Application of comprehensive evaluation methods in the clinical efficacy evaluation of traditional Chinese medicine: a narrative review

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Background and Objective: Clinical effect is necessary for the inheritance and development of traditional Chinese medicine (TCM). The conventional single primary outcome evaluation method is difficult to reflect the advantages of multi-target and multi-dimensional treatment of TCM. The comprehensive evaluation method can combine multiple dimensional outcomes such as Western medicine-related outcomes, TCM-related syndromes, and patient report outcomes into a single-dimensional comprehensive outcome, which can reflect the advantages of the multi-dimensional efficacy of TCM, and has been gradually applied to the clinical efficacy of TCM in recent years. In this study, we aimed to introduce comprehensive evaluation methods and guide TCM researchers use these methods correctly, then provide methodological aid for the comprehensive and objective evaluation of true clinical effect of TCM.
Methods: We searched the primary Chinese and English electronic databases systematically [PubMed, CENTRAL, China National Knowledge Infrastructure (CNKI), Wanfang, and VIP] and collected randomized controlled trials (RCTs), non-RCTs, or follow-up or secondary analysis of the original trials data until June 30, 2021.
Key Content and Findings: In this study, we introduced seven comprehensive evaluation methods commonly used in the field of TCM, we compared the advantages and disadvantages of these methods and their specific implementation in clinical efficacy evaluation, and demonstrated the application of each evaluation method with examples. We also gave some suggestions for applying comprehensive evaluation methods.
Conclusions: The development of comprehensive evaluation methods will provide new research ideas for the evaluation of clinical efficacy of TCM. This article introduces several commonly used comprehensive evaluation methods in the field of TCM, in order to guide the appropriate selection and use for TCM clinical researchers.

Keywords: Comprehensive evaluation method; randomized controlled trials (RCTs); traditional Chinese medicine (TCM); efficacy evaluation

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Introduction

Clinical effect is necessary for the inheritance and development of traditional Chinese medicine (TCM). In recent years, some TCM researchers have done many studies in this field (1-4). However, the lack of clinical effect evaluation methods that can be accepted by both TCM and Western medicine (WM) researchers is still an urgent problem, and it is also an important limitation restricting the modernization and internationalization of TCM (5-7). In 2019, the China Association for Science and Technology also listed the "Innovative methods and technologies for evaluation of clinical efficacy of traditional Chinese medicine" as 1 of the 20 major scientific and engineering issues, and suggested to concentrate on innovation and breakthroughs (8).

TCM theory emphasizes a holistic view, through multi-target, multi-way, multi-channel intervention to realize the global treatment. It not only focuses on the improvement of WM-related laboratory indicators and control of disease activities, but also focuses on improving the body's Qi and blood functions, the symptoms reflecting syndrome elements, and improves the patient's subjective feelings and quality of life.

As the statistical guidelines for clinical trials, ICH Harmonised Tripartite Guideline Statistical Principles Clinical Trials E9 (ICH E9) (9) and China's Biostatistics Guidelines for Drug Clinical Trials (10) both suggest that one primary outcome should be set in clinical trials, but this is mainly based on hypothesis test theory of statistics. The clinical effect evaluation of TCM is a comprehensive evaluation of the complex intervention process. Since the secondary outcomes are only used for exploratory or reference purposes, they have limited effect on explanation of clinical efficacy. While, in clinical trials of TCM, if only one primary outcome (usually the conventional WM-related laboratory outcomes) is used, it is difficult to comprehensively and objectively evaluate the overall treatment effect of TCM. The conventional single primary outcome evaluation method is difficult to reflect the advantages of multi-target and multi-dimensional treatment of TCM, which will limit the development of TCM clinical studies.

Some researchers suggested that an appropriate TCM clinical effect evaluation system should include (11-13): (I) the recognized WM-related effect evaluation outcome for "disease"; (II) outcomes reflecting TCM syndromes; (III) quality of life outcomes. Our team has proposed multiple primary outcomes evaluation methods including WM-related disease laboratory outcome, syndrome outcome and quality of life outcome (14), hoping to provide methodological support for the comprehensive and objective evaluation of the true clinical effect of TCM. At present, there are five categories of evaluation methods for multiple primary outcomes, including multiple tests with adjustment to the overall significance level, omnidirectional test, comprehensive evaluation method, hierarchical model and global statistical test (15). Comprehensive evaluation method forms a linear combination of all outcomes, to test treatment difference on this composite outcome of different groups (16). It can combine multiple dimensional outcomes such as laboratory outcomes, TCM syndromes and quality of life into a single dimensional composite outcome, which can test the comprehensive and multi-dimensional treatment advantages of TCM. Therefore, it has been widely used in the clinical effect evaluation of TCM in recent years. In this study, we introduced seven comprehensive evaluation methods commonly used in the clinical effect evaluation of TCM, we hope to guide TCM researchers use these methods correctly and provide methodological aid for the comprehensive and objective evaluation of true clinical effect of TCM. We present the following article in accordance with the Narrative Review reporting checklist (available at https://lcm.amegroups.com/article/view/10.21037/lcm-21-63/rc).

Methods

The search strategy summary is listed in *Table 1*.

Narrative

Comparative analysis of seven commonly used comprehensive evaluation methods

In clinical studies, comprehensive evaluation method is not the simple addition of multiple outcomes, it uses some statistical or mathematical methods to formulate an appropriate evaluation model to comprehensively and objectively evaluate the interventions. The implementation process of all comprehensive evaluation methods is similar, including the following steps: (I) select appropriate evaluation outcomes according to the evaluation purpose. It is not recommended to include all outcomes, those primary outcomes that reflect the purpose of the study should be selected. The selected outcomes should be clear and specific;

Table 1 The search strategy summary

Items	Specification
Date of search	July 15, 2021
Databases and other sources searched	PubMed, CENTRAL (Cochrane Central Register of Controlled Trials), CNKI, Wanfang, and VIP databases
Search terms used	"Comprehensive evaluation", "efficacy evaluation", "traditional Chinese medicine" or "Chinese herbal medicine" were used as the search terms. Taking the search strategy in PubMed as an example, the specific search strategy was in Appendix 1
Timeframe	The dates were all from library construction to June 30, 2021
Inclusion and exclusion criteria	Randomized controlled trials, non-randomized controlled trials, follow-up or secondary analysis of the original trials data published in English or Chinese language were selected, there is no limitation on interventions or diseases. The followings were excluded: (I) protocols or conference paper; (II) full text is not available
Selection process	Jing Hu and Huina Zhang conducted the selection independently, any disagreements were solved by discussion and consensus with a third reviewer (Bo Li)

CNKI, China National Knowledge Infrastructure.

(II) determine the corresponding weight coefficient of each outcome according to the importance of the outcome; (III) reasonably determine the evaluation grade of each single outcome, it needs to be based on professional knowledge to check the rationality of evaluation grade; (IV) select the appropriate comprehensive evaluation method, establish a comprehensive evaluation model and calculate the value of composite outcome of interventions based on the selected outcomes, then test treatment difference on this composite outcome; (V) in the process of comprehensive evaluation for similar diseases, the established comprehensive evaluation model is evaluated, to continuously correct, modify or supplement the model, then promote and apply this model for similar diseases. Although there are some comprehensive evaluation methods, none of them can be suitable for all situations and solve all problems. Each method has its own advantages and disadvantages. We compared the advantages and disadvantages of seven comprehensive evaluation methods commonly used in the field of TCM and their specific implementation in clinical effect evaluation (*Table 2*), and demonstrated the application of each evaluation method with examples.

Comprehensive index method
Comprehensive index method is a type of methods that uses unified outcomes to summarize the comprehensive level of many statistical outcomes. Ran (27) used literature search to select the clinical effect evaluation outcomes of

diabetic retinopathy, then classified the outcomes into three dimensions: WM-related laboratory outcomes, quality of life and TCM syndromes. The weights of the outcomes contained in different dimensions were determined by the entropy method of objective weighting method, and the comprehensive evaluation values of each dimension in the two groups were calculated according to the comprehensive evaluation method. Xu (28) used comprehensive index method to compare the clinical treatment effect of McKenzie therapy with that of traditional massage on the low back pain patients.

Comprehensive scored method
Comprehensive scored method is a type of methods that comprehensively evaluates different technical solutions through scoring. Shi *et al.* (29) followed up 104 patients with primary osteoporosis for 22 months, used the comprehensive scoring method to calculate the comprehensive scores of four dimensions, including the total score of symptoms and signs, two total scores of quality of life and the comprehensive score of physical and laboratory outcomes, and analyzed the correlation between them, so as to establish a comprehensive evaluation method based on multi-dimensional effect evaluation outcomes of TCM interventions. Zhou (30) established a comprehensive evaluation model with comprehensive scored method, and conducted empirical research to verify the scientificity and feasibility of the model, the method of this study can guide

Table 2 Advantages and disadvantages of seven comprehensive evaluation methods and their specific implementation in clinical effect evaluation

Seven comprehensive evaluation methods	Advantages	Disadvantages	Specific implementation in clinical effect evaluation
Comprehensive index method	Simple calculation; No strict requirements on data distribution and number of outcomes	Weight of outcomes has a great impact on the results	The evaluation outcomes of different categories and different measurement units are indexed into a set, which are synthesized, and then different interventions are compared to draw a conclusion (17)
Comprehensive scored method	Introduce the concept of weight to make the results of evaluation more scientific	Weights of evaluation outcomes are difficult to be reasonably defined	Select effect evaluation outcomes according to the evaluation purpose, the characteristics of TCM interventions and diseases, then formulate the evaluation grades of each outcome, each grade is expressed by score, the weight of each outcome is determined, and select the method for accumulating the total score and the total score range of the comprehensive evaluation grade, evaluate the evaluation object and draw a conclusion (18)
Analytic hierarchy process	Can combine qualitative and quantitative outcomes; Especially suitable for complex problems that are difficult to be completely analyzed with quantitative outcomes	When there are too many outcomes, the data statistics are complex; The weight is difficult to determine	Establish a hierarchical structure including the multi-dimensional and multi-target effect outcomes of TCM, and form a tree diagram to obtain the evaluation goals of each layer. The bottom layer is specific effect evaluation outcomes, and then calculate a comprehensive score index based on these outcomes to evaluate the overall effect of TCM interventions (19,20)
Data envelopment analysis	The evaluation results are generated based on actual data, without giving weight coefficients in advance, and the evaluation results are objective	Very sensitive to outliers	Evaluate and compare the relative effect of TCM interventions with multiple input indicators and output indicators, and select the best treatment interventions (21)
Technique for order preference by similarity to ideal solution	No special requirements for the type of sample data, this method is flexible and easy to use	There is a reverse order problem	Establish a data matrix of evaluation outcomes, and perform unified trend and normalization of these outcomes to find out the optimal and worst targets of all outcomes, then calculate the distance between the optimal target and the worst target of each patient in the intervention group and control group respectively, to obtain the relative proximity between each patient to the optimal target, which is used as the basis for evaluating the advantages and disadvantages of the intervention group and control group (22-24)
Fuzzy comprehensive evaluation	Can solve the fuzziness in comprehensive evaluation, such as the fuzzy phenomenon of TCM diagnostic methods, or the fuzzy concept of prescriptions, etc.	Complicated calculation; The determination of outcome weight is subjective	Regarding to the qualitative and quantitative fuzziness of different effect outcomes, quantify the outcomes that are difficult to quantify, such as TCM syndromes, and consider the interactions between outcomes at different hierarchies and categories, so as to comprehensively evaluate the outcomes with complex and interrelated structure (25)
Fuzzy-hierarchy technique for order preference by similarity to an ideal solution	Combine the advantages of technique for order preference by similarity to ideal solution and analytic hierarchy process	Complicated calculation	Calculate the weight of each outcome, then use fuzzy language to evaluate and quantify the outcomes, establish a fuzzy decision matrix, calculate weights, scores and relative closeness of outcomes, through rank to screen the best treatment (26)

TCM, traditional Chinese medicine.

the medical service quality evaluation of TCM hospitals.

Analytic hierarchy process (AHP)

AHP decomposes complex clinical effect evaluation system layer by layer, and analyzes outcomes at different layer to obtain the value of weight ratio. Wang et al. (31) used the Delphi method to determine the first, second, and third layers of the outcomes contained in the clinical effect evaluation system, and used the Satty scoring method of AHP to construct the outcome importance judgment matrix, then calculated the outcome weight and tested the consistency. This study showed that Delphi method combined with AHP is an effective method to establish the clinical effect evaluation system of integrated TCM and WM related outcomes, which can quantify the qualitative description of the effect evaluation of stable angina pectoris. Li (32) used Delphi method to select the effect evaluation outcomes of TCM in the treatment of diabetic nephropathy, then used AHP to establish the judgment matrix, determined the combined weight of each outcome and formed the effect evaluation model of diabetic nephropathy. Zhang et al. (33) used Delphi method combined with AHP to establish the effect evaluation system for hypertension of liver-yang hyperactivity syndrome.

Data envelopment analysis (DEA)

DEA is a non-parametric evaluation method, which is a method for comprehensive effect evaluation of the relative effectiveness of multiple input outcomes and output outcomes on the same type of decision-making units. Xing (34) used DEA to evaluate the effect of two groups with different comprehensive TCM interventions for early and middle stage of type 2 diabetic nephropathy with Qi and Yin deficiency and blood stasis syndrome. This study used the sum of drug cost, examination cost and treatment cost as the input indicators, and seven effect evaluation outcomes after treatment as the output indicators. C^2R model and BC^2 model were selected to analyze the efficiency and relaxation variables. The results showed that the core Chinese medicine (CM) group was closer to the ideal condition in improving the quantification of 24-hour urinary protein and urinary albumin, fasting and 2-hour postprandial blood glucose, the new CM group was closer to the ideal condition in improving blood creatinine and TCM symptom score. Ye et al. (22) used DEA to observe the clinical effect of Pestle needle on relieving pain of the syndrome at low back with Qi-stagnancy and blood stasis syndrome. Xie et al. (35) evaluated the clinical effect of pestle needle in the treatment

of lumbar disc herniation with DEA.

Technique for order preference by similarity to ideal solution (TOPSIS)

TOPSIS method, that is, approximate ideal solution sorting method. Wang et al. (36) used TOPSIS method to comprehensively evaluate the clinical effect, activities of daily living, treatment cost, safety and other factors of patients with Qi deficiency and blood stasis syndrome in the recovery stage of cerebral infarction. The study showed that the Ci value of the combination of acupuncture and CM group is higher than that of the CM group and the WM group, suggesting that the combination treatment group is the optimal treatment. Chen et al. (37) used TOPSIS method to evaluate clinical effect of Shengmai capsule in the treatment of chronic congestive heart failure. This study concluded that TOPSIS method can be used to comprehensively evaluate effect of TCM and rank the effect levels. Xu (38) comprehensively assessed the effect of the coronary heart disease treatment by warming heart-yang to strengthen the heart using TOPSIS method, this study concluded that establish the comprehensive evaluation system including subjective outcomes, objective outcomes, and quality of life using TOPSIS method, would evaluate the clinical effect of TCM comprehensively.

Fuzzy comprehensive evaluation (FCE)

FCE is a type of methods to quantify some fuzzy and uncertain factors by using the principle of fuzzy relationship synthesis, and then conduct comprehensive evaluation. Zhang et al. (39) used the FCE method to analyze the clinical effect of comprehensive TCM intervention in the treatment of patients with mild cognitive impairment of leukoaraiosis. This study established the evaluation set and frequency distribution table, which are used for establishing the fuzzy matrix, then combined with expert survey to determine the weight of four evaluation outcomes, and carried out the fuzzy relation calculation. The results showed that the clinical effect of compound CongRongYizhi capsule combined with particular therapies of TCM was better than that of the non-drug intervention group. Guo et al. (40) used FCE method to evaluate the effect of Shenxiong Bushen capsules for patients with vascular dementia.

Fuzzy-hierarchy technique for order preference by similarity to an ideal solution (FH-TOPSIS)

FH-TOPSIS is a comprehensive evaluation method that

integrates TOPSIS method and AHP. Wang *et al.* (41) based on the pre-constructed effect evaluation system of chronic obstructive pulmonary disease, used FH-TOPSIS method, quantified the fuzzy language by expert questionnaire survey combined with triangular fuzzy number, and the relative weight of each evaluation outcome is determined hierarchically. According to the weight and score of outcomes, the fuzzy decision matrix was established to comprehensively evaluate the outcomes, determined the fuzzy positive ideal and fuzzy negative ideal, calculated the distance D value of the two groups between relative positive and negative ideal solutions, and calculated the relative proximity C value of the two groups as the comprehensive evaluation index. The results showed that the C value of the intervention group (TCM syndrome differentiation treatment combined with WM treatment) was closer to the optimal intervention, and the clinical effect was better than that of the control group (WM treatment).

Suggestions for applying comprehensive evaluation methods

Using the combination weighting methods combining with subjective and objective weight

Subjective weighting method is a type of qualitative analysis methods, in which experts make subjective judgments on outcomes based on experience, then some method is used to obtain weights, such as expert scoring method, pairwise comparison method, or Saaty weight method, etc. (42). The advantage of subjective weighting method is that experts are not influenced by others and have no psychological pressure when scoring, so they can maximize their personal creativity; the disadvantage is that the weight of the evaluation outcomes will change with the depth and breadth of the expert's personal knowledge, in addition, it cannot show the dynamic change of the importance of evaluation outcomes over time.

Objective weighting method is a type of quantitative analysis methods. The weight is obtained through evaluating the relationship of outcomes based on historical data using some method, such as fuzzy weighting method, rank sum ratio method, entropy weight method, or correlation coefficient method, etc. (43). The advantage of objective weighting method is that the weight is not affected by human factors, the disadvantage is that the weight cannot reflect the importance of the value of each outcome, in addition, the weight will depend on the sample.

The combination weighting methods combining with subjective and objective weight combines these two weighting methods to assign weight, combining the analysis of historical data and expert experience to make the weight coefficients more reliable. There are usually two types of combination methods. Multiplicative combination method is suitable for a large number of outcomes and the distribution of weight coefficients of each outcome is relatively uniform, this method also has a "multiplier effect", those with large weights will become larger, and small weights will become smaller, which restricted the use of the method. Additive combination method can obtain the linear combination coefficient of each weight, then determine the combination weight, the result is more objective than multiplicative combination method. So we suggest using the additive combination method to combine subjective and objective weight (42). The combination weight can be computed as:

$$w_j = \frac{\sqrt{\alpha_j \beta_j}}{\sum_{j=1}^{n}\sqrt{\alpha_j \beta_j}} \qquad [1]$$

W_j is the subjective and objective combination weight; α_j is the subjective weight; β_j is the objective weight.

Combining the results of different comprehensive evaluation methods

The results of different comprehensive evaluation methods may be inconsistency (44). To work out this problem, two or more comprehensive evaluation methods can be used to evaluate the same evaluation object, then combine the evaluation results in some certain ways, and obtain the conclusion after ranking the combined evaluation results. Guo (45) used average method, Borda method, Copeland method, and fuzzy Borda method to combine conclusions from different comprehensive evaluation methods. Wang (46) used the Monte Carlo simulation technology to develop a stochastic simulation model of sampling errors, based on the results of this model, and combined the probability results.

Summary

At present, the clinical effect evaluation of TCM is mainly the single primary outcome evaluation method. It usually takes WM-related outcomes (such as pathological and biochemical outcomes, etc.) as the primary outcome, and takes some TCM-related outcomes (such as TCM syndromes and patient reported outcome, etc.) as the secondary

outcomes. For the statistical analysis, each outcome is evaluated separately and draw a conclusion. While, TCM treatment of diseases is multi-dimensional, which not only focuses on the recovery of WM-related objective outcomes, but also improves the discomfort symptoms of patients' subjective feelings. This needs global and comprehensive clinical evaluation methods. The single-dimensional primary outcome method is difficult to reflect the comprehensive treatment advantages of TCM, which is not conducive to the evaluation of the real clinical effect of TCM.

Establishing a comprehensive clinical evaluation system and method suitable for multi-dimensional intervention of TCM, including conventional WM-related outcomes, TCM syndromes and patient reported outcomes, to provide the best evidence for the clinical effect of TCM, has been a research focus in recent years.

The development of comprehensive evaluation methods will provide new research ideas for the evaluation of clinical effect of TCM. This article introduces seven commonly used comprehensive evaluation methods in the field of TCM, in order to guide the appropriate selection and use for TCM clinical researchers, and provide methodological support for comprehensive and objective evaluation of the true clinical effect of TCM.

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Footnote

Reporting Checklist: The authors have completed the Narrative Review reporting checklist. Available at https://lcm.amegroups.com/article/view/10.21037/lcm-21-63/rc

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Appendix 1

Taking the search strategy in PubMed as an example, the specific search strategy followed were: ((((comprehensive evaluation[Title/Abstract]) OR (efficacy evaluation[Title/Abstract] OR (comprehensive evaluation[MeSH Terms] OR (efficacy evaluation[MeSH Terms])))) AND ((((((traditional Chinese medicine[Title/Abstract]) OR (Chinese herbal medicine[Title/Abstract]) OR (traditional Chinese medicine[MeSH Terms]) OR (Chinese herbal medicine[MeSH Terms]) OR (alternative medicine[Title/Abstract]) OR (alternative medicine[MeSH Terms]))))))).