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Original Research

Midterm Outcome of Hybrid Transcatheter and Minimally Invasive Left Ventricular Reconstruction for the Treatment of Ischemic Heart Failure

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ABSTRACT

Background: Left ventricular (LV) remodeling after anterior myocardial infarction (AMI) can cause a pathological increase in LV volume, reduction in LV ejection fraction (EF), and symptomatic heart failure (HF). This study evaluates the midterm results of a hybrid transcatheter and minimally invasive surgical technique to reconstruct the negatively remodeled LV by myocardial scar plication and exclusion with microanchoring technology.
Methods: Retrospective single-center analysis of patients who underwent hybrid LV reconstruction (LVR) with the Revivent TransCatheter System. Patients were accepted for the procedure when they presented with symptomatic HF (New York Heart Association class $\geq$ II, EF $<$ 40%) after AMI, in the presence of a dilated LV with either akinetic or dyskinetic scar in the anteroseptal wall and/or apex of $\geq$50% transmurality.
Results: Between October 2016 and November 2021, 30 consecutive patients were operated. Procedural success was 100%. Comparing echocardiographic data preoperatively and directly postoperatively, LVEF increased from 33 $\pm$ 8% to 44 $\pm$ 10% ($p < 0.0001$). LV end-systolic volume index decreased from 58 $\pm$ 24 mL/m^2 to 34 $\pm$ 19 mL/m^2 ($p < 0.0001$) and LV end-diastolic volume index decreased from 84 $\pm$ 32 mL/m^2 to 58 $\pm$ 25 mL/m^2 ($p < 0.0001$). Hospital mortality was 0%. After a mean follow-up of 3.4 $\pm$ 1.3 years, there was a significant improvement of New York Heart Association class ($p = 0.001$) with 76% of surviving patients in class I-II.
Conclusions: Hybrid LVR for symptomatic HF after AMI is safe and results in significant improvement in EF, reduction in LV volumes, and sustained improvement in symptoms.

ABBREVIATIONS

AMI, anterior myocardial infarction; CABG, coronary artery bypass graft; CT, computed tomography; EF, ejection fraction; HF, heart failure; ICD, implantable cardioverter defibrillator; IHF, ischemic heart failure; LGE CMR, late gadolinium enhancement cardiac magnetic resonance; LV, left ventricle; LVEDV, left ventricular end-diastolic volume; LVEDVI, left ventricular end-diastolic volume index; LVESV, left ventricular end-systolic volume; LVESVI, left ventricular end-systolic volume index; LVR, left ventricular reconstruction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RV, right ventricle; RV-LV^A, external anchor pair placed with the use of the Antonius stitch; RV-LV^H, internal and external anchor pair placed with the hybrid technique; SVR, surgical ventricular reconstruction; TC, TransCatheter; TTE, transthoracic echocardiography.

Introduction

Ischemic heart disease is a leading cause of death worldwide[1,2] and is estimated to globally affect approximately 126 million individuals, corresponding to 1.72% of the world's population.[2] Ischemic heart disease can lead to ischemic heart failure (IHF) if it remains undiagnosed or untreated.[3] Early myocardial reperfusion using primary percutaneous coronary intervention (PCI) often reduces the size of infarction and preserves left ventricular ejection fraction (LVEF). However, not all patients with anterior myocardial infarction (AMI) maintain cardiac

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function[4] due to negative LV remodeling.[5] Negative LV remodeling leads to LV dilation and reduction of LVEF and occurs in around 30% of patients after anterior infarcts despite timely PCI and the optimal use of medical therapy, that is, angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers, beta-blockers, and aldosterone inhibitors.[6] In order to restore the shape, size, and function of the LV, operative treatment options can be considered. Conventional surgical ventricular reconstruction (SVR) as a treatment for IHF is a highly invasive open-heart surgical procedure that requires a full median sternotomy with the use of extracorporeal circulation and cardioplegic myocardial arrest.[7] In the past decade, conventional SVR through a full median sternotomy has evolved toward a hybrid transcatheter and less invasive LV reconstruction (LVR), also known as the less invasive ventricular enhancement procedure. The second-generation Revivent TransCatheter (TC) System enabling hybrid LVR received CE marking certification in 2016. With the INTERSECT study, we aimed to assess the midterm outcome of LVR with the use of the Revivent TC System.

Material and Methods

Ethical Statement

Approval of the INTERSECT study was obtained from the Medical Research Ethics Committee and Local Hospital Committee on July 05, 2021 (Z21.060). Written informed consent was collected for all patients.

Patient Selection

All patients with IHF who underwent hybrid LVR using the microanchoring technology of the Revivent TC Ventricular Enhancement System (BioVentrix Inc, San Ramon, California) in our hospital between October 2016 and January 2022 were retrospectively assessed. A dedicated team consisting of a cardiac surgeon, interventional cardiologist and imaging cardiologist, conducted the baseline assessment and determination of treatment strategy of all patients.

Patients were accepted for the procedure when they presented with symptomatic HF corresponding to New York Heart Association (NYHA)-class II or higher as a consequence of LV dysfunction (LVEF $<40\%$) after previous AMI and negative LV remodeling. Patients either showed a globally negatively remodeled LV with an LV end-systolic volume index (LVESVI) ≥ 60 mL/m^2 or showed a delineated apical aneurysm in the absence of midventricular or basal dilatation. In the presence of the latter, the LVESVI can still be below the LVESVI threshold of 60 mL/m^2, but the combination of such a clear LV apical aneurysm causing symptoms and/or elevated NT-proBNP still formed an indication for surgery in our cohort. All patients showed either akinetic or dyskinetic scar in the anteroseptal wall and/or apex of $\geq 50\%$ transmurality. Patients were operated after maintaining optimized guideline-derived medical therapy for ≥ 90 days, meaning that the AMI or index event occurred at least 3 months before screening.

Important contraindications for hybrid or surgical LVR with the Revivent TC System were the presence of an intracardiac thrombus, cardiac valve disease necessitating repair or replacement, estimated systolic pulmonary arterial pressure >60 mmHg derived from tricuspid regurgitations on echocardiography and contraindication to open-heart surgery in case of conversion after occurrence of a complication.

Procedural Technique

A hybrid transcatheter and minimally invasive technique that relies on the microanchoring technology of the Revivent TC Ventricular Enhancement System (BioVentrix Inc, San Ramon, California) was used to reconstruct the LV by plication of the fibrous scar. A series of paired internal and external micro anchors are brought together over apoly-ether-ether-ketone tether to form a longitudinal line of apposition between the LV free wall and the anterior septum from the mid ventricle to the apex. Internal anchors are deployed by transcatheter technique on the right side of the ventricular septum through the right internal jugular vein. External anchors are advanced through a left sided mini-thoracotomy and the anchor pairs are brought together under measured compression forces. Additional external apical anchor pairs complete the reconstruction. High-risk patients for whom an endovascular approach was not feasible underwent an external-only approach.

Dependent on the distribution of myocardial scar tissue, LVR with Revivent TC mainly includes 4 different optional approaches (Table 1).

Type I

Patients with septal myocardial scar distribution were preferably operated with the use of a true hybrid RV-LV approach. With the true hybrid technique, one or more internal and external anchor pairs were placed. If more septal scar was present basally to the implanted pair(s), an externally deployed RV-LV anchor pair was placed, sacrificing a small part of the RV. This external RV-LV stitch is called the "Antonius stitch" (RV-LV^A) after its development in the St. Antonius Hospital in Nieuwegein, the Netherlands. If scar tissue was also present in the apex, additional external LV-LV anchor pairs were implanted to complete the reconstruction.

Type II

When septal myocardial scar distribution was present, but the endovascular approach was considered high risk and not feasible, an external-only approach was applied by placing one or more RV-LV^A anchor pairs. If additional apical myocardial scar distribution was present, LV-LV anchors were implanted to complete the reconstruction. When there is a negatively remodeled LV with severe dilation in combination with significant LV dysfunction and elevated left and right sided pressures (pulmonary artery (PA) hypertension with PA-pressure >60 mmHg), the endovascular approach is considered high risk because of the risk for ventricular arrhythmia's and hemodynamic collapse due to manipulation or mechanical stimulation.

Type III

In the presence of a true LV apical aneurysm with anterolateral scar, a LV-double purse string suture was placed in de scarred border zone of the aneurysm together with external LV-LV anchor pairs. If septal scar was also present, one or more additional RV-LV^A anchor pairs were implanted.

Type IV

In case of isolated myocardial scar distribution in the anterior or anterolateral wall, LV-LV anchor pairs were placed.

Data Collection and Patient Follow-Up

Preoperative, intraoperative, postoperative, and follow-up data were obtained from electronic medical records and entered into an internally maintained database.

Table 1
Overview of technical approaches of LVR with the Revivent TC System

Type of technique	Indication
• Type I: RV-LV^H +/− RV-LV^A +/− LV-LV	Septal +/− basal septal +/− apical scar
• Type II: RV-LV^A +/− LV-LV	Septal +/− apical scar
• Type III: LV-LV with double purse-string +/− RV-LV^A	Apical aneurysm + anterolateral scar +/− septal scar
• Type IV: LV-LV	Anterolateral scar

Notes. LV-LV, external anchor pair placed on the left ventricle; RV-LV^A, Antonius stitch: external anchor pair between right ventricle and left ventricle; RV-LV^H, hybrid anchor pair between right ventricle and left ventricle.
LV, left ventricle; LVR, left ventricular reconstruciton; RV, right ventricle; TC, TransCatheter.

When patients were referred to another hospital after the procedure, all files were requested. At the end of the study, telephone follow-up was conducted to complete mid- to long-term follow-up.

Imaging Analysis

A detailed and comprehensive preoperative imaging assessment of all patients who were screened for LVR with the Revivent TC System was performed and included transthoracic echocardiography (TTE), computed tomography (CT), and/or cardiac magnetic resonance (CMR) imaging with late gadolinium enhancement (LGE). CT-derived three- and four-dimensional reconstructions were used to visualize the ventricular aneurysm as part of procedural planning.

Preoperatively, TTE was utilized to systematically assess LV dilatation, LVEF, LVESVI, and LV end-diastolic volume index (LVEDVI), regional wall akinesis or dyskinesis and valvular incompetence. When procedural eligibility was confirmed by initial TTE evaluation, LGE CMR imaging was performed to determine the location, extent, and transmurality of myocardial scar. In patients with intracardiac devices that are incompatible with CMR, a four-dimensional cardiac CT scan with triphasic injection of contrast was performed to determine regional wall thickness and motion abnormalities.

Intraoperatively, hemodynamics and LV configuration were monitored by transesophageal echocardiography and fluoroscopy. Standard preoperative and postoperative echocardiographic analysis was conducted and registered intraoperatively. Changes in LV volume indices were assessed in all patients.

Statistical Analysis

Continuous data are presented as mean ± SD or as median (interquartile range [IQR]). Categorical outcomes were summarized with numbers and percentages. Preoperative and postoperative continuous, normally distributed data were compared using the paired Student's t-test, whereas non-normally distributed data were compared using the Wilcoxon signed rank test for paired samples. Categorical outcomes were analyzed using the Wilcoxon signed rank test. Contingency tables were created to visualize transitions between NYHA classes preoperatively and postoperatively.

SPSS Statistics 26.0 (IBM Corp, Armonk, New York) was used for analysis. Statistical significance was acknowledged at a *p*-value less than 0.05.

Results

Baseline Characteristics

Baseline data including patient demographics, medical history, preoperative medication, and functional status of all included patients are presented in Table 2. Between October 2016 and November 2021, 30 HF patients (25 males, 5 females; mean age 62 ± 12 years) were operated in our center. Patients presented with a mean NYHA class of 3 ± 1, corresponding with 76% of patients in NYHA class III-IV, despite optimal guideline-directed medical therapy. A previous PCI was performed in 70% of patients. Forty seven percent of patients had an implantable cardioverter defibrillator (ICD) at baseline. The baseline 6-minute walking test (6MWT) distance was 397 ± 165 m. The N-terminal-pro hormone B-type natriuretic peptide (NT-proBNP) level at baseline was 527 (277-1679) pg/mL.

Procedural Data

Procedural data are summarized in Table 3. Between October 2016 and November 2021, 30 HF patients were operated in our center. Successful device implantation was achieved in all patients (100%), with a corresponding mean procedural time of 156 ± 68 min. On average, 2.3 ± 0.8 anchor pairs were used for LVR. A true hybrid LVR (Type I) with the application of RV-LV anchors with or without an additional Antonius stitch and LV-LV anchors was performed in 53% of patients. An apical aneurysm (with or without septal scar distribution) was present in 33% of patients, for which LV-LV anchors were placed together with a double purse-string suture (Type III). As a bailout for the endovascular approach, isolated RV-LV^{A} anchor pairs were placed in one patient with a high operative risk (3%) (Type II). Three patients (10%) showed isolated myocardial scar distribution in the anterior or anterolateral wall without septal extension for which only LV-LV anchor pairs were placed (Type IV). All LV reconstructions were isolated and hence no concomitant surgery was performed. One patient (3%) was converted to median sternotomy due to dislocation of an organized thrombus, after which removal of the thrombus and a reconstruction of the LV (with the

Table 2
Baseline characteristics

Variable	All patients (n = 30)
Age (y)	62 ± 12
Male (%)	24 (80%)
BSA	2.0 ± 0.2
NYHA class (1-4)	3 ± 1
ICD	14 (47%)
Pacemaker	1 (3%)
History of atrial fibrillation	5 (17%)
Previous PCI	21 (70%)
Previous CVA	3 (10%)
Renal function (GFR)	64 ± 17
Hypertension	16 (53%)
Diabetes mellitus	10 (33%)
Active smoking	7 (23%)
COPD	8 (27%)
6MWT (m)	397 ± 165
NT-proBNP (pg/mL)	527 (277-1679)
Medication	
Statin	28 (93%)
Beta-blocker	26 (87%)
ACE-inhibitor	14 (47%)
ARB	6 (20%)
ARNI*	4 (13%)
Diuretic	21 (70%)
Aldosterone antagonist	15 (50%)
P2Y12-inhibitor	12 (40%)
Vitamin K antagonist	21 (70%)
Salicylate	12 (40%)
Long/short-acting nitrate	13 (43%)

Notes. Values are mean ± SD, median (interquartile range) or n (%).
6MWT, 6 minute walk test; ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor II blocker - neprilysin inhibitor; BSA, body surface area; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; GFR, glomerular filtration rate; ICD, implantable cardioverter defibrillator; NT-proBNP, N-terminal-pro hormone B-type natriuretic peptide; NYHA, New York Heart Association; PCI, percutaneous coronary intervention
* Sacubitril/valsartan.

Table 3
Procedural data

Variable	All patients (n = 30)
Anchor pairs (n)	2.3 ± 0.8
Type of technique	
• Type I: RV-LV^{H} +/− RV-LV^{A} +/− LV-LV	16 (53.3%)
• Type II: RV-LV^{A} +/− LV-LV	1 (3.3%)
• Type III: LV-LV with double purse-string +/− RV-LV^{A}	10 (33.3%)
• Type IV: LV-LV	3 (10%)
Operating time (min)	156 ± 68
Conversion to sternotomy (n)	1 (3%)
ICU stay (d)	2 (1-4)
Hospital stay (d)	7 (6-11)

Notes. Values are mean ± SD, median (interquartile range) or n (%). RV-LV^{H}, hybrid anchor pair between the right ventricle and left ventricle; RV-LV^{A}, Antonius stitch: external anchor pair between right ventricle and left ventricle; LV-LV, external anchor pair placed on the left ventricle.
ICU, intensive care unit; LV, left ventricle; RV, right ventricle.

Revivent TC System) was performed on bypass. The median hospital stay was 7 (6-11) days, and the median stay in the intensive care unit was 2 (1-4) days.

Early Safety Outcomes

Major and minor adverse events within 30 days are listed in Table 4. There were no in-hospital deaths (0%). Atrial fibrillation was observed in 14 patients (47%), of whom 4 patients (13%) had a history of AF at baseline. Acute kidney insufficiency (defined by an increase in serum creatinine ≥150%) occurred in 4 patients (13%). Respiratory failure (requiring prolonged ventilation or reintubation) was observed in 3 patients (10%). One patient (3%) underwent pericardiocentesis because of pericardial effusion. One patient (3%) was operated for a second time to remove a hybrid RV-LV anchor pair because of RV failure. The RV failure occurred because the external anchor was placed relatively medial on the external surface of the LV in relation to the posterior location of the pairing internal anchor on the right ventricular side of the interventricular septum. This created bulging of the plicated scarred septum toward and into the RV.

Follow-Up Safety Outcomes

Major and minor adverse events after 30 days are listed in Table 5. The mean clinical follow-up was 2.7 ± 1.6 years. Late mortality (after 30 days) occurred in 4 patients (13%). One patient died due to COVID-19 (at 4 months), one due to complications following hospitalization for a dens fracture (at 16 months), one due to cardiac arrest (ventricular fibrillation at 7 months), and one due to heart failure (at 21 months). Two patients (7%) underwent a cardiac reintervention. One patient underwent a tricuspid valve replacement 7 months postoperative as a consequence of an increase of tricuspid regurgitation caused by a lesion of the tricuspid subvalvular apparatus during the procedure. The other patient underwent closure of a gap with persistent filling of the excluded LV aneurysm with an Amulet device 15 months postoperatively. In addition, one patient (3%) underwent a PCI because of non-ST-elevation myocardial infarction approximately 6 months postoperatively. One patient (3%) was readmitted for HF approximately 4 months postoperatively. Two patients received an ICD 5 months postoperatively and 28 months postoperatively.

Echocardiographic Outcome

Echocardiographic paired data from all treated patients showed significant LV volume reduction directly postoperatively compared to baseline (Table 6).

Comparing echocardiographic data prereconstruction and directly postreconstruction by three-dimensional transesophageal echocardiography, mean LVEF increased from 33 ± 8% to 44 ± 10% ($p < 0.0001$). The mean LVESVI decreased from 58 mL/m^2 ± 24 mL to 34 ± 19 mL/m^2 ($p < 0.0001$), corresponding to a reduction of 41%. The mean LVEDVI decreased from 84 mL/m^2 ± 32 mL/m^2 to 58 ± 25 mL/m^2 ($p < 0.0001$), corresponding to a decrease of 31%. Although stroke volume did not show a significant increase ($p = 0.217$), the mean LVEF was significantly increased by 36% ($p < 0.0001$).

Table 4
Clinical outcomes within 30 days

Variable	Values (n = 30)
Mortality	0 (0%)
Stroke	0 (0%)
Myocardial infarction	0 (0%)
Late cardiac arrest	0 (0%)
Respiratory failure	3 (10%)
Acute kidney injury*	4 (13%)
Pericardial effusion requiring intervention	1 (3%)
Reintervention	1 (3%)
New ICD or PM implantation	1 (3%)
Atrial fibrillation	14 (47%)

Notes. Values are n (%).
ICD, implantable cardioverter defibrillator; PM, pacemaker.
* According to the VARC-3 criteria.

Table 5
Late clinical outcomes (>30 days)

Variable	Values (n = 30)
All-cause mortality	4 (13%)
Stroke	0 (0%)
Myocardial infarction	1 (3%)
Cardiac reintervention	2 (7%)
Rehospitalization for HF	1 (3%)
Heart transplantation	0 (0%)
LVAD implantation	0 (0%)
New ICD or PM	2 (7%)

Notes. Values are n (%).
HF, heart failure; ICD, implantable cardioverter defibrillator; LVAD, left ventricular assist device; PM, pacemaker.

Functional Outcome

A significant reduction ($p < 0.0001$) of NYHA class was found from class 3 ± 1 at baseline to class 1.9 ± 0.6 at early follow-up, measured at a mean follow-up of 5 ± 4 months. More specifically, 21 patients (86%) out of 24 patients with available early follow-up were in NYHA class I-II.

Table 7 shows the specific changes in NYHA class for each patient between baseline and latest follow-up, corresponding to a minimum follow-up duration per patient of 1 year (mean follow-up 3.4 ± 1.3 years). Patients who were deceased (n = 4), who had a follow-up of less than 1 year (n = 3), or did not have any follow-up data available (n = 2) were removed from the analysis. A significant reduction ($p = 0.001$) of NYHA class was detected at latest follow-up (NYHA class 1.8 ± 0.8). At the latest follow-up, 16 (76%) out of 21 patients were in NYHA class I-II. All 5 patients (24%) who were in NYHA class III postoperatively were also in class III preoperatively. One patient (3%) was not symptomatic preoperatively (NYHA class I) but was operated due to severe LV systolic dysfunction and extensive myocardial scarring. This patient remained asymptomatic at follow-up. In the total group, an improvement in NYHA class at latest follow-up was found in 14 (67%) patients and no difference between baseline and latest follow-up was found in 7 (33%) patients. No patients (0%) deteriorated in functional class at latest follow-up.

Discussion

LV remodeling after AMI is characterized by the alteration of LV architecture, with associated increase in LV volume, altered chamber configuration because of cell hypertrophy, cell apoptosis and interstitial fibrosis and myocardial dysfunction.[8] The enlarging LV changes its shape

Table 6
Echocardiographic outcome

Variable	Directly preoperatively (n = 30)	Directly postoperatively (n = 30)	*p*-value
LVEF (%)	33 ± 8	44 ± 10	<0.0001
SV (mL)	55 ± 23	52 ± 20	0.217
LVEDV (mL)	169 ± 69	118 ± 53	<0.0001
LVESV (mL)	116 ± 50	68 ± 38	<0.0001
LVEDVI (mL/m^2)	84 ± 32	58 ± 25	<0.0001
LVESVI (mL/m^2)	58 ± 24	34 ± 18	<0.0001

Notes. Values are mean ± SD.
LVEDV, left ventricular end-diastolic volume; LVEDVI, left ventricular end-diastolic volume index; LVEF, left ventricular ejection fraction; LVESV, left ventricular end-systolic volume; LVESVI, left ventricular end-systolic volume index; SV, stroke volume.

Table 7
Contingency table with changes in NYHA class at latest follow-up*

		Postoperative value				
	NYHA class	I	II	III	IV	Total
Preoperative value	I	1	0	0	0	1
	II	4	1	0	0	5
	III	5	5	5	0	15
	IV	0	0	0	0	0
	Total	10	6	5	0	21

NYHA, New York Heart Association.
* Only patients with at least 1 year of follow-up were included in this analysis. All deceased patients were removed from this analysis.

from elliptical to spherical, thus further reducing normal systolic torsion. The myofibrils of such a spherical LV are shifted in a more transverse direction, away from the normal oblique axis. As a consequence, myofibril shortening is reduced and can generate only part of the normal ejection fraction that can be delivered in an elliptical ventricle with natural torsion.[9]

The mechanical adaptation of increasing LV volumes to declining systolic function initially aids in the preservation of stroke volume and cardiac output but can eventually lead to HF.[7,10] Given that both LV volumes and LV remodeling are major determinants of survival after recovery from AMI, the value of LV remodeling has become a surrogate end point in HF trials and is a primary target for treatment.[11] Although previous trials have shown that optimal guideline-directed medical therapy after AMI can result in benefit in terms of mortality, morbidity and LV remodeling,[1,6] severe negative LV remodeling can be inevitable. In order to restore the physiological volume and shape of the LV and hence improve LV function, operative treatment options could be considered. SVR was introduced as an optional therapeutic strategy to reduce LV volume and create a more natural elliptical chamber by excluding scarred akinetic or dyskinetic segments.[9,12] In dedicated centers, SVR was shown to be associated with excellent results in selected patients. However, conventional SVR does require open-heart surgery through a full median sternotomy with the use of extracorporeal circulation and cardioplegic myocardial arrest.[7] Clearly, SVR is a highly invasive procedure, with associated substantial associated mortality and morbidity due to the surgical trauma. Hence, hybrid transcatheter and minimally invasive surgical off-pump LVR (Revivent TC System) was developed to achieve an equally effective LVR through a limited access approach and utilizing transcatheter techniques. With the micro-anchoring technology of the hybrid LVR, a longitudinal line of apposition between the LV free wall and the anterior septum of the right ventricle (RV) is created. By reducing the enlarged LV volume, a decrease in wall stress and increase of LVEF can be achieved.[5]

Dependent on myocardial scar distribution, less invasive ventricular enhancement therapy with Revivent TC include different technical approaches and range from true hybrid RV-LV anchor-placement (Type I) to an isolated external approach (Type II-IV). The latter can be preferred either in the absence of septal scar or in case of severe increased risk associated with an endovascular approach (such as in patients with very severe LV dilation and dysfunction and severe pulmonary artery hypertension [PA pressure $>$ 60mmHg]).[13] Importantly, the presence of septal myocardial scar requires either hybrid (Type I) or external placement of RV-LV anchor pairs (Type II/III). If scar tissue is present in the apex, additional external LV-LV anchor pairs should be placed and can be combined with an LV double purse-string suture in case of LV apical aneurysm formation. Logically, Type I and II could have been combined with LV double purse-string sutures in all cases with apical aneurysm morphology, but this was not an option in our earlier experience due to the development of the technique over the years. Nowadays, when there is a clear apical aneurysm with anterolateral scar in the absence of septal scar distribution, an LV double purse-string suture is recommended to be placed together with external LV-LV anchor pairs.

Hybrid LVR has been shown to be an effective treatment option based on our postoperative echocardiographic outcome directly postoperatively. In our study, a significant increase in LVEF was found together with a significant decrease in LV end-systolic and end-diastolic volume indices (p-values < 0.0001). A comparable significant improvement in LVEF and reduction of LVESVI and LVEDVI was found in the majority of previously published cohorts after LVR with the first or second generation Revivent TC System.[13-16] The RESTORE group also reported a similar significant improvement of LVEF and LVESVI in 1198 postinfarction patients who underwent conventional surgical SVR.[17]

Major adverse events were observed in a limited number of patients. Importantly, our conversion rate (3%) is similar to that of Naar et al., (4%) and somewhat higher than the large multicenter European cohort described by Klein et al. (0%).[14,15] Cardiac reinterventions were performed in 3 patients (10%) of our cohort, of which one tricuspid valve replacement for tricuspid regurgitation. In the case series of Naar et al.,[15] 2 patients were reoperated for tricuspid regurgitation within 2 months postoperatively.

Interestingly, the rehospitalization rate for HF in our study population was considerably low (3%). In the SOLVD trial, by comparison, patients with an LVEF $\leq$35% after prior myocardial infarction showed a hospitalization rate for decompensated HF of 26% after receiving medical therapy including enalapril. This result further indicates the potential superiority of hybrid LVR compared to medical treatment alone.[18]

Furthermore, this study showed absence of 30-day mortality (0%) after hybrid LVR, which compares favorably with the reported mortality rates of 2 previous cohorts described with a rate of 9%.[14,19] Procedural mortality was also found to be lower in our series compared to that of SVR studies.[17,19] Cardiac mortality during follow-up in our study was 7%. When coronary artery bypass graft (CABG) was compared to medical therapy alone, the Hypothesis 1 STICH trial reported a cardiovascular mortality rate of 33% after receiving medical therapy alone and 28% after receiving medical therapy plus CABG.[20] The latter highlights the safety of hybrid LVR in this cohort.

In this study, we have reported a mid- to long-term follow-up on the functional status of 24 patients, corresponding to a mean follow-up of 3.4 $\pm$ 1.3 years. Functional follow-up could not be performed in 6 patients due to mortality (n = 4) and loss to follow-up (n = 2). Although all previous Revivent cohorts conducted a follow-up on the symptomatic status of patients, only one study has previously performed a long-term follow-up.[15] Despite the fact that our patients were more symptomatic at baseline than the patients described by Naar et al., a comparable and significant improvement in NYHA class was found. Patients in the STICH trial who were randomized to medical treatment with CABG and SVR also significantly improved in functional class at a mean follow-up of 48 months, with 86% of patients in NYHA class I or II.[19] This 10% difference with our cohort in favor of the STICH trial might be explained by the difference in symptomatic status at baseline, as 76% of our patients were in NYHA class III-IV at baseline, compared to only 49% of patients in the STICH trial.

Although our clinical and functional results remain promising, we would like to emphasize that additional long-term clinical and echocardiographic follow-up is needed to evaluate the volumetric and functional results.

Limitations

This is an observational retrospective and prospective single-center observational cohort study with its corresponding restrictions. Despite the fact that all patient files were retrieved and living patients were interviewed at the end of the study, the follow-up period differed between patients due to the consecutive enrollment. Of note, dosages of guideline-directed medical therapy at baseline were not provided in this overview. Furthermore, the number of patients in this cohort remains relatively small. Nevertheless, this cohort is the largest cohort to date that describes mid- to long-term clinical follow-up of hybrid LVR.

Patients underwent an LVR through a minithoracotomy with or without the concomitant use of transcatheter anchor delivery and the results were not compared between each of the 4 optional approaches with its different anchor-combinations (Type I-IV). The focus of these results was the effectiveness of the LVR based on the most suitable anchor-positioning, as determined by the distribution of myocardial scar in each patient.

Although clinical and functional mid- to long-term follow-up of the vast majority of patients was conducted, echocardiographic long-term follow-up would further substantiate our positive results. Moreover, comprehensive preoperative and postoperative CMR imaging with LGE and/or CT would enable a more detailed assessment of LV remodeling including LV strain.

Conclusion and Prospects

These data indicate that the Revivent TC System can be used as a minimally invasive and equally effective beating heart alternative to SVR to reconstruct a negatively remodeled LV after a large AMI to treat IHF. Although serious adverse events were observed in a limited number of patients, the safety outcome of this procedure is expected to further improve with increased experience and adequate patient selection. In addition to achieving a significant improvement in LVEF and LVESVI, long-term functional improvement can be obtained in selected patients. By an anatomical and scar-determined tailored approach, a durable result can be achieved for all individual scar-patterns. In order to further assess the benefit of the Revivent TC System over guideline-directed medical therapy in the treatment of IHF, the results of randomized controlled trials (such as REVIVE-HF) are eagerly awaited.

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Ethics Statement

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