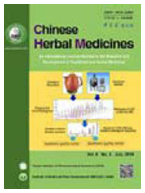

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Review

A New Concept on Quality Marker for Quality Assessment and Process Control of Chinese Medicines

Chang-xiao Liu[1*], Yi-yu Cheng[2], De-an Guo[3], Tie-jun Zhang[4], Ya-zhuo Li[1], Wen-bin Hou[4], Lu-qi Huang[5], Hai-yu Xu[5]

1. Research Center for New Drug Evaluation, Tianjin Institute of Pharmaceutical Research, Tianjin 300193, China

2. Institute of Pharmaceutical Information, Zhejiang University, Hangzhou 310058, China

3. Shanghai Institute of Materia Medica, Chinese Academy of Sciences, Shanghai 201203, China

4. Research Center for Modern Chinese Medicines, Tianjin Institute of Pharmaceutical Research, Tianjin 300193, China

5. Institute of Chinese Materia Medica, China Academy of Chinese Medical Sciences, Beijing 100700, China

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ABSTRACT

Chinese medicine (CM) is the most typical conventional therapy compared with any other traditional or alternative medicine systems. The active components of CMs are either primary or secondary metabolites generated by metabolic and biosynthetic enzymes in plants, protecting the plants from environmental stress. The characteristics of these metabolites are diverse, complicated and unique. In this paper, current approaches for quality assessment were extensively reviewed, a new concept of quality marker (Q-marker) was then proposed for CM quality assessment. Additionally, definition of the Q-marker, as well as the relevant methods, were discussed, on the basis of the biosynthetic pathways of secondary metabolites and source of biological active components. Study design of Q-marker is complex system for quality assessment and production process control of CM products with transitivity and traceability. Therefore, the system with characteristics of transmission and traceability is expected to be established for regulation of quality. Upon the concept which the transitivity and traceability in the quality assessment and production process control covered the entire process, such as raw materials, decoction slices, processing, extraction and production can be further enhanced. The transitivity and traceability will inevitably require close attention to "who, what, where, when, and why" details at each stage of Q-markers of CM production form raw materials to patent product. The establishing quality standards are enablers of many and various transitivity and traceability solutions, not a solution in them. It means that the transitivity and traceability system is readily link between products and across borders in quality. According to the thinking mode and methods of investigation on quality assessment of CM product, we focus on the entire process, in terms of safety and effectiveness and quality control. The standard preparation of CM or CM decoction is not only the basis for study of Q-marker, but also the basis for transmission and traceability of the quality of CM product.

Key words

Chinese medicine; formulation; medicinal resource; quality administration; quality marker; quality standard; quantitative analysis; secondary metabolites

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[*]**Corresponding author: Liu CX** E-mail:liuchangxiao@163.com

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1. Introduction

Chinese medicine (CM) is the most typical conventional therapy comparing with any other traditional or alternative medicine systems. According to the origin, CMs cover traditional medicines, herbal medicines, folk medicines, and phytomedicines in China. CMs are well known for their pharmacological effects widely used for thousands of years. The widespread and global acceptance as well as the utilization of herbal medicines is suggestive of their safety and efficacy. Therefore, CM has become an important and indispensable part of public healthcare globally. Challenges, however, still remain, with respect to the new drug research and development (R&D) of CM. For instance, those issues related to finance, ethics, quality and standardization of product, study design and regulatory affairs need to be fully addressed.

It is well known that the difference can be attributed to the regulation of CMs in developed countries where CMs are produced and utilized in accordance with requirements of good agricultural practice (GAP), good manufacturing practice (GMP), good laboratory practice (GLP) and good clinical practice (GCP) for establishing appropriate specifications of their products, intermediates and starting substances in R&D of pharmaceuticals.

According to literature, the active components of CMs are either primary or secondary metabolites generated by metabolic and biosynthetic enzymes in plants with diverse, complicated and unique features. In order to promote the rapid development of pharmaceutical industry, improve the quality standard system, such as pharmacopoeia standards, and product quality standards of Chinese medical materials and their formulations, current approaches for quality assessment were analyzed, a new concept of quality marker (Q-marker) of CMs and their products was then proposed (Liu et al, 2016; Zhang et al, 2016a; 2016b; Xiong and Peng, 2016; Kang et al, 2014; Chen et al, 2016; Ding et al, 2016; 2017; Zhou et al, 2017). In the following sections, the factors affecting the quality of CMs and secondary metabolites, quality standards and regulatory affairs to define quality markers of CMs, as well as the research methods, in terms of evaluation of applications, were discussed.

2. Chinese medicine is a complex system

2.1 Chinese medicine is a multi-component system

CM product is a multiple-component complex system (Figure 1), in particular its chemical components remain unclear, which makes it rather difficult to define the functions of CM from material basis and chemical properties. In terms of chemistry, CM consists of a large number of constituents, which may undergo biotransformation or chemical changes. In addition, the contents of chemical substances are generally complicated and changes, in terms of quality and quantitative criteria of products, increasing difficulties for CM development, for instance, the origins, culture conditions, harvest, parts of the plants used as medicines, formulation production and clinical application. It is of great importance to strengthen the quality control and standard for ensuring the effectiveness and safety of CM products. Due to the complexity of traditional Chinese medicine (TCM), many issues, particularly quality and relevant standards still remain unsolved (Liu, 2013; 2001; Li et al, 2015).

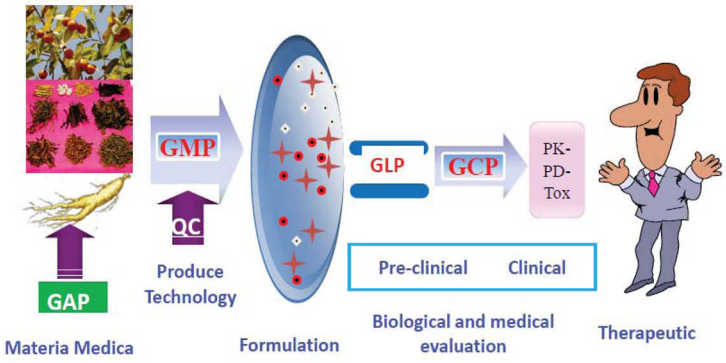

Figure 1 CM product is a complex system

2.2 Difficulties and challenges of CM quality control

The difficulties of quality assessment of CM products can be listed as following: (1) It is associated with Good Agricultural Practice, Good Collection Practice (GACP), and Good Supplement Practice (GSP); (2) Specific eco-geographic regions (EGRs) of botanical raw materials is of particular importance; (3) How to reduce the variability from the plant raw materials to production process; and (4) Based on well-known mechanism of action (MOA) and TCM theory, potency evaluation of bioactive response become flexible for control of the manufacturing process. Based on the above statement, it is suggested as follows: (1) CM products are complex with multiple chemical components (known and unknown active components) and natural variations; (2) Generally CM product is the mixture of the active pharmaceutical ingredients (API) and inactive ones from raw materials of herbs; (3) CM products are very difficult to satisfy the identical requirement of quality, safety and efficacy as that of chemical drugs; and (4) Based on TCM theory, the principle of multiple-flavor prescription is also far from that of chemical composition of western drugs.

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