

Safety and efficacy of less-invasive ventricular enhancement procedure with the transcatheter Revivent TCTM system in patients with left ventricular aneurysm: a systematic review

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Left ventricular (LV) aneurysm following acute myocardial infarction (MI) represents a less common complication, but with worse clinical outcomes. Ventricular surgical reconstruction is not always the intervention of choice due to high surgical risk. There were proposed less invasive LV aneurysm exclusion techniques such as the less invasive ventricular enhancement (LIVE) procedure. Our paper represents the first systematic approach to investigate the efficacy and safety of LIVE procedure using Revivent TCTM anchor system for LV aneurysm exclusion. Studies were considered if they reported original data regarding LIVE procedure's efficacy and/or safety using the Revivent TCTM system in patients with LV aneurysms. Five studies met the inclusion criteria. The procedure is associated with a reduction in LV volumes and an improvement in LV ejection fraction (LVEF). The means of preoperative LVEF varied between 22.8% and 35.6%, while postoperative LVEF means ranged between 34% and 45.9% (P < 0.005) across studies. All included papers reported a significant difference between preoperative and postoperative LV end-systolic volume in $dex (P \le 0.001)$ and LV end-diastolic volume index $(P \le 0.001)$. Three out of four studies achieved statistical significance ($P \le 0.001$) when comparing preoperative (means range: 2.6-3.4) and postoperative (means range: 1.4-1.9) New York Heart Association (NYHA) class. One study reported a survival rate of 90.6 (95% CI, 84.6-97.0) at 12 months following the procedure. LIVE appears to be a promising and appropriate treatment strategy for a complex condition, which could extend the indication of LV aneurysm exclusion in the future.

Keywords

Revivent; Left ventricular aneurysm; Ventricular enhancement procedure; Systematic review; Safety; Efficacy

1. Introduction

Left ventricular (LV) aneurysm following acute myocardial infarction (MI) represents a less common complication in the current era of percutaneous coronary interventions (PCI) and thrombolytic therapy, but with worse short- and long-term clinical outcomes.

Epidemiological data regarding the incidence of LV aneurysms in patients with acute MI are discrepant. One study [1], with a small cohort of patients (n = 158), observed that 22% of them developed LV aneurysm during one-year follow-up. However, a recent study [2] with an impressive number of patients with acute MI (n = 11,622,528) observed that 0.2% of them had LV aneurysm. Notably, patients with LV aneurysm had a greater incidence of ventricular arrhythmias (17.6% vs 8.0%), mechanical complications (2.6% vs 0.2%), cardiac arrest (7.1% vs 5.0%), pump failure (26.3% vs 16.1%), and cardiogenic shock (10.0% vs 4.8%). Also, these patients developed LV thrombus and stroke more frequently. Even if patients with LV aneurysms represent a small population, they should benefit from a more individualized approach, including follow-up and treatment strategy, including various surgical and percutaneous interventions.

A state-of-the-art review pointed out criteria that could help identify patients who would benefit from surgery. Surgical ventricular reconstruction could be indicated in the case of anterior or posterior MI, LV end-systolic volume index (LVESVI) >60 mL/m², LV dysfunction with dyskinetic or akinetic areas documented by cardiac magnetic resonance (CMR) and NYHA class III or IV [3]. However, ventricular surgical reconstruction is not always the intervention of choice due to high surgical risk, presence of comorbidities, and induced cardioplegia. Less invasive LV aneurysm exclusion techniques were proposed in the last years.

One of such interventions is represented by the less invasive ventricular enhancement (LIVE) procedure, which implies a percutaneous approach and a minithoracotomy on the left side [4]. An anchor system, Revivent TCTM (BioVentrix Inc., San Ramon, CA, USA), is used to plicate the scar tissue with the subsequent exclusion of LV aneurysm. Withal, this procedure is suitable only for patients with anteroseptallateral aneurysms. In 2019, the U.S. Food and Drug Adminis-

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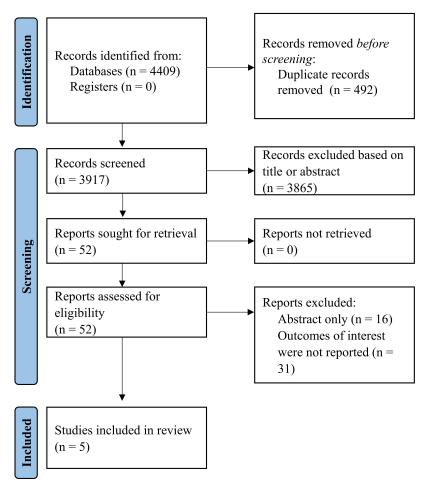


Fig. 1. Flow diagram of the selection process.

tration granted Breakthrough Device Designation status for Revivent TC^{TM} system in heart failure treatment. Also, Revivent TC^{TM} received CE Mark in 2016.

Our systematic review aims to assess the efficacy and safety of the LIVE procedure reported in clinical trials to treat patients with heart failure and LV aneurysm.

2. Materials and methods

The present systematic review was conducted according to the updated Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) [5], as illustrated in the PRISMA checklist (**Supplementary Table 1**). The protocol was primarily registered on PROSPERO (CRD42021248643).

2.1 Data sources and search strategy

We performed a literature search from inception to April 2021 in MEDLINE (PubMed), Embase, and Cochrane library databases, with no time interval restriction (**Supplementary Table 2**). We also examined Google Scholar and references of the cited publications to detect additional studies. A registry of clinical trials (Clinical Trials.gov) was screened for supplementary data. We provided entire search strategies for all databases and total records retrieved in **Supplemen-**

tary Table 2, in line with the PRISMA search checklist. For MEDLINE and Embase databases, the search was restricted to trials involving humans. The following combinations of MeSH terms and essential keywords were used in the search process: "left ventricular aneurysm exclusion", "Revivent", "less-invasive ventricular enhancement", and "left ventricular reconstruction".

2.2 Eligibility criteria and outcomes

Studies were considered for inclusion in the present systematic review if they enrolled adult humans aged ≥18 years and reported original data regarding LIVE procedure's efficacy and/or safety using the Revivent TCTM system in patients with LV aneurysm. Inclusion criteria were developed in concordance with PICO criteria [6]: population of interest (patients with LV anteroseptal-lateral aneurysm), intervention (LIVE procedure with Revivent TCTM system), comparison (guideline-directed medical therapy or ventricular surgical reconstruction) when available, and outcomes of interest (LV diastolic and systolic volumes, LVEF, NYHA class, cardiovascular and all-cause death during hospitalization and follow-up, mechanical and other complications related to the procedure, when available). Several critical exclusion criteria were set: unpublished data, studies available only in abstract,

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case reports, studies with overlapping populations, letters, editorials, and inability to extract data. Two independent investigators decided if studies met the inclusion criteria and disagreements were solved by consensus.

2.3 Data collection

Two independent investigators extracted from included studies in the final systematic review the following data: first author, year, study design, number of patients enrolled and their age, LV dimensions and volumes, outcomes investigated, and duration of follow-up. Data were presented as percentage, the corresponding 95% confidence interval (CI) when available, mean value with standard deviation, and *P*-value. Any discrepancies in data extraction were solved by consensus.

2.4 Quality assessment

The quality of observational studies that did not include a control group was assessed using a National Institutes of Health (NIH) [7]. This tool contains 14 key questions which guide critical appraisal of the overall study quality.

3. Results

We searched the prespecified databases and retrieved 4409 references. After excluding duplicate citations and records based on title or abstract, 52 studies were left for eligibility assessment. Five studies met the inclusion criteria and were finally included in the present systematic review, as 16 abstract-only papers and 31 citations which did not report outcomes of interest were excluded. The flow diagram of the screening process was presented in Fig. 1.

General characteristics of analyzed studies, including design, population, outcomes, clinical setting, and follow-up, were presented in Table 1 (Ref. [8–12]). All studies [8–12] had an observational, non-randomized design, and three of them were performed in multiple centers [8, 9, 12]. Also, two studies enrolled patients prospectively [9, 11]. As this hybrid procedure was addressed to a specific population, all patients included in clinical studies had a history of MI and a reduced LVEF, \leq 35% [10, 12], <40% [8, 11] or \leq 45% but >15% [9]. Almost all studies included patients with NYHA class II-IV [8, 9, 11, 12] and with LVESVI >60 mL/m² [9–12]. Results and outcomes reported in clinical studies included in the present systematic review were illustrated in Table 2 (Ref. [8–12]).

The effects of this less-invasive procedure on LVESVI and LV end-diastolic volume index (LVEDVI) were consistent across studies. Klein *et al.* [8] observed that postoperative LV volume reduction was statistically significant (P < 0.001), and LVEF was improved when compared to preoperative measures. However, there was no amelioration regarding NYHA class (P = 0.58) and sphericity index (P = 0.7). The fact that clinical and echocardiographic outcomes were measured only in the early postoperative period might have contributed to these discrepancies. None of the patients experienced death during hospitalization. As a procedural complication, one pa-

tient developed RV perforation, which required a full sternotomy. One patient had low cardiac output postoperatively due to RV restriction, which required removing one pair of anchors using left anterior thoracotomy. The median number of anchor pairs used to reconstruct LV geometry was 2.6 \pm 0.7 (internal anchors, 1.3 \pm 0.5 and external anchors, 1.2 \pm 0.7). Nevertheless, the small number of patients enrolled (n = 9) limits the study results.

In one international multicentre study [9] with longer follow-up period (12 months), less-invasive ventricular reconstruction determined a significant LVESVI and LVEDVI reduction (respectively, P < 0.001 and P < 0.0001) in addition to LVEF improvement (P < 0.005). Compared with the previous study, the authors observed a statistically significant improvement in patients' NYHA class at follow-up (P < 0.001) since the proportion of patients in NYHA class III decreased from 59% to 22%. Moreover, 6-minute walk distance and quality of life were enhanced after LV reconstruction (P < 0.001 for both). LV reconstruction was associated with a 90.6% survival rate at 12 months (95% CI, 84.6-97.0). However, four patients died during hospitalization, caused by LV injury, subendocardial necrosis, pulmonary artery injury, and a bowel perforation. Additional four deaths were recorded during late follow-up caused by sudden cardiac death, lung cancer, and stroke. No difference was observed regarding Nterminal pro-B-type natriuretic peptide (NT-proBNP) concentration (P = 0.365).

Similar results were reported in another study with a smaller population [10]. Loforte et al. observed that LV reconstruction was associated with a reduction in LV volumes and LVEF (P = 0.001). Also, patients' NYHA class was improved during follow-up (P = 0.001). The sphericity index remained unchanged postoperatively (P = 0.621), concordant with data from studies above mentioned. RV perforation was observed in one patient and required sternotomy. The authors used a 3.0 \pm 0.9 anchors number for the LIVE procedure. There was no communication between the LV cavity and excluded aneurysm postoperatively, suggesting the procedure's efficacy. Notably, patients analyzed had a high EuroScore II, and open-heart surgery was not a feasible treatment strategy. Nevertheless, results are limited by the small number of patients included (n = 7). More extensive trials are needed to confirm these data.

In a recent prospective study, Wang *et al.* [11] reported that in the case of patients who underwent LV reconstruction using Revivent TC^{TM} system, LVEF was significantly improved at nine months follow-up, as measured by echocardiography (P < 0.001) and cardiac magnetic resonance (CMR, P < 0.001). In line with other studies, LV volumes were decreased (P < 0.001 for both LVESVI and LVEDVI), and the 6-minute walk test distance was higher (P < 0.001). Also, patients' NYHA class was ameliorated (P < 0.001), but NT-proBNP levels did not change significantly (P = 0.916). Regarding major adverse events, one patient was re-hospitalized multiple times for heart failure symptoms,

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Table 1. General characteristics of studies included in the present systematic review.

Author, year	Design	Patients, No	Age, me- dian/mean	Setting	Outcomes	Follow-up	
				-History of anteroseptal MI with akinetic or dyskinetic scar;	-NYHA class		
				-LVEF <40%;	-LVEF		
				-NYHA class ≥II	-LV dimensions and volumes		
Klein et al, 2019 [8]	Observational, multicentre	9	60 ± 8	-BSA $2.0 \pm 0.3 \text{ m}^2$;	-Sphericity index	Before hospital discharge	
				-Diabetes mellitus: 2 patients (22%)	-Presence of MR and TR		
					-RV perforation		
					-Hospital mortality		
Klein et al, 2019 [9]	Observational, prospective, multicentre	89	60.4 ± 9.9	-History of MI	-LV volumes and LVEF		
				-Akinesia and/or dyskinesia of anteroseptal, anterolateral	-NYHA class		
				walls and/or apical regions;			
				-LVEF $>$ 15% and \leq 45%;	-6-minute walk test	6 months and 1 year	
				-NYHA class II–IV;	-Quality of life score		
				-LVESVI \geq 60 mL/m ² and \leq 120 mL/m ²	-Changes in MR		
				-BMI 28.9 \pm 5.7 kg/m 2 ;	-Length of hospital and ICU stay		
				-Creatinine 1.04 \pm 0.32 mg/dL;	-Survival at 12 months		
				-Diabetes mellitus: 16 patients (19%)	-NT-proBNP		
Loforte et al, 2019 [10]	Observational, retrospective, single centre	e 7	72 ± 8.9	-History of anteroseptal MI	-LV volumes and	189.7 \pm S104.5 days	
				-LVEF <35%	-LVEF		
				-LVESVI $>$ 60 mL/m 2 and $<$ 120 mL/m 2	-Sphericity index		
				-NYHA class III–IV	-Length of hospital and ICU stay		
				-BSA 1.9 \pm 0.8 m 2	-RV perforation		
					-NYHA class		
Wang et al, 2020 [11]	Observational, prospective, single centre	26	57.8 ± 12.5	-Transmural anteroseptal or apical scar	-LV dimensions and volumes		
				-LVEF <40%	-LVEF	1, 3, 6 and 9 months	
				-LVESVI >60 mL/m ²	-6-minute walk test		
				-NYHA class II–IV	-NYHA class		
				-BMI 21.2 \pm 10.0 kg/m 2 ;	-NT-proBNP		
				-Diabetes mellitus: 10 patients (38.5%);			
				-Hypertension: 9 patients (34.6%)			
Wechsler et al, 2013 [12]	Observational, multicentre	11	N/A	-Large anteroseptal scars			
				-LVESVI $>$ 60 mL/m ²	LV volumes	1, 3, 6, and 12 months	
				-LVEF < 35%	L v voiumes		
				-NYHA class II–IV			

BMI, body mass index; BSA, body surface area; ICU, intensive care unit; LV, left ventricle; LVEF, left ventricular ejection fraction; LVESVI, left ventricular end-systolic volume index; MI, myocardial infarction; MR, mitral regurgitation; NT-proBNP, N-terminal pro B-type natriuretic peptide; NYHA, New York Heart Association; RV, right ventricle; TR, tricuspid regurgitation.

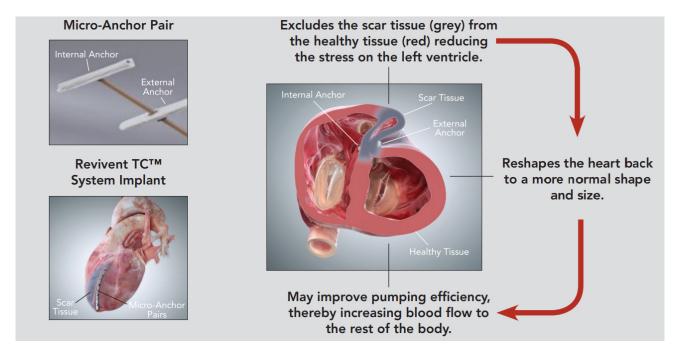


Fig. 2. Graphical illustration summarizing the Revivent TCTM anchor system for LV aneurysm exclusion (published with permission from BioVentrix; San Ramon, CA, USA).

and one patient died after almost two months due to multisystem organ failure. The total anchor pairs number used for the procedure was 2.7 \pm 0.7.

Wechsler *et al.* [12] documented the LV reconstruction procedure's efficiency with Revivent TCTM system in LV volume reduction. At six months of follow-up, both LVESVI and LVEDVI were significantly reduced, respectively P < 0.0003 and P < 0.0001. Similar results were found at 12 months of follow-up (P < 0.0001 for LVESVI; P < 0.0002 for LVEDVI).

NIH tool designed for observational studies was used to assess the included studies, illustrated in **Supplementary Table 3**. In general, the quality was judged to be fair, as none of the studies was randomized or blinded.

4. Discussions

To the best of our knowledge, this systematic review is the first one to investigate the efficacy and safety of LIVE procedure using Revivent TC^{TM} anchor system (Fig. 2) for LV aneurysm exclusion reported in clinical studies.

Data regarding surgical LV reconstruction in patients with ischemic cardiomyopathy are discrepant in the literature. In general, LV aneurysmectomy is performed concomitant with other open-surgery procedures involving heart valves or coronary arteries. A comprehensive preoperative evaluation is mandatory, including assessment of heart failure symptoms, LV volumes, and cavity measurements using echocardiography or CMR, as well as scar tissue transmural extension. Surgical LV reconstruction could be indicated in highly selected patients and performed in experienced centers [3].

In some cases, surgery is contraindicated due to induced cardioplegia, severe RV dysfunction, or LV restrictive diastolic dysfunction [3]. Other contraindications for surgical LV reconstruction include extensive coronary artery disease not suitable for revascularization, multiple MI areas, and significant pulmonary hypertension [13]. These patients are at high risk of adverse cardiovascular events, and therapeutic resources are limited to guidelines-directed heart failure medical treatment.

The new hybrid intervention, LIVE procedure, using a percutaneous approach and a left minithoracotomy, emerged as a therapeutic option for LV aneurysm exclusion. Significantly, patients with high surgical risk could benefit from this procedure as it is performed without induced cardioplegia, cardiopulmonary bypass circuit, and ventriculotomy [10, 12].

The LIVE procedure with Revivent TCTM system is associated with a reduction in LV volumes and an improvement in LVEF, maintained in studies included in this systematic review. Overall, patients undergoing the LIVE procedure had a better postoperatively NYHA class, excepting one study with no statistically significant association [8]. Also, the 6-minute walk test distance was higher after the intervention for LV aneurysm exclusion [9,11]. Concerning mitral regurgitation, which could cause heart failure symptoms, studies reported a postoperatively reduction of regurgitation grade due to LV reshaping and LVEF improvement [8–10]. More extensive clinical trials are warranted to establish the LIVE procedure's impact on short- and long-term mortality.

Data provided by studies available only in the abstract were similar, reducing LV volumes and LVEF improvement [14–17]. Moreover, the LIVE procedure was associated with

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Table 2. Results reported in studies included in present systematic review.

Study	Outcomes		Results			
		Preoperatively	Postoperatively			
	LVEF (%)	28 ± 8	40 ± 10	P < 0.001		
	LVESVI (mL/m ²)	53 ± 8	30 ± 11	P < 0.001		
	LVEDVI (mL/m ²)	75 ± 23	45 ± 6	P = 0.001		
Klein et al, 2019 [8]	Sphericity index	0.5 ± 0.1	0.5 ± 0.1	P = 0.7		
	NYHA class	2.7 ± 0.4	2.3 ± 0.7	P = 0.58		
	RV perforation	1 patient				
	Hospital mortality	09	%			
	ICU stay (days)	2 (IQR, 1–46)				
		Baseline	At 12 months			
	LVEF (%)	29 ± 8	34 ± 9	P < 0.005		
	LVESVI (mL/m ²)	74 ± 28	54 ± 23	P < 0.001		
	LVEDVI (mL/m ²)	106 ± 33	80 ± 26	P < 0.0001		
ZI : I 2010 [0]	NYHA class	2.6 ± 0.5	1.9 ± 0.8	P < 0.001		
Klein <i>et al</i> , 2019 [9]	6-minute walk test (m)	363 ± 92	416 ± 106	P < 0.001		
	MLHFQ score	39 ± 21	26 ± 22	P < 0.001		
	MR grade	1.12 ± 0.73	0.86 ± 0.64			
	NT-proBNP (pg/mL)	1175.1 ± 1655.2	913.9 ± 1090.4	P = 0.365		
	Survival at 12 months (%)	90.6 (95% CI, 84.6-97.0)				
		Preoperatively	Postoperatively			
	LVEF (%)	22.8 ± 8.1	35 ± 7.2	P = 0.001		
	LVESVI (mL/m ²)	93.2 ± 10.5	52.1 ± 15.1	P < 0.001		
	LVEDVI (mL/m ²)	137.2 ± 20.1	78 ± 10.2	P = 0.001		
Loforte <i>et al</i> , 2019 [10]	Sphericity index	0.5 ± 0.1	0.4 ± 0.1	P = 0.621		
	NYHA class (follow-up)	3.4 ± 0.6	1.4 ± 0.9	P = 0.001		
	ICU stay (days)	7.8 (rang	7.8 (range, 1–22)			
	RV perforation	1 patient				
		Preoperatively	Follow-up			
	LVEDD-AP (mm)	63.6 ± 7.1				
	LVESVI (mL/m ²)	84.8 ± 25.7	65.6 ± 24.4	P < 0.001		
	LVEDVI (mL/m ²)	107.8 ± 33.2	90.5 ± 31.8	P < 0.001		
W	LVEF (%, Echocardiography)	35.6 ± 8.8	45.9 ± 9.8	P < 0.001		
Wang et al, 2020 [11]	LVEF (%, CMR)	28.9 ± 8.3	38.6 ± 10.5	P < 0.001		
	6-minute walk test (m)	368.8 ± 40.0	461.5 ± 61.2	P < 0.001		
	NT-proBNP (pg/mL)	758.6 ± 1261.1	508.4 ± 399.1	P = 0.916		
	NYHA class	2.7 ± 0.6	1.7 ± 0.7	P < 0.001		
	MACE 2 patients (7.7%)					
		At baseline	At 6 months			
	LVESVI (mL/m ²)	72.6 ± 26.9	46.2 ± 22	P < 0.0003		
W. 1.1	LVEDVI (mL/m ²)	102.5 ± 27.3	$\textbf{73.2} \pm \textbf{28.7}$	P < 0.0001		
Wechsler et al, 2013 [12]		At baseline	At 12 months			
	LVESVI (mL/m ²)	72.6 ± 26.9	43.9 ± 22	P < 0.0001		
	LVEDVI (mL/m ²)	102.5 ± 27.3	69.5 ± 27.2	P < 0.0002		

CMR, cardiac magnetic resonance; ICU, intensive care unit; LV, left ventricle; LVEDD, left ventricular end-diastolic antero-posterior diameter; LVEDVI, left ventricular end-diastolic volume index; LVEF, left ventricular ejection fraction; LVESVI, left ventricular end-systolic volume index; MACE, major adverse cardiovascular events; MLHFQ, Minnesota Living with Heart Failure Questionnaire; MR, mitral regurgitation; NT-proBNP, N-terminal pro B-type natriuretic peptide; NYHA, New York Heart Association; RV, right ventricle.

88.7% and 87.1% survival rates at 1- and 2-years follow-up, respectively [14]. A comparable survival rate at two years (88%) was found in a multicentre trial [18]. One study [17] compared the LIVE procedure's efficacy with optimal medical therapy and revealed that LVEF was improved at follow-up

only in patients treated invasively.

The mainstay of the LIVE procedure is represented by careful patient selection. Clinical studies included in our systematic review enrolled patients with prior MI, anteroseptal aneurysm, reduced LVEF, LVESVI >60 mL/m 2 , and NYHA

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class II–IV. Patients with primary involvement of interventricular septum or LV walls other than anteroseptal are not candidates for the LIVE procedure due to technical difficulties regarding anchor system placement. In concomitant valve surgery or CABG, the LIVE method could decrease the cardiopulmonary bypass circuit time compared to surgical LV reconstruction, limiting heart injury. Also, patients with implanted cardiac defibrillators or cardiac resynchronization therapy could undergo the LIVE procedure [12].

Notably, patients received oral anticoagulant therapy with Warfarin (target international normalized ratio, 2.0–2.5) for three months. Therefore, patients at high risk of bleeding or contraindications to anticoagulant therapy might not benefit from the LIVE procedure [9, 11]. Besides, patients with documented left atrial or LV thrombus could receive anticoagulant therapy for 2–3 months before the intervention; otherwise, the LIVE procedure is contraindicated [9].

Another important aspect regarding the procedure is represented by the number of internal and external anchor pairs required. On the one hand, anchors should occlude aneurysm entirely; on the other hand, they could lead to RV restriction with subsequent low cardiac output, as documented in one study [8]. RV restriction was solved by removing one pair of anchors using left thoracotomy as in the initial intervention. Also, the anchor system could cause RV perforation [8, 10], a mechanical complication requiring classic sternotomy.

Arrhythmic events, in particular sustained ventricular arrhythmias, may be caused by the LIVE procedure due to mechanical stimulation of healthy myocardium during anchors implantation [10, 19, 20]. Therefore, a primed cardiopulmonary bypass (CPB) machine or extracorporeal membrane oxygenation (ECMO) are recommended to be readily available [10] in case of emergency. However, data are still scarce based on the small series currently reported [12], and the documented arrhythmogenic risk is mainly theoretical. To gain more evidence-based insights, with more extended follow-up data, we do still have to wait for the results of the CONFIGURE-HF (NCT01568164) and REVIVE-HF trials (NCT03845127) [8].

In addition to arrhythmic events and RV restriction and perforation, other reported complications are stroke, ventricular septal defect, tricuspid valve chordae, or leaflets damage [8, 10]. These possible complications may be due to insufficient training as this novel procedure requires consistent coaching and guidance. For this reason, Loforte et al. [10] wisely concluded: "This is why the ReviventTM procedure requires a well trained and dedicated multidisciplinary 'heart team', which includes an interventional cardiologist, a cardiac surgeon, and an edocardiographer, experienced in structural interventions".

Results are limited by the small number of patients enrolled and the observational design of the studies included, which did not have a control arm (medical therapy or surgical LV reconstruction). Also, the learning curve can be a source of variability for both outcomes and complications rate [9, 11].

Causes of the ventricular aneurysm, other than ischemic, are traumatic, infective, congenital, or idiopathic etiologies, systemic arterial hypertension, use of steroids, and non-steroidal anti-inflammatory drugs, Chagas disease, or sarcoidosis [21, 22]. 85% to 90% of the aneurysms occur in ischemia settings [21], explaining the lack of published studies to date reporting outcomes of the LIVE procedure in settings other than post-myocardial infarction. However, there are currently no theoretical reasons to limit the LIVE method for any aneurysms other than the absence of evidence-based data. Thereby, we are looking forward to the BioVentrix Revivent TCTM System Clinical Study (NCT02931240) that is currently recruiting patients with LV aneurysm regardless of the etiology.

5. Conclusions

The LIVE procedure represents a new hybrid intervention for LV anteroseptal aneurysm exclusion in patients with ischemic cardiomyopathy. This technique was associated with excellent outcomes not only in terms of LV volumes, LVEF, and functional status but also in terms of survival rate. The LIVE procedure appears to be a promising and appropriate treatment strategy for a complex condition, which could extend the indication of LV aneurysm exclusion in the future. However, more studies with a control arm are needed, focusing mainly on major adverse cardiovascular events and long-term mortality.

Author contributions

CB and AB conceived and designed the study; CB and AB performed the search; CB and AB analyzed the data; CB, AB and IVP wrote the paper; AB and MC revised the paper.

Ethics approval and consent to participate Not applicable.

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Conflict of interest

The authors declare no conflict of interest.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at https://rcm.imrpress.com/E N/10.31083/j.rcm2202050.

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