Speech on the evidence-based traditional Chinese medicine research 20th anniversary conference

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Editorial

Academician Changxiao Liu is a pioneer in the field of pharmacokinetics in China. In recent years, he has conducted in-depth research in the field of scientific supervision of Chinese medicine and is the pioneer of scientific supervision of Chinese medicine. Meanwhile, the theme of CRIA2020 was Evidence-based Research in Traditional Chinese Medicine. Academician Changxiao Liu came to witness the moment and give an academic report "Try to Explain the Issues of Evidence-based Medicine in Clinical Research of Traditional Chinese Medicine". This paper is the thought of academician Changxiao Liu after the conference.

Introduction

Academician Changxiao Liu is a Chinese pharmacologist and pharmacokineticist. A native of Yongxing County, Chenzhou City, Hunan Province. He graduated from Beijing Medical College in 1965 with a bachelor's degree. He is currently the director of the State Key Laboratory of Drug Release Technology and Pharmacokinetics of Tianjin Pharmaceutical Research Institute, and formerly the chairman of the Committee of Drug Metabolism of the Chinese Pharmacological Society.

Liu is one of the leaders and pioneers in the field of pharmacokinetics in China. Who established the first pharmacokinetic laboratory in 1968. He was the first to use the subject for new drug evaluation in 1975, and published the first pharmacokinetics study monographs in 1980. Proposed model optimization and data batch processing schemes in the identified pharmacokinetics programs, which have been applied to hundreds of units in China, and have been adopted or cited in more than 4700 papers in worldwide.

Liu has published more than 340 papers, 17 monographs in Chinese and English, and won 17 new drug certificates and multiple international and domestic awards. He was awarded the State Council subsidy in 1992 and was rated as a national, provincial and municipal advanced worker. In 2000, he was awarded the Hong Kong Bauhinia Medical Achievement Award. In 2003, he was elected as an academician of the Chinese Academy of Engineering. In 2005, he was awarded the title of National Model Worker and International Medicine in 2013. ISSX Special Contribution Award. In December 2020, he won the CRIA2020 Evidence-based Chinese Medicine Lifetime Achievement Award.

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The integration of Traditional Chinese Medicine (TCM) and Evidence-based Medicine (EBM) research has given rise to a new area of research termed the Evidence-based Traditional Chinese Medicine (EBTCM) research. For the past twenty years, the development of EBTCM has greatly promoted the use of the evidence-based approach (a scientific and standardized way) to clinical decision-making and facilitated the modernization and globalization of TCM.

Early in the 1990s, I was among the first group of people in China engaging in the work of establishing clinical research centres for new drug investigation, drafting GCP (Good Clinical Practice) guidance documents and inspecting clinical investigator sites. As an inspector, I joined in the on-site evaluation and accreditation of the GCP centres with the Peking Union Medical College Hospital, the Beijing Hospital, the Chinese People’s Liberation Army General Hospital and with several other hospitals based in northeast China such as Liaoning and Jilin provinces. I also worked for many years as one of the principal investigators of a multi-centre clinical trial, which is part of an Alzheimer's disease drug development project. The drug was discovered by my fellow researchers with the Peking Union Medical College Hospital.

In my keynote speech “Thoughts on the EBM Issues in the Clinical Research of TCM” on the EBTCM research 20th-anniversary conference, I mentioned TCM is an essential part of China’s medical supply system. It is important, unique and complicated. I also talked about the challenges we faced in developing TCM in innovative ways. The objective of a clinical study needs to be adjusted as the findings are expected to inform different parties, for instance, pharmaceutical companies, policy-makers, health care providers or others. I also talked about the need for consistency between a research protocol and the findings of EBTCM research from the aspects of the participants, the evidence for a diagnosis and the evidence for choosing a treatment regimen. I concluded from contemplations that EBTCM research would pave the way for high-quality TCM research, and it would be imperative to conduct clinical research in an evidence-based and standardized way.

It is important to identify values in the development of any science. Before we decide on a research design it is crucial to make it clear why and for whom we do it. Therefore, I believe it is time to highlight the roles of the regulatory science in EBM from the aspects of decision-making, quality, basic research, training, information and rights. The progress in regulatory science will help improve efficiency and reduce risks in the clinical research of TCM.

I also highlighted the importance of the evidence-based approach in ensuring the rights and obligations of each party and the value of EBTCM research. Given that the quality of TCM basic research is improving and that a TCM therapy is different from a western medicine therapy in terms of medicinal use and the principles of treatment, it is time to standardize clinical research. Therefore, I proposed that advances in the regulatory science would help improve efficiency, reduce risks and promote the innovative development of RBTCM and also proposed six possible roles of the regulatory science, i.e., making policies, monitoring basic science, cultivating qualities, transmitting information, providing training and protecting the rights of the participants.

The past two decades have witnessed great progress in the clinical research of TCM. As EBM and TCM originated from different cultures, they had different solutions to a clinical question and varied beliefs in rehabilitation and intervention. Therefore, one might find it hard to interpret the clinical efficacy of TCM using the evaluation methods of EBM.

A TCM therapy is different from a chemical drug because it is typically composed of a formula of multiple herbal medicines, each containing multiple constituents. Theoretically speaking, the TCM therapeutic principle of administrating treatment according to pattern diagnosis targets the person rather than his illness, which is different from the standardized western precision medicine therapy with a single compound chemical. I believe the development of EBTCM need to priorate the advantages and characteristics of TCM and the localization of EBM. The classic concepts of organic wholeness and pattern diagnosis need to be properly represented in EBTCM research. This work will be of scientific significance and practical value to the modern development of TCM, as guided by the spirits of “inheriting essence and keeping innovation”.

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