A Case Study of Heart Failure Resulting from Dilated Cardiomyopathy Treated with Sacubitril Valsartan Sodium Tablets in Combination with Qiliqiangxin Capsules

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Abstract This article presents a case study of a 20-year-old male patient diagnosed with dilated cardiomyopathy (DCM) (NYHA IV). This condition was diagnosed as "heart failure disease" (water overflowing due to yang deficiency, intermingled phlegm and stasis) in traditional Chinese medicine (TCM). The treatment approach employed a combination of TCM and Western medicine. Western medicine involved the administration of sacubitril valsartan sodium tablets to inhibit ventricular remodeling, in conjunction with diuretics and cardiotonic agents. Initially, TCM utilized a static infusion of Shenfu injection, which was subsequently supplemented with Qiliqiangxin capsules to invigorate qi, warm yang, activate blood circulation, and promote diuresis. After a follow-up period of 3 years, the patient's ejection fraction (EF) improved from 23% to 51%, and the left ventricular end diastolic diameter (LVed) decreased from 68 to 52 mm, accompanied by a significant alleviation of symptoms. These findings indicate that the combined treatment of TCM and Western medicine can synergistically enhance cardiac function and impede the progression of the disease, thereby offering valuable insights for the optimal management of DCM.

Key words Dilated cardiomyopathy (DCM), Heart failure, Sacubitril valsartan sodium tablets, Qiliqiangxin capsules, Chest tightness, Shortness of breath

1 Introduction

Dilated cardiomyopathy (DCM) is a heterogeneous condition characterized by the dilation of the left ventricle or both ventricles, accompanied by a reduction in systolic function. The diagnostic process must exclude secondary factors, including valvular heart disease, congenital heart defects, hypertensive heart disease, and ischemic heart disease, irrespective of the presence of congestive heart failure. The disease typically exhibits a progressive course, with a risk of mortality present at all stages. The precise etiology of the disease remains incompletely understood, but it is currently believed to be associated with infections, genetic factors, autoimmune mechanisms, and cellular immune responses. Common complications include heart failure and cardiac arrhythmias, and the disease may culminate in multi-organ failure in advanced stages.

At present, there exists a range of clinical treatments for DCM, which primarily encompass pharmacological and surgical interventions. Pharmacological treatments predominantly involve the administration of positive inotropic agents, beta-receptor antagonists, and vasodilators. In contrast, surgical approaches include cardiac pacing, surgical ventricular restoration, cardiac transplantation, and cardiac resynchronization therapy. Pharmacotherapy serves as a primary intervention that can effectively suppress arrhythmias, enhance myocardial metabolism, and manage or diminish the incidence of cardiovascular adverse events, including heart failure, thereby contributing to an improved quality of life and better prognostic outcomes for patients. Sacubitril valsartan sodium tablets represent a novel pharmacological intervention for heart failure. This combination medication comprises sacubitril, an enkephalinase inhibitor, and valsartan, an angiotensin receptor antagonist. It is regarded as a critical therapeutic option for the management of DCM, as it functions to decrease endogenous vasoactive peptides, thereby offering cardiovascular protection[1].

The primary symptoms exhibited by the patient included chest tightness, shortness of breath, and edema in both lower extremities, which are classified as manifestations of "heart failure" according to traditional Chinese medicine (TCM). *Miraculous Pivot* informs that "when the heart is distended, symptoms such as shortness of breath, distress, and restlessness while in bed may occur," which aligns with the symptoms presented by the patient. Based on extensive clinical experience and research studies, Associate Professor Xu Li posits that the disease is primarily characterized by a deficiency at its origin and an excess at the superficial level. The disease is localized in the heart and is associated with the lungs, spleen, and kidneys. The deficiency at the origin is fundamentally attributed to the insufficiency of the heart and lungs, specifically heart yang deficiency and a lack of kidney yang. The excess at the superficial level is characterized by the presence of intermingled phlegm and stagnation, as well as an excess of water-dampness. *Yizong Bidu* (*Required Readings for Medical Professionals*) states: "Although water is regulated by the spleen, it is actually controlled by the kidneys. The kidneys are fundamentally associated with water, and the primordial yang is contained within them. A decline in the fire from the gate of life not only fails to generate yin cold but also does not provide warmth to the spleen-earth. Consequently, yin is unable to follow yang, leading to the transformation of essence into water; thus, edema syndromes are primarily attributed to the decline of fire." The heart's yang is deficient, resulting in weak pulsations and subse-

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quent chest tightness. When the lung qi is inadequate, the lung is unable to receive qi, leading to shortness of breath. A harmonious relationship between the heart and kidney, along with sufficient heart yang, contributes to a vigorous ministerial fire. Conversely, when heart yang is deficient, kidney yang is also weakened, disrupting the regulation of kidney qi and consequently resulting in edema in both lower extremities. Consequently, the treatment should aim to tonify qi and warm yang, promote blood circulation and eliminate blood stasis, and induce diuresis to alleviate edema. Clinically, Qiliqiangxin capsules, which contain Astragali Radix, Radix Ginseng, Radix Aconiti Lateralis Preparata, Radix Salviae Miltiorrhizae, Semen Lepidii, Alismatis Rhizoma, Rhizoma Polygonati Odorati, Cinnamomi Ramulus, Carthami Flos, Cortex Periplocae, and Citri Reticulatae Pericarpium, are frequently utilized for symptomatic treatment.

2 Medical history information

2.1 General information The patient, Gan, was a 20-year-old male from Bijie City, Guizhou Province. The initial diagnosis was made on November 21, 2019, and the onset of the disease occurred prior to the Minor Snow event.

2.2 Medical history More than 3 months ago, the patient reported experiencing chest tightness and shortness of breath following exposure to rain after the consumption of alcohol. These symptoms became more pronounced with physical exertion and progressively deteriorated over time. Accompanying symptoms included cough, expectoration, and pitting edema in both lower extremities. Notably, the patient did not report any occurrences of palpitations, chest pain, chest tightness, dryness, chills, fever, dyspnea, orthopnea at night, nausea, vomiting, abdominal pain, or diarrhea. The patient was admitted to Guizhou Provincial People's Hospital, where he received a diagnosis of DCM. Following appropriate treatment, the patient was subsequently discharged from the hospital (specific details regarding the treatment administered remain unknown). Following multiple episodes of post-fatigue and a progressive decrease in activity tolerance, the patient sought medical attention at Chongqing Xinqiao Hospital, Bijie People's Hospital, and Fuwai Hospital of the Chinese Academy of Medical Sciences. The patient received a consistent diagnosis across these institutions and was subsequently discharged after undergoing relevant treatments (specific details regarding the diagnostic and therapeutic interventions remain unknown). Two days ago, the patient exhibited symptoms including chest tightness, shortness of breath, and unexplained fatigue, which were exacerbated by physical activity. Additionally, the patient reported occasional palpitations and pitting edema in both lower extremities. There were no indications of headache, periorbital ecchymosis, visual disturbances such as halos or rotational impairment, impaired intention, chest pain, nausea, vomiting, or other associated symptoms. Later, the patient presented to the outpatient department of Guizhou University of Traditional Chinese Medicine for a comprehensive diagnosis and treatment plan that integrates both traditional Chinese and Western medical practices. The outpatient department admitted the patient for the management of DCM.

2.3 Specific symptoms At the time of his consultation with the physician, the patient reported experiencing chest tightness and shortness of breath, which exacerbated following physical activity. He also noted intermittent palpitations, accompanied by upper abdominal discomfort, occasional coughing, and the expectoration of a small quantity of yellow, viscous phlegm. Additionally, he presented with pitting edema of bilateral lower extremity. However, he denied experiencing headaches, transient blackouts or syncope, any loss of consciousness, chest pain, radiating pain in the shoulders and back, as well as nausea or vomiting. Upon experiencing illness, the patient reported increased fatigue and a diminished urinary output, approximately 20 mL per void. Additionally, the patient experienced a cessation of bowel movements for 2 d. There was no significant past medical history, personal history, allergy history, or family history noted.

3 Auxiliary examination

A plain scan and enhanced cardiac MRI performed at Chongqing Xinqiao Hospital on September 5, 2019 revealed an enlarged heart, suggestive of possible DCM. Additionally, findings included prolapse of the anterior mitral valve accompanied by mitral regurgitation, as well as pericardial effusion and bilateral pleural effusion. Following admission, the electrocardiogram revealed a sinus rhythm with a heart rate of 105 beats/min, a normal axis, and significant ST-segment changes, which should be interpreted in conjunction with clinical findings. Cardiopulmonary pentad results indicated a BNP level of 2 380 pg/mL and a DDIM level of 675 ng/mL, and comprehensive echocardiogram revealed an ejection fraction (EF) of 23%.

4 Diagnosis and diagnostic basis of TCM and Western Medicine

4.1 Diagnosis of TCM The primary clinical manifestations observed in the patient included chest tightness and shortness of breath, which are consistent with the diagnosis of heart failure. The patient was a young male with a preference for greasy foods, which can adversely affect the spleen and stomach. These organs are critical for the proper ascending and descending of qi throughout the body. The spleen plays a vital role in the transportation and transformation of nutrients derived from food, and in the processes of ascending and clearing. When spleen qi is deficient, its ability to transport and transform becomes impaired. This dysfunction can lead to the accumulation of water and fluids in the middle energizer, resulting in the formation of phlegm. The phlegm may become turbid, obstructing the lungs. Consequently, the lung qi is unable to disperse and descend appropriately, lead-

ing to an upward rise of lung qi, which manifests as coughing and expectoration. The presence of phlegm and turbidity obstructs the flow of qi, resulting in impaired blood circulation and the occurrence of blood stasis. The interplay between phlegm and blood stasis can lead to the obstruction of the heart's vessels, consequently resulting in symptoms such as chest tightness, shortness of breath, and palpitations. The accumulation of water and fluids in the middle energizer leads to the formation of phlegm. This condition is associated with dysfunction in the transportation and transformation functions of the spleen and stomach. Consequently, the ascent of stomach qi obstructs the movement of qi, resulting in pain due to this obstruction, which manifests as discomfort in the upper abdomen. The accumulation of phlegm and turbidity in both lower extremities results in the obstruction of local meridians. This condition disrupts the normal metabolism of bodily fluids and impairs the circulation of qi and blood, ultimately resulting in edema in the lower extremities. The lungs are responsible for regulating the joints and overseeing all meridians, while the heart also plays a crucial role in governing the meridians. When there is a deficiency in the qi of both the heart and lungs, and the movement of qi is impeded, this can result in the internal development of blood stasis. Consequently, this interplay between phlegm and blood stasis may manifest as a dark purple tongue accompanied by a white and greasy coating. A thready and rapid pulse suggests a deficiency of heart yang and the outward invasion of deficient yang. This condition is primarily associated with the heart and is interconnected with the lungs, spleen, and kidneys. It represents a syndrome characterized by a deficiency in origin and an excess at the superficial level. The deficiency in origin pertains to the insufficiency of the heart and lungs, and a lack of heart yang, whereas the excess at the superficial level is attributed to the mutual accumulation of phlegm and blood stasis.

4.2 Diagnosis of Western medicine The condition was diagnosed as DCM (NYHA IV). A plain scan and enhanced cardiac MRI performed at Chongqing Xinqiao Hospital on September 5, 2019 revealed an enlarged heart, suggestive of possible DCM. At that moment, the patient exhibited symptoms of chest tightness, shortness of breath, palpitations, and edema in both lower extremities, with a BNP level of 2 380 pg/mL. These findings, in conjunction with the results of echocardiogram, fulfill the diagnostic criteria for DCM.

5 Intervention measures

The patient presented for an initial consultation on November 21, 2019, reporting symptoms of chest tightness and shortness of breath that exacerbated with physical activity. Additionally, the patient experienced intermittent palpitations, pitting edema of bilateral lower extremity, a dark purple tongue with a white, greasy coating, and a thready, rapid pulse. The diagnosis indicated the presence of heart failure, classified as a type of water overflowing resulting from yang deficiency. In light of the patient's critical condition, the administration of TCM via oral routes was temporarily contraindicated. Instead, Shenfu injection was administered intravenously to invigorate qi and warm yang. Western medicine offered various therapeutic interventions aimed at enhancing cardiac function, promoting diuresis, and alleviating cardiac workload. These interventions included the oral administration of furosemide tablets, spironolactone tablets, tolvaptan tablets, hydrochlorothiazide tablets, and torasemide tablets. Additionally, intravenous administration of furosemide injection, in conjunction with dopamine hydrochloride injection and torasemide via an intravenous pump, was utilized to facilitate diuresis and decrease cardiac load. It is essential to adjust the dosage of these medications in a timely manner based on the patient's clinical condition throughout the treatment process. Metoprolol succinate sustained-release tablets were administered orally to regulate the ventricular rate. Digoxin tablets were also given orally to enhance cardiac function. Additionally, lyophilized recombinant human brain natriuretic peptide was administered intravenously to improve glomerular filtration rate, promote diuresis and sodium excretion, and alleviate cardiac workload. The oral administration of sacubitril valsartan sodium tablets effectively inhibited ventricular remodeling and reduced cardiac load. The patient received diuretic therapy; consequently, potassium chloride sustained-release tablets were administered orally for prophylactic potassium supplementation. Additionally, ivabradine hydrochloride tablets were prescribed orally to stabilize the ventricular rate, decrease myocardial oxygen consumption, and further inhibit ventricular remodeling. The intravenous administration of dexamethasone sodium phosphate was utilized for its anti-inflammatory properties to enhance the body's immune response. Following discharge, patients were scheduled for regular follow-up appointments at the outpatient department to facilitate medication adjustments.

The patient attended a follow-up appointment on March 17, 2020, during which he reported experiencing occasional chest tightness and shortness of breath, particularly following physical activity. Notably, the frequency of palpitations had significantly decreased than before, and mild edema was observed in both lower extremities. A comprehensive echocardiogram revealed an EF of 34% and a left ventricular end diastolic (LVed) of 68 mm. The detection findings indicated left ventricular enlargement, mild mitral regurgitation, and a reduction in both left ventricular systolic and diastolic function. Additionally, there was a general observation of slightly diminished left ventricular wall motion at rest. The patient's condition had shown significant improvement in comparison to the previous assessment. However, it is important to note that the patient continued to exhibit symptoms of heart failure, including chest tightness, shortness of breath, and palpitations. Consequently, the diagnosis was determined as a syndrome of heart failure characterized by deficient and weak yang qi. 1.2 g of Qiliqiangxin capsules was administered orally three times daily to

enhance qi and warm yang, facilitate blood circulation to alleviate meridian obstruction, and promote diuresis while reducing edema.

The patient attended a follow-up appointment on June 30, 2020, during which he reported experiencing occasional chest tightness, particularly noticeable following physical activity. The patient also noted a decreased tolerance for activity, mild shortness of breath, and denied any significant palpitations or edema in both lower extremities. A comprehensive echocardiogram revealed an EF of 32% and an LVed of 70 mm. The detection results revealed left ventricular enlargement, mild to moderate mitral regurgitation, mild tricuspid regurgitation, diminished left ventricular systolic and diastolic function, and a reduced motion amplitude of ventricular wall at rest. Administration of sacubitril valsartan sodium tablets, in conjunction with the oral administration of Qiliqiangxin capsules, was utilized to enhance the symptoms of heart failure and inhibit ventricular remodeling.

On May 11, 2021, the patient attended a follow-up appointment. The patient reported a significant improvement in chest tightness and shortness of breath compared to previous assessments, although occasional palpitations were still experienced. There was no evidence of edema in either lower extremity. The comprehensive echocardiogram revealed an EF of 43% and an LVed of 58 mm. The detection results indicated left ventricular enlargement, moderate mitral regurgitation, mild tricuspid regurgitation, and a reduction in both left ventricular systolic and diastolic function. Additionally, there was a generalized decrease in the motion amplitude of left ventricular wall at rest. Consequently, it was recommended to maintain the existing medication regimen.

The follow-up visit of the patient on October 12, 2021 revealed the absence of chest tightness or shortness of breath, no edema in either lower extremity, and no limitations in daily activities. The comprehensive echocardiogram indicated an EF of 50% and an LVed of 55 mm. The detection results revealed left ventricular enlargement, mild to moderate mitral regurgitation, mild tricuspid regurgitation, and a reduction in both left ventricular systolic and diastolic function. Additionally, there was a generalized slight decrease in the motion amplitude of the interventricular septum at rest.

During the follow-up visit on July 5, 2022, the comprehensive echocardiogram revealed an EF of 53.5%. The findings indicated a slightly enlarged left ventricle, mild to moderate mitral regurgitation, mild tricuspid regurgitation, reduced left ventricular diastolic function, and a generalized slight reduction in the motion amplitude of the left ventricular wall at rest.

On May 22, 2023, the patient attended a follow-up appointment, during which he reported the absence of significant chest tightness, shortness of breath, chest pain, palpitations, or any other symptoms. Additionally, there was no evidence of edema in either lower extremity, and the patient did not experience any limitations in daily activities. A comprehensive echocardiogram revealed an EF of 47.2% and an LVed of 53 mm. The diagnostic findings indicated a mildly enlarged left heart, moderate mitral regurgitation, mild tricuspid regurgitation, and diminished left ventricular systolic and diastolic function. Additionally, there was a slight reduction in the motion amplitude of the left ventricular wall at rest.

On February 26, 2024, the patient attended the final follow-up visit, during which he reported the absence of chest tightness, shortness of breath, chest pain, palpitations, and edema in both lower extremities. An echocardiogram indicated an EF of 51% and an LVed of 52 mm. The diagnostic results indicated a slight enlargement of the left ventricle, moderate mitral regurgitation, mild tricuspid regurgitation, and a normal lower limit of left ventricular systolic function. Additionally, there was a slight reduction in the motion amplitude of the ventricular septum at rest.

6 Therapeutic outcome

The patient exhibited no recurrence of chest tightness or shortness of breath, no edema in either lower extremity, and no limitations in daily activities. The echocardiogram indicated an increase in EF from 23% to 51%, and a reduction in LVed from 68 to 52 mm (Fig. 1).

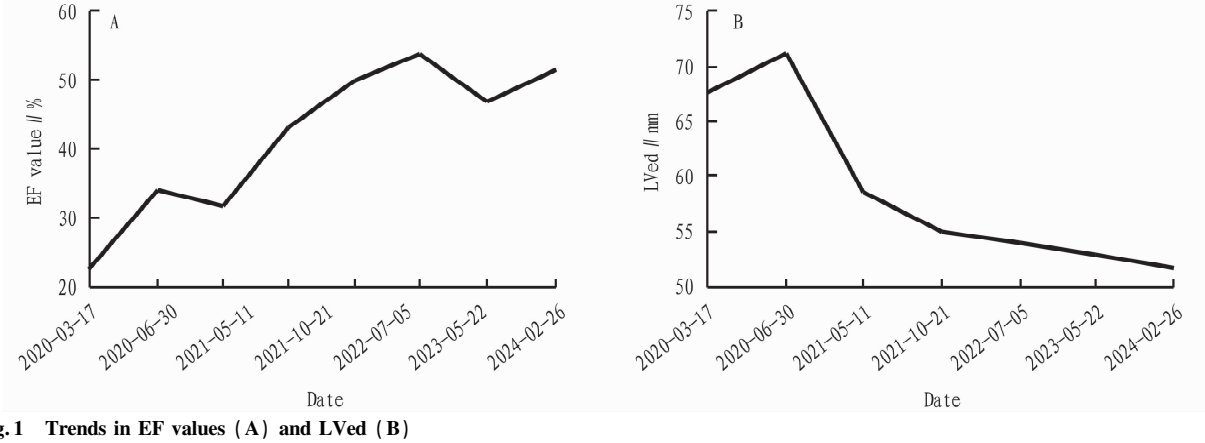

Fig. 1 Trends in EF values (A) and LVed (B)

7 Clinical experience

7.1 Pathologic mechanisms and therapeutic advances in heart failure Heart failure is a multifaceted clinical syndrome characterized by the inability of cardiac output to satisfy the metabolic requirements of the body, resulting from structural or functional abnormalities of the heart. This condition is frequently observed in the advanced stages of various cardiac diseases. The primary pathophysiological mechanisms encompass cardiac dysfunction and an imbalance in neurohumoral regulation. These factors subsequently lead to the congestion of the pulmonary or systemic circulation, resulting in clinical manifestations such as dyspnea and reduced activity tolerance.

Inhibiting the overactivation of the neuroendocrine system and delaying myocardial remodeling represent critical strategies in the management of chronic heart failure. Sacubitril valsartan sodium, classified as a dual angiotensin receptor neprilysin inhibitor (ARNI), functions by concurrently blocking angiotensin receptors and inhibiting the degradation of enkephalinase. This mechanism results in a reduction of sympathetic excitability, antagonism of the rennin angiotensin aldosterone system (RAAS) activation, promotion of vasodilation, and delay of cardiovascular remodeling, ultimately leading to significant improvements in cardiac function[2].

7.2 Clinical advantages of combined TCM and Western medicine treatment Current research indicates that the efficacy of a combined approach utilizing both TCM and Western medicine in the treatment of chronic heart failure is superior to the efficacy of either Western medicine or TCM administered independently. In this instance, Doctor Xu Li diagnosed heart yang deficiency as the underlying cause of the patient's clinical manifestations, which included observations related to the tongue and pulse. Additionally, intermingled phlegm and stagnation were identified as the presenting symptoms. To address these issues, she administered Qiliqiangxin capsules in conjunction with conventional Western medical treatment. The formulation consists of Astragali Radix, Radix Ginseng, Radix Aconiti Lateralis Preparata, Radix Salviae Miltiorrhizae, Semen Lepidii, Alismatis Rhizoma, Rhizoma Polygonati Odorati, Cinnamomi Ramulus, Carthami Flos, Cortex Periplocae, and Citri Reticulatae Pericarpium, with intended functions of enhancing qi, warming yang, activating blood circulation, and resolving phlegm. Radix Ginseng and Astragali Radix are known to nourish vital energy while strengthening the spleen and lungs. Carthami Flos facilitates blood circulation and menstruation, alleviates blood stasis, and mitigates pain. Semen Lepidii is effective in purging the lungs and relieving asthma, and promoting diuresis and reducing swelling. Radix Aconiti Lateralis Preparata is recognized for its ability to restore yang and alleviate adversity, thereby assisting yang and reinforcing the foundational aspects of health.

Recent pharmacological studies have demonstrated that Qiliqiangxin capsules possess the ability to dilate peripheral blood vessels, decrease left ventricular end diastolic pressure, exert diuretic effects, and alleviate myocardial load, thereby delaying the progression of ventricular dysfunction. Furthermore, when administered in conjunction with sacubitril valsartan sodium, patients exhibited significant improvements in clinical symptoms, thereby substantiating the benefits of a synergistic approach that integrates both TCM and Western medical practices[1].

7.3 Treatment strategy of integrating TCM and Western medicine In the *Medical Records of the Three Kingdoms*, Zhang Xichun posits that the application of medicinal treatments is analogous to the deployment of military forces, emphasizing the necessity of comprehending the distinct characteristics of various medicines to facilitate flexible treatment administration. Clinical evidence indicates that the integration of TCM with Western medical practices can create a synergistic effect, thereby mitigating the limitations associated with monotherapy. However, this integrative approach imposes greater demands on the physician's expertise, necessitating a precise understanding of the principles governing both TCM and Western medicine, and the ability to develop individualized treatment plans to optimize clinical outcomes.

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