

Reflection and Exploration on "Real World Research of Traditional Chinese Medicine"

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Keywords: Evidence-based medicine; Chinese medicine; real-world research; narrative medicine

Abstract: In the process of the spread and development of evidence-based medicine and narrative medicine in China, it has increasingly highlighted the high compatibility between real-world research and TCM scientific research, and real-world research of TCM is scientific and necessary, which can accurately answer the scientific problems to be solved in TCM scientific research. While carrying out real-world research on Chinese medicine taking into account its own experience summary and paying attention to clinical efficacy, it also increases the scientific evidence of Chinese medicine scientific research, aiming to reach a consensus on the treatment plan of Chinese medicine specialty, form the characteristics of Chinese medicine, refine the characteristic advantages of Chinese medicine, and focus on solving key clinical problems. Focusing on real-world research on TCM cases, famous and old TCM and acupuncture clinics, it proves that real-world research will become an important methodological support for the inheritance and innovative development of TCM. Putting forward the opportunities and challenges faced by the current clinical research of Chinese medicine in the real world, based on the background of the times, and committed to concentrating on development, it will surely promote the vigorous development of Chinese medicine and promote Chinese medicine to the world.

1. Introduction

Evidence-based medicine has been introduced into China and promoted for more than 30 years, and has achieved phased results in the field of traditional Chinese medicine research. The concept of evidence-based medicine originated from traditional Chinese medicine. As an important concept in the development of medicine, it has produced many branches according to its different application objects. Evidence-based medicine requires that in medical and health decision-making and clinical practice, objective and scientific research results should be used as decision-making basis as far as possible; through the observation of medical experience to obtain a large number of clinical information, the obtained information integration analysis and refining theory, build a more complete

knowledge system, after two studies continue to verify the formation of evidence [1]. Evidence-based medicine is a revolution in the history of medical research. The reliability of the conclusions obtained through analysis and summary is much higher than that of past empirical studies. Most of them focus on the conclusions drawn from multi-center large sample randomized controlled trials. Therefore, modern medicine widely uses the conclusions of evidence-based medicine research to guide clinical diagnosis and treatment [2].

Narrative medicine is a combination of narrative literature and medical practice, which adds humanistic connotation and emotional temperature to the current medical practice model. However, narrative medicine research lacks strong evidence, so it is difficult to prove its significance and therapeutic value in specific medical practice. In addition, the research on narrative medicine of traditional Chinese medicine is still in its infancy. The development focuses on the publicity and popularization of the definition, theory and significance of narrative medicine, and obviously lacks the research and specific experiments on the application of narrative medicine methodology in clinical practice. If narrative medicine, TCM clinical research and real world research are combined, it is a necessary attempt to truly implement it into clinical practice, and it is also an objective therapeutic effect of TCM diagnosis and treatment and humanistic care evaluated by the doctor-patient co-construction model [3].

Real-world research can play a role in providing diversified evidence in the process of joint clinical research, which can improve the conversion efficiency of evidence and is the basis for increasing the extrapolation of evidence application. Because of this, the environmental conditions for the implementation of clinical research are the main criteria for distinguishing the real world from the ideal world [4]. Real-world clinical scientific research refers to the scientific research activities carried out to obtain evidence in conventional medical conditions and non-restricted medical environments. It is based on the data further generated by the diagnosis and treatment records generated in clinical practice. In this process, medical professionals must be patient-centered, give full play to their independence and initiative, select appropriate diagnosis and treatment methods to improve and protect the health status of patients, and conduct research. The information generated by the practice of diagnosis and treatment is the artificially generated information. Through medical records, various physical and chemical detection methods, doctor's advice records, admission records, etc., special norms are imposed on patients, doctors, detection conditions, etc.

2. Research on the real world of TCM

With the continuous acceleration of the modernization process and the aging of the population, the people's demand for the health of traditional Chinese medicine is becoming more and more intense. For Chinese medicine practitioners, it is urgent to inherit and develop the cause of traditional Chinese medicine, give full play to the role of traditional Chinese medicine construction in deepening the reform of the health system, and further build a medical collaborative scientific research and innovation system centered on "politics, production, learning, research and application" [5]. In recent years, the continuous progress of information technology has also continuously promoted the internal demand of medical research methodology. The real-world clinical research data is increasingly transforming into clinical research evidence, which also provides objective conditions for the promotion of real-world research of traditional Chinese medicine. Because the research object of the real world research of traditional Chinese medicine is the patients in the real medical environment, the analysis of the actual situation of the diagnosis and treatment and prognosis of various diseases and syndromes of traditional Chinese medicine can effectively evaluate the role of the intervention in clinical practice. Such research results have strong external authenticity. As far as the problem of medical research is concerned, how to choose the research design is the first to analyze which research

design can answer the scientific problems to be solved most accurately. The real world research of traditional Chinese medicine can formulate different research designs to adapt to the actual clinical situation according to the different research objects or research purposes. Not only that, for the same research problem, different research schemes can be designed to solve scientific problems in multiple ways.

2.1. The real world research of TCM is scientific and necessary

In 2011, the Lower State Medical Center of State University of New York ranked the level of evidence from high to low, forming a visual pyramid of evidence, in which real-world evidence is not equivalent to low-level evidence, which is different from basic observational research. Through the completion of experimental design and research, random allocation interventions can be introduced under real medical conditions to conduct randomized controlled trials in real environments [6]. The real world study takes patients as the core. The study is based on the perspective of patients, observes and evaluates various interventions in the process of clinical real diagnosis and treatment, and records and analyzes its efficacy and possible adverse reactions. The core idea of this study is to restore the intervention items of the study to the real clinical practice conditions to the greatest extent. The purpose is to provide evidence for doctors and patients to choose the appropriate individual diagnosis and treatment plan by emphasizing the effect comparison. The real world research of traditional Chinese medicine is not a simple integration of clinical information and random data. The research process pays great attention to the data collection specification and quality control [7].

Only under the conditions of the real world, the unique advantages of TCM syndrome differentiation and comprehensive treatment can be fully exerted and implemented. Based on real-world big data management and tools, it can achieve "only what is not expected, nothing can not be done". The clinical research in the real world follows the development law of traditional Chinese medicine. As a new world view of clinical research, it will gradually move towards the mainstream of clinical research. The integration of clinical research of traditional Chinese medicine is the main form of inheritance and innovation of traditional Chinese medicine in the real world, and also the core of clinical research of traditional Chinese medicine, including people-centered, data-oriented, problem-driven, from clinical to clinical [8]. The development of contemporary Chinese medicine uses modern digital information technology, electronic technology and other means to collect and analyze the information collected in clinical diagnosis and treatment, sublimate it into general knowledge, understanding and logical tools and then return to clinical practice. Among them, clinical practice activities are to diagnose and treat diseases more effectively. The innovative theories and methods of scientific research are to achieve better clinical efficacy, and more effective diagnosis and treatment practices will generate new information needed for scientific research. The virtuous cycle has far-reaching significance for promoting the overall development of traditional Chinese medicine.

2.2. The characteristics of traditional Chinese medicine are highly consistent with real world research.

In the long struggle against diseases, traditional Chinese medicine has gradually formed a relatively unique theoretical system, diagnosis and treatment methods and ways of thinking. Among them, the overall concept and syndrome differentiation and treatment are the two most prominent characteristics of traditional Chinese medicine. The overall concept is to control the disease and improve the quality of life, subjective feelings and functional recovery; syndrome differentiation and treatment emphasizes that specific problems should be analyzed in the process of diagnosis and treatment, and different treatment plans should be formulated according to different pathological conditions. Both of them can reflect the characteristics of individualized diagnosis and treatment

different from the modern medical system, and are the source of survival and development of traditional Chinese medicine for thousands of years. However, the development of traditional Chinese medicine must not be separated from the times. Facing the challenges posed by the new era to traditional Chinese medicine and seizing the opportunities provided by the era of big data, it is undeniable that the participation of big data can directly promote the rapid development of real world research. With the support of data processing software and data analysis methodology, the concept of real world research can be fully projected into practical research, and more practical and promotional evidence can be put forward to promote patients to improve their health status and enter a new journey [9].

The real world is the traditional research mode of traditional Chinese medicine. The traditional Chinese medicine theory focuses on coming from the clinic to the clinic, discovering the law of disease development from the practice, using the method of summarizing the inheritance for a long time, returning the law to the practice to verify, and then improving the improvement and re-induction of the law in practice. In the process of practice, the role of traditional Chinese medicine thinking is played to improve the understanding of the disease. Therefore, the study of traditional Chinese medicine is fundamentally the process of real world research. In the past, the academic thought of traditional Chinese medicine was mainly obtained and innovated through the form of teacher inheritance and personal clinical practice. There are problems of slow professional development and single inheritance form, but the use of real world big data can objectively present the unique thinking and practical experience of traditional Chinese medicine. Collecting huge medical information to form big data of traditional Chinese medicine for sharing, integration and analysis can accelerate the summary of the laws and characteristics of traditional Chinese medicine, and can also greatly promote the inheritance and innovation of traditional Chinese medicine [10].

3. Development of real world research on traditional Chinese medicine

3.1. The only way for the real world research of traditional Chinese medicine

Traditional Chinese medicine has relied on experience summary since ancient times. The initial clinical efficacy evaluation mainly follows the comparison before and after diagnosis and treatment. The evaluation index is relatively simple. It is an established standard centered on subjective symptom changes and pathogenesis changes, resulting in a large bias in the evaluation results compared with the randomized controlled trials with more objective criteria. It is precisely because the development of TCM efficacy evaluation system is more for individual patients, and the research height cannot rise to the level of law suitable for all mankind, which limits its evidence-based nature. This restricts the sustainable development of clinical efficacy evaluation of traditional Chinese medicine, and also restricts the inheritance and promotion of traditional Chinese medicine. Therefore, it is particularly important to establish a perfect and recognized technical method system for clinical efficacy evaluation of traditional Chinese medicine in line with the characteristics of traditional Chinese medicine thinking. Using real-world research methods combined with traditional Chinese medicine, we try to explain the clinical efficacy of traditional medicine by using the statements contained in modern medicine. The clinical efficacy evaluation system of traditional Chinese medicine is still in the process of exploration and improvement to transform the research conclusions into personalized treatment to guide clinical practice [11,12].

The fine processing and high-speed computing ability of big data on clinical small data of traditional Chinese medicine can effectively accelerate the establishment of clinical big data application, analysis, calculation and analysis system of traditional Chinese medicine with the characteristics of traditional Chinese medicine. It is a necessary partner for the artificial intelligence and modernization of traditional Chinese medicine. It can not only promote the inheritance of

traditional Chinese medicine experience, help the research and development of new drugs and medical devices of traditional Chinese medicine, standardize the clinical diagnosis and treatment of traditional Chinese medicine, but also provide more opportunities for the development of clinical diagnosis and treatment technology of traditional Chinese medicine and the innovation of traditional Chinese medicine theory, and form excellent clinical research feedback and circulation [13].

3.2. The foundation of the real world research of traditional Chinese medicine

The root of the existence and development of traditional Chinese medicine is clinical efficacy. Contradictions inevitably arise between the development model of traditional Chinese medicine inherited for thousands of years and the contemporary model of evidence-based medicine, especially in international recognition, health policy formulation, medical decision-making, and guideline formulation. However, throughout the history of the development of traditional Chinese medicine, it has always been based on the principle of inclusiveness, innovation and openness, absorbing, digesting, and integrating advanced knowledge and concepts of other disciplines. As long as it is slightly combined with real-world research, focusing on the key scientific issues to be solved, the research design, experiment and evaluation of the complex intervention of individual diagnosis and treatment of traditional Chinese medicine have extremely far-reaching significance for the construction of traditional Chinese medicine efficacy evaluation indicators that combine disease and syndrome, macro and micro. Real world research is highly consistent with the characteristics of individualized diagnosis and treatment of traditional medicine and holistic diagnosis and treatment, which can provide a new verification method for the evaluation of the efficacy of TCM syndrome differentiation and treatment. By combining the clinical data information obtained from practice, high-quality and effective evidence can be obtained after design, integration, analysis and evaluation, which can provide scientific basis for clinical application [15]. Most of the new academic thoughts, new principles, new prescriptions and new treatment schemes of holistic medicine of traditional Chinese medicine come from clinical practice. In real world research, the development of new medicine and new ideas is not a spiral rise, but a step-by-step model combining gradual and sudden progress [16]. This requires us to adhere to carry forward the thinking mode with traditional Chinese medicine characteristics in the clinical practice of traditional Chinese medicine, recognize and solve the problems in all aspects of scientific and objective clinical efficacy evaluation of traditional Chinese medicine, and constantly improve the modern clinical evaluation system.

3.3. The way forward for the real world research of traditional Chinese medicine

The concept of real world research has provided new ideas for health policy formulation and clinical evaluation after its introduction into China. Since the first real-world study of traditional Chinese medicine was published in 2008, the number of published papers has been on a steady upward trend. As of 2018, the number of real-world studies published in the field of traditional Chinese medicine has reached 373. However, there are still differences in the understanding of the value and positioning of its application in clinical research of traditional Chinese medicine: on the one hand, it is overly respected, believing that it can solve the current dilemma faced by clinical research and supervision of traditional Chinese medicine; on the one hand, it is believed that it is only a conceptual innovation and cannot bring valuable output to traditional Chinese medicine [17]. Therefore, we must fully understand what is the real world research, what is the use, how to use, what are the difficulties, how to solve a series of problems, in order to better understand and carry out the real world research of traditional Chinese medicine. When the controversy was preserved in the academic circle of traditional Chinese medicine, the Chinese Academy of Chinese Medical Sciences organized and constructed the big data center of traditional Chinese medicine, established the clinical

data sharing system of traditional Chinese medicine, formed the data standard and sharing management of traditional Chinese medicine, and built a health cloud platform with the characteristics of traditional Chinese medicine [18]. In practice, it is found that real world research is suitable for the safety evaluation of traditional Chinese medicine, for the discovery of the clinical action law of traditional Chinese medicine, for the evaluation of the effect of non-drug therapy, for the evaluation of "preventive treatment of disease" technology, for the study of endpoint events, for the evaluation of the interaction between traditional Chinese medicine and Western medicine, for the evaluation of the efficacy of traditional Chinese medicine decoction pieces, for the optimization design of randomized controlled experiments, for the formation of research hypothesis, syndrome distribution and evolution law, the construction and verification of syndrome diagnostic criteria, the correlation between syndrome and objective indicators, the clinical representation of syndrome and the correlation between syndrome and disease prognosis [19].

Under the guidance of the clinical research paradigm of traditional Chinese medicine in the real world, the data of clinical diagnosis and treatment information of traditional Chinese medicine is realized by using structured electronic medical records of traditional Chinese medicine. Combined with the implementation and application experience of the sharing system in the national TCM clinical research base, the data implementation process of TCM clinical diagnosis and treatment information in the real world has been systematically sorted out. At the same time, it also strengthens the quality control in the process of data implementation, establishes the principles and requirements of data, ensures the integrity, accuracy, consistency, real-time and convenience of data, puts forward specific measures for data quality control, obtains high-quality clinical scientific research data of traditional Chinese medicine, and provides data support for analyzing and mining clinical experience results of traditional Chinese medicine [20]. Taking the patients as the object, the clinical data as the guide, the solution of clinical practical problems as the starting point, and the technical platform as the support, the research of disease big data is carried out to evaluate the diagnosis and treatment effect of specialized diseases and the curative effect of traditional Chinese medicine experience, so as to achieve the consensus of the treatment plan of specialized diseases of traditional Chinese medicine, refine the advantages of traditional Chinese medicine characteristics, and provide strong evidence for solving key clinical problems [21].

4. Combination of traditional Chinese medicine and real world research

The core value of traditional Chinese medicine is its safety and effectiveness. At present, it is urgent to make a scientific and objective evaluation of evidence-based research in line with the theoretical characteristics and clinical practice of traditional Chinese medicine. Randomized controlled trials are the gold standard of clinical research methods in the past, but it is obviously difficult to reflect the advantages of traditional Chinese medicine diagnosis and treatment, and real world research pays more attention to clinical practice than randomized controlled trials. Although real world research is still in its infancy in China, in the future work, we can deepen the relevant research around its existing problems, make full use of the concept of real world research, constantly break through the research methods, fully excavate the research results, clarify the curative effect and individual advantages of various diagnosis and treatment schemes, and promote the development of traditional Chinese medicine with high-quality evidence [22]. Real-world research requires that the test process should be open and transparent in the clinical research process, because there are many interference factors in the real-world research environment. If there is a lack of strict normative control, it is difficult to achieve transparency in the whole process. A variety of complex factors will further affect the results of the study, resulting in false negative or false positive results [23].

4.1. TCM medical records combined with real world research

Based on the characteristics of TCM medical records, this paper explores the characteristics of TCM medical records data, analyzes the dilemma of TCM medical records research, and combines real world research to explore the method of forming real world evidence from TCM medical records data [24]. It is found that the data of TCM medical records have the characteristics of authenticity, regularity, individualization and selective difference in content, and are dynamic and complex in form. Combining with the real world research method, respecting the characteristics of individualized and dynamic diagnosis and treatment of traditional Chinese medicine, starting from the basic research work, realizing the objectification of symptoms and curative effects, evaluating the dialectical diagnosis and treatment ideas and medical records as a whole from the single diagnosis, and proposing the establishment of medical record quality evaluation system, taking individual cases as the evidence of TCM efficacy and safety evaluation, taking the diagnosis times as the unit as the data of efficacy and safety evaluation, constructing TCM clinical evidence system and grading system, so as to further improve the reliability and universality of the research results of TCM medical records, in order to provide new ideas and methods for the evaluation of TCM efficacy and safety.

4.2. Old Chinese medicine combined with real world research

As an outstanding representative of the clinical practice and scientific and technological level of contemporary Chinese medicine, the experience of practicing medicine is its valuable crystallization. It integrates the theory of traditional Chinese medicine, the inheritance of predecessors and the rich practical experience. It is an important wealth and part of traditional Chinese medicine. It plays an important role in the inheritance and innovation of traditional Chinese medicine. It is precisely because of the continuous accumulation and inheritance of famous old Chinese medicine in the past dynasties that the traditional Chinese medicine has a long history and keeps pace with the times [25]. Based on this, the information generated in the daily medical process of famous Chinese medicine can be collected, and the standardized unified data can be studied and analyzed by using modern data mining tools [26]. Then, the clinical experience and research results of the inheritance are followed and put into clinical practice, and the research methods of real world research are introduced. After verification, they are promoted [26]. In the process of subsequent promotion and application, doctors can combine personal experience, academic thought and clinical practice again, and repeatedly use this method for re-verification and promotion. Only in this way can the inheritance of traditional Chinese medicine continue to develop and maintain vitality.

5. Discussion

Although the real-world clinical research of traditional Chinese medicine has achieved phased results, there are still some problems in the development of such research, such as the lack of global high-quality, multi-center, large-sample research, the lack of transparency and openness in the research process, and the high autonomy of the test process. It is difficult to ensure the quality of research. It is known that in the context of the in-depth development of medical informatization and big data penetration, traditional clinical trials have been greatly tested, and traditional clinical data collection models are not fully applicable to the needs of real-world data collection. However, by combing the current status of clinical research information collection, we can improve the data collection methods from the aspects of collection scenarios and collection roles, such as the coherence and sharing of cross-scenario medical health data and the short time range of individual health data collection [27]. We need to actively transform the research paradigm of the real world, establish multiple clinical research issues, and use them as guidance. As a result, we can improve the quality

of real-world data and improve the methodology of high-quality causal evidence. Moreover, we can fully understand the long-term nature of traditional Chinese medicine research and the importance of high-quality development of TCM from the ontological perspective of clinical diagnosis and treatment in TCM [28]. If analogical acupuncture wants to achieve better clinical efficacy, it is required to fully combine disease differentiation, syndrome differentiation and meridian differentiation, and at the same time emphasize the time, place and person, so as to formulate a targeted individualized acupuncture treatment plan [29]. Therefore, real-world research should be based on the characteristics of traditional Chinese medicine, which emphasizes the integration of heaven, earth and man, respects individual differences and follows the characteristics of syndrome differentiation and treatment, so as to take different interventions [30], and on this basis, the advantages of special diseases or special diseases should be constructed. The difference is mainly manifested in the control of deviation in the design stage and the control of confusion in the analysis stage; the data collection after the preset scheme has obvious purpose, and the standardized and unified patient database is established by unifying the definition of data variables and the frequency of data collection, and the single center analysis or multi center cooperative research is carried out. In the process of database analysis, multiple imputation of missing values can be processed by using a variety of propensity score algorithms, and negative control can be used to identify confounding factors.

6. Summary

In summary, the combination of real world research and scientific research of traditional Chinese medicine is an important research direction. While preserving the characteristics of traditional Chinese medicine, it does not lose the scientific nature of scientific research of traditional Chinese medicine. Real world research will become an important methodological support for the inheritance and innovative development of traditional Chinese medicine, and will also achieve scientific research results in line with the real clinical situation. We should actively give full play to the original advantages of traditional Chinese medicine, promote the transformation of traditional Chinese medicine from "experience " to "evidence" and new breakthroughs in the field of life science in China, build a model suitable for the evaluation of the efficacy of traditional Chinese medicine based on the local diseases and diagnosis and treatment in China, improve the documentation of real world research under the guidance of a standardized methodological system, and answer China 's problems with Chinese data, so as to further promote the vigorous development of traditional Chinese medicine in China and promote traditional Chinese medicine to the world.

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