Recurrent Heart Failure in a Patient With the Parachute Device Implantation: A Case Report

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Case report

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Abstract

Background:

The parachute device is made to isolate of the aneurysm to exclude the dysfunctional myocardium might be a promising concept to improve clinical prognosis. However, the clinical practice revealed the device might result in death and worsen heart failure (HF).

Case presentation:

Herein, we report a male subject who received parachute device implantation after the ventricular aneurysm development caused by myocardial infarction. Even with standard treatment, the patient was still hospitalized for six times because of heart failure in the next 19 months and passed away before the transplantation was scheduled. This is a very rare case that a HF subject received parachute device implantation with early death.

Conclusions:

The progressive maladaptive remodeling would delay the reendothelialization of the device. The subsequent device displacement may enhance the mitral regurgitation and result in poor clinical outcome.

Clinical Trial Registration: PARACHUTE China Approval Trial, NCT02240940, Registered September 16, 2014, https://clinicaltrials.gov/ct2/show/NCT02240940

Background

Heart failure (HF) is a growing public health problem around the world[1]. Myocardial infarction (MI) is one of the leading causes of HF, which promotes cardiomyocyte necrosis and apoptosis, left ventricular (LV) remodeling, and cardiovascular death eventually[2]. The parachute device (Cardiokinetix, Redwood City, CA, USA) is designed to partition off the akinetic or aneurysmatic portion of the LV in patients with ischemic heart failure. The parachute device could reduce cardiac dimensions and end-diastolic wall stress and improve cardiac output [3-6]. However, three-year results suggested a reduction of LVEF and stroke volume[4]. The PARACHUTE IV trial has been terminated in June 2017 because of death or worsened heart failure (clinicaltrials.gov= NCT01614652). Under these circumstances, very few patients received this treatment. Besides, the device relevant prognosis analysis is rare to see. Herein, we present a case of parachute device post-implantation, developed progressive HF and early death. We based on the transthoracic echocardiography (TTE) to analyze the poor prognosis of this patient.

Case Presentation

A 67-year-old male patient with a history of hypertension presented acute onset severe retrosternal chest pain and was diagnosed with extensive anterior myocardial infarction based on tombstone ST segment elevation in V1-V6 leads and remarkably increased cardiac troponin I. His physical examination revealed an accentuated pulmonary component of the second heart sound, tricuspid systolic murmur, and increased breath sound. An emergent coronary angiogram revealed occlusion in the left anterior descending coronary artery (LAD). After LAD revascularization, TTE was employed for cardiac morphology and function assessment, the left ventricular ejection fraction (LVEF) was 52%, and the left ventricular end diastolic diameter was 56 mm. He was discharged on dual anti-platelet therapy with aspirin and ticagrelor, as well as rosuvastatin, beta-blocker, and ACE inhibitor.

The patient did not follow the rehabilitation advices after discharge from our center. He often participated in high-intensity physical activity such like mountain climbing and long-distance running and experienced colds twice. Six months later, despite the complete revascularization of LAD and standard heart failure therapy, he started to experience progressive shortness of breath and fatigue because of the progression of HF, a New York Heart Associate Function class III–IV. He referred to our center again for further assessment and treatment, and the TTE revealed a notable reduction of LVEF (35%) and left ventricular enlargement (diastolic diameter, 66 mm). Moreover, the left aneurysm was developed, the estimated pulmonary artery pressure (PAP) was 30 mmHg, and the concentration of NT-proBNP increased to 1,424 pg/ml with normal renal function.
Considering the remarkable maladaptive LV remodeling and considerable LVEF reduction. The patient refused to undergo surgical ventricular reconstruction. To reconfigure the geometry of left ventricle and improve the cardiac function, he accepted to evaluate the possibility of parachute device implantation and received further computed tomography (CT) for proper device size selection (Fig. 1). The patient experienced multi-slice CT scan to check if he has left ventricular thrombus, pseuduchorda, or severe calcification, which could affect parachute deployment. Thereafter, left ventricular morphological parameter was measured by core laboratory. The quantitative assessment included diastolic and systolic assessment. Furthermore, maximum diameter shortening and diameter shortening based on mean diameter was carried out, and LV ejection was evaluated by CT. According to his left ventricular anatomy, we recommended the parachute device with a size of 85 mm and standard foot height.

Details of the device and procedure have been previously published[3, 7, 8]. In brief, the device includes a delivery system with a balloon that facilitates the expansion of the device and a pre-shaped delivery catheter and dilator. After the device is expanded, the occlusive membrane provides a barrier to seal off the static chamber on the distal side of the device (Figs. 1F and 1G). With parachute deployment, the patients received low-dose aspirin and anticoagulation with warfarin to prevent potential thrombosis. We performed TTE 4-day post-implantation, and his LVEF increased to 44%, the diastolic diameter decreased to 59 mm, and the estimated PAP decreased to 26 mmHg. His shortness of breath and fatigue was remarkably relieved, and NT-proBNP decreased to 771 pg/ml. The patient was discharged after his international normalized ratio (INR) became stable at 1.8–2.5, remained with statin, ACEI, and beta-blocker treatment.

However, in the next 19 months, the patient was hospitalized for six times because of heart failure progression. The patient did not follow our advice strictly, improper exercise enhanced the remodeling of the left ventricle. In addition to progressive HF, his blood pressure, LVEF met remarkable reduction. Besides, the diameter of LV, estimated pulmonary artery pressure, and NT-proBNP dramatically increased. In the terminal stage of his life, we also found a thrombus at the top of the parachute device. The patient has stopped warfarin treatment for 6 months at that time, and his INR was 1.25, which is insufficient to dissolve the thrombus. The regurgitation flow through the parachute (in the highlighted circle of Fig. 2D) indicate that the device has deviated from the original location.

We have conducted coronary angiography to exclude potential coronary vessel stenosis. The TTE revealed that his diastolic diameter of LV was remarkably elevated to 72 mm, the LVEF decreased to 32%, and the concentration of NT-proBNP exceeded 30,000 pg/ml (Table 1). The worsened condition of this patient was supported by the echocardiogram (Fig. 2). Before and right after the parachute implantation, even with dilated left ventricular chamber, only slight regurgitation was observed (Figs. 2A and 2B). The device was deployed to cover the aneurysm, it did not affect the function of papillary muscle. However, the continuous maladaptive remodeling enlarged the chamber of left ventricle, revealing a notable mitral regurgitation (Figs. 2C and 2D). The patient refused to accept ICD, CRT, and CRTD treatments. Ultimately, severe mitral regurgitation enhanced myocardial afterload. His disease symptoms advanced aggressively, and he passed away even before the heart transplantation. The total illness duration was 19.7 months since parachute implantation.

Discussion

This is a rare case that a HF subject received parachute device implantation with early death. In this case, we reported a parachute implantation case with poor prognosis. The maladaptive remodeling of left ventricular post myocardial infarction is very common in clinical practice. The remodeling is characterized by LV dilation. According to the law of Laplace, increased LV volume elevates the filling pressure, resulting in progressive subendocardial myocardial ischemia, HF, and death. The beneficial effects of drugs or medical devices on LV remodeling have also been associated with reduced long-term mortality. Therefore, effective and safe treatment strategies are urgently needed to restore LV function and improve outcomes of patients with HF.

Parachute system is made to isolate the aneurysm from the normal part of LV and decrease the LV volume. Hence, excluding the dysfunctional myocardium might improve the clinical prognosis[7]. Parachute device implantation immediately decreases LV volume and increases LVEF. Moreover, in our patient, contractility was significantly improved by the geometrical change of LV after device implantation. This short-term improvement of cardiac geometry and function were checked in our case.
We have carefully assessed the cause of mitral regurgitation. First, as indicated in Figures 3C and 3D, the advanced maladaptive dilation of LV may enhance the regurgitation. In addition, the thrombus caused the displacement of the device, thus oppressing the root of papillary muscle and affecting the function of mitral valve chordae tendineae, possibly resulting in iatrogenic mitral regurgitation. Lastly, the structure of the parachute might have changed in Figure 3D (not verified by autopsy). Figure 2D shows the regurgitation blood flow through the device, and the parachute may not fit for the advanced dilated chamber. It finally affects the systolic function of ventricle.

The thrombosis in the device is another vital cause of poor prognosis. Thrombus caused the displacement of parachute device, and it could also be the source of cardioembolic stroke. All subjects who received parachute are required to receive 12 months of aspirin and 6 months of clopidogrel post-device implant. However, the thrombus was found in the LV apex, indicating that this kind of recommendation need personalized treatment planning to avoid potential thromboembolic disease.

The PARACHUTE IV was terminated in 2017 because of the potential death and worsening of HF enhancement[5]. In our center, we have conducted six cases of parachute implantation. All patients received low-dose aspirin and anticoagulation with warfarin for at least 12 months post-device implantation. Three patients maintained good physical conditions, three patients suffered from coronary stenosis or heart failure, and one patient died (data not showed). To reveal the crucial factor in progressive HF in this cohort, we carefully analyzed the death case and found that the continuous heart maladaptive remodeling may contribute to poor prognosis. The reendothelialization of the device was delayed with progressive dilation of the left ventricle. Similarly, patients with atrial fibrillation (AF) with elevated stroke risk may receive invasive treatment of the occlusion of left atrial appendage (LAA). Patients who received LAA occlusion by WATCHMAN device are only recommended to undergo 3 months of anticoagulation treatment, followed by long-term antiplatelet therapy. Extra anticoagulation is unnecessary when the implants are completely reendothelialized. The concept is also applicable to the parachute device. Hence, the parachute device may need to be refined to fit the geometry of the dilated ventricle.

**Conclusions**

The parachute device is designed to isolate aneurysm from the normal part of LV and decreased LV volume. However, the reendothelialization of the device would be delayed if the progressive maladaptive remodeling occurs. Under these unfavorable circumstances, thrombus build up and device displacement may build up the poor prognosis by enhancing mitral regurgitation.

**List Of Abbreviations**

- **HF**: heart failure
- **MI**: myocardial infarction
- **LV**: left ventricular
- **LVEF**: left ventricular ejection fraction
- **TTE**: transthoracic echocardiography
- **LAD**: descending coronary artery
- **PAP**: pulmonary artery pressure
- **CT**: computed tomography
- **INR**: international normalized ratio
- **ICD**: implantable cardioverter defibrillator
- **CRT-D**: cardiac resynchronization therapy
AF: atrial fibrillation

LAA: left atrial appendage

Declarations

Ethics approval and consent to participate: The experimental protocol was established, according to the ethical guidelines of the Helsinki Declaration and was approved by the Human Ethics Committee of Shenzhen people's hospital. Written informed consent was obtained from individual participants.

Consent for publication: Not applicable

Availability of data and materials: All data generated or analyzed during this study are included in this published article

Competing interests: Not applicable

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Authors' contributions: JH Li, SH Dong, and TZM Li contributions to the conception or design of the work, and interpretation of data for the work. JH Li, W Xiong, and TZM Li contribute to the data acquisition and analysis. JH Li drafting the work and TZM Li revising it for important intellectual content. All authors have read and approve the submission of the manuscript.

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Tables

Table 1: Time line of this patient hospitalization in our center, essential echocardiography and biochemical parameter in each time. AMI: acute myocardial infarction; Implantation: The Parachute device implantation; HFH, heart failure hospitalization; BP, Blood pressure; HR, Heart rate; LVEF Left ventricular ejection rate; LVEDD, left ventricular end diastolic diameter; PAP, pulmonary artery pressure estimated by echo; LA, Left atrial diameter. INR, International normalized ratio; NT-proBNP, N-terminal pro-brain natriuretic peptide.

| Days since deployment | BP (mmHg) | HR (per min) | Echocardiography Parameter | Biochemical Test |
|-----------------------|-----------|--------------|----------------------------|------------------|
|                       |           |              | LVEF (%) | LVEDD (mm) | PAP (mmHg) | LA (mm) | INR | Creatinine (mmol/L) | NT-proBNP (pg/ml) |
| AMI                   | -186      | 110/83       | 82       | 52         | 56         | 46      | 34  | 1.12               | 86               | 597               |
| Implantation          | 0         | 119/76       | 59       | 35         | 66         | 30      | 37  | 1.84               | 97               | 1424              |
| 1st HFH               | 81        | 128/87       | 86       | 45         | 64         | 63      | 44  | 1.75               | 116              | 4544              |
| 2nd HFH               | 180       | 99/70        | 83       | 42         | 62         | 34      | 42  | 1.25               | 175              | 27760             |
| 3rd HFH               | 368       | 94/72        | 61       | 41         | 62         | 40      | 40  | 1.13               | 123              | 1589              |
| 4th HFH               | 515       | 88/73        | 90       | 21         | 70         | 65      | 44  | 1.09               | 143              | 13280             |
| 5th HFH               | 539       | 92/70        | 79       | 32         | 72         | 70      | 43  | 1.3                | 152              | 11068             |
| 6th HFH               | 564       | 119/80       | 101      | 32         | 72         | 72      | 43  | 1.25               | 175              | >30000            |

Figures
Figure 1

Patient Selection by CT assessment and the left ventricular angiography before and after parachute device implantation. A, B and C: evaluated by CT, the diastolic measurements, systolic measurements, and other measurements with maximum diameter shortening and diameter shortening based on mean diameters by LV ejection fraction (%). D–E: the left ventricular angiography at diastole and systole before device implantation, respectively; F and G: after implantation, the diastole and systole ventricular angiography, respectively. The dotted line represents the outline of geometry of ventricle before device treatment.
Figure 2

Cardiac structure and function evaluated through echocardiogram in different stage of this patient. A, TTE before device implantation; B, pictures captured 4 days after device implantation; C, patient experienced advanced heart failure 516 days after the deployment; D, the terminal stage of this patient. LV: left ventricle; RV: right ventricle; LA: left atrium; RA: right atrium; AO: aorta; white arrow indicates the implanted Parachute and thrombus.
Figure 3

The assessment of parachute device affects the function of papillary muscle through apical 3-chamber view. A, B, C, and D indicate the echocardiogram performed before device implantation, 7 days after device implantation, progressively heart failure, and terminal stage, respectively. The white arrow indicates the parachute device and the root of papillary muscle, respectively.