Post-Print: Collection and Determination of Clinical Questions and Outcome Measures for the Clinical Practice Guideline for the Diagnosis and Treatment of Hemorrhoids Integrating Traditional Chinese and Western Medicine

Authors: Zhi Congcong, Yicheng Cheng, Huang Zichen, Wang Xiaolong, Li Xue, Zheng Lihua, Zheng Lihua

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Abstract

Background: Hemorrhoids represent the most prevalent disease in colorectal surgery, affecting a substantial patient population. The integrated Chinese and Western medicine approach demonstrates distinct clinical advantages in diagnosis and treatment. However, high-quality guidelines or recommended standards are currently lacking, underscoring the critical importance of standardizing integrated Chinese and Western medicine practices for hemorrhoid management.

Objective: To identify and delineate the core clinical questions and outcome indicators for the "Guidelines for Integrated Chinese and Western Medicine Diagnosis and Treatment of Hemorrhoids", thereby providing a foundation for subsequent evidence synthesis and guideline formulation.

Methods: An initial list of questions was developed through literature analysis, expert interviews, and clinical investigations. Two rounds of Delphi expert consultations were conducted. Data analysis was performed using SPSS 26.0 and Excel 2021, calculating positive response rates, means, full-score rates, coefficients of variation, and Cronbach's α coefficients. Inclusion criteria comprised: mean score of clinical questions $\geq$ 3 points, mean score of outcome indicators $\geq$ 7 points, full-score rate $\geq$ 50%, and coefficient of variation <30%. Quality control standards included: expert positive response rate $\geq$ 75%, Kendall's coefficient of concordance >0.7, and Cronbach's α coefficient $\geq$ 0.7 as quality control benchmarks for the Delphi questionnaire.

Results: Preliminary investigation yielded 27 clinical questions (9 basic questions and 18 PICO-formulated questions) and 9 outcome indicators. Following

two Delphi rounds with 34 experts from relevant fields, the final set comprised 28 clinical questions (9 basic questions and 19 PICO-formulated questions) and 9 key outcome indicators. Expert positive response rates were 85% and 97% for the two rounds, respectively, with Kendall' s coefficients of concordance of 0.837 and 0.826. Cronbach' s α coefficients for clinical questions and outcome indicators were 0.929, 0.866, and 0.923, 0.803, respectively, demonstrating high expert engagement, minimal disagreement, strong coordination, good questionnaire reliability, and robust results. After internal expert discussion, 28 clinical questions (9 basic questions and 19 PICO-formulated questions) were finalized for inclusion in the guideline, covering traditional Chinese medicine characteristics of hemorrhoids, preoperative assessment, integrated Chinese and Western medicine treatment modalities, perioperative management, etc.

Conclusion: The clinical question and outcome indicator framework established through multi-dimensional investigation and the Delphi method provides a scientific structure for guideline development, emphasizing the crucial role of multidisciplinary consensus in formulating integrated medicine guidelines.

Full Text

Methods Research: Collection and Determination of Clinical Questions and Outcome Indicators for the *Guideline for the Diagnosis and Treatment of Hemorrhoids with Integrated Traditional Chinese and Western Medicine*

ZHI Congcong[1], CHENG Yicheng[1], HUANG Zichen[2], WANG Xiaolong[2], LI Xue[2], ZHENG Lihua[1]*

[1] China-Japan Friendship Hospital, Beijing 100029, China
[2] Graduate School, Beijing University of Chinese Medicine, Beijing 100029, China

Corresponding author: ZHENG Lihua, Chief physician; E-mail: btv126@126.com

Abstract

Background: Hemorrhoids are the most common diseases in anorectal surgery, with a large patient population. The integrated diagnosis and treatment approach combining traditional Chinese and Western medicine demonstrates clear clinical advantages. However, there is currently a lack of high-quality guidelines or recommended standards, making it critically important to standardize the integrated management of hemorrhoids.

Objective: To screen and define the core clinical questions and outcome indicators for the *Guideline for the Diagnosis and Treatment of Hemorrhoids with Integrated Traditional Chinese and Western Medicine*, providing a foundation for subsequent evidence synthesis and guideline development.

Methods: An initial list of questions was developed through literature analysis, expert interviews, and clinical investigation. Two rounds of expert consultation were conducted using the Delphi method. Data analysis was performed using SPSS 26.0 and Excel 2021, calculating positive coefficients, mean scores, full score rates, coefficients of variation, and Cronbach' s α coefficients. Inclusion criteria were: mean score $\geq$ 3 points for clinical questions, mean score $\geq$ 7 points for outcome indicators, full score rate $\geq$ 50%, and coefficient of variation $<$ 30%. Quality control standards required an expert positive coefficient $\geq$ 75%, Kendall' s harmony coefficient $>$ 0.7, and Cronbach' s α coefficient $\geq$ 0.7.

Results: After preliminary investigation, 27 clinical questions (9 basic questions and 18 PICO-formulated questions) and 9 outcome indicators were drafted. Following two rounds of Delphi surveys with 34 experts in relevant fields, the final set comprised 28 clinical questions (9 basic questions and 19 PICO-formulated questions) and 9 key outcome indicators. The expert positive coefficients were 85% and 97% for the two rounds, respectively. Kendall' s harmony coefficients were 0.837 and 0.826. Cronbach' s α coefficients for clinical questions and outcome indicators were 0.929, 0.866, 0.923, and 0.803, respectively, indicating high expert engagement, minimal disagreement, strong coordination, good questionnaire reliability, and robust results. After internal discussion, 28 clinical questions (9 basic and 19 PICO-formulated) were finalized for inclusion in the guideline, covering TCM characteristics of hemorrhoids, preoperative assessment, integrated treatment modalities, and perioperative management.

Conclusion: The clinical question and outcome indicator system established through multi-dimensional research and the Delphi method provides a scientific framework for guideline development, highlighting the importance of multidisciplinary consensus in formulating integrated medical guidelines.

Keywords: Hemorrhoids; Clinical practice guidelines; Problem construction; Efficacy evaluation; Integrated traditional Chinese and Western medicine; Delphi method

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Hemorrhoids are among the most common anorectal diseases in clinical practice. Although prevalence estimates vary across countries, hemorrhoids represent a significant health burden both domestically and internationally [1-3], with over 2.2 million patient visits annually in the United States alone [3]. According to national surveys reported by Chinese colorectal disease associations, the overall prevalence of anorectal diseases in China is 59.1%, with hemorrhoids accounting for the highest proportion (51.56%) and representing 87.25% of all anorectal conditions [1]. Circular mixed hemorrhoids, in particular, present numerous postoperative complications and patient dissatisfaction, posing significant challenges for clinicians, especially at primary care facilities. In recent years, extensive clinical practice and research have been conducted on the integrated management of hemorrhoids; however, standardized guidelines remain lacking. Exist-

ing guidelines or consensus statements are relatively simplistic and outdated, lacking comprehensive summaries of different integrated treatment modalities, providing insufficient guidance for managing common postoperative complications, and suffering from inadequate evidence bases and inconsistent evaluation systems [4-5].

Given this context, our team, commissioned by the China Association of Chinese Medicine, initiated the development of the *Guideline for the Diagnosis and Treatment of Hemorrhoids with Integrated Traditional Chinese and Western Medicine* (project approval number: 20230802-BZ-CACM; International Practice Guidelines Registry: PREPARE-2024CN1185). The establishment of clinical questions and outcome indicators represents a core component of guideline development, directly determining the scope and number of recommendations, as well as guiding the breadth of evidence searches. The scientific rigor of this process is critical to guideline quality. As the first interdisciplinary guideline spanning TCM, Western medicine, integrated medicine, surgery, and internal medicine for colorectal conditions, this effort faces challenges including numerous cross-disciplinary clinical questions and low-level evidence. The Delphi method, a structured communication technique that anonymously solicits expert opinions through multiple rounds, has been widely applied in clinical guideline development [6-7]. The guideline development team employed the Delphi method to organize national experts in colorectal surgery and methodology, following international and professional society principles to integrate new knowledge and advances in both medical traditions and construct the guideline' s clinical questions. This study summarizes the clinical question formulation process to establish a foundation for future integrated guidelines on hemorrhoid management.

1.1 Formation of the Expert Panel

The expert panel comprised specialists in traditional Chinese medicine, Western medicine, and integrated medicine from the field of colorectal surgery, involving multiple clinical disciplines including TCM colorectal surgery, general surgery, gastrointestinal surgery, and dermatology. All experts held senior professional titles and represented six major geographical regions across China, ensuring both professional rigor and regional representation.

1.2 Literature Search and Expert Interviews

Based on preliminary literature review and expert interviews, the development team established an initial list of clinical questions. The team conducted literature searches in CNKI, Wanfang Data, VIP, PubMed, Embase, and Cochrane Library using keywords including "hemorrhoids," "integrated traditional Chinese and Western medicine," "surgery," "postoperation," "traditional Chinese medicine," "lifestyle interventions," "hemorrhoids," "traditional Chinese medicine," "operation," "postoperation," and "lifestyle interventions." A question collection team of two interviewers conducted 10-20 minute interviews with

four senior experts from China-Japan Friendship Hospital specializing in hemorrhoid treatment. Interview content included: (1) questionnaire purpose, requirements, and significance; (2) basic expert information (name, gender, age, education, department, title, professional background); and (3) clinical questions covering hemorrhoid classification, diagnosis and treatment, and outcome indicators. Interview findings were synthesized with clinical experience to draft initial clinical questions and outcome indicators for the guideline, which formed the basis for designing the Delphi survey questionnaire.

1.3 Delphi Method for Clinical Question Determination

This study employed the Delphi method to construct the clinical question and outcome indicator evaluation system. Clinical question importance was rated on a 5-point scale (1-5), while outcome indicators used a 9-point scale (1-9), with higher scores indicating greater importance. Outcome indicators were categorized into three levels: 7-9 points for critical outcomes, 4-6 points for important outcomes, and 1-3 points for general outcomes. The study implemented two rounds of expert consultation. The first-round questionnaire used a composite design (scoring combined with open-ended questions) for preliminary assessment of clinical questions and outcome indicators. Items with clinical question mean scores < 3, outcome indicator mean scores < 5, or coefficient of variation $> 30\%$ were eliminated, while semantically redundant items were consolidated and out-of-scope projects excluded. Based on first-round results, a second-round questionnaire was optimized and, after statistical analysis, final inclusion criteria were applied: clinical question mean score ≥ 3, outcome indicator mean score ≥ 7, full score rate $\geq 50\%$, and coefficient of variation $< 30\%$.

1.4 Statistical Methods

Data analysis was performed using SPSS 26.0 and Excel 2021. Count data were expressed as frequency and percentage (%), while normally distributed measurement data were presented as mean $\pm$ standard deviation ($\bar{x} \pm s$). Expert positive coefficient, mean score (X), full score rate (K), and coefficient of variation (CV) were calculated for importance evaluation [8].

1.4.1 Expert Positive Coefficient: This refers to the questionnaire response rate, calculated as (valid returned questionnaires / total questionnaires) $\times$ 100%. A coefficient $\geq 75\%$ was considered valid, with high response rates indicating strong expert engagement and ensuring questionnaire accuracy [8].

1.4.2 Expert Opinion Centralization: Centralization was quantified through mean importance scores (X) and full score rates (K) for each item. X represents the arithmetic mean of item scores, while K (%) indicates the percentage of experts assigning full marks. Higher values reflect greater item importance and expert consensus: items with $X \geq 2.50$ and $K \geq 50.00\%$ were considered highly important, while those with $X < 1.00$ or $K < 30.00\%$ were candidates for deletion. These metrics effectively reflect consensus levels in

Delphi studies.

1.4.3 Expert Opinion Coordination: Coordination was assessed using coefficient of variation (CV) and Kendall' s harmony coefficient (W). CV reflects score dispersion, with values positively correlated with expert disagreement; CV $< 30\%$ indicated valid consensus. W represents overall coordination among experts in evaluating the item set, a classic metric in health research ranging from 0 to 1, with values approaching 1 indicating significantly improved coordination. This dual-indicator system scientifically measures consistency and coordination in Delphi studies [9].

1.4.4 Questionnaire Reliability: Cronbach' s α coefficient was used to reflect overall questionnaire reliability and/or reliability of major categories, as well as result dependability. Values ≥ 0.70 indicated good reliability and high result credibility.

Results

2.1 Basic Information of Experts

The expert panel consisted of 34 specialists from integrated TCM and Western medicine colorectal surgery, general surgery, gastrointestinal surgery, and dermatology nationwide, including 24 males and 10 females. Twenty experts (58.82%) were over 50 years old. All held senior professional titles with extensive clinical experience, broad academic perspectives, and familiarity with current research status and hotspots in the field, demonstrating high professional authority. Thirty-one experts (91.18%) had over 15 years of work experience. Panel members represented 15 regions including Beijing, Hebei, Inner Mongolia, Shandong, Jiangsu, Shanghai, and Guangdong, covering six major geographical areas of China. Detailed information is presented in Table 1 .

2.2 Screening Process for Clinical Questions and Outcome Indicators

The first-round consultation included 27 clinical questions (9 basic and 18 PICO-formulated) and 9 outcome indicators. After the first Delphi survey, scoring results for each item were obtained and expert supplementary questions were collected, resulting in one additional clinical question (Table 2) for inclusion in the second-round survey (Table 3). Following internal expert discussion and analysis, 28 clinical questions (9 basic and 19 PICO-formulated) and 9 key outcome indicators were finalized for evidence grading and recommendation formulation (Table 4).

2.3 Survey Results

2.3.1 Positive Coefficient: The first-round questionnaire response rate was 85% (29/34), and the second-round rate was 97% (33/34), demonstrating high expert engagement and attention to this study.

2.3.2 Expert Opinion Centralization: In Table 3, all 28 clinical questions had mean scores $>$ 4 points and full score rates $>$ 50%, while all 9 outcome indicators had mean scores $>$ 7 points with nearly all full score rates $>$ 40%, indicating strong expert consensus on the importance of included questions and indicators.

2.3.3 Expert Opinion Coordination: In Table 3, coefficients of variation for all 28 clinical questions and 9 outcome indicators were $<$ 30.0%, with a Kendall' s harmony coefficient of 0.826, demonstrating minimal expert disagreement and high coordination.

2.3.4 Questionnaire Reliability: Cronbach' s α coefficients for clinical questions and outcome indicators were 0.929 and 0.866 in the first round, and 0.923 and 0.803 in the second round. Both rounds exceeded 0.7, indicating good questionnaire reliability and high result credibility.

Discussion

The Delphi method is a crucial approach for expert consultation and a key step in constructing clinical questions, outcome indicators, and ultimately developing recommendations in clinical guidelines [10]. The *Guideline for the Diagnosis and Treatment of Hemorrhoids with Integrated Traditional Chinese and Western Medicine* synthesizes the best available evidence from comprehensive clinical research in this field to inform clinical decision-making. Clinical questions in guidelines form the basis for literature searching and systematic reviews, with their number directly determining guideline scope and recommendation quantity [11-12].

Through the Delphi method, extensive clinical investigation, expert interviews, and multiple survey rounds, this project identified 19 PICO-structured clinical questions. Preliminary literature searches and investigations were conducted to ensure quality. Initial expert interviews and clinical surveys revealed that key issues in integrated hemorrhoid management focus on the integration points between TCM and Western medicine and surgical technique selection. Based on these findings, 27 initial clinical questions and 9 outcome indicators were drafted. The 9 basic questions addressed: definition, etiology, clinical symptoms and signs, classification, pathological features, diagnosis and differential diagnosis, auxiliary examinations, TCM syndrome differentiation, and TCM treatment principles and formulas. For surgical management, technique selection and quality critically impact postoperative recovery. With numerous TCM and Western surgical approaches currently available but lacking unified recommendations, optimal clinical protocols require clarification. Therefore, the 18 PICO-formulated questions and 9 outcome indicators focused on: TCM treatment principles and formulas [13-14], surgical methods for internal, external, and mixed hemorrhoids [15-17], hemorrhoid injection therapy, rubber band ligation [18-19], radiofrequency ablation, copper ion electrochemical therapy, Doppler-guided hemorrhoidal artery ligation, stapled hemorrhoidopexy (PPH)

[20-21], non-surgical treatments, and prevention and nursing care. All questions and indicators were clinically derived to formulate optimal integrated treatment protocols.

After the first Delphi round, all clinical questions and outcome indicators were retained based on mean scores, indicating they were all priority concerns. Analysis of supplementary comments revealed that treatment for special populations or hemorrhoids with comorbidities was also critical, prompting addition of one clinical question. The first round resulted in 9 basic questions, 19 PICO-formulated questions, and 9 outcome indicators for the second survey. Based on second-round statistics using inclusion criteria (clinical question mean ≥ 3, outcome indicator mean ≥ 7, full score rate $> 50\%$, CV $\leq 30\%$) and internal expert discussion, 28 clinical questions (9 basic, 19 PICO-formulated) and 9 outcome indicators were finalized. All included questions will generate recommendations, and all outcome indicators are classified as critical.

This study has notable strengths. First, it strictly followed international standard development protocols and standardized office procedures. Clinical questions covered etiology, basic diagnosis, integrated treatment, and preventive care, while outcome indicators were established through preliminary literature searches, expert interviews, and clinical surveys to ensure professionalism and comprehensiveness. Second, expert panel composition critically influenced quality. The panel included TCM, Western, and integrated medicine physicians from colorectal surgery, general surgery, gastrointestinal surgery, and dermatology. All held senior titles, with 30 experts (88.24%) having over 15 years of experience. Broad geographical representation across six regions ensured comprehensive and authoritative guideline content. Survey response rates exceeded 85% in both rounds, demonstrating high engagement. Mean CVs of 12.36% and 12.81% and Kendall' s harmony coefficients of 0.837 and 0.826 indicated minimal disagreement and effective consensus. Cronbach' s α coefficients > 0.7 for both rounds confirmed high reliability. Furthermore, all clinical questions and outcome indicators were oriented toward solving practical clinical problems, ensuring clinical utility and providing industry standards for integrated hemorrhoid management.

This study has limitations. The guideline targets primary care institutions, but the expert panel lacked primary care representation, consisting mainly of specialists from large tertiary hospitals—providing strong professional but potentially less comprehensive perspectives. Additionally, panel diversity could be improved by including nursing, anesthesiology, and methodology experts. While geographical coverage included six regions, Northeast China was not represented. Furthermore, patient perspectives were not solicited due to question complexity, representing another limitation. Regarding clinical questions, while treatment methods were comprehensively discussed, selection of surgical techniques for different hemorrhoid severity grades requires further refinement.

In summary, the *Guideline for the Diagnosis and Treatment of Hemorrhoids with Integrated Traditional Chinese and Western Medicine* identified 19 PICO-

structured questions and 18 key content areas through literature review, expert interviews, clinical surveys, and Delphi method screening, establishing a credible, authoritative, and representative framework. This process laid the foundation for guideline structure and recommendation development, providing evidence for integrated management advantages and methodological reference for core clinical question and outcome indicator construction in colorectal guidelines and evidence-based TCM guideline development.

Author Contributions: ZHI Congcong drafted the manuscript; ZHI Congcong, CHENG Yicheng, HUANG Zichen, WANG Xiaolong, and LI Xue distributed and collected questionnaires; CHENG Yicheng, HUANG Zichen, WANG Xiaolong, and LI Xue organized and analyzed returned questionnaires; ZHENG Lihua conceptualized the clinical questions; ZHI Congcong and ZHENG Lihua were responsible for questionnaire development during clinical question construction, manuscript review, and quality control.

Conflict of Interest: None declared.

ORCID iDs:
ZHI Congcong https://orcid.org/0000-0003-3151-8382
ZHENG Lihua https://orcid.org/0000-0001-8643-9855

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Note: Figure translations are in progress. See original paper for figures.