· Short Communications ·

Opening up a Way of Evaluating Evidence-based Medicine in Traditional Chinese Medicine

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Evidence-based medicine is an authoritative way of evaluating the clinical efficacy of drugs, which provides the direct evidence for clinical medication. The rise of evidence-based medical research brought about the changes in Chinese medicine from the empirical medical era into the era of evidence-based medicine. Chinese medicine, as the experience accumulation and theory quintessence of the working people struggling with diseases, has been tempered in the clinical practice for thousands of years, yet its clinical efficacy has not been recognized by the international mainstream medicine. Traditional Chinese Medicines (TCM) must be tested by evidence-based medicine before it makes worldwide impact. The newly finished evidence-based medicine study of Chinese medicine has achieved exciting results. They provide a reference for introducing evidence-based medicine to evaluate the clinical efficacy of Chinese medicine and contributing to TCM to take its place in the world.

The clinical study of *Shensong Yangxin* Capsula to resist arrhythmia, an evidence-based medicine of Chinese medicine, has been completed by 32 hospitals in 1476 patients with arrhythmia were selected, including 859 cases of premature ventricular contractions, paroxysmal atrial fibrillation in 349 cases, and 268 cases of slow arrhythmia. The results showed that the treatment of non-organic premature ventricular contractions by *Shensong Yangxin* Capsula is distinctly superior to placebo, and better than mexiletine for the organic premature ventricular contractions. The treatment of paroxysmal atrial fibrillation or propofenone shows no difference; The treatment of slow arrhythmia such as sick sinus syndrome has the precise effect and the heart rate can be enhanced an average of 7.15 times/min. Ventricular rate in patients with lower heart rate increase more evidently. The heart adverse reactions were not found in *Shensong Yangxin* Capsula group, while 5.1% of them was found in Western medicine group.

Clinical trials of *Tongxinluo* Capsula were led by Beijing Fuwai Hospital and nine other upper first class domestic hospitals participated in preventing and controlling the intervention of acute myocardial infarction (AMI) myocardial no-reflow in, another evidence-based medicine of Chinese medicine. Clinical investigators selected the patients with acute myocardial infarction of ST segment enhancement within 12 h. Based on conventional Western medicine, they were divided into *Tongxinluo* treatment group (n = 108) and placebo control group (n = 111), follow-up of 180 d, and we adopt the internationally recognized objective criterion to appraise the prevention of emergency percutaneous coronary intervention (PCI) for AMI with no-reflow and the protection of cardiac function by *Tongxinluo* Capsula. In the course of the two studies of evidence-based medicine, internationally recognized evidence-based medicine approach was used to strengthen the quality control. Cases are

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included in the establishment, quality control monitoring standard operating procedure (SOP), case report form (CRF), and the original records to verify SOP, test documents, and drug administration SOP have also been established; The kick-off meeting, site training, and regular monitoring are organized to ensure the smooth conduct of the trial; Drug based blinding, data management, and statistical analysis are implemented independently by an third-party statistical department; A central laboratory has been set up and the important data read respectively by doubled- blind method. All these strict quality control ensure the test results to be scientific, objective, and authoritative. The results showed that *Tongxinluo* Capsula can promote ECG ST-down obviously within 24 h after acute PCI, reduce no-reflow, promote effective myocardial perfusion of 7 d and 180 d, reduce the infarct area, and improve the overall systolic function of heart of 180 d. No drug-related adverse event was found in the test.

The two studies of evidence-based medicine showed the exact efficacy of dredging collaterals drugs and provided a possible approach to resolve the current problems plaguing the medical profession. The progress of arrhythmic drug therapy has been slow in the past decades, the majority of anti-arrhythmic effects of Western medicine are poor and there are side-effects such as arrhythmogenic, damage to cardiac function, and even increased mortality. Bradyarrhythmia is lack of targeted drugs. There is great need for anti-arrhythmic drugs with safety and precise clinical efficacy in clinical cure. With the unique role of treating rapid or chronic disease at the same time, regulating anti-arrhythmic integrally, *Shensong Yangxin* Capsula has an obvious advantage to Western medicine in medicament safety, thus providing a new choice for patients with arrhythmia.

Thrombolytic therapy or PCI is the first choice for the treatment of coronary recanalization of ST-segment elevation acute myocardial infarction (STEAM), but after the restoration of coronary flow, no-reflow due to the myocardial microvascular injury makes effective myocardial reperfusion impossible, and increase severe complications such as myocardial damage, left ventricular dilatation, and heart failure. No-reflow is the next challenge for the world of international medicine to treat STEAM. At present, the international medical community has no single method or drug that can be used to prevent and cure myocardial no-reflow effectively. *Tongxinluo* Capsula provides a preliminary evidence of evidence-based medicine to solve this problem and hopefully achieve a breakthrough of reperfusion of AMI.