Congestive heart failure (CHF) refers to symptomatic myocardial dysfunction resulting in a characteristic pattern of hemodynamic, renal and neurohormonal responses. Also called chronic heart failure, cardiac decompensation, and myocardial decompensation, this condition affects 2.3 million Americans, with 400,000 new cases per year.

Its prevalence rates by age are: 45-54 years - 2.6/1000 population; 55-64 years - 7/1000; and 65-74 years - 15/1000. The male-to-female ratio of sufferers of this condition is 1.5:1.¹

Congestive heart failure develops when plasma volume increases and fluid accumulates in the lungs, abdominal organs (especially the liver) and peripheral tissues. In many forms of heart disease, the clinical manifestations of heart failure may reflect impairment of either the left or right ventricle. Left ventricular failure commonly develops in coronary artery disease, hypertension, and most forms of cardiomyopathy, as well as with various congenital defects. Right ventricular failure is most commonly caused by prior left ventricular failure. However, it may also be due to mitral stenosis, primary pulmonary hypertension, multiple pulmonary emboli, pulmonary artery or valve stenosis, and right ventral infarction. Other causes of CHF are diabetes and emphysema. Shortness of breath and swelling of the ankles are two common symptoms of heart failure.²

Precipitating factors in predisposed individuals include reduction of therapy, heart rhythm disorders, severe infections, obesity, pregnancy, anemia, hyperthyroidism, and excessive heat and humidity. Western medical treatment for heart failure includes diuretics, ACE inhibitors, the angiotensin II receptor blocker losartan, digitalis preparations, vasodilators, beta-blockers, calcium channel blockers, etc. Heart transplantation is the only Western medical treatment that potentially alters the natural history of heart failure long-term.

Within Chinese medicine, the clinical symptoms of this condition fall under the traditional Chinese disease categories of "heart palpitations (xin jì)," "water swelling (shuì zhòng)," "phlegm rheum (tán yín)" and "heart impedance (xin bì)." According to Chinese medicine, the underlying root mechanism of this disease is due to vacuity, even though its branch symptoms present as replete conditions. In other words, if, for any reason, the qi becomes too vacuous and weak to control the normal movement and transportation of blood
and fluids, these may become static and accumulate, thus producing the main symptoms of this condition.

Beginning in Jan. 1997 and running through Dec. 1998, Yi Shi-hong, et al. treated 60 cases of congestive heart failure with a Chinese herbal formula called *xin li shu kang wan* (heart power soothing & healing pills). At the same time, another 40 patients with CHF were treated with 12.5mg of the antihypertensive and ACE inhibitor captopril administered orally three times per day. At the end of treatment, the outcomes of these two groups were compared.³

**Cohort Description**

Among the 60 patients in the Chinese medicinal treatment group, there were 31 males and 29 females whose ages ranged from 38-65, with a median age of 52.64 ± 6.20 years. The duration of their disease had lasted from 1-21 years, with a median duration of 6.48 ± 5.41 years. Heart function grading was grade II in three cases; grade III in 34 cases; and grade IV in 23 cases. Onset of the disease was associated with atherosclerosis in 20 cases; pulmonary heart disease in 14 cases; rheumatic cardiovalvulopathy in 11 cases; hypertensive heart disease in 10 cases; and dilated congestive myopathy in five cases.

In the comparison group treated with Western medicine, there were 21 males and 19 females whose ages ranged from 27-63, with a median age of 51.78 ± 7.22 years. Their course of disease had lasted from 1-20 years, with a median duration of 6.34 ± 5.50 years. Heart function grading was grade II in two cases; grade III in 23 cases; and grade IV in 15 cases. Onset of disease was associated with atherosclerosis in 12 cases; pulmonary heart disease in nine cases; rheumatic cardiovalvulopathy in eight cases; hypertensive heart disease in nine cases; and dilated congestive myopathy in two cases. Therefore, in terms of sex, age, disease course, heart function grading and associated pathophysiology, there was no marked statistical difference between these two groups (P > 0.05).

**Diagnostic Criteria**

Diagnostic criteria were based on the Ministry of Health’s 1993 publication, *Xin Yao (Zhong Yao) Lin Chuang Yan Jiu Zhi Dao Yuan Ze (Reference Principles for the Study of New Medicinals [Chinese Medicinals])*. Heart function grading was based on the grading criteria promulgated by the New York Heart Disease Association (NYHA). Criteria for Chinese medical pattern discrimination were based on the same 1993 Ministry of Health publication mentioned above.
Inclusion Criteria

All of the patients enrolled in this study were diagnosed with the Western medical diagnosis of congestive heart failure and the Chinese medical pattern discrimination of qi vacuity and blood stasis with collection of water (qi xu xue yu shui ting). Their main symptoms included: heart palpitations; shortness of breath; chest oppression; panting with inability to lie supine; fatigue; lack of strength; cough; dark facial complexion; cyanotic lips; looking angry; distended neck veins; abdominal distention; hypochondral lumps; edematous face and/or limbs; possible water within the chest or abdomen; purple macules or static spots on the tongue with either thin, white or slimy, white fur; and a fine and choppy, weak, knotted, or regularly intermittent pulse.

Exclusion Criteria

Patients were excluded from this study if: 1) their condition was due to serious liver or kidney organ function failure leading to heart failure; 2) they were either pregnant or lactating females; 3) they were allergic to the medicinals in this study; 4) if they suffered from psychiatric disease; and 5) if they were unable to consistently take the medications.

Treatment Method

Patients in the Chinese medicinal treatment group were orally administered xin li shu kang wan. These pills consisted of radix astragali membranacei (huang qi), 333g; radix stephaniae tetrandrae (han fang ji), 4167g; flos carthami tinctorii (hong hua), 67g; radix salviae miltiorrhizae (dan shen), 333g; and semen lepidii seu descurianiae (ting li zi), 167g. These five ingredients were ground into fine powder. One hundred grams of the resulting powder was mixed with 35-50g of honey and a suitable amount of water to form into pills, which were then dried for use. The pills used in this study were manufactured by the No. 2 Pharmaceutical Manufactury affiliated with the Hunan College of Chinese Medicine. Ten grams of these pills were administered three times per day.

Outcomes Criteria

The outcomes criteria were similarly based on the criteria in the 1993 Ministry of Health publication mentioned above. Clinical cure meant that heart function either returned to normal or was grade I, that the patients’ symptoms basically disappeared, and that all other tests basically returned to normal. Marked effect meant that the patients’ heart function improved two grades, that their symptoms basically
disappeared, and that all other tests markedly improved. Some effect meant that heart function improved one grade, but no one achieved grade I function. At the same time, symptoms and tests showed some improvement. No effect meant that there was no marked change in heart function, that heart function got worse, or that the patient died.

Treatment Outcomes

Based on the above criteria, within the Chinese medical treatment group, four patients (6.6%) were judged cured; 36 (60.0%) experienced a marked effect; another 16 (26.6%) experienced some effect; and four (6.6%) experienced no effect. Thus the total amelioration rate in the Chinese medical treatment group was 93.33%. In the Western medicine comparison group, one patient (2.5%) was judged cured; 16 (40.0%) experienced a marked effect; 17 (42.5%) experienced some effect; and six (15.0%) got no effect, for a total amelioration rate of 85.00%. Both groups experienced a marked positive improvement in their main symptoms from before to after treatment (P < 0.01). The difference in symptomatic improvement between these two groups was statistically significant (P < 0.05). In both groups, there was a marked positive improvement in left ventricular diastolic function from before to after treatment (P < 0.05 and P < 0.01, respectively). The difference in improvement in left ventricular diastolic function between these two groups was not statistically significant (P > 0.05).

Rationale for Formula Composition

According to this study’s authors, within this formula, astragalus is the main or ruling medicinal which is meant to boost the qi and disinhibit water. It is combined with stephania to increase its function of disinhibiting water. Salvia quickens the blood and transforms stasis. Once stasis has been removed, the new can be engendered. At the same time, salvia moves but it doesn’t break. Carthamus scatters static blood and frees the flow of the channels and vessels. Lepidium drains the lungs and stabilizes panting; disinhibits water; and disperses swelling. The heart and lungs reside in the upper burner. The lungs face the hundreds of vessels and are the upper source of water. The heart rules the blood vessels and empowers the movement of qi and blood. Therefore, lepidium’s draining of the lungs and disinhibition of water assists the heart vessel’s normal movement. When all of these medicinals are used together, they strike to the center of the disease mechanism due to their function of boosting the qi, quickening the blood, and disinhibiting water.
Author’s Discussion

In Chinese medicine, the qi moves the blood. If the qi moves, the blood moves; if it stops, the blood stops. In addition, the blood and fluids move together. This means that failure in the circulation of one can cause or aggravate failure in the circulation of the other. Therefore, if for any reason the qi becomes too weak to move the blood and/or body fluids, it may lead to blood stasis and fluid or water accumulation. In addition, the heart and lung qi together form the ancestral or so-called chest qi (zong qi). This means that the qi of the heart and lungs are interdependent. If the qi of one becomes vacuous and weak, so will the qi of the other over time. Therefore, the above formula is meant to strongly boost the heart and lung qi through the use of astragalus. This addresses the vacuity that is the root disease mechanism of this condition.

The rest of the medicinals in this formula are meant to address the branch conditions of blood stasis and water stoppage or collection. Further, qi is transformed and engendered out of both blood and body fluids. However, it cannot be engendered out of static blood or evil dampness. Therefore, by draining these evil repletions, the engenderment and transformation of qi is indirectly assisted. In this case, supplementation and drainage must go hand in hand. In fact, these two treatment principles mutually complement each other. Draining evils promotes the supplementation of the righteous, while supplementation of the righteous empowers the drainage and discharge of evils. This is a good example of how a professionally prescribed Chinese herbal formula is not just a collection of medicinals that empirically treat the same condition, but a carefully crafted combination of synergistic ingredients whose sum is greater than its parts.

References

4. This medicinal should not be confused with radix aristolochiae fangchi (guang fang ji). This latter medicinal contains aristolochic acid, which can cause irreversible kidney failure as well as gastrointestinal tract cancers.
5. This means that new qi and blood can be engendered, since static blood hinders the engenderment of
new blood and blood is the mother of the *qi*.

6. Moving is a so-called attacking therapy in Chinese medicine. Attacking implies potentially damaging the correct or righteous *qi*. In this case, salvia is used because it moves the blood without damaging it.

7. This means that the lungs govern or supply the *qi* for the downbearing of body fluids to the kidneys and bladder for excretion.