



REVIEW

Treatment of Dilated Cardiomyopathy with Qilan Qiangxin Capsule Combined with Sakubatra and Valsartan: A Case Report

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ABSTRACT

A case of dilated cardiomyopathy was reported, including the course of onset and long-term application of Qilan Qiangxin Capsule combined with a new anti-heart failure drug, Sakubatril Valsartan, in order to improve the symptoms of heart failure, increase the LVEF (left ventricular ejection fraction), and reduce the plasma NT-proBNP (N-terminal B-type natriuretic peptide) level. The effect of improving ventricular remodeling is obvious, and the quality of life of patients is improved.

1. Introduction

Dilated cardiomyopathy (DCM) is a primary cardiomyopathy of unknown cause. The disease is characterized by enlargement of left or right ventricles or bilateral ventricles, accompanied by decreased ventricular systolic function, and congestive heart failure. The incidence of the disease is relatively common, with the incidence of 13-84/100,000 in China. The disease

is progressively aggravated, and death can occur at any stage of the disease. At present, comprehensive treatment including beta-receptor antagonist, angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor antagonist (ARB) is mainly used to slow down ventricular remodeling and further myocardial damage and delay the development of lesions^[1]. However, some patients still have poor prognosis. Qilu Qiangxin Capsule is a Chinese patent medicine for heart failure based on collateral

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disease theory of traditional Chinese medicine^[2]. This medicine has the merits of benefiting the temperature and yang, promoting blood circulation and dredging collaterals, promoting water and reducing edema. It has a good curative effect for patients with heart failure syndrome which belongs to deficiency of yang-qi and stagnation of collaterals and blood stasis. Sakubatril valsartan is the first angiotensin receptor enkephalin inhibitor, which can improve cardiac systolic and diastolic function, better reverse ventricular remodeling and improve left ventricular ejection fraction (LVEF)^[3]. This patient was treated with Qilu Qiangxin Capsule combined with Sakubatra and Valsartan. The curative effect is good. The report is as follows.

2. Summary of Medical Records

The patient, a 22-year-old woman, was hospitalized on February 01, 2018. Complaint: Paroxysmal shortness of breath, edema of both lower limbs for 1 month, aggravation with cough and sputum for 1 week. History: Before January, the patient began to suffer from shortness of breath during night supine rest, reduced shortness of breath in high pillow or sitting position, affecting sleep, concomitant depressed edema of lower limbs, no fever, chills, dizziness, headache, abdominal pain, abdominal distension and other symptoms. Then he went to the local hospital to see a doctor and improve the relevant examinations. B-type brain natriuretic peptide showed 1646 pg/ml, electrocardiogram showed myocardial ischemia, echocardiography showed abnormal segmental motion of left ventricular wall and bilateral enlargement. Considering heart failure, Digoxin was given, spironolactone diuretic was given, beta-blocker inhibited sympathetic excitation, and Benazepril reversed heart function. Symptomatic supportive treatment such as ventricular remodeling is ineffective. 1 weeks ago, the patient developed sudden shortness of breath, aggravated breathing, difficulty breathing, especially slight movement and supine position, with cough, expectoration, white foam sputum, and fatigue when resting. Then he came to the First Affiliated Hospital of Shaanxi University of traditional Chinese medicine. Mild reflux, a small amount of pericardial effusion (left ventricular end-diastolic diameter: 57 mm, left atrial anteroposterior diameter: 55 mm, right ventricular anteroposterior diameter: 27 mm, right atrial transverse diameter: 54 mm, EF: 30%). The outpatient clinic was admitted to the hospital with "Class IV Cardiac Function of Dilated Cardiomyopathy". Admission symptoms: shortness of breath, dyspnea, limited lying time, cough, sputum, fatigue, no fever, no nausea and vomiting, poor appetite, bad night rest, no abnormal stool and urine.

Physical examination: body temperature 36.4, pulse 103 times per minute, breathing 24 times per minute, blood pressure 124/84 mmHg, young women, clear mind, poor mental state, cyanosis of lips, jugular vein enlargement, chest symmetry and no deformity, bilateral respiratory mobility consistent, bilateral pulmonary percussion was voiced, bilateral pulmonary respiratory sounds were thick, bilateral lung floor was covered with moist rales, no protuberance in the anterior heart region, Apical enlargement, heart rate 103 beats/min, rhythm, blunt heart sounds, diastolic galloping rhythm can be heard in mitral stethoscope, systolic murmurs of grade 2/6 can be heard in apex, and pathological murmurs cannot be heard in remaining valves stethoscope. The lower extremities were moderately depressed edema with obvious edema on both feet. The tongue is pale, the fur is white and greasy, and the pulse is fine. Auxiliary examination: ECG: sinus rhythm ventricular rate 110 times per minute myocardial ischemia; B-type brain natriuretic peptide (BNP) 2249pg/ml, NT-proBNP 614pg/ml; myocardial enzymes, blood routine, urine routine, fecal routine, liver function, kidney function, electrolyte, blood lipid, fasting blood sugar were not significantly abnormal. Chest X-ray: The texture of both lungs became thicker. Heart shadow enlarged to both sides, which accorded with cardiomyopathy. Western medicine diagnosis: dilated cardiomyopathy heart function IV; Chinese medicine diagnosis: chest arthralgia (Qi deficiency, blood stasis and water obstruction syndrome). After hospitalization, western medicine was given oxygen inhalation, the mixture of sodium nitroprusside 50 mg and 50 ml 5% glucose injection was injected by light-avoiding micro-pump to reduce the pre-and post-cardiac load, metoprolol succinate sustained-release tablets 23.75 mg once a day inhibited sympathetic nerve, furosemide tablets 20 mg once a day, spironolactone 20 mg once a day diuretic to reduce the pre-cardiac load, and Shakuba. Trivalsartan sodium tablets 50 mg twice a day corrected heart failure and inhibited ventricular remodeling. Coenzyme Q10 capsules 20 mg 3 times a day, trimetazidine hydrochloride tablets 20 mg 3 times a day, isosorbide mononitrate sustained-release capsules 50 mg once a day, intravenous infusion of levocarnitine 6 g and 250 ml 0.9% sodium chloride mixed solution nourished myocardium, protected heart, and properly supplemented potassium vitamin. Keep electrolyte balance. The mixture of 60 ml Shenmai injection and 100 ml 5% glucose injection was given intravenously and three capsules of Qilanqiangxin capsule were taken orally three times a day. On the 6th day after admission, shortness of breath, dyspnea, cough and phlegm were relieved obviously. The patient could lie on his back and rest. Blood pressure was 112/76 mmHg,

heart rate was 83 beats/min, jugular vein was not full, and edema of both lower limbs was obviously relieved. On the 14th day after admission, the patient had no shortness of breath, dyspnea, cough and sputum, and his fatigue was significantly alleviated. He took cocoa, had nighttime rest and had no abnormal stool and urine. Blood pressure 110/78 mmHg, heart rate 77 times/min, lip no cyanosis, jugular vein no filling, bilateral lung percussion was clear, bilateral lung breathing sounds clear, no moist rales, apex can be heard 2/6 systolic murmur, bilateral lower limbs, bilateral feet no edema, pale tongue, thin white coating, fine pulse. The NT-proBNP403.05 pg/ml was reexamined. The electrocardiogram showed that the T-wave of low level had risen, suggesting that heart failure had been corrected. Sakubatroxol valsartan sodium tablets were adjusted to 100 mg twice a day, and metoprolol succinate sustained-release tablets were increased to 47.5 mg once a day. The patient was diagnosed clearly and his symptoms improved. He was ordered to discharge. After discharge, he was given oral drugs: coenzyme Q1020 mg 3 times a day, trimetazidine hydrochloride tablets 20 mg 3 times a day, metoprolol succinate 47.5 mg 1 time a day, spironolactone tablets 20 mg 1 time a day, furosemide tablets 20 mg 1 time a day, sakubatrovalsartan 100 mg 2 times a day, Qiqiangxin capsules 3 times a day./ Day.

On March 05, 2018, the patient's first visit showed no obvious shortness of breath, difficulty in breathing, lying on his back at night, no restrictions on daily activities, no cough, sputum, general fatigue, no edema of lower limbs, dim tongue, thin white coating, fine pulse, 110/72 mmHg of blood pressure, 68 beats/min of heart rate. Chest X-ray reexamination showed that the heart shadow was larger (smaller than before), which was consistent with the manifestation of dilated heart disease. Color Doppler echocardiography showed that left ventricular diastolic function was normal, systolic function was reduced by 39%, mitral regurgitation was moderate, tricuspid regurgitation was mild. Compared with the admission date on February 01, 2018, the patient had no obvious symptoms of heart failure, grade II of heart function, decreased heart function, increased left ventricular ejection fraction, blood pressure and heart rate, increased metoprolol succinate to 95 mg once a day, valsartan to 200 mg twice a day, continued to take Qiqiangxin capsule 3 times a day, the rest. The medicine remains unchanged.

On June 25, 2018, the patient's third visit showed stable symptoms, no shortness of breath, no edema of lower limbs, dim tongue, thin white fur, fine pulse, 114/70 mmHg of blood pressure and 74 beats/min of heart rate. Color Doppler echocardiography showed changes in myocardial involvement, left ventricular enlargement

with minor mitral regurgitation, left ventricular systolic function decreased by LVEF45%, coronary sinus widened (persistent left superior chamber may be). ECG showed improvement of myocardial ischemia and discontinuation of trimetazidine hydrochloride. Re-examination of NT-proBNP334.04 pg/ml showed that metoprolol succinate had been increased to 190 mg once a day and sakubatrovalsartan to 200 mg twice a day, which had reached the maximum dose tolerated by patients. The patients' liver function, kidney function, blood potassium, blood pressure and heart rate were monitored regularly. Qiqiangxin capsules were still taken orally three times a day, while the rest drugs remained unchanged.

On January 08, 2019, the fifth visit of the patient showed no obvious shortness of breath, edema of both lower limbs, pale red tongue, thin white fur and fine pulse. Blood pressure 116/76 mmHg, heart rate 72 times/min. Color Doppler echocardiography showed that left ventricle enlarged, left ventricular anterior septum and anterior wall motion decreased, left ventricular wall motion was uncoordinated, left superior chamber persisted, tricuspid regurgitation was mild (left ventricular end-diastolic diameter: 56 mm, left atrial anterior and posterior diameter: 36 mm, right ventricular anterior and posterior diameter: 21 mm, right atrial transverse diameter: 37 mm, EF: 51%). NT-proBNP 74pg/ml was reexamined. Up to now, the patient's condition has been stable. Continue to observe and adjust the medication.

3. Discussion

Dilated cardiomyopathy has no specific name in traditional Chinese medicine. According to its clinical manifestations, it can be classified as "chest pain", "edema", "palpitation", "asthma syndrome" and "heart distention". The disease is mostly seen in young and middle-aged people, and its location is in the heart. It often involves the lungs, spleen, liver, kidney and other organs^[4]. Due to the lack of innate endowment, acquired loss of nutrition, chronic illness, deficiency of Yang Qi, unstable external defense, warm heat and toxic pathogens, heart sinking, heart-Yin depletion, and eventually a series of symptoms of heart loss and nourishment. The main pathogenesis is the mixture of deficiency and excess, deficiency of yang-qi as the basis, phlegm and drink, blood stasis, water and dampness as the criteria. According to the different stages and clinical manifestations of the disease, the disease can be divided into three stages^[5]: in the early stage, the deficiency of cardiopulmonary Qi is dominant, phlegm and blood stasis is relatively light, mainly manifested as panic, shortness of breath and fatigue; in the middle stage, the deficiency of heart and kidney yang can cause palpitation fatigue,

fear of cold limbs, edema and other symptoms; in the late stage, the deficiency of yin and Yang is dominant, and the patients appear mental fatigue, dyspnea, palpitation, and depression of Now. The disease is based on deficiency and excess, and is treated according to syndrome differentiation of qi, blood and body fluid. Clinically, they are divided into Qi deficiency and blood stasis type, Qi deficiency and Yin deficiency and blood stasis type, Qi deficiency and blood stasis and water stasis type, Yang deficiency and blood stasis and water stasis type, etc^[6]. According to the symptoms and signs of the patients, the patients are mostly due to Pingyu deficiency, combined with inappropriate regulation and nourishment, insufficient Yang Qi in the heart, heart loss, poor blood circulation, obstruction of the heart vein, stasis and water stoppage, and chest obstruction, which is suitable for warming yang and invigorating qi, activating blood circulation and dredging collaterals, and reducing edema. Qilu Qiangxin Capsule is the first Chinese patent medicine to treat chronic heart failure established under the guidance of collateral disease theory in China^[7]. The theory of TCM venation explores the pathogenesis of chronic heart failure from the aspects of qi, blood and water. Qi, blood and water cemented each other, blood stasis can not only directly block the veins, leading to obstacles in water circulation, but also block the movement of Yingwei Qi, aggravating the dysfunction of Yingwei Qi; water pathological changes also block Yingwei Qi, causing abnormal blood flow and blood stasis; Qi, blood and water are mutually harmful, forming a vicious pathological cycle, and eventually leading to the accumulation of heart collaterals. This is consistent with the long-term over-activation of neuroendocrine system in Western medicine, which directly damages the heart and blood vessels, leads to myocardial hypertrophy and deterioration of cardiac function, and aggravates the activation of neuroendocrine system, thus forming a vicious cycle process^[8]. Aiming at the pathogenic characteristics of chronic heart failure such as deficiency of Qi and yang, stagnation of collateral stasis and accumulation of collateral interest, this paper puts forward the treatment principle of “treating qi, blood and water together, dividing and dispelling” guided by the theory of collaterals, and determines the treatment method of “benefiting temperature and yang, promoting blood circulation and dredging collaterals, promoting edema and eliminating edema”. On this basis, an innovative prescription of Qilu Qiangxin Capsule is developed. It mainly consists of safflower, Salvia miltiorrhiza, Astragalus membranaceus, cinnamon twig, ginseng, Alisma orientalis, aconite, incense peel, orange peel, Yuzhu and amaranth. Among them, Astragalus membranaceus and aconite are the monarch drugs. Astragalus

membranaceus is beneficial to Qi deficiency and Yang deficiency, and it is also beneficial to water and swelling^[9]. It is especially suitable for those who are weak in Qi and Yang and have more than weak in sweat. Ginseng, Salvia Miltiorrhiza, Amaranthus Chinensis, Ginseng Dabu Yuanqi, Heart and Lung Tongjing Huoxue, Ginseng participates in the combination of astragalus, Astragalus partially supplements Wei Qi, Ginseng is the main tonifying Qi and Yang, Gubiao Zhituo Gong^[10]; Salvia Miltiorrhiza Huoxue Huayu; Amaranthus Chinensis purging lung and circulating water, three drugs Qi, blood and water are used as courtier drugs. The adjuvant medicine safflower activates blood circulation and dissipates blood stasis, orange peel regulates Qi and dampness, Alisma orientalis and incense plus peel slightly permeate water, and Yuzhu nourishes Yin to maintain healthy qi. It warms up the Yang and turns the gas into the air of Cinnamomum cassia twig. All medicines are used to treat dilated cardiomyopathy by warming Yang Qi, activating blood circulation and promoting blood circulation, promoting water retention and detumescence. Modern pharmacology believes that Salvia miltiorrhiza can dilate coronary artery and increase coronary artery blood flow^[11]; ginseng can dilate blood vessels, enhance myocardial contractility, cardiac output and anti-ischemic ability of myocardium will also be enhanced; purslane can reduce phlebitis and reduce cardiac load^[12]; Astragalus can reduce renin and angiotensin in patients, reverse ventricular remodeling, and reduce oxygen self-regulation. The damage of cardiac myocytes by radicals increases their oxygen tolerance^[13]. Therefore, Qilu Qiangxin Capsule can improve the cardiac function of patients with chronic heart failure and prevent chronic heart failure, which is closely related to its effects of enhancing myocardial contractility, diuresis, inhibiting the over-activation of neuroendocrine system such as RASS, inhibiting inflammation, myocardial fibrosis, apoptosis and autophagy, improving myocardial energy metabolism, promoting angiogenesis and improving endothelial function^[14]. Other studies have shown that Qilu Qiangxin Capsule does not cause electrolyte disturbance, but can reduce the occurrence of arrhythmia without significant impact on liver function, renal function and myocardial enzymes^[15]. It is also the only recommended Chinese patent medicine in China’s guidelines for the diagnosis and treatment of heart failure. This case was treated with western medicine and Qilu Qiangxin Capsule. It can warm yang and invigorate qi, activate blood circulation and dredge collaterals, relieve edema, treat both symptoms and symptoms, and has a good effect.

At present, there is no specific treatment for dilated cardiomyopathy in Western medicine. Early drug interven-

tion is still the basic treatment of dilated cardiomyopathy, including the use of ACEI or ARB, beta blockers, aldosterone receptor antagonists, diuretics, vasoactive drugs and other drugs^[16]. The main purpose is to slow down ventricular remodeling and further myocardial damage and delay the development of lesions. ACEI or ARB, beta-blocker and aldosterone receptor antagonist are called “golden triangle” drugs for heart failure. They should be used as early as possible without contraindication. Starting from small dosage, the dosage should be gradually increased to reach the maximum dose that different patients can tolerate. However, in the actual use process, most patients are difficult to reach due to various adverse reactions. At the target dose, the 5-year mortality rate is still over 50%^[17]. In recent years, new angiotensin receptor enkephalin inhibitors (ARNI) have emerged, forming a “new golden triangle” based on ARNI with beta blockers and aldosterone receptor antagonists. Sakubastral valsartan is the first angiotensin receptor brain natriuretic peptide inhibitor in the world, and has the drug properties of Sakubastral and Valsartan^[18]. Damage of cardiac myocytes in patients with heart failure causes changes in size, shape and function of cardiac myocytes, resulting in overactivation of RASS and sympathetic nervous system, ventricular remodeling and hemodynamic changes. While RASS and sympathetic nervous system are activated, natriuretic peptide system is also activated. Natriuretic peptide has the functions of dilating blood vessels, lowering blood pressure, lowering sympathetic nerve activity, lowering vasopressin, reducing aldosterone, and inhibiting ventricular remodeling^[19]. Natriuretic peptide metabolism is mainly through two processes: self-receptor mediated scavenging and enkephalin degradation. Sakubastral is a precursor drug, which is metabolized into a kind of active NEPI (neutral endopeptidase inhibitor) in vivo. It can inhibit enkephalin, enhance the effects of natriuretic peptide, bradykinin, adrenomedullin, angiotensin I / II and other vasoactive activities. However, the emergence of NEPI also increased the concentration of angiotensin I, II and endothelin-1, which counteracted each other. Therefore, the use of enkephalin inhibitors alone had little effect on heart failure and offset its potential benefits. To inhibit enkephalin, RASS must be blocked in order to avoid the elevation of angiotensin I, II and endothelin-1. Valsartan is the AT1 R blocker, which can block the RASS system. Therefore, ARNI has dual effects of ARB and NEPI, which can inhibit both RASS and natriuretic peptide system, and inhibit ventricular remodeling^[20]. In addition, PARADIGM-HF results showed that compared with the traditional golden triangle drug ACEI, sakubastrol could reduce the risk of cardiovascular death, hospitalization risk of heart failure and all-

cause death risk. It can also improve the common daily activity limitation of patients with heart failure and almost all physical and social activity items in the total score of the Kansas Cardiomyopathy Questionnaire (KCCQ). The greatest improvement is in sexual relations. At the same time, the adverse reactions such as renal function damage, hyperkalemia and cough in the Sakubastrol and Valsartan group were less^[21]. This study provides high-level evidence-based support for ARNI’s position in the guidelines. The new edition of heart failure guidelines in Europe and the United States strongly recommended ARNI for the treatment of patients with symptomatic decreased ejection fraction. The latest guidelines for diagnosis and treatment of heart failure in China also recommend that ARNI should be used instead of ACEI/ARB in order to further reduce the incidence and mortality of heart failure if NYHA has symptomatic Ejection Fraction (Ejection Fraction) decline and can tolerate ACEI/ARB.

The initial treatment of this patient was based on the traditional “golden triangle” drug of ACEI or ARB, beta-blocker and aldosterone receptor antagonist, and the effect was not good. According to the guideline of medication for heart failure, ARNI was used as the cornerstone and the new “golden triangle” drug of beta blocker and aldosterone receptor antagonist was added. Combining with Qi’an Qiangxin Capsule, the curative effect was very good.

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