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Percutaneous Left Ventricular Restoration In Chronic Ischemic Heart

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Research Article

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ABSTRACT

Heart failure remains a leading cause of cardiovascular morbidity and mortality following myocardial infarction. Progressive cardiac remodeling results in altered shape and geometry of left ventricle (LV) with increased LV end diastolic volume and LV dilatation, reduced ejection fraction (EF) and heart failure. Medical therapy is the mainstay in state of art management of heart failure. However, surgical ventricular restoration to reverse cardiac remodelling has been attempted. More recently percutaneous ventricular restoration using “Parachute device” is emerging as a new strategy for the treatment of ischemic heart failure. The present study aims to present the recent data on this new device.
INTRODUCTION

Occlusion of left anterior descending coronary artery results in acute myocardial infarction involving the anterior wall and antero-apical portion of left ventricle (LV). This often results in progressive LV remodeling resulting in LV dilatation, aneurysm formation and chronic heart failure [1]. LV remodeling is characterized by alteration in cardiac structure, geometry and shape in response to pathological stress of myocardial infarction, scarring and interstitial fibrosis [2]. There is an increase in left ventricular end-diastolic volume (LVEDV) with LV dilatation, reduced ejection fraction (EF) and eventually heart failure (HF). Since cardiac remodeling is a progressive phenomenon, there is a need to reverse the process of LV remodeling to improve survival and to reduce mortality [3]. After the development of heart failure, quality of life (QOL) becomes poor due to frequent hospitalizations and impaired physical strength. The mortality remains unacceptably high after the development of heart failure [4]. Bagai and Piano (2014) [5] have outlined the various therapeutic options for the treatment of dilated ischemic heart failure. Intensive risk reduction with lifestyle modifications and various pharmacological drugs including angiotensin converting enzyme inhibitors (ACEI) or angiotensin receptor blocker (ARB), beta blockers, aldosterone antagonists, antiplatelet drugs and vasodilators remain the principal methods to control the heart failure [6,7]. Reversible ischemia may warrant percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG) in selected patients. In patients refractory to optimal medical therapy (OMT), cardiac resynchronization therapy (CRT) or automatic implantable defibrillator (AICD) or Combo may be indicated. Ventricular assist device (VAD) and cardiac transplantation are considered as the last options in refractory heart failure.

Progressive remodeling occurred in 33% patients of myocardial infarction enrolled in GISSI-3 TRIAL (n=13679) [8]. There exists a causal relationship between remodeling and reduced pump failure of the heart. Therapies which reduce myocardial stress and reverse remodeling, are becoming the cornerstone in the management of dilated ischemic heart failure. Surgical ventricular restoration (SVR) has been performed with the aim to reduce the LV volume and to restore the elliptical shape. SVR is usually done with CABG. The earliest SVR remodeling operation (reduction left ventriculoplasty) involved excision of the necrotic portion of LV and a portion of viable tissue from LV (Batista operation). However, it failed to change the natural history and course of ischemic heart failure. It was associated with surgical complications and has been largely abandoned. Excision of aneurysm with direct suturing is rarely performed today. DOR operation of left ventricular reconstruction involves endocardial patch plasty using a circular suture and a Dacron patch to correct LV aneurysm. RESTORE (Reconstructive Endoventricular Surgery returning Torsion Original Radius Elliptical shape) was performed by the restore - group of cardiothoracic surgeons on 1198 patients [10]. Ejection fraction (EF)
improved from 29.6±11.0% to 39.5±12.3% (P < 0.001); LVEDV decreased from 80.4±51.4 ml/m² to 56.6±34.3ml/m² (p< 0.001) and overall 5 year survival was 68.6±2.8%. RESTORE surgeons concluded that SVR improved LV functions and was highly effective therapy in the treatment of ischemic cardiomyopathy with excellent five-year survival (68.6 %). However, RESTORE is major cardiac surgery which requires a sternotomy, cardiopulmonary bypass and expert surgical team.

PERCUTANEOUS VENTRICULAR RESTORATION (PVR)

The concept of PVR is based on the premise that a dedicated partitioning device which can be delivered percutaneously, will result in LV volume reduction and geometrical reconfiguration to give LV a more elliptical shape without the risk of invasive surgery. The concept was realized in early 2005 and resulted in the development and refinement of “Parachute” device (Cardiokinetix Inc, Menlo Park, CA, USA). It is a novel transcatheter device for ventricular partition which tends to reverse LV remodeling in patients with myocardial infarction and treat heart failure. The device is under advanced stage of investigation in Europe, USA and China. Recently it has been approved in S.Korea. Parachute device is a minimally invasive device, CE approved in Europe and is a new strategy in the armamentarium of interventional cardiologist.

OBJECTIVE

The aims of the present study are to describe the “Parachute” device briefly, outline the procedure for implantation and present the results of various published reports and trials with the aim to determine its efficacy, safety, indications & complications.

METHODOLOGY

The literature on percutaneous ventricular Parachute device was searched and the results critically analyzed. Besides recent journals, we searched Med Pub, Mediscape, recent AHA/ACC/ESC congress 2014 / 2015 for percutaneous ventricular restoration and Parachute device. We also searched the official site of Cardiokinetix Inc, Marlo Park, CA, USA for the latest information.
PARACHUTE DEVICE (Figure 1 & 2)
The parachute device (Cardiokinetix Inc, Marlo Park, CA, USA) is deployed at the apex of the LV cavity via percutaneous route under mild conscious sedation and local anaesthesia. It is a catheter based intraventricular device. The first published description of the parachute device and its deployment was made by Sharkey et al (2006) \[11\] from the University of California, CA, USA. The concept of percutaneous ventricular partition was conceived by Dr. Branislav Radovencevic and Serjan Nikolic in 1999. The original parachute device was available in two sizes but it is now available in eight sizes (65/65S, 75/75S, 85/85S, 95/95S). Briefly, the device consists of a conical, self-expanding nitinol frame covered with a polytetrafluoroethylene (ePTFE) impermeable membrane. The NITI frame is in the configuration of an inverted umbrella. The device has a radio-opaque atraumatic polymer foot attached to the apex of the cone. The foot projects 2mm to anchor the device polymer to the apex of the LV. The conical frame is supported by struts. The whole device is advanced over a wire via 14/16F sheath in the femoral artery. The device is then passed into the left ventricle till the foot abuts the apex under the guidance of transthoracic echocardiography (TTE) and left ventriculography. The NITI frame is self-expandable but the device has a built-in balloon which can be inflated to assist in full expansion of the frame. After the device is successfully implanted, the balloon is deflated and delivery catheter is withdrawn leaving the device in left ventricle attached to the apex. The whole procedure of implantation may take 1-2 hours for completion. Once the device has been successfully implanted, the anchors engage the myocardium of left ventricle and stabilize the device preventing its dislodgement and migration. The occlusive membrane forms a barrier and separates LV into a lower akinetic portion (including the apical aneurysm) and a larger upper dynamically active LV. In view of the separation of LV into two parts, device is also called ventricular partition device (VPD). Postoperatively, the patients are kept on prophylactic warfarin for 3 months or more along with optimal medical therapy (OMT).

RESULTS

CLINICAL STUDIES

The first in man successful implantation of parachute device in a patient with chronic ischemic heart failure was performed in Europe (Belgrade and Serbia) \[11, 12, 13\] with follow-up for 3-12 months. Sagic et al (2010) \[14\] implanted parachute device successfully in 15 out of 18 patients (success rate 83%) of antero-apical myocardial infarction with heart failure. The device had to be explanted in two patients (out of 15) due to displacement and nondevice infection. The remaining 13 implanted patients were followed for 12 months. The mean diameter of device attachment zone of LV was 56.4±6.1mm. 8 patients were implanted with 75mm device and 7 with 85mm device. The procedural time was 60.6±29.0 minutes and an average of 340±99 ml of contrast was given per patient. Clinical progress, hemodynamic data and quality of life (QOL) vide Minnesota Living With Heart Failure (MLWHF) Questionnaire scale. Observations are summarized in Table 1.
Table 1: Functional capacity and hemodynamic data during 6/12 months follow up in 13 device implanted patients

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Baseline</th>
<th>6 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class</td>
<td>2.2±0.57</td>
<td>1.28±0.46</td>
<td>1.23±0.43</td>
</tr>
<tr>
<td>LVEF %</td>
<td>28±7</td>
<td>32±7</td>
<td>33±9</td>
</tr>
<tr>
<td>LVESV (ml)</td>
<td>189±45</td>
<td>142±29</td>
<td>151±48</td>
</tr>
<tr>
<td>LVEDV (ml)</td>
<td>260±47</td>
<td>208±33</td>
<td>425±140</td>
</tr>
<tr>
<td>6min walk (metres)</td>
<td>382±123</td>
<td>409±129</td>
<td>425±140</td>
</tr>
<tr>
<td>QOL points (MLWHF)</td>
<td>21.7±18.9</td>
<td>16.7±12.3</td>
<td>20.8±16.9</td>
</tr>
</tbody>
</table>

*(Sagic et al 2010)* [14]

(NYHA- New York Heart Association, LVEF-left ventricle ejection fraction, LVESV-left ventricle end systolic volume, LVEDV-left ventricle end diastolic volume, QOL-quality of life)

The authors concluded that VPD (PVR) was a safe and feasible procedure. 6-12 months follow up showed reduction in symptoms and improvement in 6 minute walk distance and LVEF with reduced LVESV and LVEDV at 6 months. Successful implantation of parachute device was done in 5 patients in a Portuguese centre with reduction in LV volumes which are surrogates of heart failure [15]. During follow-up for 6 months, renal function and cardio-biomarkers remained normal indicating that there was no damage to the myocardium during implantation. Muzzaferri et al (2012) [16] enrolled 39 patients in a multinational nonrandomized longitudinal investigation. The device implantation was successful in 31 out of 34 patients (success rate 91%). Patients were followed for 12 months. Results are shown in Table 2.

Table 2: Clinical and echocardiography data in 31 implanted patients

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Baseline</th>
<th>12 months</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NYHA Class</td>
<td>Class 3</td>
<td>1.5</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>QOF (MLWHF)</td>
<td>38.6±5.</td>
<td>128.4±4.4</td>
<td>&lt; 0.002</td>
</tr>
<tr>
<td>LVEF %</td>
<td>26.9±1.4</td>
<td>29.4±1.4</td>
<td>NS</td>
</tr>
<tr>
<td>LVESV (ml/m2)</td>
<td>93.6±4.1</td>
<td>79.5±3.6</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>LVEDV (ml/m2)</td>
<td>127.2±4.2</td>
<td>110.4±4.6</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*(Muzzaferri et al 2012)* [16]
Major adverse cardiovascular events (MACE) occurred in 5 patients (16%) and included emergent cardiac surgery (1), device migration / embolism (2) and re-hospitalization for heart failure (2). The authors concluded that parachute device is a safe and potentially effective treatment of heart failure due to old myocardial infarction. Bozadag –Turan et al (2013) [17] have highlighted the importance of adequate screening and proper selection of patients to improve the outcome and better results. They have emphasized the usefulness of two screening procedures namely (i) two-dimensional echocardiography (2DECHO) and (ii) 3-dimensional cardiac computed tomography (Cardiac CT) before undertaking parachute implantation. 2D-ECHO determines ejection fraction (EF), LV wall motion abnormality and presence of apical thrombus. Cardiac CT assesses the anatomy of LV architecture, geometry, shape, trabeculations and endocardial calcium deposits. The presence of apical thrombus, impaired trabeculae and severe calcification impair the chances of successful implantation. Thus out of 50 patients initially screened for PVR, only 8 patients were implanted with parachute device after proper screening with 2D-ECHO and cardiac CT [18]. Costa et al (2014) [19] reported 3 years outcome in 39 patients with ischemic heart failure, NYHA Class II-IV, EF 15-40% and dilated / akinetic anterior wall apex without the need of revascularization. PVR was successfully done in 31 out of 34 patients (success rate 91%). The hemodynamic data for 3 years was available in 19 patients. Results are summarized in Table 3.

Table 3 Clinical outcome of 31 implanted patients

<table>
<thead>
<tr>
<th>Parameters</th>
<th>End of 12 months</th>
<th>End of 24 months</th>
<th>End of 36 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of patients (n=31)</td>
<td>28</td>
<td>27</td>
<td>23</td>
</tr>
<tr>
<td>Mortality</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Cardiac transplant / VAD</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Hospitalization for HF</td>
<td>4</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

(VAD-ventricular assist device, HF – heart failure)
(B) Hemodynamic data in 19 patients (mean values)

<table>
<thead>
<tr>
<th>Mean Data</th>
<th>Baseline</th>
<th>12mth</th>
<th>24mth</th>
<th>36mths</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEDV1 (ml/m2)</td>
<td>125.7</td>
<td>108.9</td>
<td>108.9</td>
<td>114.4</td>
</tr>
<tr>
<td>LVESV1 (ml/m2)</td>
<td>89.6</td>
<td>76.7</td>
<td>76.7</td>
<td>87.0</td>
</tr>
<tr>
<td>LV Length (cm)</td>
<td>10.1</td>
<td>8.8</td>
<td>8.9</td>
<td>8.6</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>28.9</td>
<td>30.0</td>
<td>30.0</td>
<td>27.0</td>
</tr>
</tbody>
</table>

(Costa et al, 2014)\(^{[19]}\)

The cumulative incidence of HF hospitalization and death was 16.1%, 32.3% and 38.7% at 12, 24 and 36 months respectively. The author concluded that PVR device is feasible and safe up to 3 years post implantation. LVEDVI and LVESVI decreased over 3 years and LV dilatation decreased indicating reduction in LV remodeling. One year data from 111 patients from European Cohort A and B & US Feasibility Parachute 3 trial was presented at ACC 2014\(^{[20]}\). The success rate was 96% and hospital stay was < 3 days. At 12 months, there was 14% reduction in LV volume and 2% increase in LVEF with improved NYHA class in 54%. The major complications occurred in 7.2%; 1 year stroke and all cause mortality were 2.9% and 5.7% respectively. Ulrich Schafer (2015)\(^{[21]}\) from Germany presented data of Parachute III European Post Market trial at ACC 2015. 73 out of 100 patients had completed 24 months follow-up. Analysis confirmed the safety and efficacy of parachute trial in treatment of ischemic heart failure. A meta-analysis of PVR therapy using Parachute device in 133 patients with ischemic dilated heart failure was presented at EURO PCR 2013\(^{[22]}\). The success rate of implantation was 90%. Prof Thomas outlined the inclusion and exclusion criteria and analysed first 91 patients with successful implant. Major procedural complications were injury to aortic valve requiring AVR, bleed and injury to mitral valve and LV wall. Combined mortality and rehospitalization for HF was 17.9% at 6 months. Post implant NYHA improved in 53% and maintained in 36%. Mean LVESV and LVEDV also decreased with mild improvement of 6 minute walk distance. Thomas et al (2015)\(^{[23]}\) have recently published the results of 100 patients with ischemic dilated heart failure in NYHA Class II-IV, EF 15-40% and dilated akinetic antero-apical wall without the need of coronary revascularization from PARACHUTE III European Trial. Device was successfully implanted in 97 of 100 subjects. Echocardiography, LV volume indices and functional assessment by a standard 6 minute walk revealed favourable outcome with adequate reduction of LV volume (P < 0.0001) and improvement of 6 minute walk distance (p < 0.01), thus supporting adoption of parachute technique in selected patients as a therapeutic option for HF subjects. Two year data is available from parachute cohort A, Parachute US Feasibility and Parachute III for 134 selected patients where device implantation was successfully in 128 patients (96%) (Abraham, 2015)\(^{[24]}\). The rates of stroke, all cause death and combined HF hospitalization & death were 2.4%, 8.8% and 2.3% respectively. There was improvement in LV function (p < 0.05) assessed by LV volume indices, EF %, stroke work and contractibility index with improved diastolic function. NYHA class also improved from a mean base line 2.5±0.5 to 1.9±0.7 (p < 0.001). 6 minute walk improved from 360 metres at baseline to
391 metres at one year. The meta-analysis confirmed the safety and efficacy of the Parachute device in treating HF.

MECHANISM OF ACTION OF PARACHUTE DEVICE

1. PVR device divides LV into (a) an upper dynamic active contractile chamber with reduced LV volume and diameter with improved diastolic compliance and (b) a lower static akinetic chamber with a compliant parachute device, which provides an outward force at the anchors to facilitate diastolic filling of the upper chamber. The flexible frame allows the device to follow the contractions of the left ventricle.
2. Parachute device makes LV into a more elliptical / conical shape and allows torsional contraction with reduced stress on the wall of upper chamber of LV.

SCREENING INVESTIGATIONS BEFORE PVR

1. Echocardiography (2D or 3D) to determine ejection fraction (EF), LV wall motion abnormality and presence of apical thrombus.
2. Cardiac computed tomography (Cardiac CT) to assess the anatomy of LV and apex with wall thickness, ventricular trabeculae and endocardial calcium deposits. The presence of apical thrombus, impaired trabeculae and severe calcification impairs the chances of successful device implantation.

INCLUSION CRITERIA FOR DEVICE IMPLANTATION

The device is usually recommended if the following conditions are fulfilled:
1. EF 15-40%
2. Presence of akinesia or apical aneurysm of the anteroapical region of LV
3. Presence of appropriate anatomy of LV for device implantation as under:
   (a) LV end diastolic diameter - 57-70mm
   (b) LV wall thickness < 3.5mm
   (c) LV apical diameter 4.0 cm x 5.0 cm

EXCLUSION CRITERIA

1. Idiopathic dilated cardiomyopathy.
2. Clinically significant reversible / treatable CAD by CABG / PCI
3. Optimum medical therapy as per existing guidelines has not been given for a minimum of 12 weeks.
4. LV wall thickness < 3.5mm, excessive calcification and intraventricular bands
5. Extremely dilated LV > 70mm
POTENTIAL COMPLICATIONS OF PVR

(A) Procedural Complications: Include aortic valve damage, bleeding, mitral valve damage and embolism. The procedural success in properly selected patients is 85-94%.

(B) Post-Procedural Complications:
1. Dislodgement of device requiring urgent surgery
2. Infection of the device / endocarditis
3. Ventricular tachycardia (25)
4. Thrombo-embolic stroke

PATHOLOGY OF EXPLANTED DEVICE

Ladich et al (2013) [26] have examined the pathological features of 7 parachute devices which had been explanted at autopsy or cardiac transplant. The average duration of implant was 408 days (15-1533 days). All had organized thrombus with development of fibrosis and neo – endocardial thickening at the edges of device. Two implanted device (Duration > 300 days) had developed fractures of the struts and foot; one had tearing of the expanded ePTFE membrane. This study is a possible indicator of the life span of the device (Ige et al 2015) [27].

INDICATIONS FOR EXPLANTATION

1. Dislodgement
2. Infected device
3. Cardiac transplantation

COMPARISON OF SURGICAL VENTRICULAR RESTORATION (SVR) AND PERCUTANEOUS VENTRICULAR RESTORATION (PVR)

SVR has been studied in RESTORE [28] and STICH [29,30] and compared with PVR. Both methods serve the patients of HF as adjunct to the optimum medical therapy in controlling and restoring LV size and reverse LV remodeling. PVR is less invasive compared to SVR and is performed under conscious sedation while SVR is an open heart surgery and requires sternotomy, cardiopulmonary bypass. SVR operation takes a much longer time. Parachute device provides a more flexible barrier while suture related scar in LV may produce a firmer flat scar in SVR. PVR provides a more elliptical / conical shape of LV, while in SVR, it is operator dependent. Both PVR and SVR, provides reduction in LV size, LVESV and LVEDV and tends to improve NYHA Class and QOL. Post-operative complications and MACE appear comparable although surgery has a little higher rate of complications. The life span of PVR device is not known. It is not clear how long the reductions in LVESV and LVEDV observed after device implantation will continue to persist. However PVR is a new novel innovation and its safety, efficacy and durability are expected to improve in future with newer generation of device and further refinement.
PARACHUTE RESEARCH

Parachute trials / research are an ongoing process since 2005. The progress of various research programmes / trials is summarized in Table 4.

Table-4 Parachute Trials

<table>
<thead>
<tr>
<th>Name of Trial</th>
<th>Type of Trial</th>
<th>Number of patients enrolled and implanted</th>
<th>Location of Trial</th>
<th>End points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parachute Trial Cohort A &amp; B</td>
<td>Dual arm, open label multicentre</td>
<td>Cohort A 14/18 Cohort B 59/80</td>
<td>Europe (14 centres)</td>
<td>6 month MACE, ECHO and CT</td>
</tr>
<tr>
<td>Parachute US Feasibility Trial</td>
<td>Single arm, open label multicentre</td>
<td>Patients 20 Implant 17</td>
<td>US (8 centres)</td>
<td>As above</td>
</tr>
<tr>
<td>Parachute III Trial (Parachute vs OMT)</td>
<td>Enrolling</td>
<td>100</td>
<td>Europe (20 centres)</td>
<td>1. Mortality 2. Hospitalization for HF</td>
</tr>
<tr>
<td>Parachute IV US</td>
<td>Enrolling</td>
<td>Enrolling (80 centres)</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Parachute CHINA Trial</td>
<td>Single arm, open label multicenter</td>
<td>Enrolling</td>
<td>China (7 centres)</td>
<td>1. LVESV1 2. NYHA Class 3. QOL</td>
</tr>
<tr>
<td>Parachute V (Parachute vs OMT)</td>
<td>Dual arm, open label multicentre</td>
<td>Enrolling (20 centres)</td>
<td>Germany</td>
<td>1. Stroke index 2. QOL</td>
</tr>
</tbody>
</table>

{Adapted from the source - cardiokinetics.com (downloaded 21.1.)}

MACE: major adverse cardiovascular events, ECHO-echocardiography, CT – computerized Tomography, OMT-optimal medical therapy, QOL-quality of life
**FUTURISITIC (PIVOTAL) TRIALS**

Parachute IV is a pivotal FDA trial. The trial is expected to enrol 560 post LAD territory MI / HF patients in US who have NYHA III-IV status with EF 15-35%, LV wall movement motion abnormalities (Akinesia or aneurysm) and suitable LV anatomy assessed by 2D-ECHO and cardiac CT. The endpoint of the study will be all cause mortality, hospitalization for HF, QOL and hemodynamic parameters. The study is likely to afford answers to many queries. University of LOWA’s Heart Failure Programme (USA) is currently following Parachute device implantation under Parachute IV clinical trial. If found safe and cost effective, the pivotal trial may pave the way to its approval by FDA. The parachute China trial and parachute V trial in Germany will further add data to its safety, efficacy and durability of the device.

**CONCLUSION**

PVR is under development through various clinical trials since 2006. Eight different sizes of device CE marking are now available. Development of guide catheter and delivery system had reduced aortic valve trauma. FDA approval is still awaited. Clinical trials have shown reduction in LVEDV and LVESV which are surrogates of heart failure. There are indications of improvement in NYHA class and QOL. Success rate of implantation has been over 90%. Continued clinical experience and Parachute IV & V trials may establish the future of this new device in the management of post-infarction heart failure.

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