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Analysis of active patents to investigate the frequency and patterns of Chinese herbal extract combinations claiming to treat heart disease

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Abstract *Objective:* Using Chinese patents in force to investigate the frequency and patterns of Chinese herbal extract combinations claiming to treat heart disease.

Methods: Patent documents were retrieved from the official website of the State Intellectual Property Office of the People's Republic of China. Cluster, frequency, and fuzzy cluster analyses were applied.

Results: A high number of patents in force included high-frequency herbs such as *Salvia miltiorrhiza*, *Panax ginseng*, and *Panax notoginseng*, as well as high-frequency herbal families such as Araliaceae, Leguminosae, Labiatae, and Umbelliferae. Herb pairs such as *P. ginseng* + *Ophiopogon japonicus*, *S. miltiorrhiza* + *Dalbergia odorifera*, and *P. ginseng* + *Schisandra chinensis* are also commonly used, as well as herbal family pairs such as Araliaceae + Liliaceae, Lauraceae + Leguminosae, and Araliaceae + Schisandraceae. Traditional treatment principles for preventing and treating heart diseases was most-commonly based on simultaneously treating the liver and heart and treating the lung and spleen secondarily for choosing herbal combinations.

Conclusion: Most of the high-frequency Chinese herbs in the patents investigated belong to the high-frequency herbal families, and herb pairs were commonly selected to coincide with the commonly-used herbal family pairs. Low-frequency Chinese herbs were also used, but generally belonged to the high-frequency herbal families, and were therefore similar to the high-frequency herbs in terms of traditional categories of taste and channel entered. The results reflect the use of traditional principles of formula composition, and suggest that these principles may indeed be an effective guide for further research and development of Chinese herbal

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extract combinations to prevent and treat heart diseases.

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Introduction

In China, traditional Chinese herbs have long been used to treat cardiovascular diseases. In traditional Chinese medicine (TCM), disorders that involve the cardiovascular system fall under the rubric of “heart system disease,” and are also comprised of illnesses involving other biomedical systems of the body, in particular mental (psychologic) and brain disorders. According to the World Health Organization, an estimated 17.7 million people died from cardiovascular diseases in 2015, and this number will continue to grow to estimated 22.2 million in 2030.¹ Because heart disease is a serious threat to human health, it has become a focus of research worldwide.

As more and more patients and consumers demand natural, organic, or side-effect free treatments, the use of herbal medicine (also known as botanic medicine, or phytomedicine) is increasingly being used to prevent and treat heart disease. Chinese medicine may have an important contribution to make in this area. However, TCM has still not been accepted in many countries. To a large extent, this is due to problems with safety and stability. Problems may arise when original medicinal plants or decoction pieces (semi-processed, dried and cut herbs) from different geographic regions are used interchangeably without investigating possible differences in medicinal properties. The complex chemical composition of the multi-herb preparations and the lack of clear evidence of their exact mechanisms of action are also important issues.^{2,3} Prepared medicines, typically in pill, powder, or capsule form from TCM extracts may be a solution to these problems.^{4,5} Herbal extracts are a type of TCM product processed by using a solvent, typically water or ethanol, to release the active chemical constituents.⁶ The extract can then be considered to be a substitute for dried plant matter (decoction pieces) or as an active ingredient that can be incorporated into other medicinal products or combination pharmacologic products. Due to these advantages, TCM extracts have become more popular in recent years and prescribing Chinese herbal extract combinations has become a new alternative for herbal administration. As TCM expands worldwide, many TCM research and development units have begun to pay more attention to herbal extracts.

Patent in force, or active patent, refers to a patent that has effective status. Most patent rights cease to exist before their expiration, due to either the low quality of the patent, lack of commercialization, or inadequate profitability after commercialization.⁷ Hence the time that a patent is maintained is a reliable indicator of the scientific and technologic innovation capacity and market competitiveness. As one of the most systematic, comprehensive, and active information resources, patent documents should not be overlooked as a source of innovative ideas for new

drugs. By studying the technical description of the active patent of a Chinese herbal extract combination, new medical resources, including a patent strategy, can be developed.⁸

To date, TCM patent document research of Chinese and overseas offices has mainly focused on Chinese herbal compounds and extracts to analyze the patentability, patent protection awareness, or simple bibliometric analysis of herbal formulas. Although there has been some research on Chinese herbal compound patents designed to treat cardiovascular diseases, methods have been limited to simple bibliometric analyses. We have not found any systematic statistical analysis and qualitative research on active patents of Chinese herbal extract combinations for preventing and treating TCM heart system disease.

Data mining, which is widely used in TCM research, is a useful tool for investigating the aforementioned patent documents.^{9,10} Data mining in the form of cluster analysis and frequency analysis have been applied to the identification of Chinese herbs, studies of the regularity of traditional Chinese medicinal compounds, classification of traditional Chinese herbs among other areas.^{11,12}

In this study, we applied frequency analysis, cluster analysis, and fuzzy cluster analysis to explore the combinatorial patterns of Chinese herbal extracts for the treatment of heart system diseases. Our retrieval criteria were the Chinese equivalent of “Chinese herbal extract combination patents”. Based on our analysis, suggestions are made for the development of new drugs.

Materials and methods

Patent retrieval and establishment of databases

Patent documents used in this research were retrieved from the official website of the State Intellectual Property Office of the People’s Republic of China. There are four query systems that can be accessed through the website. Therefore, we believe the information we obtained is accurate and complete.

According to Chinese patent law, patent applications are published within 18 months after the earliest priority date of the patent application. The patents in this study were all approved, and 2014 was the most recent year with complete coverage of the granted patents. To acquire an objective perspective on TCM extract combination patents, active patents granted from 1995 through 2014 were selected.

Chinese keyword combination was “traditional Chinese medicine OR Chinese herbs OR natural drugs” AND “extract OR extractive”. These keyword combinations were identified through literature survey. Initial search targeted

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