Long-term Prognosis Analysis of PARACHUTE Device Implantation in Patients with Ischemic Heart Failure: A Single-Center Experience of Chinese patients

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Abstract

Background: Heart failure (HF) is one of the leading causes of mortality and morbidity. The PARACHUTE device is designed to partition for left ventricular (LV) apical aneurysm post extensive anterior myocardial infarction. However, the long-term prognosis of the PARACHUTE device post-implantation is unclear.

Methods: From November 2015 to April 2017, six subjects with New York Heart Association Class II, III and IV ischemic HF, LV ejection fraction between 15% and 40%, and LV anterior apical aneurysm were enrolled in our center. The cumulative event rates for myocardial infarction, hospitalization, and mortality were documented respectively. Further assessment of LV ejection fraction, LV end-diastolic diameter, and estimated pulmonary artery pressure were determined by echocardiography core laboratory. For quantitative data comparison, paired *t*-test was employed.

Results: Device implantation was successful in all six enrolled subjects, and acute device association adverse events were not observed. At 4.6 ± 1.7 years follow-up, MACEs were found in 50% patients, and the survival rate was 86.7%. We found that the LV ejection fraction was significantly elevated after deployment ($46.00 \pm 6.00\%$ vs. $35.83 \pm 1.47\%$, $P=0.009$). Besides, the LVEDD elevated after MI (51.17 ± 3.71 vs. 62.83 ± 3.25 , $P<0.001$) was revealed, but the device sustained preserved LVEDD after implantation.

Conclusion: The PARACHUTE device is an alternative therapy for patients with severe LV maladaptive remodeling. The procedure of PARACHUTE implantation is safe and has a potential benefit in long-term mortality reduction. However, the device seems to increase the HF ratio.

Clinical Trial Registration: NCT02240940, <https://clinicaltrials.gov/ct2/show/NCT02240940>

Introduction

Left ventricle (LV) maladaptive remodeling after acute myocardial infarction (MI) has been well documented in experimental and clinical trials(1, 2). During the past decades, the number of hospitalizations for acute MIs has exploded significantly. Despite the treatment improvement in MI, the long-term prognosis of MI-related LV remodeling remains unfavorable. Progressive LV dilation post-MI occurs in 33% patients(3). Heart failure (HF) is associated with significant morbidity and mortality and places an enormous burden on the healthcare system(4). Once MI-related HF develops, the overall 1-year mortality can reach 32%(5), which is unacceptably high despite the modern era of pharmacological and mechanical approaches.

The current guideline recommends implantable cardioverter defibrillator (ICDs) and defibrillators with cardiac resynchronization therapy (CRT-Ds) in HF subjects. Despite optimal pharmacological treatment or medical devices applied, LV aneurysms and remodeling are still progressively developing and may lead to inevitable congestive HF. Surgical ventricular reconstruction (SVR) has shown to be beneficial for short-

term outcome improvement by aneurysmectomy. However, SVR has been the topic of intense debate in terms of appropriate patient selection and techniques(6).

The concept of percutaneous ventricular restoration (PVR) therapy of dilated LV is based on the premise of a dedicated partitioning device for LV volume reduction and geometric reconfiguration(7–9). PARACHUTE® (Cardiokinetix, Redwood City, CA, USA) is the first device designed for PVR, and it minimizes the risk of other invasive methods. The PARACHUTE device consists of a conical nitinol frame covered with a fluoropolymer (expanded polytetrafluoroethylene, ePTFE) membrane that can be compressed into a delivery catheter and deployed into the LV apex to partition off akinetic and dyskinetic LV aneurysms.

Previous clinical trials implied that the PARACHUTE device may reduce cardiac dimensions and end-diastolic wall stress, thereby benefitting patients with LV dilation post-MI. However, little is known about the long-term cardiac function, life quality, and MACEs of PARACHUTE-implanted patients. Therefore, we retrospectively collected the clinical and average 4.6 years follow-up data to analyze the PARACHUTE device-related outcomes and complications, and we have performed a per- vs post-implantation pairwise comparison of patients' echocardiography parameter. In addition, we investigated the potential factor of an adverse event in these patients.

Methods

Study design and patient selection criteria

The Percutaneous Ventricular Restoration in Chronic Heart Failure due to Ischemic Heart Disease (PARACHUTE) China (NCT02240940, [https:// clinicaltrials.gov/ct2/ show/NCT02240940](https://clinicaltrials.gov/ct2/show/NCT02240940)) was a prospective, non-randomized observational study designed to assess safety and efficacy of the PARACHUTE device. Clinical and echocardiographic follow-up was performed.

Inclusion criteria were as follows: enrolled cases were patients with symptomatic ischemic HF with NYHA Classes II, III, and IV. These patients were 18–75 years old with LV motion abnormalities secondary to anterior MI. LV ejection fraction (EF) ranged from 15% to 40%, which was measured by the 2D echocardiography core laboratory (core lab). All participants with myocardial ischemia underwent revascularization and received optimal and standard HF medical therapy for at least 3 months before enrollment.

The exclusion criteria were as follows: significant valvular stenosis or regurgitation, chronic obstructive pulmonary disease, end-stage renal disease requiring hemodialysis, cerebral vascular accident, or transient ischemic attacks occurring within 6 months. Selected computed tomography (CT) was applied for proper device size selection. All sites obtained approval from the Ethics Committee before the study began, and written informed consent was obtained for all patients at the appropriate time before involvement in this study. After the implantation of the device, clinical and echocardiographic follow-up was performed annually for up to 3 years.

Study device and procedure

Details of the device and procedure have been previously published(7-9). In brief, the procedure was performed in a catheterization laboratory with the patients usually under conscious sedation. Multi-slice CT (seen in Supplementary Figure 1) was implemented to provide accurate measurements and rule out LV apical thrombus, pseudochochorda, or severe calcification, which could have precluded safe deployment. The PARACHUTE system (CardioKinetix, Inc., CA, USA) is designed to exclude the damaged muscle, leading to isolation of the non-functional muscle from the other part of LV, which includes the device, a delivery system with a balloon that facilitates the expansion of the device, and a pre-shaped delivery catheter and dilator. Wall stress can be reduced by changing LV geometry and decreasing LV volume. The device comprises a fluoropolymer membrane stretched over a nitinol frame. The frame is shaped like an umbrella with 16 ribs, and the tip of each rib ends in an anchor designed to attach on the ventricular wall and prevent migration and shedding after implantation. The frame expands the impermeable polytetrafluoroethylene membrane and atraumatic polymer foot, which has eight sizes (65, 75, 85, and 95 mm in diameter, each offered in standard and short foot height). The distal atraumatic foot provides a contact point on the LV apical wall. The access system consists of a guiding catheter and dilator (14 Fr or 16 Fr) to create a pathway, the contact point is selected to orient the device with a vector toward the outflow tract. After the device is expanded, the occlusive membrane provides a barrier to seal off the static chamber on the distal side of the device. All patients received low-dose aspirin and anticoagulation with warfarin for at least 12 months of the post-device implant.

Transesophageal echocardiography

Patients underwent 3D-transthoracic echocardiography (TTE) and 2D-TEE with IE-33 Philips systems (Andover MA, USA) by using a 3D X5-1 purewave matrix-array transducer. Images were digitally acquired for off-line reconstruction (for 3D-TEE images) and interpretation. 2D-TEE was used from basal to mid-esophageal levels, whereas 3D-TEE was used from basal to mid-esophageal levels. To achieve the highest spatial and temporal resolution, we obtained electrocardiographically triggered multiple-beat (4 beats) high-density full volume images with the narrowest possible sector scan during breath-holding (expiration). (10)

Contrast echocardiography(11) was conducted following 2D-echocardiography in gray-scale ultra-harmonic mode. Mean transmitting frequency and receiving frequency were 1.3 and 3.6 MHz, respectively. Intravenous contrast medium (Levovist; Shering, Berlin, Germany) was administered at a rate of 750 mg/min with a concentration of 300 mg/mL. Images from myocardial contrast echocardiography (MCE) were captured every four beats in the end-systolic phase from the apical four-chamber view. LV opacification (LVO) was performed with end-systolic triggering images, and real-time images were used to detect LV thrombus after MCE.

Date collection and follow-up

All study-related data were collected on standardized case report forms(7-9). We assessed of the successful delivery and deployment of the PARACHUTE device. The average of 4.6 years of follow-up data on major adverse cardiac events (MACEs) was recorded. MACEs were defined as cardiac death, emergent cardiac surgery, cardiac tamponade, peripheral embolization, new or worsening HF, endocarditis or device infection, device migration or embolization. We collected echocardiography measurements, including LV end diastolic diameter (LVEDD), LV ejection fraction (LVEF), and estimated pulmonary artery pressure (PAP). Functional parameters such as NYHA functional class ranking were also determined. Data management was performed by contract research organization, and adverse events were adjudicated by an independent clinical events committee.

Statistical design and statistical analysis

The key efficacy evaluation was based on transthoracic TTE analysis from baseline to device implantation, as well as the follow-up data. The MACEs and efficacy analyses were performed on those who were discharged from the hospital after being treated with the study device. The following baseline characteristics were summarized using the mean $\pm$ standard deviation (SD) for continuous variables and counts and percentages for categorical variables. Paired t-test was used to compare the quantitative data; the signed-rank test was applied for the ranked data comparison. All statistical tests were performed using a two-sided test; $P \leq 0.05$ was considered statistically significant. All analyses were performed using SPSS 21.0 (USA).

Results

Patient characteristics

From November 2015 to April 2017, 139 patients with post-anterior MI were initially enrolled in our trial (Fig. 1). These patients were screened by 2D transthoracic echocardiography and Doppler examinations. A total of 122 of these patients were ineligible, 98 subjects had not developed an aneurysm in the LV, and 24 patients had an LVEF less than 15% or over 40%. Device sizing and anatomical approval were granted by the central CT core lab. Seventeen patients received CT scan for proper PARACHUTE device selection; 11 were excluded for LV false tendons (4 subjects), LV thrombosis (2 subjects), and not being structurally fit the device (3 subjects); and 2 patients withdrew their consent. Six patients were discharged with the PARACHUTE device and followed up for cardiac function and clinical outcomes. The mean follow-up time was 4.6 ± 1.7 years.

All the patients must have had a diagnosis of NYHA class II, III, or IV before enrollment to be included in this study. Ischemic heart disease was present in all patients. All subjects with LV descending artery MI had a prior percutaneous coronary intervention. The average age of the patients was 55.7 ± 11.3 years old, the average time from an acute MI to PARACHUTE implantation was 13.5 ± 12.9 months, and BMI was 26.0 ± 2.0 . 50% patient had single-vessel occlusion, the rest had multivessel disease, all revascularization was complete in their first hospitalization (data not shown). There were five males and

one female. We hospitalized one patient for HF within 12 months. The baseline demographic data is shown in Table 1. All patients had LV post-MI aneurysm, and no patient received ICDs nor CRTs.

As shown in Table 2, the PARACHUTE devices were implanted through the femoral artery of all the six subjects (Fig. 2A). The procedure was successful in six (100%) patients, without a perforation case. We attributed the lack of clinical adverse events to device procedure through a minimum of 12 months of follow-up. All four diameters (65, 75, 85, and 95 mm) of the PARACHUTE were implanted in 0%, 50%, 33.3%, and 16.7% of subjects, respectively. No major vascular complications were found, and no PARACHUTE device was expanded or deployed improperly. In addition, no acute thrombosis and emergent surgery occurred during the procedure.

The procedure of the device implantation is briefly illustrated in Fig. 2. the PARACHUTE device was expanded and implanted in the LV apical wall. LV angiography was performed once again to evaluate the geometry of LV (Figs. 2E and 2F). As shown in Fig. 2, LV volume was remarkably reduced both in the systole and diastole phases.

Clinical And Functional Outcomes

Patients in our center were followed up for 4.6 ± 1.7 years. Safety end-points are illustrated in Table 3 and Fig. 3. MACEs occurred in three (50%) patients (Fig. 3A). The most frequently reported MACEs were HF and unplanned interventional therapy. Three subjects (50%) received coronary artery intervention; one of them was diagnosed with non-ST elevation MI, other two have progressive angina attack. Three patients developed HF in 85, 418, and 1599 days. One of them died at 568 days because of progressively worsening HF. However, the worsening HF was outside the predefined end-point (within 6 months of the implantation). The device-related MI and emergent/selective cardiac or aortic surgery were not observed (Table 3).

Thus, our center observed the successful delivery of the PARACHUTE device through 6 months follow-up without device-related MACE. The medication therapy of subjects was consistent from inclusion into the trial up to 1-year follow-up. DAPT, Statin, Warfarin, and β -blocker were 100% taken in all patients; ACEI/ARB and spironolactone were 83.3%. Even though all patients received warfarin for more than 12 months, device-related embolization was found in one subject by CT and TTE.

Our center analyzed echocardiographic parameters of these subjects at baseline and each time of follow-up, including the LVEF, LVEDD, and estimated pulmonary artery pressure (estimated PAP). We collected the baseline data after the first attack of anterior MI. Subsequently, data were obtained before the PARACHUTE device implantation and 1 week, 6 months, 1 ± 0.25 year, 2 ± 0.5 years, and 3 ± 0.5 years after device implantation.

We further performed a per- vs post-implantation pairwise comparison of echocardiography. Results of TTE-based cardiac function assessment are shown in Fig. 4. Compared with the baseline, the LVEF was

significantly reduced at the time when patients enrolled in the trial ($50.67\% \pm 0.82\%$ vs. $35.83\% \pm 1.47\%$, $P < 0.001$). PARACHUTE remarkably elevated LV systolic function in 1 week ($35.8\% \pm 1.47\%$ vs. $46.00\% \pm 6.0\%$, $P = 0.009$; illustrated in Figs. 4A and 4B). For the subjects without MACEs, compared with the 1-week measurement, the LVEF demonstrated relatively sustained improvement when we referred to the latest follow-up ($42.33\% \pm 3.51\%$ vs. $43.67\% \pm 3.06\%$, $P = 0.757$). By contrast, patients with MACEs often showed a moderate decline ($49.67\% \pm 6.03\%$ vs. $35.67\% \pm 4.04\%$, $P = 0.112$).

Patients showed a significant chronic increase in LV end-diastolic diameter before the procedure ($51.17\% \pm 3.71\%$ vs. $62.83\% \pm 3.25\%$, $P < 0.001$). After the implantation, TTE showed no pronounced change in LVEDD, and the progressive LV enlargement was inhibited (Figs. 4C and 4D). We further measured estimated PAP in Figs. 4E and 4F, except for the early death of one patient due to HF. The estimated PAP was comparable in each time evaluation.

Notably, the device-related MACEs also contributed to the poor prognosis. Here, we found one case of embolization that may worsen the state of illness (Fig. 5). Figure 5A is an image captured immediately after PARACHUTE implantation. Compared with Fig. 5A, the latest contrast-enhanced CT of the LV (Fig. 5B) showed the occurrence of device-associated embolization. We conducted a 3D TTE and Doppler scan to exclude device migration (Figs. 5C and 5D). Furthermore, MCE and LVO were employed to confirm the thrombus located in the LV apex (Figs. 5E and 5F). These results suggested that the patients should continue to receive warfarin to prevent stroke, even though no embolization-associated adverse events were found. Moreover, long-term anticoagulant treatment may help prevent thrombus-related events.

Discussion

In this study, we demonstrated that PARACHUTE therapy could be beneficial for maladaptive remodeling of patients with post-MI by restoring LV ejection and suppressing continuous and overwhelmed LV enlargement, thereby improving patients' long-term prognosis especially in LVEF-sustained preserved subjects.

Typical LV dilation is common in patients with an anterior infarction(12). As a consequence of anterior MI, the LV continuously develops geometrically from ellipsoid to spherical(13), accompanied with chamber dilation and wall motion abnormalities. The dilation of the LV maintains cardiac output through inotropic and chronotropic effects by the Frank-Starling mechanism. However, according to the law of Laplace, increased LV volume elevates filling pressure, resulting in the enhanced burden of remaining myocytes, progressive subendocardial myocardial ischemia(14), a hemodynamic disorder such as functional mitral regurgitation(8), HF, and death(15). Many studies proved that LV remodeling is an independent clinical predictor of prognosis in patients with HF(16). The beneficial effects of drugs or medical devices on LV remodeling have also been associated with reduced long-term mortality(17). Therefore, effective and safe treatment strategies are urgently needed to restore LV function and improve outcomes of patients with HF.

PARACHUTE device has been investigated in several clinical trials, such as the Percutaneous Ventricular Restoration in Chronic Heart Failure due to Ischemic Heart Disease (PARACHUTE) I, II, III, and IV trials. The PARACHUTE First-In-Human trial simultaneously conducted in USA and Europe for 39 patients(8) demonstrated safety and feasibility for patients with HF (LV ejection fraction between 15% and 40%) and dilated LV. There was a stable and remarkable reduction in LV end-diastolic volume up to 3 years follow-up. Echocardiography revealed that stroke volume and LV ejection fraction were reduced as well. The PARACHUTE III(18) trial was a prospective, non-randomized observational study conducted in Europe. It included 100 subjects, with LV volumes significantly reduced and 6 minutes' walk distance improved from 372 m to 397 m ($p < 0.01$). The following PARACHUTE IV(19) clinical trial was the first randomized controlled trial aiming to enroll 478 New York Heart Association (NYHA) classes III and IV, with LVEF of 15–40% and the use of optimal medical therapy. employed CT imaging was employed to assess optimal device implantation. The primary endpoint was death or hospitalization for worsening HF. Unfortunately, the study was terminated in June 2017 because of death or worsening HF (clinicaltrials.gov ≠ NCT01614652).

In this trial, 139 patients were diagnosed anterior myocardial infarction were informed this procedure (Fig. 1). However, this device is believed that could provide additional help to the patients with Left aneurysm. LVEF > 40% implies relative preserved LV function, and LVEF < 15% suggests end-stage heart failure. Therefore, these subjects were excluded. In order to exert the maximum benefit effect to heart failure patients restricted heart features were carefully evaluated, false tendons, ventricular thrombosis are contraindications of PARACHUTE procedure. At last 6 eligible subjects enrolled to the study, the cautiously HF patients selection also contribute to procedural safety eventually.

Despite the continuous improvement in the treatment of acute and long-term MI over recent decades, adverse LV remodeling is the principal reason for clinical HF. Both functional and structural measures of adverse LV remodeling, such as LVEF and LVEDD, are associated with mortality and cardiovascular events(20). The beneficial effect of drugs or medical devices on LV remodeling has been associated with reduced long-term mortality(21). 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 HF. The aforementioned studies(8, 18, 19, 22) suggested that the PARACHUTE device can reduce cardiac dimensions and end-diastolic wall stress and improve cardiac output. However, the 3 year results suggested a reduction of LVEF and stroke volume. The PARACHUTE IV trial was terminated because of death or rehospitalization for worsening HF.

Medication treatment such as angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, β -blockers, and aldosterone antagonists remain the cornerstone of HF therapy, and these treatment agents were applied in our cohort. However, the six enrolled subjects eventually suffered from ventricular desynchrony. Surgical ventricular restoration (SVR) is an alternative for patients that require severe LV remodeling. Compared with the percutaneous delivery and insertion of the PARACHUTE device into the LV cavity, one might expect a lower rate of infectious complications associated with the use of PARACHUTE compared with the SVR(23). We carefully selected six of 139 patients with post-anterior MI. With TTE and

CT evaluation, PARACHUTE implantation was performed successfully without acute device-related adverse events (Table 2, and Table 3).

As indicated in Fig. 2, except for a premature death that occurred in 1.8 years post-implantation due to worsening HF, no other mortality occurred at an average of 4.6 years follow-up, the survival rate was 83.3%. With current aggressive invasive strategies and advanced pharmacotherapy, acute MI survival rates have increased but may have led to a group of patients with a high risk of developing HF. Survival after HF diagnosis has improved over time, as shown by data from the Framingham Heart Study(24) and the Olmsted County Study(25). However, the death rate remains high: about 50% of people diagnosed with HF will die within 5 years. To this extent, the PARACHUTE implantation improved patients' prognosis. In addition, subjects enrolled in our trial suffered from severe LV maladaptive remodeling with cardiac output reduction. Even with the assistance of PARACHUTE, half of them demonstrated worsening HF during follow-up. On the basis of pooled data from the National Heart, Lung, and Blood Institute (NHLBI), after the first MI, 20% of men and 23% of women will die within 5 years(26). In terms of the HF hospitalization data, the PARACHUTE device seems to increase the HF ratio, which is consistent with the PARACHUTE IV(27) trial. However, we believe that this finding was not completely attributed to the side effect of the device but partially because the selected patients suffered from serious MI and remodeling. Because no severe ventricular arrhythmia was observed, we have no patient implanted ICD in this cohort.

The device restored enrolled patients' LV systolic function, and this result was consistent with findings of former studies(8, 9, 18). LVEF significantly improved from preimplantation to 7 days after deployment ($35.83\% \pm 1.47\%$ vs. $46.00\% \pm 6.00\%$, $P = 0.009$). Besides, the LVEDD and estimated PAP were relatively stable, which suggested that this therapy was effective and safe for patients. The improvement in NYHA functional class was also observed in other patients (shown in Fig. 3).

Patients with prior MI have a much higher risk to develop HF and multivessel coronary artery disease than their counterparts(28). The device is designed to prevent maladaptive LV remodeling, which is helpless to inhibit recurrent coronary attack. Therefore, personalized treatment should be sought to decrease coronary risks. The HF that occurred in half of our enrolled patients may be partly because the patients we selected suffered from severe cardiac remodeling, thereby enhancing the ratio of cardiac adverse events. However, the device-related MACEs also contribute to the poor prognosis.

As this clinical trial previously designed, all patients received low-dose aspirin and anticoagulation with warfarin for at least 12 months post-device implantation. Drug-eluting stents (DESs) improved the efficacy of percutaneous coronary intervention by modulating vascular inflammation and preventing neointimal proliferation and restenosis. DES effectively reduced neointimal proliferation but also slowed reendothelialization and the healing process. Dual antiplatelet therapy is recommended under delayed reendothelialization to prevent stent-related thrombosis(29). For patients with atrial fibrillation (AF), who have elevated stroke risk, and require percutaneous approaches to occlusion of the left atrial appendage (LAA), the device is an option for patients who are suitable for short-term warfarin treatment but unable to undergo long-term oral anticoagulation. Patients who received LAA occlusion by WATCHMAN device are

only recommended to undergo 3 months of anticoagulation treatment, followed by long-term antiplatelet therapy(30). DES and WATCHMAN device are prevalent in coronary atherosclerosis and AF treatment, respectively. With proper antiplatelet or anticoagulation, device-related embolization rarely occurs. The duration of antiplatelet or anticoagulation is based on the spontaneous reendothelialization time. Extra anticoagulation is unnecessary when the implants are completely reendothelialized. The concept is also applicable to the PARACHUTE device. In color doppler flow imaging, we observed that blood flow crossed the device, suggesting it was not entirely reendothelialized even after 3 years, so thrombosis may be promoted. The evidence implies that the PARACHUTE device may need to be refined to fit the geometry of the dilated ventricle.

Despite this small number of patients in our center, we have the longest clinical observation of the PARACHUTE cohort in China. In this trial, the efficiency and safety of the PARACHUTE procedure were investigated, and long-term MACE and cardiac function were evaluated as well. These data add additional evidence to PARACHUTE studies and prove that the ventricular partition device is relatively safe and may reduce long-term death. However, the PARACHUTE device could increase the HF ratio.

Limitations

The present study was limited by its small sample size; unblinded, single-arm nature; and single-center clinical observations. Given that it was conducted in self-control mode and lacked a control group using standardized medical therapy or SVR, we could not rule out potential bias in the adjudication process. Furthermore, a robust conclusion could not be made without control group efficacy.

Conclusions

The PARACHUTE device is an alternative therapy for patients with severe LV maladaptive remodeling. The procedure of PARACHUTE implantation is safe and leads to potential benefits in long-term mortality reduction. However, the PARACHUTE device seems to increase the HF ratio at 4.6 years follow-up.

Abbreviations

HF

Heart failure;

LV

left ventricular;

LVEDD

LV end-diastolic diameter;

ICDs

implantable cardioverter defibrillator;

CRT-Ds

cardiac resynchronization therapy;

SVR

surgical ventricular reconstruction;

NYHA

New York Heart Association;

TTE

transthoracic echocardiography;

MCE

myocardial contrast echocardiography;

LVO

LV opacification;

MACEs

major adverse cardiac events;

PCI

percutaneous coronary intervention;

CABG

coronary artery bypass grafting;

PVR

percutaneous ventricular restoration;

ACEI

angiotensin-converting enzyme inhibitors;

ARB

Angiotensin receptor blocker;

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 analysed during this study are included in this published article

Competing interests Not applicable

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Authors' contributions

JH Li, SH Dong, W Ma, BW Zhang, and TZM Li contributions to the conception or design of the work, and interpretation of data for the work

JH Li, HD Liu, QY liu, C Liu, 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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Disclosures:

None

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Tables

Table 1
Baseline demographic data

Characteristics	Value
Age (Years)	55.7 ± 11.3
Male n, (%)	5 (84.3%)
BMI	26.0 ± 2.0
Previous medical history	
Hypertension n, (%)	5 (66.7%)
Hyperlipidemia n, (%)	1 (16.7%)
Diabetes n, (%)	1 (16.7%)
Stroke n, (%)	0 (0%)
Smoking n, (%)	5 (66.7%)
Recent rehospitalization of HF n, (%)	1 (16.7%)
Time form previous MI (month)	13.5 ± 12.9
Prior ICD implantation	0 (0%)
Prior CRT device	0 (0%)
Prior PCI	6 (100%)
Prior CABG surgery	0 (0%)
LV wall motion types	
Akinetic	0 (0%)
Dyskinetic	0 (0%)
Aneurysm	6 (100%)
Abbreviation: BMI, body mass Index; HF, heart failure; MI, myocardial infarction; ICD, implantable cardioverter defibrillators; CRT, cardiac resynchronization therapy; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting. LV, left ventricular.	

Table 2. Procedural data	
Procedure data (N = 6)	
Success deployment n, (%)	6 (100%)
LV perforation n, (%)	0 (0%)
Operative approach	
Femoral artery n, (%)	6 (100%)
Device Size	
PVR 65/65 s n, (%)	0 (0%)
PVR 75/75 s n, (%)	3 (50%)
PVR 85/85 s n, (%)	2 (33.3%)
PVR 95/95 s n, (%)	1 (16.7%)
Device related adverse events (N = 6)	
Unsuccessful delivery n, (%)	0 (0%)
Unsuccessful deployment n, (%)	0 (0%)
Vascular complications n, (%)	0 (0%)
Acute thrombosis n, (%)	0 (0%)
Emergent surgery n, (%)	0 (0%)
Abbreviation: PVR, percutaneous ventricular restoration.	

Table 3 Major Adverse Cardiac Events and Medication Therapy	
Major Adverse Cardiac Events	
All-cause mortality n, (%)	1 (16.7%)
Myocardial infarction n, (%)	1 (16.7%)
Emergent cardiac or aorta surgery n, (%)	0 (0%)
Selective cardiac or aorta surgery n, (%)	0 (0%)
Unplanned interventional therapy n, (%)	3 (50%)
New or worsening HF	3 (50%)
Erosion of device through LV	0 (0%)
Cardiac tamponade	0 (0%)
Device migration	0 (0%)
Device embolization	1 (0%)
Peripheral embolization/stroke	0 (0%)
Medication Therapy	
DAPT n, (%)	6 (100%)
Statin n, (%)	6 (100%)
Warfarin n, (%)	6 (100%)
β-Blocker n, (%)	6 (100%)
ACEI/ARB n, (%)	5 (83.3%)
Spironolactone n, (%)	5 (83.3%)
Abbreviations: ACEI, angiotensin-converting enzyme inhibitors; ARB, Angiotensin receptor blocker;	

Figures

Figure 1

Figure 1

Disposition of subjects enrolled. Six post-myocardial infarction eligible subjects with aneurysm received the PARACHUTE device.

Figure 2

Figure 2

Sequence of the PARACHUTE device implantation in the left ventricle. The operation was performed through the femoral artery (A). LV angiography was executed to observe the systolic (B) and diastolic (C) LV geometry. The device was placed in contact within the LV apical wall (D). After balloon inflation to facilitate device expansion, the LV geometric reconfiguration was evaluated in the systolic (E) and diastolic (F) phases. The white dotted line indicates the outline of the chamber morphological characteristics before the device implantation. The white arrow indicates the implanted PARACHUTE device.

Figure 3

Figure 3

Cumulative incidence of cardiovascular events in PARACHUTE-implemented patients. A Cumulative event rates for the composite of cardiovascular death, myocardial infarction, stroke, hospitalization for unstable angina, coronary revascularization, or heart failure end-point. B, C, and D Cumulative myocardial infarction, hospitalization, and mortality, respectively. E Changes in functional capacity according to

NYHA. MACEs, major adverse cardiovascular events; MI, myocardial infarction; HFH, hospitalization for heart failure. NYHA, New York Heart Association class.

Figure 4

Transthoracic echocardiograph-based cardiac function assessment. Transthoracic echocardiography (TTE)-based cardiac function evaluation was performed at baseline (the first time for MI treatment); before the PARACHUTE device procedure; and at 1 week, 6 months, 1 year, 2 years, and 3 years after

device implantation. A, C, and E Comparison of each time point for the left ventricular ejection fraction, left ventricular end-diastolic diameter, and estimated pulmonary artery pressure assessment, respectively. B, D, and F Changes in the TTE-based parameter measurement mentioned above. ***: $P < 0.001$, compared with baseline; ##: $P < 0.01$, compared with the PARACHUTE procedure; NS: not significant. mm: millimeter.

Figure 5

Figure 5

Case with left ventricular thrombus after device implantation by contrast echocardiography. (A). CT scan right after the PARACHUTE implantation to check potential device-related migration or embolization. (B). Latest follow-up detected by contrast-enhanced CT. The filling defect appeared in the apical left ventricle. (C) and (D) 3D-TTE and 2D-TEE were applied to exclude device migration, respectively. The white arrow indicates the implanted device. (E) and (F) Left ventricular thrombus confirmed by LVO and MCE, respectively. The white arrow points to the filling defect-implied LV apical thrombus

Supplementary Files

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