

World Journal of *Clinical Cases*

World J Clin Cases 2023 September 16; 11(26): 6031-6317



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RESPONSIBLE EDITORS FOR THIS ISSUE

Production Editor: Hua-Ge Yin; Production Department Director: Xu Guo; Editorial Office Director: Jin-Lei Wang.

NAME OF JOURNAL

World Journal of Clinical Cases

ISSN

ISSN 2307-8960 (online)

LAUNCH DATE

April 16, 2013

FREQUENCY

Thrice Monthly

EDITORS-IN-CHIEF

Bao-Gan Peng, Jerzy Tadeusz Chudek, George Kontogeorgos, Maurizio Serati, Ja Hyeon Ku

EDITORIAL BOARD MEMBERS

<https://www.wjgnet.com/2307-8960/editorialboard.htm>

PUBLICATION DATE

September 16, 2023

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INSTRUCTIONS TO AUTHORS

<https://www.wjgnet.com/bpg/gerinfo/204>

GUIDELINES FOR ETHICS DOCUMENTS

<https://www.wjgnet.com/bpg/GerInfo/287>

GUIDELINES FOR NON-NATIVE SPEAKERS OF ENGLISH

<https://www.wjgnet.com/bpg/gerinfo/240>

PUBLICATION ETHICS

<https://www.wjgnet.com/bpg/GerInfo/288>

PUBLICATION MISCONDUCT

<https://www.wjgnet.com/bpg/gerinfo/208>

ARTICLE PROCESSING CHARGE

<https://www.wjgnet.com/bpg/gerinfo/242>

STEPS FOR SUBMITTING MANUSCRIPTS

<https://www.wjgnet.com/bpg/GerInfo/239>

ONLINE SUBMISSION

<https://www.f6publishing.com>



Retrospective Study

Lyophilized recombinant human brain natriuretic peptide for chronic heart failure: Effects on cardiac function and inflammation

Feng Li, Hao Li, Rong Luo, Jia-Bao Pei, Xue-Ying Yu

Specialty type: Cardiac and cardiovascular systems

Provenance and peer review: Unsolicited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's scientific quality classification

Grade A (Excellent): 0
Grade B (Very good): B
Grade C (Good): C
Grade D (Fair): 0
Grade E (Poor): 0

P-Reviewer: Bayraktutan U, United Kingdom; Christiansen EH, Denmark

Received: April 24, 2023

Peer-review started: April 24, 2023

First decision: May 8, 2023

Revised: May 20, 2023

Accepted: August 3, 2023

Article in press: August 3, 2023

Published online: September 16, 2023



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Abstract

BACKGROUND

Chronic heart failure (CHF) is a serious and prevalent condition characterized by impaired cardiac function and inflammation. Standard therapy for CHF has limitations, prompting the exploration of alternative treatments. Recombinant human brain natriuretic peptide (BNP) has emerged as a potential therapy, with evidence suggesting that it can improve cardiac function and reduce inflammation in patients with CHF. However, further research is required to determine the efficacy and safety of lyophilized recombinant human BNP in CHF patients and its impact on microinflammatory status. This study aimed to investigate the effects of lyophilized recombinant human BNP therapy on CHF patients' cardiac function and microinflammatory status.

AIM

To investigate the effects of freeze-dried recombinant human BNP therapy on cardiac function and microinflammatory status in patients with CHF.

METHODS

In total, 102 CHF patients admitted to our hospital from January 2021 to January 2022 were randomly assigned to control and observation groups ($n = 51$ patients/group). The control patients were treated with standard HF therapy for 3 d, whereas the observational patients were injected with the recombinant human BNP for 3 d. Clinical efficacy, inflammatory factor levels, myocardial damage, cardiac function before and after the treatment, and adverse reactions during treatment were compared between the two groups.

RESULTS

The overall clinical efficacy was higher in the observation group than in the control group. Compared with baseline, serum hypersensitive C-reactive protein, N-terminal proBNP, and troponin I level, and physical, emotional, social, and economic scores were lower in both groups after treatment, with greater re-

ductions in levels and scores noted in the observation group than in the control group. The overall incidence of adverse reactions in the observation group was not significantly different compared with that in the control group ($P > 0.05$).

CONCLUSION

Freeze-dried recombinant human BNP therapy can improve heart function and enhance microinflammatory status, thereby improving overall quality of life without any obvious side effects. This therapy is safe and reliable.

Key Words: Chronic heart failure; Lyophilized recombinant human brain natriuretic peptide; Cardiac function; Microinflammatory state

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Core Tip: Lyophilized recombinant human brain natriuretic peptide therapy can improve heart function and reduce microinflammation in patients with chronic heart failure, which signifies its potential as a safe and effective treatment option.

Citation: Li F, Li H, Luo R, Pei JB, Yu XY. Lyophilized recombinant human brain natriuretic peptide for chronic heart failure: Effects on cardiac function and inflammation. *World J Clin Cases* 2023; 11(26): 6066-6072

URL: <https://www.wjgnet.com/2307-8960/full/v11/i26/6066.htm>

DOI: <https://dx.doi.org/10.12998/wjcc.v11.i26.6066>

INTRODUCTION

Chronic heart failure (CHF) is a complex syndrome in cardiovascular medicine. It mostly occurs in middle-aged and older people and often clinically manifests as symptoms such as insufficient tissue perfusion and impaired circulation. Most drugs currently used in clinics are cardiostimulant, diuretic, and vasodilator drugs that can relieve clinical symptoms and achieve some therapeutic effects. However, they are ineffective in the prognosis of patients' recovery. Therefore, more effective treatments are required to improve patient prognosis and increase patient survival rates[1-3]. The lyophilized recombinant human brain natriuretic peptide (BNP) is an exogenous peptide that is widely used in cardiovascular diseases. The main action mechanism of this recombinant BNP is to bind to relevant receptors in the body and regulate the imbalance of the vascular system, improve the heart's pumping capacity, inhibit sympathetic excitability, regulate cardiac hemodynamics, inhibit myocardial remodeling, and improve the symptoms of patients with cardiovascular diseases[4,5]. The present study investigated the effects of lyophilized recombinant cardiovascular drugs. We also determined the clinical effects of the lyophilized recombinant human BNP in CHF patients.

MATERIALS AND METHODS

General data

From January 2021 to 2022, 102 Swiss French patients who had CHF Control group and were Observation group ($n = 51$ patients/group) were enrolled in the present study. The patients were randomly assigned to the control or observation group. The control group included 27 men and 24 women. The mean patient age was 63–80 years (71.42 ± 5.33 years). The length of their disease was 2–16 years (11.03 ± 2.67 years). The disease etiology in the control group was: cardiomyopathy in six patients, valvular and precordial diseases in four, and ischemic myocardial damage in 41. New York Heart Association (NYHA) classification[6]: There were 15 cases of grade IV, 26 cases of grade III and 10 cases of grade II. The observation group included 26 men and 25 women. The mean age of these patients was 65–79 years (71.45 ± 5.28 years). The length of their disease was 3–15 years (11.05 ± 2.70 years). The disease etiology in the observation group was: cardiomyopathy in five, valvular and precordial diseases in five, and ischemic myocardial damage in 41. According to the NYHA classification, 17 patients had grade IV HF, 23 patients had grade III HF, and 11 patients had grade II HF. No significant difference was observed between the two groups ($P < 0.05$). This study was approved by the hospital's medical ethics committee, and all patients and their family members signed written informed consent forms. Based on the guidelines for the diagnosis and treatment of HF[7-9], the patients were diagnosed as having CHF. We included patients with a diagnosis of CHF, as confirmed through Doppler ultrasound or 2D echocardiography, and who met the aforementioned diagnostic criteria; typical clinical symptoms such as weakness, fluid retention, and dyspnea; left ventricular ejection fraction (LVEF) $\leq 40\%$, and manifestations such as an enlarged left ventricle and increased left ventricular end-systolic volume; and NYHA classification of grade II–IV. Patients with immune system disorders; impaired liver and kidney function; allergy to the study drugs; malignant tumors; and potassium > 5.0 mmol/L were excluded.

Treatment

The control group was administered standardized anti-HF treatment, namely oral metoprolol tartrate tablets (Yantai Ju Xian Pharmaceutical Co., Ltd., Guoxin H37022364, specification: 25 mg/tablet) at an initial dose of 12.5 mg/time twice daily. Then, according to the severity of the patient's condition, the dose was adjusted up to a maximum of 200 mg/d; spironolactone tablets (Shanghai Fuda Pharmaceutical Co. Ltd., Guo medicine Quan Zhi H31020841, specification: 20 mg/tablet) at a dose of 20 mg/time once daily; and olmesartanate tablets (Beijing Fuyuan Pharmaceutical Co., Ltd., Guo medicine Quan Zhi H20061312, specification: 20 mg/tablet) at a dose of 20 mg/time once daily for conventional cardiotonic, diuretic, and vasodilator treatment, respectively. The observation group was administered the recombinant human BNP injection (Chengdu Nordicom Bio-Pharmaceutical Co., Ltd., State Drug Quantification S20050033, specification: 0.5 mg/500 U/bottle) on top of the control group, that is, 0.5 mg BNP was added to 50 mL saline for intravenous infusion. The initial dose intravenously injected was 1.5 µg/kg, followed by 0.0075 µg/kg/min intravenously for 72 h. Both groups were treated continuously for 3 d.

Observation index

Clinical efficacy: The focus needs to be on the internal disease during the comparison between before and after treatments[10-13]. Effective: clinical dyspnea and other symptoms disappeared, serum creatinine and BNP levels were normal, and NYHA-classified HF status improved by grade II or above. Effective: clinical dyspnea and other symptoms, and serum creatinine and BNP levels improved significantly, and the NYHA-classified HF status improved by grade I. Ineffective: clinical dyspnea and other symptoms, and serum creatinine and BNP levels did not improve. The NYHA classification remained almost unchanged. Total effective rate = (effective + effective) cases/total cases × 100%.

Inflammatory response and myocardial injury index: Before including this patients in the study, he was sent to the laboratory to determine the high-sensitivity C-reactive protein (hs-CRP), NT proBNP, and troponin I (cTnI) levels.

Cardiac function: LVEF and output per beat (SV) were measured before and after treatment using a Philips EPIQ7C ultrasound device for comparison between the two groups.

Quality of life: The value of life in both groups was determined before using the LHFQ scale for heart disease[14-16]. This scale consists of four main dimensions: physical, emotional, social, and economic, with a total score of 40, 25, 20, and 20 for each dimension, respectively.

Adverse reactions: No adverse reactions were observed during treatment, including headache, nausea, and hypotension.

Statistical analysis

SPSS 20.0 software was used for data analysis. The data were calculated using the hex 2 test [settings (%)], and the *t* test (mean ± SD). *P* < 0.05 was considered statistically significant.

RESULTS

Comparison of clinical outcomes between the two patient groups

As shown in Table 1, the overall clinical efficacy of the treatment was significantly higher in the observation group than in the control group (*P* < 0.05).

Comparison of inflammatory response and myocardial injury indicators between the two patient groups

As shown in Table 2, compared with the pretreatment period, serum hs-CRP, NT-proBNP, and cTnI levels were lower in both groups after treatment. The serum hs-CRP, NT-proBNP, and cTnI levels were significantly lower in the observation group than in the control group (*P* < 0.05).

Comparison of cardiac function between the two patient groups

As shown in Table 3, compared with the pretreatment period, LVEF and SV increased in both groups after treatment. LVEF and SV were significantly larger in the observation group than in the control group (*P* < 0.05).

Comparison of quality of life between the two patient groups

As presented in Table 4, compared to the pretreatment period, physical, emotional, social, and economic scores were lower in both groups after treatment, with the observation group exhibiting significantly lower scores than the control group (*P* < 0.05).

Comparison of adverse reactions between the two patient groups

No significant difference in the overall incidence of adverse reactions was observed between the observation and control groups during treatment (*P* > 0.05; Table 5).

Table 1 Comparison of the clinical outcomes between the two study groups, *n* (%)

Group	Visible effect	Effective	Invalid	Total validity
Control group (<i>n</i> = 51)	15 (29.41)	19 (37.25)	17 (33.33)	34 (66.67)
Observation group (<i>n</i> = 51)	25 (49.02)	20 (39.22)	6 (11.76)	45 (88.24)
χ^2 value				6.793
<i>P</i> value				0.009

Table 2 Comparison of the inflammatory response and myocardial injury indicators between the two study groups (mean \pm SD)

Group	hs-CRP (mg/L)		NT-proBNP (pg/mL)		cTnI (mg/L)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group (<i>n</i> = 51)	15.23 \pm 1.57	8.78 \pm 0.94 ^a	1548.67 \pm 255.81	953.18 \pm 115.55 ^a	0.24 \pm 0.07	0.18 \pm 0.03 ^a
Observation group (<i>n</i> = 51)	15.32 \pm 1.41	4.11 \pm 0.65 ^a	1564.74 \pm 256.92	764.85 \pm 86.74 ^a	0.23 \pm 0.05	0.04 \pm 0.01 ^a
<i>t</i> value	0.305	29.182	0.317	9.309	0.830	31.616
<i>P</i> value	0.761	< 0.001	0.752	< 0.001	0.408	< 0.001

^a*P* < 0.05 vs pretreatment.

hs-CRP: High sensitivity C-reactive protein; BNP: Brain natriuretic peptide; cTnI: Troponin I.

Table 3 Comparison of the cardiac functions between the two study groups (mean \pm SD)

Group	LVEF (%)		SV (mL)	
	Before treatment	After treatment	Before treatment	After treatment
Control group (<i>n</i> = 51)	31.43 \pm 4.54	51.71 \pm 7.98 ^a	44.28 \pm 6.52	52.85 \pm 6.58 ^a
Observation group (<i>n</i> = 51)	30.32 \pm 4.45	58.13 \pm 7.62 ^a	43.65 \pm 6.47	76.47 \pm 8.24 ^a
<i>t</i> value	1.247	4.155	0.490	15.996
<i>P</i> value	0.215	< 0.001	0.625	< 0.001

^a*P* < 0.05 vs pretreatment.

LVEF: Left ventricular ejection fraction; SV: Stroke volume.

Table 4 Comparison of the quality of life between the two groups (mean \pm SD, score)

Group	Physical strength		Emotions		Society		Economy	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Control group (<i>n</i> = 51)	34.48 \pm 3.56	22.72 \pm 2.93 ^a	17.42 \pm 2.14	7.12 \pm 1.81 ^a	12.23 \pm 2.54	7.84 \pm 1.52 ^a	10.25 \pm 1.23	6.52 \pm 1.28 ^a
Observation group (<i>n</i> = 51)	34.35 \pm 3.41	17.15 \pm 2.64 ^a	17.63 \pm 2.25	5.83 \pm 1.24 ^a	12.62 \pm 2.45	5.41 \pm 1.24 ^a	10.36 \pm 1.25	4.25 \pm 0.57 ^a
<i>t</i> value	0.188	10.086	0.483	4.199	0.789	8.847	0.448	11.570
<i>P</i> value	0.851	< 0.001	0.630	< 0.001	0.432	< 0.001	0.655	< 0.001

^a*P* < 0.05 vs pretreatment.

Table 5 Comparison of the adverse reactions between the two study groups, *n* (%)

Group	Headaches	Nausea	Low blood pressure	Total occurrence of adverse reactions
Control group (<i>n</i> = 51)	1 (1.96)	1 (1.96)	1 (1.96)	3 (5.88)
Observation group (<i>n</i> = 51)	0 (0.00)	1 (1.96)	1 (1.96)	2 (3.92)
χ^2 value	0.000			
<i>P</i> value	1.000			

DISCUSSION

CHF is a complex cardiovascular disease associated with a complex etiology. In CHF, the blood pumping capacity of the heart is reduced because of myocardial remodeling. To improve this condition, a series of compensatory mechanisms are initiated in the body that increases myocardial oxygen consumption and myocardial hypertrophy[17]. Conventional drugs can improve hemodynamics and promote respiratory function recovery, but the use of these drugs is limited by their lack of neuroendocrine regulation and their inability to inhibit myocardial remodeling.

The synthetic exogenous B-type natriuretic peptide, lyophilized recombinant human BNP, can bind to relevant receptors in the body, dilate blood vessels, participate in sodium excretion and diuresis, and improve hemodynamics[18]. The LHFQ scale can visually reflect the quality of life of patients. The higher the LHFQ score is, the better the quality of life is; that is, an improvement in patient-specific symptoms. The results revealed that critical attributes in the observation group were higher than those in the control group and the physical, emotional, social[19].

The inflammatory response can contribute to CHF progression. The higher the inflammatory factor levels in the body, the faster the disease progression. This is mainly because inflammatory factors promote cardiac remodeling and coronary atherosclerosis in CHF patients. NT-proBNP and cTnI indicate the extent of myocardial injury. They are positively correlated with the degree of myocardial injury. High expression of cTnI, a myocardial regulatory protein, in serum, indicates myocardial damage and hypoxia. High expression increases the permeability of myocardial cell membranes and worsens patients' clinical symptoms of CHF. If LVEF and SV, which are ultrasound indices for clinically evaluating cardiac function, are abnormal in CHF patients, the heart's pumping function is abnormal and the excitatory contraction of cardiomyocytes is inhibited, which eventually aggravates the clinical symptoms[20]. Lyophilized recombinant human BNP can promote mitochondrial metabolism in cardiomyocytes and enhance the use of ATP in cardiomyocytes, thereby regulating the contractile function of cardiomyocytes, improving the heart's pumping function, reducing the degree of hypoxic injury in cardiomyocytes, and promoting cardiac function recovery. In addition, the recombinant human BNP can act on the renin-angiotensin-aldosterone mechanism, inhibit norepinephrine and aldosterone secretion and release in the body, reduce the load on cardiomyocytes, protect coronary artery cells, inhibit endothelial cell apoptosis. The study revealed that the treatment of myocardial cells was effective in reducing the load on myocardial cells. The aforementioned treatment also protected coronary artery cells and inhibited endothelial cell apoptosis, thereby correcting acute compensatory dysregulation of the body, relieving the body's stress response, inhibiting inflammatory factor secretion and release, and reducing the degree of myocardial damage.

CONCLUSION

Lyophilized recombinant human BNP therapy can enhance cardiac function, improve the microinflammatory status of the body, and thus enhance the overall quality of life without causing any significant adverse effects. This therapy is safe and reliable and worthy of clinical promotion and application. The shortcomings of this study are that it included only a small population, which was not representative. Additional studies with a larger sample size and a population with a greater age span are warranted to improve the accuracy and reliability of the results.

ARTICLE HIGHLIGHTS

Research background

Chronic heart failure (CHF) needs effective treatment, and the lyophilized recombinant human brain natriuretic peptide (BNP) has the potential to improve heart function and inhibit myocardial remodeling.

Research motivation

This study explored the potential of lyophilized recombinant human BNP therapy as a safe and effective treatment for CHF patients and to determine its ability to improve the clinical outcomes and overall quality of life in these patients.

Research objectives

This study aimed to investigate the effects of freeze-dried recombinant human BNP therapy on cardiac function and

microinflammatory status in CHF patients and compare the clinical efficacy, inflammatory factor levels, myocardial damage, cardiac function, and adverse reactions with those of standard HF therapy.

Research methods

A total of 102 CHF patients were randomly assigned to the control or observation group, and both groups received treatment for 3 d. The control group received standard HF therapy, and the observation group received recombinant human BNP therapy. Clinical efficacy, inflammatory factor levels, myocardial damage, cardiac function, and adverse reactions were compared between the two groups before and after treatment.

Research results

After treatment, the observation group exhibited higher overall clinical efficacy than the control group. Serum high sensitivity C-reactive protein, N-terminal proBNP, and troponin I levels were lower in both groups after than before treatment, with greater reductions noted in the observation group. Physical, emotional, social, and economic scores were also lower in both groups after than before treatment, with greater improvements noted in the observation group. No significant difference was observed in the incidence of adverse reactions between the two groups. These findings suggest that freeze-dried recombinant human BNP therapy is safe and reliable and can improve heart function and reduce microinflammation in CHF patients.

Research conclusions

Freeze-dried recombinant human BNP therapy effectively improves heart function, reduces microinflammation, and enhances the overall quality of life of CHF patients. It causes no significant adverse reactions. These results suggest that this therapy can potentially be used as a safe and reliable treatment for CHF, and further studies are warranted to explore its long-term efficacy and safety.

Research perspectives

Future studies can focus on exploring the long-term efficacy and safety of freeze-dried recombinant human BNP therapy in CHF patients, as well as on investigating its potential use in combination with other therapies for improving clinical outcomes. Additional studies may be warranted to explore the underlying mechanisms to clarify how this therapy improves heart function and reduces microinflammation.

FOOTNOTES

Author contributions: Li F and Li H contributed equally to this work; Li F, Li H, Luo R, Pei JB, and Yu XY designed the research study; Li F, Li H, Pei JB, and Luo R performed the research; Yu XY and Li F contributed new reagents and analytic tools; Li F, Li H and Pei JB analyzed the data and wrote the manuscript; and all authors have read and approve the final manuscript.

Institutional review board statement: The study was reviewed and approved by the People's Hospital of Jieshou Institutional Review Board.

Informed consent statement: All study participants, or their legal guardian, provided informed written consent prior to study enrollment.

Conflict-of-interest statement: All authors have no conflicts of interest.

Data sharing statement: No additional data are available.

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S-Editor: Wang JL

L-Editor: Kerr C

P-Editor: Xu ZH

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