

A General Introduction of HIV/AIDS Treatment with Traditional Chinese Medicine in China

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Abstract: This paper gives a general introduction of HIV/AIDS treatment with Traditional Chinese Medicine (TCM) in China during the past 20 years. Although the role of TCM in treatment of HIV/AIDS is promising, there is still a long way to go.

Key words: HIV/AIDS; Traditional Chinese Medicine (TCM); General introduction

Since the early 1980's over 40 million individuals have been infected by HIV worldwide and over 12 million people have died. AIDS caused 16155 deaths in China since the first case was reported in 1985. In addition more than two hundred thousand people were living with HIV and a further more than fifty thousand individuals had developed AIDS defining illnesses. The medical, social and economic implications of HIV infection are devastating.

In the middle 1990's the introduction of HAART therapy finally declined the death rate from AIDS after a decade of relentless rises. However, the cost of combination therapy is very expensive especially for most suffers in developing countries, and there is increasing evidence of viral resistance and severe side effects. In the meantime there is a role worldwide for Traditional Chinese Medicine to support people living with HIV/AIDS, to help to alleviate some of the side effects of the current drug therapy, to improve quality of life and to assist in the treatment of individuals who

are either unwilling, unresponsive or resistant to combination therapy.

This paper gives a general introduction of HIV/AIDS treatment with Traditional Chinese Medicine (TCM) in China over the past 20 years.

WHY TCM CAN TREAT AIDS

TCM is a kind of greatly ancient traditional medicine

TCM is a complete medical system with its unique philosophy, diagnostics and treatment methods. As a medical science with thousand years of history, the reason why TCM could exist after such a long time is efficacy in clinical practice helping ancient people keep alive under arduous environment. The basis of TCM theory is Yin-yang and five elements which related to the whole universe, so TCM views the human body and nature as a integrated whole, not divided one. A healthy human is under the state of relatively dynamic balance maintained by both inside

and outside of the body. And, if the balance is broken, the illness occurs. TCM aims to recover the balance, just like the old saying in TCM: once Yin balances with Yang, there comes the harmony of the body and the spirit.

The characteristics of TCM

Syndrome differentiation and integral regulation are two main characteristics of TCM. TCM focuses on differentiation of syndromes with the holistic and dynamic perspective and aims to the patients suffering disease instead of only the disease itself. The constitutions of patients are different, the illness phases are different, the body responses are diverse, and the manifestations are not the same, therefore the treatment varies accordingly.

The basic theory of AIDS treatment with TCM

AIDS is a new viral infectious disease, which was discovered only 26 years ago. Although we can't find its name in the ancient literature of TCM, according to the factors like: patterns of spreading, state of diffusing, characteristic of onset and clinical manifestations, there are some resemblances among AIDS pestilence and deficiency of the body *et al* in TCM. These provide theory basis and successful clinical experiences for the treatment of AIDS with TCM. Western medicine treats disease itself, but TCM aims at the patient suffering disease instead of only the disease itself. The purpose of TCM is to maintain the strong energy and body resistance so as to arrest the progressing of the disease. If someone has enough strong energy and body resistance in TCM, even if infected with HIV, he can live with it, being a long term HIV carrier, so as to postpone onset and death. Based on this principle, individualized TCM treatments which combined disease and syndrome differentiation together win scores in AIDS treatment.

The best time of intervening in AIDS with TCM

For the patient in early (HIV carrier) or middle stage (ARC) of infection, the key aim of TCM is to maintain and enhance the immune-function so as to delay its progression to AIDS stage.

For the AIDS stage, TCM treatment focuses on relieving symptoms of patients who have AIDS-related opportunistic infection so as to improve the quality of life or combines with HAART therapy to alleviate the side effects of biomedical drugs.

The advantage of treating AIDS with TCM

TCM applies many kinds of methods like herbal medicine, acupuncture and moxibustion, Qigong to patients, in order to enhance immune function of the body, delay the development of disease, and reduce or remove the symptom-signs, so as to improve quality of life and prolong life expectancy. The advantages of treatment with TCM are as follows: small toxic-side effect, starting slow effect but maintainable, low price, strengthening or stabilizing immune function, improving symptom-signs and quality of life. Although HAART therapy has affirmative effects on treating people living with HIV/AIDS, it still has problems, such as drug resistance and toxic-side effect. These disadvantages not only discount the drug effect, but also reduce the compliance of patients.

WHERE IS THE VIRTUAL EVIDENCE OF TREATING AIDS WITH TCM

Chinese herbal medicine screening

Tens of thousands of herbs have been screened for anti-HIV activity. Many of them demonstrated to harbor inhibitory activity against HIV, such as Radix Arnebiae (紫草)、Herba Violae (紫花地丁)、Flos Lonicerae (金银花)、Flos Chrysanthemi Indici (野菊花)、Fructus Mume (乌梅)、Cortex Cinnamomi (肉

桂)、Fructus Ligustri Lucidi (女贞子) *etc* (1,10,11). Some bioactive materials extracted or isolated from medicinal herbs showed anti-HIV activities, for example: polysaccharides (such as polysaccharides of Radix Ginseng, *Glossogyne tenuifolia* Cass, Radix Astragali, *Ganoderma Lucidum* seu *Japonicum*, Radix Actinidiae); protein components (such as glucoprotein in Aloe, a component from Radix Trichosanthis, Alpha and Beta Momordicines in *Momordica charantia*, Ricin bond A, cimigenol saponin); alkaloids (such as castanospermine and colchicines); lactones (such as baicalein and hypericin); terpenes (such as glycyrrhizin and goddypol) *etc*. The action mechanisms of them included inhibiting the activities of reverse transcriptase, protease and integrase or weakening infection at the level of viral entry. Among them, trichosanthin is a kind of prospective one that acquired worldwide attention. It was shown that trichosanthin can inhibit HIV replication in infected cells of lymphocyte and mononuclear phagocytic lineage, with no measurable toxicity in uninfected cells. And it was applied in the treatment of patients with AIDS or AIDS-related complex in phase I and II studies (2, 3, 8, 12, 13, 14).

Many more herbs or herb extracts may attenuate the course of HIV infection via immune enhancement, cytokine or other pathways, such as Radix Astragali (黄芪)、*Cordyceps* (冬虫夏草) both of which have been reported to enhance helper lymphocyte T and promote CD4/CD8 ratio (5, 7). Shikonin (紫草素) was shown to decline the expression of CCR5 and CCR5mRNA (4).

Many herbal compounds have been reported to have potent inhibitory activity against HIV and their experimental or clinical manifestation may provide valuable leads for further investigations, for instance,

Xiao chaihu tang (18), Zhongyan-1 (6), Zhongyan-2, Zhongyan-4, Compound SH (9), Tangcao Tablets *etc*.

Clinical trials

According to the regulation of SFDA in China, new Chinese patent medicine treating AIDS should be classified into anti-HIV patent that testified through *in vitro* and *in vivo* experiments and supplementary patent for AIDS treatment that either has synergistic effects or alleviates toxic-side effects on antiretroviral drugs already existed. Tangcao Tablets is the first patent approved by SFDA for alleviating symptoms and signs of HIV/AIDS patients. And 5 other relatively mature compounds (Qiankunning capsule, Keaito capsule, Chuankezhi injection, Zhongyan-2 Granule and Compound Sanhuangsan) are still under clinical trials.

Tangcao Tablets: Wu *et al* recruited 173 HIV/AIDS patients for randomized double blind placebo controlled clinical study in 5 medical centers (15). After 6 months treatment, it was shown that Tangcao Tablets could significantly raise CD4 count, improve the patients' symptoms (such as the weight gained and CD4/CD8 ratio increased), and be possible to delay the replication of the HIV.

Zhongyan-2 Granule: Wang *et al* recruited 29 HIV infected patients for a self-control before and after treatment (16). After 3 months of treatment, the count of CD4 cells being elevated in 8 cases, lowered in 14 cases, and not changed in 7 cases; the ratio of CD4/CD8 being elevated in 2 cases, lowered in 1 case, and not changed in 16 cases; viral load being elevated in 8 cases lowered in 6 cases, and not changed in 2 cases. The total effective rate was 42.28% on the basis of comprehensive assessment of viral load, immune function, body weight and symptoms-signs.

Zhongyan-4 Granule: Wang *et al* recruited 72

HIV/AIDS patients for a randomized double-blind placebo-controlled trial for 6 months (17). Results showed that 15 out of 30 patients in Zhongyan-4 group had their CD4 counts increased by $7.70 \pm 150.96/\text{mm}^3$, markedly higher than that in placebo group, and no adverse reaction was found.

Medical care

Since 2004, five provinces such as Henan, Hebei, Anhui, Hubei, Guangdong had been chosen to advocate pilot project of AIDS treatment using TCM by the State Administrative Bureau of Traditional Chinese Medicine. The therapeutic effects on 1107 cases from five provinces are as follows: some of the patients had stable immune function; common symptoms like diarrhea, skin rash, night sweat, short of breath, fatigue and low fever were reduced or disappeared, some of the toxic-side effect of HAART was alleviated; And no adverse reaction was found in TCM treatment. Other six locations such as Beijing, Jiangxi, Hunan, Guangxi, Yunnan, Shanxi were included in this project last year, planning to give TCM medical care to many more 4500 HIV/AIDS patients in China.

HOW TO EVALUATE THE EFFECTIVENESS OF TCM IN AIDS TREATMENT

Although TCM gain more and more popularity and was accepted by HIV/AIDS patients especially for those who are living in rural areas, it seems TCM haven't shown obvious effects according to the current used effectiveness evaluation "gold standard": viral load and count of CD4⁺ T cell which are generated from western medicine. Does this "gold standard" fit for TCM? Does it have good reflection of clinical effectiveness of TCM in AIDS treatment? Some HIV/AIDS patients had improved quality of life or prolonged life after TCM treatment, but their viral

load might be still in a high level and count of CD4⁺ T cell had no significant elevation. As to patients, improvements in other aspects rather than biomedical parameters means more to them. So if clinical effectiveness evaluations of TCM take items such as patients reported outcomes (PRO), quality of life, clinical end points (morbidity, mortality, life span), activities in daily life (work ability) and so on. into consideration, or even let those items play key part in the evaluation, they might be more appropriate for TCM evaluation.

In general, TCM as a treatment modality for people living with HIV/AIDS is still at an early stage. There is a need for more controlled and well designed trials which are able to indicate the efficacy of TCM, for more suitable standard which are able to assess the real value of TCM, for studies which focus on clearly targeted symptoms such as diarrhea and neuropathy which are anecdotally reported as responsive to TCM, and for studies which explore the role of TCM combining with HAART therapy to alleviate side effects and add synergistic effect.

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