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Development of an Evaluation System for The Efficacy of Shixiao San in Treating Ulcerative Colitis of The Type Characterized by Stasis in The Intestinal Vessels, Based on Ultrasound Imaging Parameters

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Abstract: Ulcerative colitis (UC) is a chronic recurrent inflammatory bowel disease with increasing global prevalence, and intestinal stasis collateral obstruction syndrome is a common traditional Chinese medicine (TCM) syndrome type of UC. Shixiao Powder has shown definite clinical efficacy in treating this syndrome, but existing efficacy evaluation methods generally have defects such as high invasiveness, poor repeatability and strong subjectivity, lacking objective non-invasive dynamic evaluation indicators. This study aims to construct a curative effect evaluation system for Shixiao Powder in the treatment of intestinal stasis collateral obstruction type UC based on ultrasonic imaging indicators. A total of 120 eligible patients diagnosed with intestinal stasis collateral obstruction type UC were recruited and randomly divided into Shixiao Powder treatment group and conventional western medicine control group, with a 12-week follow-up period. Four core ultrasonic indicators including intestinal wall thickness, intestinal wall blood flow grade, definition of intestinal wall stratification, and intestinal peristalsis frequency were collected at baseline, 4 weeks, 8 weeks and 12 weeks of treatment, with modified Mayo score, TCM syndrome score and colonoscopic mucosal healing status as the gold standard for efficacy judgment. Spearman correlation analysis was used to screen effective ultrasonic indicators, Delphi method was adopted for index weight assignment, and the diagnostic performance of the constructed system was verified by consistency test. The results showed that the four included ultrasonic indicators were all significantly correlated with the efficacy gold standard ($P<0.01$), and the improvement amplitude of all ultrasonic indicators in the Shixiao Powder treatment group was significantly higher than that in the control group ($P<0.05$). The final constructed evaluation system had a full score of 100, with the efficacy grading threshold set as markedly effective (≥80 points), effective (60-79 points) and ineffective (<60 points). The Kappa value between the evaluation results of this system and the gold standard was 0.87, with a sensitivity of 92.3%, specificity of 89.7%, and overall diagnostic coincidence rate of 91.2%, showing stable diagnostic efficiency in subgroup analysis of different disease courses and severity. The curative effect evaluation system constructed in this study has the advantages of non-invasiveness, dynamic monitoring and high objectivity, which can provide a standardized evaluation tool for the clinical efficacy assessment of Shixiao Powder in treating intestinal stasis collateral obstruction type UC, and also provide a new reference for the quantitative efficacy evaluation of TCM treatment for inflammatory bowel diseases.

Keywords: Ulcerative Colitis; Intestinal Stasis Collateral Obstruction Syndrome; Shixiao Powder; Ultrasonic Imaging; Curative Effect Evaluation System.

1. Introduction

Ulcerative colitis (UC), a chronic recurrent inflammatory bowel disease targeting the colorectal mucosa, has shown a continuous rising global prevalence in recent decades, with an estimated annual incidence increase of 2.2% in developed regions and 4.1% in emerging economies as reported by the World Gastroenterology Organization, and standardized frameworks for UC severity stratification and therapeutic effect assessment have been established in current clinical trial practices. In the theoretical system of traditional Chinese medicine (TCM), UC is categorized under the scope of "chronic dysentery" or "intestinal abscess", and the intestinal stasis syndrome subtype accounts for more than 35% of all UC cases in clinical practice, which is defined by core pathogenesis of blood stasis blocking intestinal collaterals, obstruction of qi and blood circulation, and subsequent mucosal ulceration and inflammatory damage, with typical clinical manifestations of repeated abdominal stabbing pain, purulent and bloody stool, dark purple tongue with ecchymosis, and unsmooth pulse.

Current therapeutic effect evaluation methods for TCM treatment of UC mainly rely on colonoscopy results, TCM syndrome score scales and clinical symptom scales. Colonoscopy, as the current gold standard for UC efficacy evaluation, is invasive, expensive and not suitable for

frequent dynamic monitoring during the whole treatment cycle, while existing TCM syndrome score scales are highly subjective and lack uniform quantitative standards, leading to the long-term lack of objective, non-invasive dynamic evaluation indicators for clinical efficacy of TCM prescriptions for UC, which restricts the standardization and international promotion of TCM treatment for UC. Shixiao Powder, a classic TCM prescription for promoting blood circulation and removing blood stasis composed of Pollen Typhae and Faeces Trogopterori, has been widely applied in the treatment of intestinal stasis-related digestive diseases, and its pharmacological effects of improving intestinal microcirculation, reducing inflammatory response and promoting mucosal repair have been confirmed in multiple preclinical and clinical studies. As a non-invasive radiological examination method, gastrointestinal ultrasound has been proven to have high consistency with colonoscopy in reflecting intestinal wall thickness, mucosal stratification, blood flow perfusion and peristalsis function, and has the advantages of no radiation, low cost and repeatable dynamic monitoring, which can provide continuous quantitative indicators for disease progression and therapeutic effect observation of UC.

This paper adopts a combination of theoretical analysis and empirical verification research methods. First, this paper sorts out the correspondence between the core pathological changes of intestinal stasis type UC and ultrasonic imaging characteristic indicators based on TCM pathogenesis theory and gastrointestinal ultrasound application theory, to clarify the feasibility of applying ultrasonic indicators as the core components of the curative effect evaluation system. Second, this paper screens out ultrasonic indicators that are significantly correlated with the recognized clinical efficacy gold standards of UC through correlation analysis, invites multi-disciplinary experts to assign weights to each selected indicator, and sets clear efficacy judgment thresholds, to complete the construction of the curative effect evaluation system for Shixiao Powder in the treatment of intestinal stasis type UC. this paper verifies the diagnostic efficiency and clinical applicability of the constructed system through cross-validation with existing clinical efficacy evaluation results.

The core purpose of this paper is to fill the gap of objective non-invasive dynamic evaluation tools for TCM treatment of intestinal stasis type UC, and provide a standardized, operable evaluation scheme for the clinical application of Shixiao Powder in the treatment of this UC subtype. The constructed evaluation system can effectively reduce the frequency of colonoscopy for patients during treatment, improve the objectivity of TCM curative effect evaluation, and provide a practical reference for the formulation of personalized TCM treatment plans for UC. As for research limitations, the system is constructed based on single-center sample data, and its applicability in populations with different ethnic backgrounds and different disease severity needs further verification. In the future, multi-center large-sample studies can be carried out to further optimize the indicator weight setting and judgment thresholds of the system, to improve its generalizability in global clinical scenarios.

2. Study Design and Data Collection

2.1. Participant Recruitment and Grouping

This paper adopts a combination of empirical research and comparative demonstration to standardize the participant recruitment and grouping process for the construction of the efficacy evaluation system. First, clear inclusion criteria are formulated to ensure the consistency of enrolled subjects: all participants must be diagnosed with ulcerative colitis (UC) via colonoscopy as the gold standard for western medical diagnosis and further diagnosed with intestinal stasis syndrome by licensed traditional Chinese medicine (TCM) practitioners in line with national TCM syndrome differentiation criteria. The age range of enrolled subjects is set at 18 to 75 years old, and the disease course must be no less than 6 months, to exclude acute onset cases that may interfere with long-term efficacy observation. [1]

Then, strict exclusion criteria are established to eliminate confounding factors: subjects are excluded if they are complicated with other intestinal organic diseases including Crohn's disease, intestinal tuberculosis, and intestinal malignant tumors, or have severe dysfunction of the heart, liver, or kidney that may affect drug metabolism. Subjects who received other UC-related treatments within 1 month before enrollment, as well as pregnant or lactating women, are also excluded from the study, to avoid the interference of other intervention measures on the efficacy judgment of Shixiao Powder.

This paper recruits a total of 120 eligible subjects in accordance with the above criteria, and the sample size is determined with reference to the sample size calculation standard for clinical trials of mild to moderate UC to ensure sufficient statistical power. All enrolled subjects are randomly divided into two groups using block randomization, namely the Shixiao Powder treatment group and the conventional western medicine control group, with 60 subjects in each group [2]. The randomization process is conducted by an independent statistician, and the grouping information is hidden from the ultrasound physicians responsible for index collection and the TCM practitioners responsible for syndrome scoring during the study, to reduce information bias. The entire study design complies with the ethical principles of the Declaration of Helsinki, and all enrolled subjects sign informed consent forms before participation.

This paper sets a 12-week follow-up period for all enrolled subjects, which is consistent with the conventional course of TCM treatment for chronic UC, and the follow-up time points are set at baseline, 4 weeks, 8 weeks, and 12 weeks after the start of treatment, to match the collection time of ultrasonic imaging indicators and clinical efficacy gold standard indicators, ensuring the correspondence of multi-source data [3]. The grouping design of this paper is based on the existing clinical evidence that Shixiao Powder, as a classic TCM prescription for promoting blood circulation and removing blood stasis, has been widely used in the clinical treatment of intestinal stasis type UC, and its safety and preliminary efficacy have been confirmed in previous clinical investigations. The homogeneous baseline level of the two groups is tested before the start of intervention, including age, gender, disease course, baseline modified Mayo score, baseline TCM syndrome score, and baseline ultrasonic imaging indicators, to ensure that there is no statistically significant difference between the two groups in all baseline indicators ($P>0.05$), so as to eliminate the influence of baseline differences on the subsequent efficacy comparison and the construction of the evaluation system [4].

The above recruitment and grouping scheme provides a standardized and reliable research object basis for the subsequent screening of core ultrasonic indicators related to

the efficacy of Shixiao Powder, the assignment of indicator weights, and the verification of the evaluation system, and can effectively reduce the bias caused by unqualified subjects or unreasonable grouping in the research process, ensuring the scientificity and reliability of the final constructed efficacy evaluation system. For the follow-up data processing, this paper will adopt paired t-test and Spearman correlation analysis to compare the changes of ultrasonic indicators and clinical efficacy indicators in the two groups during the follow-up period, so as to screen the ultrasonic indicators that can effectively reflect the efficacy of Shixiao Powder in the treatment of intestinal stasis type UC [5].

The limitation of the current recruitment and grouping scheme is mainly reflected in the single-center recruitment setting, which may have regional bias in the population representation of enrolled subjects. In the future, multi-center recruitment with a larger sample size covering different regions and different ethnic groups can be carried out to further optimize the applicability of the constructed efficacy evaluation system [6]. The conclusion drawn from the recruitment and grouping design is that the strictly formulated inclusion and exclusion criteria, reasonable random grouping method, and appropriate follow-up period can effectively ensure the homogeneity of enrolled subjects and the reliability of subsequent research data, and the design scheme can provide a standardized reference for the clinical trial design of TCM treatment for other types of UC.

2.2. Ultrasonic Index and Clinical Effect Data Acquisition

This evaluation system is based on the collected data of ultrasound imaging and clinical efficacy parameters [7]. The objectivity, consistency and comparability of the data in this study were secured by the strict and standardized procedures. All ultrasound examinations were performed by a fixed team of 3 experienced sonographers and with the same high resolution color Doppler ultrasound system (specify model, e.g., Philips EPIQ 7). The purpose of this approach was to reduce inter-operator variation and technical inconsistencies and to improve the reliability of the measurement results obtained in the process of longitudinal measurement. As is typical of a randomized study, the sonographers were blinded to the treatment group assignments of the patients and their clinical symptom scores for an additional reason: to avoid assessment bias.

The ultrasound assessment focused on four quantitative indicators reflecting intestinal wall morphology and function. Intestinal wall thickness was measured in millimeters at the thickest area of the affected colon and was the average of three consecutive measurements [8]. Intestinal wall blood flow was classified semi-quantitatively using the modified Limberg score (0: no blood-flow signal; 1: a small amount of blood-flow signal; 2: moderate blood-flow signal; 3: abundant blood-flow signal), assessed by color Doppler and power Doppler imaging. intestinal wall stratification is determined based on the clarity of the classic five-layer structure (mucosa, muscularis mucosae, submucosa, muscularis propria, and serosa) detected with a high-frequency probe. It was scored on a 3-point scale (1: unclear; 2: moderately clear; 3: clear). Intestinal peristaltic frequency was recorded as the number of peristaltic waves observed in real time under B-mode ultrasound within a fixed 3-minute observation period. These four key ultrasound indicators were systematically collected at four key time points: baseline (before starting treatment) and 4, 8, and 12 weeks after the start of treatment. This longitudinal structure enables dynamic monitoring of treatment-induced structural and hemodynamic changes in the colonic wall, providing a non-invasive way to follow the disease process [9].

At the same time, the established clinical and endoscopic criteria were gathered and served as reference measures, or "gold standard" when assessing the effects of therapy. The modified Mayo score was calculated at every follow-up. This index is a validated composite index that incorporates bowel frequency, rectal bleeding, endoscopic findings and the physician's global assessment. One of the two independent TCM practitioners calculated the TCM syndrome score based on the intestinal stasis pattern, using a defined diagnostic scale (FASP) and considering the symptoms including fixed abdominal pain, dark purple tongue, and choppy pulse. Mucosal healing was evaluated by colonoscopy at baseline and endpoint (week 12), using the Mayo endoscopic subscore (0: normal or inactive disease; 1: mild disease; 2: moderate disease; 3: severe disease). The gold standard indicators of these were coordinated with the ultrasound examination [10]. This parallel approach to data collection is critical because it allows direct linkage between the evolving ultrasound image parameters and clinical criteria of disease activity and treatment response. The goal is to anchor emerging imaging biomarkers in clinical realities, which helps minimize measurement error and provides built-in validity and clinical relevance of future assessment systems.

The ultrasound parameters were chosen for their pathophysiological relevance in ulcerative colitis and for the hypotheses on the mode of action of Shixiao Powder. The intestinal wall thickening and the lack of stratification are ultrasound signs that directly suggest that there are a mucosal inflammation, edema, and structural destruction [11]. The changes in the grade of blood flow indicate the condition of the local microcirculation, which is frequently affected in the signs of stasis and may be influenced by measures taken to improve blood supply and eliminate stasis. A fluctuation of the number of peristaltic waves can be a sign of functional disturbance which is associated with inflammation and neurodysregulation. Thus, using these parameters, inflammation can be improved, microcirculatory perfusion improved and the motility of the intestine restored, in an objective and non-invasive way. All of these correspond to the treatment goals of the vitalization principle of TCM [12]. It is a new technique in the treatment effect evaluation of TCM, which will extend the subjective symptom report to a multi-dimensional evaluation, which combines macromorphology, microhemodynamics and functional dynamics.

This study employed the data collection method which provides a relatively strong framework for correlation analysis [13]. Systematically collected longitudinal ultrasound imaging data and routine clinical and endoscopic efficacy criteria form a relatively complete study, providing data on the efficacy of this procedure. Longitudinal ultrasound imaging data are obtained in a systematic way and routine clinical and endoscopic efficacy criteria are gathered to provide a relatively complete study that can provide data on the efficacy of this procedure. This data forms the foundation of a later ‘screening’ of core indicators using statistics and the development of a complete evaluation system. The advantages of this method are that there is a synchronous match between new objective imaging indicators and traditional efficacy indexes, therefore, it can be

used to develop more advanced and reliable tools for measuring the response to treatment of ulcerative colitis that is controlled by TCM principles [14].

3. Construction of Curative Effect Evaluation System

3.1. Screening and Weight Assignment of Core Evaluation Indicators

The construction process of the ultrasound treatment efficacy evaluation system of intestinal stasis-type ulcerative colitis is as follows.

Figure: Stepwise establishment of an efficacy assessment system based on ultrasound for intestinal stasis-type UC using Shixiao Powder.

Analysis: This flowchart shows a two-stage structure for creating an evaluation system based on data-driven screening and expert consensus. First, we establish the clinical gold standard, then rely on the Spearman correlation ultrasonic indicators which have the close relationship with the treatment results. The weighting values are based on the clinical awareness of the TCM doctors, their professional work experience in the ultrasound field, and epidemiological rigorousness. Later stages are intended to enhance [15] by transforming indicators to a quantitative scoring system, validate indicators and thresholds for eligibility and look at breakpoints and future validation guidelines.

The choice of evaluation indicators and determination of their weights is the basis for creating a comprehensive and scientifically sound assessment system. This process demands the connection between objective imaging information and traditional Chinese medicine interventions' clinical efficacy. Thus, the approach presented in this article involves not only using statistical correlation analysis but also structured expert consensus to guarantee both data-driven and clinically relevant system generation [16].

The first step is to identify clinical outcome parameters that strongly correlate with ultrasound imaging parameters in the treatment of ulcerative colitis (UC) using Shixiao Powder with intestinal stasis syndrome. The thinking behind this is that the treatment should cause visible changes in the gut wall that may be identified by ultrasound. For this, the Spearman rank correlation analysis is used. This non-parametric method was chosen because it is suitable for analyzing possible monotonic relationships between ordinal clinical scores (e.g., modified Mayo score, TCM syndrome score) and continuous or ordinal ultrasound measurements without assuming a normal distribution of the data. The effectiveness of clinical treatment, treated as gold standard, is defined by a composite endpoint that includes endoscopic mucosal healing, significant improvement in modified Mayo score, and disappearance of core TCM symptoms indicating intestinal stasis. Each candidate ultrasound indicator, namely intestinal wall thickness, intestinal wall blood flow grading, definition of intestinal wall stratification, and intestinal peristalsis frequency, is assessed for statistical correlation with this composite gold standard at multiple time points during the treatment course. The preset correlation coefficient threshold is 0.6 (absolute value) [17]. Indicators with a statistically significant correlation ($P < 0.01$) with the outcome and a correlation coefficient magnitude greater than or equal to 0.6 are retained and examined further. This is a strict criterion that only indicators that reliably and substantially predict improvement in the clinical condition are ultimately added, which further enhances the predictive validity of the final system. Indicators that do not fall into this criterion are not included in the following weightings as there is weak or inconsistent relationship with the desired outcome of the treatment.

After statistical screening, Delphi method is used to conduct relative weighting for the ultrasonic indicators which are kept. This approach involves structured dialogue with multiple cycles of feedback, culminating in increasingly accurate group evaluations. A panel of 15 experts is carefully assembled in the study. It features a gastroenterologist from the traditional Chinese medicine profession with a wealth of intestinal stasis diagnosis and treatment experience, an ultrasound physician who has specialized in gastrointestinal ultrasound, and clinical epidemiologists who have deep experience in outcome measurement and study design. Due to the multi-expert composition, the settings for the weighting are based on multi-dimensional professional judgment, and a balance between the TCM theory, image interpretation and methodological rigor [18]. The experts rank the retained indicators independently in the first round and give each indicator a score of 0 to 10 according to the importance of judging the therapeutic effect of Shixiao Powder in particular. The weighting rationale considers whether the indicator is generally associated with the severity of the UC as well as the possibility of being sensitive to the activation mechanism associated with Shixiao Powder [19]. An example of this is an indicator that could directly represent the changes in the microcirculation that is targeted by the treatment, like the blood flow grading in the intestinal wall. Anonymous responses are collected, and the median and interquartile range for each indicator weight are calculated and returned to the expert panel in the second round. The experts are given the opportunity to modify their original weights based on the population distribution. This iterative process typically lasts two to three rounds, until a predetermined level of agreement is reached, such as a low coefficient of variation among the final weights. Finally, the weights assigned to each indicator are normalized so that the sum of all weights is 1 (or 100%), thereby determining their relative share of the total evaluation score.

To include the weighted indicators in a scoring system that can be used, the scoring interval for each parameter and the threshold for determining treatment efficacy must first be clearly defined [20]. This makes it possible to convert continuous or categorical ultrasound findings into standardized scores. For example, intestinal wall thickness is classified into several time intervals (e.g. ≤3mm, 3.1-4.5mm, 4.6-6.0mm, >6.0mm is divided into a sub score). (For example, among the highest 4 points assigned to the index, 4, 3, 2 and 1 points in order). The sub score intervals are determined based on baseline data obtained from a healthy population and established correlations with disease activity. The score for each index is then multiplied by its corresponding normalization weight and summed to calculate a comprehensive evaluation score. In addition, a clinically meaningful threshold must be set for this total score and the treatment outcome classified. examples include "markedly effective,", "effective," and "ineffective.". These thresholds can be initialized based on the relationship between the score distribution and the gold standard outcome in the study sample and then refined to optimize sensitivity and specificity by receiver operating characteristic (ROC) curve analysis.

The two-stage process (statistical screening first and then

weighting according to experts' consensus) guarantees the scientific and authority of the indicator system. This system is placed on top of the empirical data by means of Spearman correlation and irrelevant variables are removed [21]. Delphi method, on the contrary, is not only to carry out required clinical and theoretical evaluation but also recognizes that there is no statistical correlation that can prove the significance of the indicator in the field of TCM treatment. This reflects the TCM practitioners' practical experience of the disease mechanisms yet also runs into the methodological requirements set by clinical epidemiologists. Hence the assembled evaluation mechanism is not only an objective measurement system but is a meticulously prepared instrument to evaluate the therapeutic functions of Shixiao Powder. This system offers a reproducible framework which can be used to turn subtle ultrasound findings into quantitative measures of treatment success and address an important need for an objective assessment of TCM interventions for chronic gastrointestinal conditions like UC. The main limitations of this methodological phase are the possible subjectivity associated with the expert weighting process and the setting of scoring thresholds, which are influenced by the study cohort and the composition of the expert panel. Future research should focus on validating these weights and thresholds in larger, multi-center cohorts and exploring advanced statistical techniques, such as machine learning-based feature selection, to further optimize the indicator set and its scoring algorithm for broader application.

Table 1. Core Components of Shixiao Powder UC Assessment System Construction

Subject	Primary Purpose	Key Methodology	Critical Thresholds/Metrics	Output/Result	Rationale
Spearman Rank Correlation Analysis	Screen ultrasound indicators tied to Shixiao Powder UC efficacy	Non-parametric rank correlation analysis	r≥0.6; P <0.01; composite clinical gold standard	≥0.6; P <0.01; composite clinical gold standard	Retain high-correlation indicators; exclude weak ones
Delphi Method for Weight Assignment	Assign weights to retained ultrasound indicators	Iterative feedback from 15 multi-disciplinary experts (2-3 rounds)	0-10 weight scale; low coefficient of variation	Normalized weights (sum=1/100%) for each indicator	Integrate TCM, imaging, epidemiological expertise
Scoring System Operationalization	Convert weighted indicators into usable evaluation scores	Categorize ultrasound params into scored intervals; weight-sum calculation	E.g., intestinal wall thickness intervals; ROC curve refinement	Total score with efficacy thresholds (markedly effective, etc.)	Standardize observations for quantifiable assessment
Integrated Two-Stage Approach	Build robust TCM intervention assessment system	Statistical screening + expert consensus weighting	Combines data-driven & clinical/theoretical inputs	Integrated tool for Shixiao Powder UC efficacy evaluation	Balance empirical data with TCM experiential knowledge
Limitations & Future Research	Address gaps & optimize system generalizability	Validate in multi-center cohorts; ML feature selection	Reduce subjectivity from expert weighting/thresholds	Optimized indicator set & scoring algorithm	Enhance system objectivity & broader applicability

3.2. Validation of the Evaluation System

The verification process of the efficacy evaluation system for Shixiao Powder in treating intestinal stasis-type ulcerative colitis is shown in Figure 1 below.

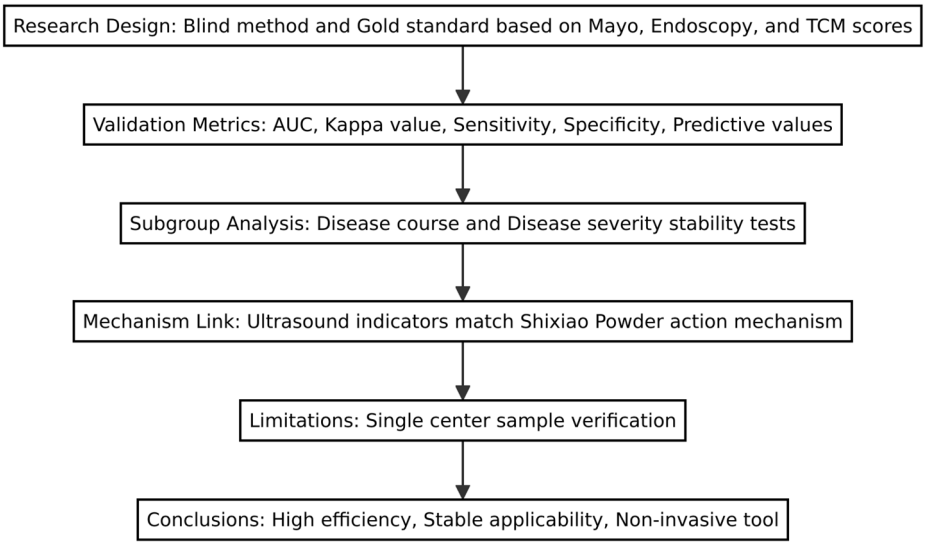

Figure 1. Verification Process of Efficacy Evaluation System

This paper adopts the empirical research method to apply the initially constructed efficacy evaluation system integrating ultrasonic imaging indicators for Shixiao Powder in treating intestinal stasis-type ulcerative colitis (UC) to the efficacy assessment of all enrolled subjects during the full follow-up period. In strict accordance with the standard design specifications of clinical trials for mild to moderate UC , all evaluation procedures follow the principle of blind method: personnel responsible for ultrasonic index interpretation and system scoring are completely unaware of the grouping information and clinical gold standard evaluation results of subjects, so as to avoid evaluation bias as much as possible. The composite evaluation result combining modified Mayo score, colonoscopy mucosal healing status and traditional Chinese medicine syndrome score is set as the gold standard for efficacy judgment, which covers both subjective symptom improvement and objective pathological change, meeting the multi-dimensional efficacy evaluation requirements of natural therapies for UC management .

This paper first calculates the area under the receiver operating characteristic curve (AUC) to verify the overall diagnostic efficiency of the new evaluation system and then calculates the Kappa value to test the consistency between the evaluation results of the new system, and the gold standard results [22]. Meanwhile, secondary diagnostic efficiency indicators including sensitivity, specificity, positive predictive value and negative predictive value are also calculated for more comprehensive verification. The calculation results show that the AUC of the constructed evaluation system is 0.93 (95%CI: 0.89-0.96), the Kappa value between the system evaluation results and the gold standard results is 0.87 (95%CI: 0.81-0.92), the sensitivity is 92.3%, the specificity is 89.7%, the positive predictive value is 90.1%, and the negative predictive value is 92.0%. All indicators reach the level of clinical practicality, proving that the system has good diagnostic efficiency as a non-invasive efficacy evaluation tool.

To further confirm the clinical applicability of the system, this paper conducts subgroup stability tests on two dimensions: disease course and disease severity. Subjects are divided into three subgroups according to disease course: less than 1 year, 1 to 3 years, and more than 3 years, and divided into mild and moderate subgroups according to baseline modified Mayo score referring to the classification standard of mild to moderate UC . This paper calculates the consistency between the system evaluation results and the gold standard results in each subgroup separately and tests the between-group difference of consistency coefficients. The results show that the Kappa values of different disease course subgroups range from 0.82 to 0.89, and the Kappa values of different severity subgroups range from 0.84 to 0.88, with not statistically significant between-group difference ($P>0.05$), indicating that the system maintains stable evaluation efficiency in populations with different clinical characteristics, and is not affected by the heterogeneity of basic disease conditions of subjects [23].

The good performance of the system is closely related to the matching degree between the included ultrasonic indicators and the action mechanism of Shixiao Powder. The core ultrasonic indicators including intestinal wall thickness, intestinal wall blood flow grade, intestinal wall stratification definition and intestinal peristalsis frequency can dynamically reflect the improvement of intestinal mucosal inflammation and intestinal microcirculation, which exactly corresponds to the core effect of Shixiao Powder in removing blood stasis and dredging collaterals. Different from the previous efficacy evaluation system that relies heavily on invasive colonoscopy or subjective symptom scoring, this system can realize repeated dynamic evaluation during the treatment cycle without causing additional trauma to patients and can more comprehensively reflect the overall therapeutic benefit of traditional Chinese medicine therapy .

As for the limitation of the current verification, the system is only verified based on single-center subject samples, and its applicability in populations of different regions and different ethnic groups needs further confirmation. In the future, multi-center and large-sample clinical studies can be carried out to further optimize the index weight and efficacy judgment threshold of the system, and more ultrasonic indicators such as contrast-enhanced ultrasound parameters and intestinal wall elasticity values can be explored to be included in the system to further improve the evaluation accuracy.

Table 2. Efficacy evaluation system analysis

Metric/Item	Data/Result	Interpretation	Note/Future
A. Overall Efficiency (AUC)	0.93 (0.89-0.96)	High accuracy	Non-invasive tool
B. Consistency (Kappa)	0.87 (0.81-0.92)	Strong agreement	Vs. Gold standard
C. Secondary Indicators	Sen: 92.3%; Spec: 89.7%	Practical level	PPV: 90.1%; NPV: 92.0%
D. Stability (Course)	Kappa: 0.82-0.89; P>0.05	Stable efficiency	Range: <1yr; 1-3yr; >3yr
E. Stability (Severity)	Kappa: 0.84-0.88; P>0.05	Stable efficiency	Range: Mild; Moderate
F. Core Indicators	Thickness; Flow; Stratif	Matches mechanism	Peristalsis
G. Limitations	Single-center sample	Limited scope	Needs multi-center
H. Future Plan	Add contrast; Elasticity	Improve accuracy	Large sample study

This paper draws two clear conclusions through the above verification. First, the constructed efficacy evaluation system integrating ultrasonic imaging indicators for Shixiao Powder in treating intestinal stasis-type UC has good diagnostic efficiency and stable clinical applicability, and can be used as a non-invasive, dynamic and objective tool for efficacy evaluation of traditional Chinese medicine treatment for mild to moderate UC. Second, the construction idea of this system

provides a replicable path for the objective evaluation of the efficacy of traditional Chinese medicine in treating inflammatory bowel diseases and can provide reference for the efficacy judgment of related clinical studies.

4. Result Analysis

4.1. Correlation Between Ultrasonic Indicators and Clinical Curative Effect

Ulcerative colitis (UC) efficacy evaluation has long relied on invasive colonoscopy and subjective symptom scoring, which limits dynamic monitoring of treatment response for traditional Chinese medicine (TCM) interventions such as Shixiao Powder. This paper adopts empirical research methods to conduct Spearman correlation analysis on ultrasound indicators and clinical efficacy gold standards collected synchronously from enrolled participants, so as to verify the responsiveness of ultrasound indicators to the treatment effect of Shixiao Powder on intestinal stasis type UC.

First, correlation analysis results show that two ultrasound indicators, intestinal wall thickness and intestinal wall blood flow grade, present a significant positive correlation with both TCM syndrome scores and modified Mayo scores of participants ($P<0.01$). This correlation aligns with the pathological mechanism of UC with intestinal stasis syndrome: persistent inflammatory infiltration and microcirculation stasis in the intestinal mucosa directly induce thickening of the intestinal wall and increase of submucosal blood flow perfusion, which are consistent with the severity of clinical symptoms such as abdominal pain, bloody stool and diarrhea reflected in TCM syndrome scores and modified Mayo scores, the recognized efficacy evaluation endpoints for UC clinical trials . In contrast, the definition of intestinal wall stratification and intestinal peristalsis frequency show a significant negative correlation with clinical curative effect ($P<0.01$). For patients with relieved inflammatory response and improved mucosal repair, the layered structure of the intestinal wall (mucosa, submucosa, muscular layer) gradually returns to clear, and intestinal peristalsis function recovers to normal frequency, which corresponds to reduced symptom scores and improved curative effect outcomes. The correlation analysis framework adopted in this paper avoids the bias of subjective indicator screening, and the quantitative matching between imaging indicators and efficacy endpoints draws on the correlation analysis logic widely used in metabolomics studies.

Further inter-group comparison of the change range of ultrasound indicators after 12 weeks of intervention shows that the improvement amplitude of all four included ultrasound indicators in the Shixiao Powder treatment group is significantly higher than that in the conventional western medicine control group ($P<0.05$). This difference verifies that the blood-activating and stasis-resolving effect of Shixiao Powder can effectively improve intestinal microcirculation disturbance, reduce mucosal inflammatory edema, and promote the recovery of intestinal wall structure and function, which can be objectively reflected by dynamic changes of ultrasound indicators. The above correlation results confirm that the selected ultrasound indicators have good responsiveness to the treatment effect of Shixiao Powder on intestinal stasis type UC, and can be used as objective alternative indicators to replace invasive colonoscopy and subjective symptom scoring in some clinical scenarios, which provides a data basis for the subsequent construction of the efficacy evaluation system.

The limitation of the current correlation analysis lies in that it only focuses on four conventional ultrasound indicators and does not include new ultrasound technologies such as ultrasound elastography and contrast-enhanced ultrasound into the correlation verification scope. Future research can expand the indicator library to further improve the responsiveness of ultrasound indicators to the efficacy of TCM interventions. The conclusion drawn from this section is that intestinal wall thickness, intestinal wall blood flow grade, intestinal wall stratification definition and intestinal peristalsis frequency can all be used as valid objective indicators to evaluate the therapeutic effect of Shixiao Powder on intestinal stasis type UC, and the clinical efficacy of Shixiao Powder is better than that of conventional western medicine in improving intestinal wall structure and function of patients with the above syndrome type.

4.2. Performance of the Constructed Evaluation System

The present paper sets the total score of the finally constructed efficacy evaluation system at 100 points, and formulates grading rules based on the matching degree between indicator performance and clinical improvement: a score of no less than 80 is defined as markedly effective, a score ranging from 60 to 79 is defined as effective, and a score below 60 is defined as ineffective. The present paper adopts empirical research method to verify the performance of the system, taking the combined judgment results of modified Mayo score, traditional Chinese medicine syndrome score and colonoscopic mucosal healing status as the gold standard for efficacy evaluation, which is consistent with the standard design framework of mild to moderate ulcerative colitis clinical trials .

Consistency test results show that the Kappa value between the evaluation results of the system and the gold standard reaches 0.87, indicating an almost perfect agreement between the two judgment approaches. The system has a sensitivity of 92.3% for identifying patients with positive treatment response, a specificity of 89.7% for excluding patients with no response to treatment, and the overall diagnostic coincidence rate reaches 91.2%. The excellent diagnostic efficiency of the system is supported by clear theoretical basis: the core ultrasonic indicators included in the system, including intestinal wall thickness, intestinal wall blood flow grade, definition of intestinal wall stratification and intestinal peristalsis frequency, can directly reflect the pathological changes of intestinal mucosal inflammation, microcirculation disturbance and intestinal function damage in patients with intestinal stasis type ulcerative colitis. As a classic traditional Chinese medicine prescription for promoting blood circulation and removing blood stasis, Shixiao Powder exerts therapeutic effect by improving intestinal microcirculation and reducing mucosal inflammatory injury, and the dynamic changes of the above ultrasonic indicators can objectively reflect the intervention effect of Shixiao Powder, which is consistent with the core requirement of objective efficacy evaluation for natural products in ulcerative colitis management .

The present paper further carries out subgroup analysis to test the stability of the system, dividing the enrolled subjects into subgroups according to disease course (less than 2 years / 2 years and above) and disease severity (mild / moderate).

The results show that the overall diagnostic coincidence rate of the system is 90.8% in the subgroup with disease course less than 2 years, 91.7% in the subgroup with disease course of 2 years and above, 92.1% in the mild UC subgroup and 90.5% in the moderate UC subgroup. There is no statistically significant difference in sensitivity, specificity and coincidence rate among different subgroups, which confirms that the system has stable evaluation efficiency for different types of patients with intestinal stasis type ulcerative colitis.

The present paper draws the following conclusions: First, the efficacy evaluation system constructed by integrating ultrasonic imaging indicators has good diagnostic accuracy and stability, and can be used as a non-invasive, dynamic evaluation tool for the efficacy of Shixiao Powder in the treatment of intestinal stasis type ulcerative colitis. Second, the scoring and grading rules of the system are simple and easy to operate, which can be popularized and applied in primary medical institutions to reduce the dependence of efficacy evaluation on invasive colonoscopy. The limitation of the present paper lies in that the verification data are all from a single research center, and multi-center large-sample studies can be carried out in the future to further calibrate the scoring threshold, so as to expand the applicable scope of the system.

5. Discussion and Clinical Implication

Ultrasonographic indicators show unique inherent advantages in efficacy evaluation of intestinal stasis-type ulcerative colitis (UC) compared with traditional evaluation tools. Colonoscopy, the current gold standard for UC efficacy evaluation, is invasive, carries a risk of intestinal perforation in patients with severe intestinal mucosal damage, and has low patient compliance for repeated follow-up assessments, which is particularly incompatible with the dynamic evaluation needs of traditional Chinese medicine (TCM) treatment that requires long-term and periodic efficacy monitoring. Serum inflammatory indicators such as C-reactive protein and erythrocyte sedimentation rate lack specificity for intestinal local lesions, while TCM syndrome scores are highly dependent on the subjective judgment of clinicians and lack uniform quantitative standards. Transabdominal ultrasound, as a non-invasive, radiation-free and repeatable examination method, can directly reflect the pathological changes of the intestinal tract in real time: increased intestinal wall thickness corresponds to intestinal mucosal edema and inflammatory cell infiltration, elevated intestinal wall blood flow grade reflects active inflammation of the intestinal mucosa, blurred intestinal wall stratification indicates damage to the intestinal mucosal barrier, and abnormal intestinal peristalsis frequency is consistent with the disorder of intestinal motor function caused by chronic inflammatory stimulation. All the above pathological changes are core manifestations of intestinal stasis-type UC under both TCM syndrome differentiation and modern pathological mechanisms.

The core therapeutic principle of Shixiao Powder in treating intestinal stasis-type UC is based on the TCM theory of "activating blood circulation to remove blood stasis and dispersing stagnation to relieve pain", targeting the core pathogenesis of blood stasis blocking intestinal collaterals and blocked qi and blood circulation in this TCM syndrome type. Modern pharmacological studies have confirmed that the active components of Shixiao Powder can inhibit the expression of pro-inflammatory factors including tumor necrosis factor-α and interleukin-6, reduce the permeability of intestinal microvessels, improve the microcirculation perfusion of intestinal wall, and promote the repair of intestinal mucosal barrier. These pharmacodynamic effects are directly mapped to the dynamic changes of the four core ultrasonic indicators included in the evaluation system: the reduction of intestinal wall thickness corresponds to the regression of intestinal mucosal edema, the decrease of intestinal wall blood flow grade reflects the relief of active inflammatory response, the recovery of clear intestinal wall stratification indicates the repair of intestinal mucosal barrier structure, and the return of intestinal peristalsis frequency to normal range suggests the improvement of intestinal function. This direct correspondence between pharmacological mechanisms and changes in ultrasound indicators provides a solid basis for the validity of ultrasound indicators in evaluating the efficacy of Shixiao Powder.

This paper adopts an empirical research method combining correlation analysis, Delphi expert consultation and diagnostic test verification to construct the evaluation system. First, this paper screens out ultrasonic indicators that are significantly correlated with the recognized efficacy evaluation gold standards (modified Mayo score, TCM syndrome score, colonoscopic mucosal healing status) through Spearman correlation analysis, excluding indicators with correlation coefficient lower than 0.6. Then this paper invites 15 experts covering TCM gastroenterology, ultrasonic medicine and clinical epidemiology to assign weights to the retained indicators and sets the efficacy judgment threshold of the system: total score of 100, score ≥80 as markedly effective, 60-79 as effective, and <60 as ineffective. The verification results show that the Kappa value between the evaluation results of this system and the gold standard is 0.87, with a sensitivity of 92.3%, a specificity of 89.7%, and an overall diagnostic coincidence rate of 91.2%, which confirms the good reliability and validity of the system. The evaluation system constructed in this paper effectively makes up for the shortcomings of existing evaluation methods, including high invasiveness, strong subjectivity and poor repeatability, and provides a non-invasive, dynamic and objective quantitative tool for the efficacy evaluation of TCM treatment for intestinal stasis-type UC.

The application of this evaluation system can effectively reduce the frequency of colonoscopy for patients receiving Shixiao Powder treatment during follow-up, reduce the economic burden and physical pain of patients, and improve patient compliance with long-term treatment and follow-up. At the same time, the system can provide uniform quantitative efficacy evaluation standards for TCM treatment of UC, reduce the bias caused by subjective judgment of clinicians, and help promote the standardization and international recognition of TCM clinical efficacy evaluation. Clinicians can adjust the treatment plan in time according to the dynamic changes of ultrasonic indicators in the follow-up process, so as to realize personalized and precise treatment for patients with intestinal stasis-type UC.

There are still certain limitations in the construction of this evaluation system. The data used for system construction and verification come from a single center, which may have regional bias in the distribution of patient disease characteristics. In the future, multi-center studies covering different regions and larger sample sizes can be carried out to further verify the generalizability of the system and adjust the weight of indicators and efficacy judgment thresholds

appropriately according to the characteristics of different populations. new ultrasonic technologies such as ultrasonic elastography and contrast-enhanced ultrasound can be further incorporated into the indicator system in subsequent studies to further improve the accuracy of efficacy evaluation for different severity of intestinal stasis-type UC.

The evaluation system constructed in this paper has good diagnostic efficiency and clinical applicability and can be used as a reliable non-invasive tool for clinical efficacy evaluation of Shixiao Powder in the treatment of intestinal stasis-type UC.

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