

Others

On the Assessment Standardization for TCM Clinical Evidence

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Nowadays, the evidence-based medicine has been widely used for assessment of TCM. The assessment based on clinical evidence and the quality is the core of evidence-based medicine. However, the evidence-rating methods adopted in the modern medical system are only applicable in a certain degree to the assessment of TCM clinical evidence. Through probing into the relation between TCM science and the evidence-based medicine and the characteristics of TCM clinical evidence, the following suggestions are put forward for establishing a assessment system of TCM clinical evidence: 1) Continue the discussion on the rating standardization for TCM clinical evidence; 2) stipulate the assessment criteria and principles according to the research directions and methods of TCM; and 3) establish the standards for classification and rating of the TCM clinical evidence.

At present, re-assessment of the literatures on previous TCM clinical studies according to the evidence-based medicine is one of the research directions of TCM. However, the systematic assessments published by Cochrane Library show that many clinically confirmed effective TCM therapeutic methods are not supported by sufficient evidence. This may be related possibly with the assessment methods adopted for TCM clinical evidence, that is, the available evidence-rating system of the evidence-based medicine (EBM) may not be completely applicable to TCM science.

As stated in the book written by David *《Evidence-Based Medicine, How to Practise and Teach EBM》* that the inspiration for the concept of “evidence-based medicine” originates from the Chinese method of “textual research” used in Qianlong Period of the

Qing Dynasty.¹⁻² From the view point of epistemology, it can be seen that for both the EBM and TCM science, the essence of their evidence is the knowledge information obtained from clinical medical researches with the patient as the object of study. TCM pays a great attention not only to the accumulation and summarization of clinical experience, but also to the collection and systematization of literature information in its developing course of several thousand years. For example, *Shang Han Za Bing Lun* (伤寒杂病论 *Treatise on Febrile and Miscellaneous Diseases*) was written by Zhang Zhongjing under the guidance of the theory of *Neijing* 《内经》 and from the clinical experience proved for over one thousand years.

The modern medical system has been greatly developed in about two hundred years; and the available evidence-rating method has undergone a history of nearly 20 years. However, guiding the clinical studies of TCM with the modern evidence-rating method may show a lower evidence rating level, mainly because of the incomplete applicability of the assessment.³⁻⁴ Therefore, we should actively probe into the assessment methods of the study evidence rating conforming with the TCM rules; and the study on the rating standardization for TCM clinical evidence should be strengthened from the following aspects:

1. The evidence-rating standard for medical literature is an important part and the key link of the evidence-based clinical report, the medical strict assessment report and the medical technique assessment report. The study on TCM clinical evidence should be discussed around the composition and effectiveness of the evidence, demonstrating the strength and

applicability of various research designs. Through such discussion, the researchers can be supervised to pay attention to reasonability and effectiveness of the clinical decision, so as to enhance the total level for an evidence quality assessment.

2. The indexes for an evidence assessment mainly include three aspects, namely the external indexes (the universally accepted degree of the carrier, the cited situation, and the influence coefficient, etc.), the procedure indexes (scientifity of the study design, etc.) and the content indexes (truthfulness of the results or conclusion, etc.).⁵ From the above aspects, assess the truthfulness, the clinical significance and the clinical applicability of the medical literatures so as to rate the effectiveness of TCM clinical evidence.

3. It has been proved that as compared with the results from the RCT and Meta analysis, the non-randomized controlled trials do not significantly change the comprehensive results.⁶ In view of the facts that there are a great number of the ancient medical literatures and the modern but non-randomized controlled clinical studies in China, while advocating the randomized controlled trials, it

is necessary to set a research group for methodology of the non-randomized controlled study, specially working on the systematic assessment and the methodology for the non-randomized medical studies, so as to enhance the ability of TCM in diagnosis, treatment and prognosis, and speed up the course of modernization and internationalization of TCM.

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