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Research Advances in Modern Analytical Techniques for Quality Control and Clinical Application of Ganmai Dazao Decoction

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Abstract: Ganmai Dazao Decoction, originating from "Jin Gui Yao Lue" (Synopsis of the Golden Chamber), is a classical prescription for treating visceral agitation. Composed of three medicinal and edible substances—licorice (Gancao), wheat (Xiaomai), and jujube (Dazao), it functions to nourish the heart and calm the mind, harmonize the middle burner and regulate Qi, and alleviate urgency and restlessness. As its clinical application has expanded from traditional emotional disorders to neurological, endocrine, and various psychosomatic diseases, establishing a scientifically precise quality control system and deeply elucidating its pharmacodynamic material basis and mechanism of action have become critical tasks. Modern analytical methods, typified by chromatography, spectroscopy, and their hyphenated techniques, with their high sensitivity, high resolution, and powerful substance characterization capabilities, have become the core driving force for standardizing the quality control and modernizing the clinical application research of this formula. This paper systematically reviews the progress of the aforementioned analytical techniques and chemometrics in interpreting the chemical composition, establishing fingerprint profiles, controlling process quality, and researching the pharmacodynamic material basis of Ganmai Dazao Decoction. Furthermore, it discusses integrated approaches combining analytical techniques with pharmacology and clinical medicine to reveal mechanisms of action and explore therapeutic biomarkers. Finally, it provides an outlook on future directions and challenges, including technological integration and innovation, standardization of whole-process quality control systems, and evidence-based research aimed at internationalization.

Keywords: Ganmai Dazao Decoction; Quality control; Modern analytical techniques; Fingerprint; Pharmacodynamic material basis; Clinical application

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1. Introduction

The vitality of traditional Chinese medicine (TCM) stems from its well-established clinical efficacy. Classical formulas like Ganmai Dazao Decoction serve as important repositories of TCM theoretical principles and

clinical wisdom. However, issues such as complex composition, an imprecise pharmacodynamic material basis, and a weak quality control system have long hindered the modernization and internationalization of Chinese herbal compound formulas. Traditional quality control approaches often rely on a single marker component or morphological identification of herbs, which struggle to systematically represent the holistic, multi-component, multi-target action characteristics of a compound formula. With the rapid advancement of analytical technology, modern techniques such as high-performance liquid chromatography (HPLC), gas chromatography (GC), mass spectrometry (MS), nuclear magnetic resonance (NMR), and their hyphenations have been extensively applied in TCM research. These provide crucial technical support for comprehensively analyzing the chemical composition of Ganmai Dazao Decoction, establishing holistic quality control models, and correlating chemical constituents with pharmacological mechanisms. This actively promotes the transition of this formula from traditional empirical use towards modern precision application. This paper systematically summarizes research progress in the application of modern analytical techniques for the quality control and clinical application of Ganmai Dazao Decoction, aiming to provide theoretical and practical guidance for its further development and scientific utilization.

2. Overview of Ganmai Dazao Decoction and quality control challenges

2.1. Formula composition and traditional application

Ganmai Dazao Decoction was first documented in "Jin Gui Yao Lue: Fu Ren Za Bing Mai Zheng Bing Zhi" (Synopsis of the Golden Chamber: Miscellaneous Diseases of Women, Pulse Syndromes and Treatment) for treating "visceral agitation in women, characterized by a proclivity to sadness and weeping, as if possessed by spirits, and frequent yawning and stretching". The formula consists of only three herbs: *Glycyrrhizae Radix et Rhizoma* (Gancao, licorice), *Tritici Aestivi Semen* (Xiaomai, wheat), and *Jujubae Fructus* (Dazao, jujube). Its composition is simple yet meticulously balanced. It specializes in harmonizing the middle burner and relieving spasms/urgency, excelling at nourishing the heart and spleen, dispelling irritability, and calming the spirit. It also possesses the functions of supplementing the middle burner and augmenting Qi, nourishing blood and tranquilizing the mind, and harmonizing the various herbs. Together, these actions achieve the effects of nourishing the heart to calm the mind and regulating the middle burner to alleviate spasms [1]. It is primarily indicated for symptoms such as mental confusion, sadness with a tendency to weep, heart vexation, and insomnia caused by excessive worry and contemplation, deficiency of both the heart and spleen, and insufficiency of visceral Yin. This formula fully embodies the TCM therapeutic principle of "when the liver suffers from urgency, sweet substances should be consumed promptly to moderate it", making it a classic prescription for treating emotional disorders. Its significant efficacy has been verified through long-term clinical practice.

2.2. Modern clinical application and pharmacodynamic material basis

In modern clinical practice, the application scope of Ganmai Dazao Decoction has significantly expanded. It is widely used to treat various psychosomatic conditions such as anxiety disorders, depression, insomnia, menopausal syndrome, attention deficit hyperactivity disorder (ADHD) in children, and emotional disturbances related to cancer, demonstrating integrated effects in regulating mood, improving sleep, and alleviating somatic symptoms. This broad range of indications reflects the formula's multi-component, multi-target pharmacodynamic material basis and complex mechanism of action. The active components mainly involve triterpenoid saponins

and flavonoids from licorice; amino acids and polysaccharides from wheat; and cyclic adenosine monophosphate (cAMP), flavonoids, and triterpenic acids from jujube. These components may synergistically regulate the levels of neurotransmitters such as serotonin and γ-aminobutyric acid (GABA), inhibit neuroinflammatory responses, modulate the function of the hypothalamic-pituitary-adrenal (HPA) axis, and reduce oxidative stress damage. Through these multiple pathways, they collectively achieve the holistic regulatory functions of calming the spirit and relieving urgency, reflecting the characteristic of compound formulas to intervene through integrated, multi-pathway approaches.

2.3. Challenges in quality control

Quality control for Ganmai Dazao Decoction still faces multiple challenges. The quality of its raw herbs is susceptible to factors such as geographical origin, cultivar, cultivation practices, harvesting process, and storage conditions, leading to instability in key component content. Critical components like glycyrrhizic acid in licorice and sugars and cyclic nucleotides in jujube show significant variation. During the decoction process, components may undergo complex physicochemical changes including dissolution, transformation, polymerization, and precipitation, resulting in a chemical composition for the decoction that is not a simple sum of the individual herb components. This complicates standardized quality evaluation [2]. Traditional quality control measures are often limited to the determination of a single marker component (e.g., glycyrrhizic acid), failing to comprehensively represent the overall chemical profile of the compound formula or effectively correlate it with clinical calming efficacy. Establishing a quality evaluation system that can systematically reflect the overall chemical characteristics of the formula, correlate with efficacy, and demonstrate good stability has become a key task for advancing its modernization.

3. Application of modern analytical techniques in component analysis of Ganmai Dazao Decoction

3.1. The leading role of chromatographic techniques

High-performance liquid chromatography (HPLC), in particular, plays a dominant role in the chemical component analysis of Ganmai Dazao Decoction due to its excellent separation efficiency, rapid analysis capability, and good reproducibility. By systematically optimizing chromatographic columns, mobile phases, and detection conditions, HPLC can simultaneously separate and accurately quantify multiple active components such as liquiritin and glycyrrhizic acid from licorice; jujubosides I, II, and III from jujube; isoliquiritin apioside; and tricin from wheat. This enables a comprehensive assessment of the quality contribution from multiple herbs within the prescription, promoting the shift in quality control approaches from single markers towards multi-marker coordination. Gas chromatography (GC) focuses on analyzing volatile components or derivatized substances like sugars and amino acids, providing an important supplement for interpreting the overall aroma characteristics and nutritional composition of the formula. The application of chromatographic techniques lays a crucial methodological foundation for the quantitative analysis and quality standardization of Ganmai Dazao Decoction.

3.2. Refined analysis via spectroscopy and hyphenated techniques

Spectroscopic techniques (such as ultraviolet and infrared spectroscopy) play a role in the rapid identification of herbs but have limitations in resolving complex compound formula systems. Hyphenated techniques like liquid

chromatography-mass spectrometry (LC-MS), combining efficient separation with high-sensitivity structural identification, have become key pathways for the in-depth interpretation of the chemical substance group of Ganmai Dazao Decoction. LC-MS/MS technology, utilizing accurate molecular weight and characteristic fragment ion analysis, comprehensively identifies dozens to hundreds of components in the decoction, including flavonoids, saponins, sugars, and amino acids [3]. High-resolution mass spectrometry can further provide accurate molecular formula data, aiding in the structural elucidation of unknown compounds. Metabolomic methods based on proton nuclear magnetic resonance (^{1}H-NMR) spectroscopy can unbiasedly and comprehensively acquire the overall profile of small molecule metabolites in a sample, presenting a holistic picture of the chemical composition. This approach is suitable for evaluating the quality consistency of products from different batches or produced with different processes and serves as a reliable tool for discovering and screening potential quality markers.

4. Analytical technology-driven innovation in quality control strategies

4.1. Fingerprint profiling and pattern recognition technology

The integration of fingerprint profiling technology with chemometric analysis provides a holistic quality control method to overcome the limitations of single-component control. Utilizing modern analytical techniques such as HPLC-DAD (diode array detection) and LC-MS to obtain chromatographic or spectral fingerprints of Ganmai Dazao Decoction enables systematic characterization of its overall chemical profile [4]. Employing pattern recognition methods like similarity analysis, principal component analysis (PCA), and cluster analysis allows for quality consistency evaluation and difference tracking among samples from different sources, batches, or manufacturers, identifying key factors affecting quality stability. Further correlation analysis between characteristic peaks in the fingerprint and pharmacological activities such as calming the mind and relieving urgency can help screen “efficacious component groups” closely related to therapeutic effects. This facilitates the construction of a comprehensive evaluation system integrating overall fingerprint recognition with multi-marker component quantification, promoting the evolution of quality control models towards greater holism and correlation.

4.2. Process quality control and standardization practice

The in-depth application of Process Analytical Technology (PAT) drives the paradigm shift in Ganmai Dazao Decoction quality control from end-product testing towards dynamic monitoring throughout the production process. In standardized production, techniques like near-infrared (NIR) spectroscopy can enable real-time, non-destructive testing of moisture content and key active components in raw materials during the feeding stage, ensuring material uniformity and controllability. During the decoction process, online monitoring of parameters such as pH, conductivity, and the concentration changes of marker components allows for dynamic optimization of various process parameters, ensuring batch-to-batch consistency in the decoction’s chemical composition and process reproducibility. Further integration of key process parameters with fingerprint information enables the creation of a full-chain quality transmission and digital traceability system from the herb source to the final preparation, thereby achieving precise control over the product’s overall chemical profile. This systematic strategy provides an important technical foundation and quality assurance for the large-scale, standardized production of modern dosage forms of Ganmai Dazao Decoction, such as granules and oral liquids.

5. Integration of analytical techniques in clinical application and mechanism research

5.1. Elucidating pharmacodynamic material basis and mechanism of action

Modern analytical techniques, integrated with approaches such as serum pharmaco-chemistry and network pharmacology, provide key methodologies for systematically elucidating the pharmacodynamic material basis and mechanism of action of Ganmai Dazao Decoction. Techniques like LC-MS can accurately identify prototype components and their metabolites that enter the bloodstream after oral administration of the decoction, thereby screening for substances potentially exerting direct effects **in vivo*. Based on this, bioinformatics databases can be utilized to predict the action targets and associated signaling pathways of these components, constructing a multi-dimensional association model of "chemical components–biological targets–pathway network–disease phenotype". Subsequently, integrating animal behavioral evaluations with molecular biology experiments allows for the validation of key predicted targets. Metabolomic techniques can then be employed to comprehensively investigate the dynamic changes in endogenous metabolite profiles before and after treatment, systematically revealing the integrative mechanisms through which the formula exerts antidepressant and anxiolytic effects by regulating endogenous metabolic networks related to tryptophan metabolism, energy metabolism, neuroinflammatory pathways, etc. This research framework aids in a deep, multi-dimensional analysis of the scientific rationale behind the "simple formula with potent effects" characteristic of Ganmai Dazao Decoction, from the perspectives of multi-component, multi-target, and multi-pathway synergy [5].

5.2. Exploring clinical efficacy biomarkers

Applying high-throughput analytical techniques such as metabolomics and proteomics to clinical research is of great significance for exploring therapeutic biomarkers of Ganmai Dazao Decoction and advancing its application in precision medicine. By systematically analyzing the dynamic changes of endogenous metabolites (e.g., specific amino acids, hormones, lipid molecules) in biological samples like blood and urine from patients with depression or menopausal syndrome before and after treatment, potential biomarkers highly correlated with clinical symptom improvement can be screened. Integrating therapeutic drug monitoring (TDM) to quantitatively analyze the exposure levels of pharmacodynamic components like glycyrrhizic acid and liquiritin in patients allows for the combination of multi-dimensional data: exogenous component concentrations, dynamic changes in endogenous biomarker profiles, and clinical efficacy scores. This facilitates the construction of efficacy prediction models, enabling the identification of patient subtypes with differential responses to treatment. This strategy can provide objective evidence for developing individualized treatment plans in clinical practice, promoting the evolution of Ganmai Dazao Decoction application from the traditional empirical model based on population experience towards a biomarker-based, individualized precision treatment model.

6. Future prospects and challenges

6.1. Directions for technological integration and innovation

The future development of analytical techniques in Ganmai Dazao Decoction research will exhibit a trend of multi-dimensional deep integration. Combining spatially resolved mass spectrometry imaging with histopathology can visualize the distribution of formula components within target organs such as the brain and gut at the tissue level, directly revealing their spatial sites of action. Artificial intelligence (AI) and machine learning can perform deep

mining of complex multi-omics data, automatically screening key chemical and biological markers highly relevant to quality control and clinical efficacy, thereby enhancing the intelligence level of quality control and efficacy prediction. Developing rapid, environmentally friendly **in situ** and online analytical techniques, combined with minimally invasive sampling methods, can facilitate real-time monitoring and dynamic adjustment during clinical treatment, guiding research on this formula towards increasingly precise, personalized, and practical directions.

6.2. Pathways towards standardization and internationalization

Promoting the internationalization of Ganmai Dazao Decoction hinges on constructing a scientifically evidence-based quality standard system that aligns with international requirements. This necessitates, based on existing research findings, identifying Critical Quality Attributes (CQAs) that encompass both quality control and efficacy correlation, and establishing corresponding acceptable ranges. Research processes must strictly adhere to internationally recognized drug development standards, utilizing multicenter, large-sample randomized controlled trials (RCTs) and employing modern analytical techniques to build objective, reproducible evidence chains linking chemical composition to biological effects. Furthermore, transforming TCM syndrome improvement into quantifiable, comparable biological indicators is crucial. Only by deeply integrating the core tenets of TCM theory with modern analytical science and clinical evidence-based medicine, and establishing a comprehensive quality control and evaluation system covering the entire chain from herb source, through production, to **in vivo** efficacy assessment, can Ganmai Dazao Decoction be understood and accepted by the international community in a more scientific and transparent manner.

7. Conclusion

The continuous advancement of modern analytical techniques provides core methodological support for the systematic research of Ganmai Dazao Decoction, permeating the entire process from exploring its chemical material basis, constructing holistic quality control systems, searching for pharmacologically active components, to interpreting clinical efficacy mechanisms. The deep integration of chromatography, mass spectrometry, spectroscopy, and their hyphenated techniques with chemometrics, metabolomics, and other systems biology methods is gradually revealing the multi-component, multi-target, multi-pathway synergistic mechanisms underlying its “simple formula with potent effects”. Achieving precise quality control and clinical application of this formula still relies on the deep interdisciplinary integration of TCM pharmacy, clinical medicine, analytical chemistry, and information science. Furthermore, continuous innovation is needed in analytical technologies, quality standards, and research paradigms. While adhering to the core principles of TCM’s holistic view and syndrome differentiation/treatment determination, actively adopting modern scientific and technological means for in-depth investigation is essential. Ganmai Dazao Decoction is anticipated to exert more targeted and scientifically meaningful clinical application value in the fields of psychosomatic medicine and health promotion.

Disclosure statement

The author declares no conflict of interest.

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