Review Article

A Practical Way of Research in Chinese Medicine

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Abstract

While modern medicine has a very well established system of clinical research which insists on evidence-based methodology, traditional medicine has not developed its own system of research, despite of its length of existence and unreceding popularity. Since there are still many problem areas in modern medicine, and traditional medicine possesses good records of efficacy in those areas, it is natural that experts in both areas should collaborate in a proper exploration to put traditional medicine into popular utilisation. One way of achieving this is to follow the requirements of modern clinical trials as much as possible. Obvious obstacles include the uncertain origin of supply of herbs and the inconsistency of their quality, manufacturing of convenient products (which has improved) and methodology for clinical trials. One practical way in pursuing this joint venture is to apply the efficacy-driven approach, which suggests the following: i) Using a simple herbal formula to try solving one difficult clinical problem and start an evidence-based clinical trial using methodology acceptable to standard clinical trials i.e., one which is randomised and placebo-controlled; ii) Organising parallel laboratory experiments to understand the mode of action; iii) Making sure that the quality of herbs or their extracts are of the best standard; and iv) Optimising the formula, once it is proven efficacious in a clinical trial, to give an upgraded product.

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Introduction

Chinese medicine individualises its treatment plan and practice and refutes any general law.[1] Therefore, Chinese medicine practitioners do not have the tradition of research. The experience of respectable practitioners and the process of application of the experiences are considered most important. In general, modern medicine has been known to be successful in most areas. However, in those areas where scientific mainstream are deficient, it may be necessary to look at complementary medicine.

The deficient areas lie where modern medicine, in spite of recent advances, have failed to obtain good solutions. The deficient areas in modern medicine that deserve contributions from complementary medicine include allergic conditions, autoimmune diseases, cancers, chronic pain, chronic derangements, degenerative diseases, nerve damages, viral infections, and other areas where modern conventional therapy fails.

The system of herbal medicine is built on the rich experience of herb users or herbalists, which has been accumulated since the birth of Chinese culture more than 2000 years ago in China. Even as basic medical sciences, e.g., anatomy and physiology, gradually developed in European territories around the Renaissance period, Chinese healers never felt the need to explore these subjects. Without a sound knowledge of anatomy and physiology, i.e., the biological structure and function of the human body, it would be impossible to investigate abnormal structures and functions, as in the case of pathology. Without understanding the pathology, it would be impossible to apply a direct means of removing the pathology. Therefore, herbal practitioners try to heal, not by direct confrontation with the pathological problem, but by indirectly supporting the individual to overcome his own derangements, and setting a balance between the contrasting inner forces affecting health.[2,3]

The herbal practitioner has means to suppress the symptoms which are manifestations of the pathology. Suppression of symptoms, such as cough, diarrhoea or

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dyspnoea, helps the sick individual to survive. While waiting for the pathological damage to heal naturally, the unaffected organs and systems need to be supported to maintain their efficient function and, in turn, they support the overall function and metabolic harmony of the living individual. This might be a modern interpretation of the yin-yang balance theory.

Therefore, the main focus of disease management for Chinese medicine is often the control of adverse symptoms. The ultimate goal is to maintain the well-being of the biological system.

General Considerations for Clinical Trials on Chinese Medicine

The common methodology for conducting clinical trials on modern medicine is logical and useful, and has played a vital role on the clinical testing of new drugs and new methods of clinical treatment. The proper analysis of data and the use of statistics have shown the reliability of certain accumulated experience, while revealing the fallacies of some well accepted and widely practised methods.[4]

The common methodology of random selection, blinding and placebo control, followed by statistical analysis, should be adopted. In the design of the trial, good clinical practice should be the objective. Good clinical practice requires that the prescribed drug for the clinical trial is thoroughly understood and uniform. However when using herbal preparations for clinical trials, there are often difficulties pertaining to insufficient technical knowledge and uniformity.

Each and every herb contains so much complicated chemistry that even extensive research might not provide the answers. At least 400 herbs are popular and possess records of action and impressive efficacy. Obtaining thorough chemical and pharmacological knowledge on just this proportion of herbs is not practical, not to mention the less commonly used 1000 to 2000 varieties.[5]

At the moment, about 50% of popular Chinese herbs are produced in special farms in China. However, these farms are scattered over different provinces, which have widely different climatic and soil environments. Good agricultural practice demands that environmental and nurturing procedures are consistent. Procedures such as soil care, water, use of fertilisers, pest prevention and harvesting. When such procedures are not uniform and no efforts are being taken to ensure a common practice, good agricultural practice is not possible.

Different species of the same herb are found or planted in different regions and provinces. These different species may have different chemical compositions. Herbal experts have extensive experience and knowledge about some special correlations between the effectiveness of particular herbs and their sites of production. Some commonly used herbs are even labelled jointly with the best sites of production. With the development of molecular biology, coupled with modern means of assessing active ingredients within a chemical product, species-specific criteria could be identified, using the "finger-printing" technique. Uniformity today should include screening using "finger-printing" techniques.

Extraction helps to separate useless components from effective ones, which not only reduces the volume of herbs used but also intensifies the biological actions. Knowing the actual effective ingredients and working out the chemical formulae would be ideal for modernisation of herbal preparations with the aim of converting the preparations into proper pharmaceuticals.

In spite of the time and effort put into herbal extractions and chemical analyses in the past 50 years, results have not been impressive, and certainly do not justify the amount of resources spent.[6] Successes are really scanty apart from some examples like taxol from Yew tree, vincristine from periwinkle and artemisinin from Qinghao.

The unsatisfactory outcome has initiated a new approach. Instead of following the scientific pathway previously taken by pharmaceuticals (which is lined with too many obstacles), a more practical line has been endorsed. Since most, if not all, herbs have been used for hundreds of years, they should be more or less reliable. The safety and efficacy of herbs are already well documented, but their practical utilisation in specific clinical circumstances needs to be further established. The traditional use of herbs has focused on symptomatic control a general management of syndromes and maintaining internal balance. Today, the aim of clinical management is directed towards curing a disease entity. We need to acquire an updated understanding on the effectiveness of the herbal preparations on disease entities. That is why we should not be satisfied with records on efficacy alone but should start a series of clinical trials to further prove the efficacy of the herbs.[7,8]

The National Institutes of Health in the United States have openly endorsed the approach of accepting traditional methods of healing as safe measures and, consequently, proper clinical trials have been and are being conducted.[9]

Quality of Life

While clinical trials aim to achieve a thorough scientific understanding of the effectiveness of specific forms of treatment, endpoints of measurement are set to give objective standards of evaluation. Primary endpoints are unique, focused, specific criteria which indicate the situation of the target against which the trial is directed. Changes in primary endpoints illustrate the efficacy directly. Secondary

endpoints are supplementary criteria created to support observations on changes and efficacy. Secondary endpoints become more important when predictably, primary endpoints do not give clear-cut, impressive results. Secondary endpoints become more important when primary endpoints are expected to change slowly and are particularly important in the case of chronic problems.

Since Chinese medicine, under most circumstances, does not operate via a direct route but rather acts indirectly to support the healthy organs and helps maintain vitality and prevents functional deterioration, critical and detailed assessment of the secondary endpoints are of utmost importance.

Quality of life is an important aspect in the assessment of care given to the chronically ill. It often measures the competency of care and the ethical standard of the society in mental disorders and other disorders that demonstrate strong social orientations. Not infrequently, reasonable outcome is observed, when using technical endpoints as results of clinical trials and, yet, patients may not be satisfied with their quality of life.

Conclusion

Complementary medicine does not have its own history of scientific development. The knowledge was built on observations and experience. In order to integrate this complementary stream of medicine into the scientific world, we must first explain why it works in the areas of our concern. We choose those areas that are not well served by scientific medicine as our targets. Hence, this makes scientific explanations even more important.

Providing scientific explanations to healing processes involve the application of methodologies that are well known and accepted by all clinical scientists. The standard way to start a scientific approach to clinical trials using traditional Chinese medicine is just an application of the same methodologies. However, this approach is not feasible if we are not willing to bend our principles. We are barred from a smooth application of the scientific methodology due to the different philosophy behind the traditional Chinese way of healing. Moreover, the lack of knowledge about the exact chemistry of the active component of the herbal remedy when herbal drug trials are being done, further jeopardises the validity of the clinical trials carried out.[10]

Evidence-based medicine takes many forms. Following the practice of an experienced authority is evidence-based, as long as the authority is trustworthy and honoured and there is no better evidence available. In the scientific world, however, an authority's word alone is no longer acceptable support for one's behaviour and practice.

Advocating one's personal experience, if well supported by authority, will form the next level of evidence. Such personal experience, though valuable can, at most, be presented in case reports and, therefore, command less clinical significance.

Grouping together a series of cases and observations will offer more objective data as long as the collaborators are not biased. Cohort studies of this nature are plentiful, including those involving Chinese medicine. We should treat them with respect. Nevertheless, in clinical medicine today, there are ways to control frequently occurring biases. That is why randomisation and double-blinding with placebo control are essential in clinical trials. No other methodology can replace these requirements.

It is therefore good to insist that in spite of the fundamental difficulties, efficacy-driven trials, utilising principles of evidence-based-medicine, are still carried out. As long as the scientific gap is successfully narrowed, the practical use of complementary medicine will become safer, more logical and deserves wider application. Lastly, those who consistently oppose the use of complementary medicine should realise that even in mainstream scientific practice, a large number of treatment protocols continue to lack evidence-based proof.[11-14]

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