

The Effects of Herbal Formula Jian Zhong Qing Jie in M.E/CFS treatment

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Abstract Immune dysfunction, entroviral or retroviral infection have been suggested in ME/CFS. **Aim:** To assess the clinical efficacy of herbal formula “Jian Zhong Qin Jie”(JZQJ) in treating patients with ME/CFS, and to discover the key treatment of ME/CFS from Traditional Chinese Medicine (TCM). **Methods:** 53 patients all had herbal formula (JZQJ) twice a day, monitored with visual analog well being scale (VAS) before treatment (week 0) and after treatment on week 1, week 4, week 8 and week 12. After completing the final treatment, measure overall response. **Result:** At the final visit, among 53 patients, 13 patients were “clinical recovered”, 18 “much better”, 15 “better”, 7 “no change”. Analog total scores were significantly improved from 3.41(week 0), 3.55(week 1) 3.69(week 4), to 5.86(week 8 with $P<0.01$), 7.28 (week 12 with $p<0.001$). 75% of acute cases and 33.3% of sub-acute cases were “clinical recovered”. 25% of acute cases and 50% of sub-acute cases were “much better”. 20% of chronic cases were “much better”. After patients had 5 to 8 weeks treatments, “much better” rate is 50%, Those who had 12 weeks treatment, “clinical recover” rate (43.5%) and the “much better” rate (52.2%) are evidently increased and “No Change” rate is reduced to zero. **Conclusion:** Significant benefits were seen after the herbal treatment than before treatment. The herbal formula can improve GI symptoms, invigorate energy and general wellbeing, cellular immune function. In terms of TCM, the herbal formula focus on strengthening spleen stomach, eliminating dampness and toxicity due to viral infection. If ME/CFS patients have a clear diagnosis from NHS in acute or sub acute stages, receive the herbal formula treatment earlier, they have a better chance of recovery.

1. Introduction

Myalgic Encephalomyelitis(ME) and Chronic fatigue syndrome(CFS) are classified as neurological diseases in the World Health Organizations International Classification of Diseases (ICD).In a large American sample of more than 28,000 adults, 422 per 10,000 had ME/CFS. It is more prevalent than lung cancer and AIDS [1] . Patients show characteristic multi-systemic symptoms: debilitating fatigue, post exertional malaise, pain, disordered sleep, cognitive disturbance. From current study, retroviral infection may link to M.E/C.F.S [2] . But US researchers found more than 80% of 165 patients were infected with an entrovirus in bowel , having severe but short lasting gut infection, then entrovirus head to attack central nervous system, heart and muscles [3] .The elevated levels of many intracellular pathogens suggest that immune dysfunction plays a primary role [4] .With conventional medicine , there may be anti viral drugs for the patients cautiously as severe side effect. [3] Traditional Chinese medicine provide holistic approach to ME/CFS. There has been little information about ME/CFS clinical research . “Jian Zhong Qin Jie” formula is my own prescription and have been used in the treatment of ME for 10 years .Therefore , the study is desired to evaluate the efficacy of the formula by using scientific methodology.

2. Materials and methods

2.1 Diagnosis All my 53 cases of M.E. patients had official diagnosis from NHS specialist (Rheumatologist or M.E specialist.)

Among those cases, the patients diagnosed with M.E 20 cases, M.E+FM 3 cases, ME+CFS 9 cases, M.E+PVFS 1 case, FMA 8 cases, CFS 7 cases, FM+PVFS 1 case, CFS+PVFS 3 cases, CFS + FMA 1 case.

2.2 Age: There were 9 male patients, 44 female patients. Age from 12-70 years old, length of ME\CFS from 3 month to 20 years.

2.3 Onset reasons: virus infection (include flu, glandular fever) 31 cases (58.5%), phoneumonia 3 cases (5.7%), recurrant tonsillitise 4 cases (7.6%), recurrant cystitis 1 case(1.95%), labyrinthitis 3 cases(5.66%), severe acne 2 cases(3.78%), no reason 9 cases (16.9%)

2.4 Outcome measures Two outcome measures were used(5)

1. Overall response (final) answers after completing the treatment
no change, better, much better, clinical recovered

2. visual analog (well being) scale (VAS) of 0—10 for 5 questions

A. How is your energy? 0 (near dead) – 10 (excellent)

B. How is your sleep? 0 (poor sleep) – 10 (excellent, uninterrupted sleep)

C. How is your mental clarity? 0 (severe “brain fog”) – 10 (normal health)

D. How is your achiness? 0 (very severe, painful) – 10 (no problem, pain free)

E. How is your overall sense of well being? 0 (horrible) – 10 (great)

2.5 Treatments:

53 patients all had herbal prescription once or twice a day. Herbal prescription is focused on strengthening the digestive system, improving immune function in term of Traditional Chinese Medicine (TCM), strengthening spleen function, eliminating toxicity due to infection. These seven herbs form the basic formula: Huang Qi, He yie, Dang shen, Bai Zhi, Lian Qiao, Can Zhu, chuan xiong.

2.6 Statistical Analysis

Significant of changes in VAS score before treatment and after treatment week 1, week2- 4, week 5-8, week9- 12 were examined with paired t-test by using Excel Analysis Toolpak.

3 Results:

1. Total clinical recovered 13 cases: all clinical symptoms cleared, cognitive function become normal, being able to have a normal life.
2. Much better group 18 cases: flu-like symptoms cleared; gastrointestinal symptoms, sleep quality and muscular-joints pain much improved; mental condition being stable, being able to maintain a normal life. But some symptoms may be recurrant (like tiredness, muscle aching) but can be recovered quickly after some rest.
3. Better group 15 cases: gastrointestinal symptoms, appetite, sleep, muscle pain improved, but mental fatigue and physical tiredness still exist.
4. No changes group 7 cases : clinical symptoms and signs have not changed.
5. Visual analog scale (VAS) total : 3.41 (baseline score ,week 0) 3.55(week 1) 3.69 (week2- 4) 5.8 6(week5- 8) 7.28 (week 9-12)

4. Discussion:

1 Relation between treatments and results

(1) history of ME\CFS and treatment results

Table 1 Relation between length of ME\CFS and results

	Clinical Recovered	Much Better	Better	No Change
Acute (3 to12 month)	3 (75%)	1(25%)	0	0
Sub-acute 1 to 2 years	8(33.3%)	12(50%)	4(16.7%)	0
Chronic Over 2 years	2(8%)	5(20%)	11(44%)	7(28%)
Total	13	18	15	7

(2) Number of treatments and results

Table 2 Relationship between number of treatments and results

	Clinical Recovered	Much Better	Better	No Change	
1week	0	0	0	7(100%)	
2—4weeks	0	1(8.3%)	11(91.7%)	0	
5—8weeks	0	2(50%)	2(50%)	0	
9—12weeks	3(42.9%)	3(42.8%)	1(14.3%)	0	
>12weeks	10 (43.5%)	12(52.2%)	1(4.3%)	0	
Total	13	18	15	7	

When analysing the relation between herbal formula and treatment result above mentioned, we can possibly find that:

1. In terms of the length of ME\CFS and the results, 75% acute cases can be recovered, whereas the recovered rate of sub-acute cases is 33.3%, chronic cases are much lower (8%), although in sub-acute cases ,the “Much Better” rate is high (50%), and in “Better Cases” are relatively higher.

2. In terms of the numbers of treatments and results, in cases of “ No Change” 7 cases only had 1 week of treatment. This indicates that the herbal formula does not give a quick result. May be financial reasons or unable to tolerate herbs or taste, the patients have given up the treatments. In cases that had 2 to 4 weeks treatments, “Better” rate is high (91.7%). particularly those that had more than 12 weeks treatments. “Clinical Recovered” rate (43.5%) and the “Much Better” rate(52.2%) are evidently increased and “No Change” rate is reduced to 0. Therefore, the most import factor for improvement is to continue to have treatments for at least 12 weeks.
3. There are 3 cases recovered during 12 weeks, 1 case is acute FM for 3 months due to virus infection. 1 case is ME 6 months due to glandular fever. 1 case is ME 12 month no specific reason. This may indicate that patients who receive the herbal treatment earlier, as soon as diagnosed by a NHS specialist, The “Clinical Recovered” rate (75%) will be higher in a shorter treatment course.
4. There is 1 case, who had more than 12 weeks treatment, in better group, Male, 52 years old with M.E 20 years. When he was 32 years old, he had chicken pox and combined severe headache, tumbling dizziness, fatigue, no gastro- intestinal symptoms ,a year later MRI scan showed brain legion marks, NHS specialist thought it was related to chickenpox. Mr K had herbal treatment, Muscle aching, and stiffness are improved but tiredness, brain fog, dizziness symptoms are a little better, This result is not satisfactory.

We found 38 of 53 cases all had long histories of gastrointestinal symptoms, IBS, constipation , diarrhoea, food intolerance, 5/38 cases had candida history.

From above information, maybe the virus attacks body and persists in brain and/or gastrointestinal systems . We found ME\CFS patients with Gastrointestinal (GI) symptoms had better response from treatment .Once their GI symptoms are improved, mental and physical fatigue start to improve. But if virus directly attacks Central nervous system(CNS), brain and is left 20+ years without any treatment, the damage may become permanent. This may be why Mr K did not have good response from herbal treatments.

5. There is one case report of feeling sick , after taking a herbal formula , which may be due to immune dysfunction .As the patient is hypersensitive to taste or smell , especially as herbs are new introduction to the body.
6. From research of the 53 cases. 31 cases (58.49%) had viral infection, 13 cases (24.52%) had various infection with long course antibiotic. This may indicate that a group of viruses can trigger ME/CFS in some people, after using strong, long course antibiotic medicine which can damp down the immune system.

7 Cases had no specific or recognised reason for onset, but were under long term physical and mental pressure. Stress may have decreased the immune function.

(3)VAS score and treatment results

Table 3. VAS scores

	VAS scores (Mean+_SE)	P value examed with paired t-test ,compare with Base linescore
Week 0 (Base line score)	3.41± 0.36	
Week 1	3.55±1.21	p>0.05
Week2- 4	3.69±0.48	p>0.05
Week 5-8	5.86±1.24	P<0.01
Week9- 12	7.28±2.03	P<0.001

From VAS score chart, comparing with Baseline score, treatment on week5- 8 and week 9-12 both p value show significant change. This suggests the herbal formula works effectively for ME /CFS patients, but patients need have at least 5-8 weeks treatment, their symptoms started improving.

2 The herbal formula (JZQJ) and treatment

In TCM, ME/CFS may belong to category “Xu Lao”, “Bi zheng”. In traditional Chinese medicine literature there is little information about ME/CFS. But insufficiency of Qi and blood, deficiency of spleen and kidney, deficiency of heart and spleen, damp-heat /damp-cold stagnation, stagnation of Qi and blood are most common applied to pathology of ME/CFS. According to my clinical experience , toxicity due to heat ,coldness, dampness and deficiency of five zang has become important factor. The toxicity can invade brain, muscles, heart and spleen, stomach and immune system. The formula is based on strengthening spleen, eliminating dampness, invigorating Zheng Qi, like Huang Qi, Dang Shen, Cang Zhu. In the formula He Yie, Bai Zhi, Chuang Xiong, these three herbs have refreshing fragrance, detoxifying function.

5 Conclusions:

The cause of ME/CFS is not clear, but may be linked to retroviral infection, but One type of retroviruses (MLV-related virus) in ME/CFS patients could reflect an increased susceptibility to viral infections due to the underlying immune dysfunction, (6) rather than a primary disease causing role in pathogenesis of ME/CFS, in other words, the retrovirus could be there as a harmless passenger (7). I think it is important to improve immune function. herbal formula focuses on strengthening spleen and digestive function, eliminating body toxicity due to viral infection. From modern research, patients with spleen deficiency, and spleen deficiency animal models all show cellular-immune dysfunction, This includes decreased Natural killer cell (NK cell) activation, and decreased function of macrophage and lymphocytes.

Spleen and stomach in TCM (traditional Chinese medicine), is a multi-function system, which include gastro-intestinal, immune, neurological, haematological systems. It is known that gastrointestinal barrier function is related to digestive function, and immune protective function. Spleen-strengthening and "Qi"-invigorating ("Qi" is energy, life force in Chinese medicine terminology) herbal medicine may pharmacologically target on small intestinal crypt-like cells. [8]

Therefore ME/CFS is treatable, but clinically needs longer treatment courses at least 5--12 weeks. "Clinical Recovered" rate and "Much Better" rate is 31/53 (59.5%). I have to point out that all patients tried different therapies before they started the herbal formula. They came to me as a last resort. If ME/CFS patients have a clear diagnosis from the NHS in acute or sub-acute stages, and receive earlier herbal prescription, they may have a better chance of recovery.

Reference

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