby providing a robust evidence-based theoretical basis for clinical syndrome differentiation and the

standardization of TCM treatment strategies for CAP.

Condition being studied Carotid atherosclerotic plaque (CAP), a common manifestation of carotid atherosclerosis and a major risk factor for ischemic stroke.

METHODS

Search strategy Information sources:
We will conduct a comprehensive search in the following four Chinese electronic databases: China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform (WanFang), Chinese Scientific Journal Database (VIP), and China Biology Medicine (CBM). We only searched Chinese databases and did not search English databases (e.g., PubMed, Embase) for this review. The search was performed on September 1, 2025, and covers publications from September 1, 2005 to August 1, 2025. No language restrictions will be applied (all databases are Chinese-language). The search will be supplemented by manually checking the reference lists of included studies.
Search strategy:
A professional/expert search strategy was employed to ensure high recall (sensitivity). The search terms combined subject headings and free-text terms using Boolean operators (AND, OR) and field-specific searches (e.g., Subject, Abstract). For the Chinese databases, the core search terms included: “颈动脉粥样硬化斑块” (carotid atherosclerotic plaque), “颈动脉斑块” (carotid plaque), “中医” (Traditional Chinese Medicine), “证候” (syndrome), and “证型” (syndrome type). The detailed search syntax adapted for the Chinese databases (using CNKI as an example) is as follows:
CNKI search strategy (example for Chinese databases):
((Subject:(颈动脉 AND 斑块) AND Abstract:(证候 OR 证型 OR 中医临床研究) AND Abstract:(中医 OR 中药)) AND Publication Date: 2005-2025)This search strategy was adapted for each database (WanFang, VIP, and CBM) with appropriate syntax adjustments to match their specific search interfaces and field codes (e.g., using Title/Keyword/Abstract instead of Subject/Abstract where applicable). The search was conducted on September 1, 2025.

Participant or population This review includes patients diagnosed with carotid atherosclerotic plaques (CAPs). The diagnosis of CAPs is based on imaging examinations, primarily carotid duplex ultrasound or other imaging methods (e.g., computed tomography angiography, magnetic resonance angiography), with diagnostic criteria defined as focal thickening of the vessel wall ≥ 1.5 mm or carotid intima-media thickness (IMT) ≥ 1.0 mm. No restrictions were placed on participants' age, gender, ethnicity, or disease duration.
Inclusion criteria for this population:
(1) The study must clearly report the number of patients with specific TCM syndromes or provide the constituent ratio/distribution proportion data of TCM syndromes in CAPs patients.
(2) The study must be conducted within the territory of the People's Republic of China (including mainland China). Studies conducted outside China are excluded.
Exclusion criteria for this population:
(1) Studies that only reported the distribution characteristics of TCM syndrome elements (e.g., blood stasis, phlegm, Qi deficiency) without explicitly classifying them into complete TCM syndrome types (e.g., Phlegm-stasis interjunction, Qi stagnation and blood stasis) are excluded.
(2) Studies that only focused on a single TCM syndrome or combined syndromes where independent syndrome information cannot be extracted are excluded.
(3) Studies involving patients with acute ischemic stroke at the time of enrollment, or those with severe comorbidities (e.g., malignant tumors, severe hepatic or renal dysfunction), are excluded if the original studies explicitly excluded them.

Intervention Not applicable. This is a descriptive systematic review and meta-analysis focusing on the distribution characteristics and constituent ratio of Traditional Chinese Medicine (TCM) syndromes in patients with carotid atherosclerotic plaques (CAPs). No specific intervention (e.g., drug, surgery, acupuncture, or other therapeutic measures) is evaluated or compared in this review.

Comparator Not applicable. This is a descriptive systematic review and meta-analysis that aims to investigate the distribution characteristics and constituent ratios of Traditional Chinese Medicine (TCM) syndromes in patients with carotid atherosclerotic plaques (CAPs). No comparison group (e.g., placebo, no treatment, conventional treatment, or alternative interventions) is involved, as this review does not evaluate the efficacy or effectiveness of any specific intervention.

Study designs to be included Study designs to be included:This review will include observational studies that report the distribution of Traditional Chinese Medicine (TCM) syndromes in patients with carotid atherosclerotic plaques (CAPs). Eligible study designs include:(1) Cross-sectional

studies;(2) Cohort studies (both prospective and retrospective);(3) Case-series studies;(4) Observational studies with a clear description of TCM syndrome classification and the number or proportion of patients in each syndrome type.Randomized controlled trials (RCTs), non-randomized controlled trials, case-control studies.

Eligibility criteria The eligibility criteria for this systematic review and meta-analysis were defined according to the PICOS framework (with modifications for descriptive studies).
Inclusion criteria:
(1) Population: Patients diagnosed with carotid atherosclerotic plaques (CAPs) based on imaging examinations (e.g., carotid duplex ultrasound, computed tomography angiography, or magnetic resonance angiography). No restrictions on age, gender, ethnicity, or disease duration.
(2) Outcome: Studies that clearly reported the number of patients with specific Traditional Chinese Medicine (TCM) syndromes or provided the constituent ratio/distribution proportion data of TCM syndromes in CAPs patients.
(3) Study design: Observational studies, including cross-sectional studies, cohort studies (prospective or retrospective), and case-series studies. No restrictions on sample size, provided that sufficient data on syndrome frequencies or proportions were reported.
(4) Geographical setting: Studies conducted within the territory of the People's Republic of China (including mainland China). Studies conducted outside China were excluded.
(5) Language: Only studies published in Chinese were included. Studies published in other languages were excluded.
Exclusion criteria:
(1) Duplicate publications (the most complete or most recent version will be retained);
(2) Studies that only reported the distribution characteristics of TCM syndrome elements (e.g., blood stasis, phlegm, Qi deficiency) without clearly classifying them into complete TCM syndrome types (e.g., Phlegm-stasis interjunction, Qi stagnation and blood stasis);
(3) Studies that did not report specific syndrome classifications and their corresponding case numbers;
(4) Studies that only focused on a single TCM syndrome or combined syndromes where independent syndrome information could not be extracted;
(5) Studies for which full text could not be accessed (after contacting authors and requesting full text via interlibrary loan);
(6) Studies with missing data on research methods, participant characteristics, intervention/observation factors, or outcome measures;
(7) Randomized controlled trials (RCTs), non-randomized controlled trials, case-control studies, case reports, animal studies, in vitro studies, reviews, meta-analyses, conference abstracts, editorials, and letters, unless they provided original, extractable data on TCM syndrome distribution in CAPs patients.

Information sources We conducted a comprehensive search in the following four Chinese electronic databases: China National Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform (WanFang), Chinese Scientific Journal Database (VIP), and China Biology Medicine (CBM). The search was performed on September 1, 2025, and covered publications from September 1, 2005 to August 1, 2025. We only searched Chinese databases and did not search English databases (e.g., PubMed, Embase) for this review. No language restrictions were applied as all databases are Chinese-language. The search was supplemented by manually checking the reference lists of included studies.

Main outcome(s) The primary outcome of this systematic review and meta-analysis is the prevalence/constituent ratio of each Traditional Chinese Medicine (TCM) syndrome type in patients with carotid atherosclerotic plaques (CAPs). Specifically, we will extract and pool the number and proportion of patients classified into each TCM syndrome type (e.g., Phlegm-stasis interjunction, Qi stagnation and blood stasis, Yang deficiency, Yin deficiency, etc.) across the included studies. The results will be presented as pooled prevalence/constituent ratios with corresponding 95% confidence intervals (CIs) for each syndrome type. Subgroup analyses may be performed based on geographical region, study quality, or sample size if sufficient data are available.

Additional outcome(s) The secondary outcomes of this systematic review and meta-analysis include:
(1) Subgroup analyses based on geographical region (e.g., northern vs. southern China) or study quality (high vs. low), if sufficient data are available.
(2) A descriptive summary of the quality assessment results of the included studies, evaluated using appropriate tools such as the Agency for Healthcare Research and Quality (AHRQ) checklist for cross-sectional studies or the Newcastle-Ottawa Scale (NOS) for cohort studies.

(3) Sensitivity analyses will be performed to test the robustness of the pooled results by sequentially excluding studies with high risk of bias or studies with relatively small sample sizes.
(4) If feasible, we will explore potential sources of heterogeneity through subgroup analyses or meta-regression, based on factors such as publication year, mean age of participants, and diagnostic criteria for carotid atherosclerotic plaques (CAPs).

Data management Data management:
All identified records will be exported to and managed using EndNote 20 (Clarivate Analytics, Philadelphia, PA, USA) reference management software. Duplicate records will be removed first. Then, two independent reviewers (MAchangrui. and HEhanyu.) will screen the titles and abstracts of all retrieved records to preliminarily exclude studies that are completely irrelevant to the research topic. The full texts of potentially eligible studies will be downloaded and read in full by the same two reviewers, who will make the final inclusion decisions based on the prespecified eligibility criteria. Any disagreements during the screening or full-text review process will be resolved through discussion or by consulting a third reviewer (LIjiajie.) to reach a consensus.
A standardized data extraction form will be developed and used to extract key information from the included studies. The extracted data will include: first author, publication year, province/region of China, age and gender characteristics of participants, sample size, criteria for TCM syndrome differentiation, and the number of cases distributed across each TCM syndrome type. Data extraction will be performed independently by the two reviewers (MAchangrui. and HEhanyu.) using the same form. The extracted data will be cross-checked to ensure accuracy; any discrepancies will be resolved through discussion or by involving a third reviewer (LIjiajie). The literature screening process will be reported in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram.

Quality assessment / Risk of bias analysis The methodological quality of the included cross-sectional studies will be independently assessed by two reviewers (MAchangrui. and HEhanyu.) using the Agency for Healthcare Research and Quality (AHRQ) recommended checklist for cross-sectional studies. The checklist comprises 11 items, and each item will be answered as "yes," "no," or "unclear." A score of "yes" will be assigned 1 point, while "no" or "unclear" will be assigned 0 points, with a total possible score of 11. Based on the total score, the overall quality of each study will be rated as high quality (score 8–11), moderate quality (score 4–7), or low quality (score 0–3). Disagreements between the two reviewers will be resolved through discussion or by consulting a third reviewer (LIjiejie.).

Strategy of data synthesis This systematic review and meta-analysis will synthesize data on the constituent ratios of Traditional Chinese Medicine (TCM) syndromes in patients with carotid atherosclerotic plaques (CAPs).
All statistical analyses will be performed using R software (with the meta package). The pooled constituent ratio and its 95% confidence interval (CI) for each TCM syndrome type will be calculated. Given the expected heterogeneity across studies due to variations in geographical regions, study populations, and diagnostic criteria for TCM syndromes, a random-effects model will be employed for all meta-analyses.
Heterogeneity will be assessed using the I^2 statistic and the Chi^2 test (with a significance level of $P < 0.10$). I^2 values will be interpreted as follows: 0%–40% (might not be important), 30%–60% (may represent moderate heterogeneity), 50%–90% (may represent substantial heterogeneity), and 75%–100% (considerable heterogeneity). If substantial heterogeneity is detected ($I^2 \geq 50\%$), we will explore potential sources through subgroup analyses based on predefined factors (e.g., geographical region, study quality, or sample size), if sufficient data are available.
To ensure the robustness of the pooled results, sensitivity analyses will be performed by sequentially excluding individual studies. Publication bias will be assessed using funnel plots and Egger's test when at least 10 studies are included for a specific outcome.
If meta-analysis is not feasible due to significant clinical or methodological heterogeneity, or insufficient data, the results will be presented as a narrative synthesis, summarizing the findings of the included studies descriptively.

Subgroup analysis If substantial heterogeneity is detected ($I^2 \geq 50\%$), we will perform subgroup analyses to explore potential sources of heterogeneity. The following subgroup analyses will be conducted if sufficient data are available:
(1) Geographical region: northern China versus southern China, based on the traditional Qinling Mountains-Huaihe River line division, considering potential differences in TCM syndrome distribution due to climate and lifestyle variations.
(2) Study quality: studies with high quality (AHRQ score 8–11) versus studies with moderate or low quality (AHRQ score ≤ 7).
(3) Sample size: studies with sample size ≥ 100 versus studies with sample size < 100 participants.

Subgroup differences will be assessed using the Chi² test, and a P value < 0.05 will be considered statistically significant.

Sensitivity analysis To test the robustness of the pooled results, we will perform the following sensitivity analyses:
Sequential exclusion of individual studies: We will sequentially exclude each included study one at a time and recalculate the pooled constituent ratios for each TCM syndrome type to assess whether any single study disproportionately influences the overall results.

Language restriction Only studies published in Chinese will be included in this systematic review and meta-analysis. Studies published in other languages (e.g., English, Japanese, Korean, etc.) will be excluded.

Country(ies) involved China.

Other relevant information This registration is submitted retrospectively, as the systematic review and meta-analysis have already been completed. The literature search, data extraction, and statistical analyses were conducted prior to registration. However, the protocol and all methods described in this registration are fully consistent with the procedures actually implemented in the completed review. No deviations from the reported methods occurred. We acknowledge that prospective registration is the preferred practice for systematic reviews, and we plan to register future reviews prospectively. The corresponding author can be contacted at [1587960916@qq.com] for any further clarification. No additional funding was received for this study, and there are no conflicts of interest to declare.

Keywords Carotid Atherosclerotic Plaques (CAPs); Traditional Chinese Medicine (TCM) Syndromes; Meta-Analysis; Cross-Sectional Studies.

Dissemination plans The findings of this systematic review and meta-analysis will be disseminated through the following channels:
(1) Publication in a peer-reviewed academic journal. We will aim to submit the completed review to an appropriate Chinese or international journal in the fields of traditional Chinese medicine, cardiovascular diseases, or evidence-based medicine.
(2) Presentation at relevant academic conferences, such as national or international conferences on traditional Chinese medicine, integrative medicine, or cardiology.

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Author 1 (Ma CR): Designed the study; performed literature search, screening, data extraction; wrote the manuscript. Author 2 (Li JJ): Cross-checked data; revised the manuscript. Author 3 (He HY): Conducted statistical analysis. Author 4 (Zhao J): Conducted statistical analysis. Author 5 (He QY): Revised the manuscript. Author 6 (Wen WB