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Heart Failure

Surgical Ventricular Restoration in the Treatment of Congestive Heart Failure Due to Post-Infarction Ventricular Dilation

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OBJECTIVES	The purpose of this study was to test how surgical ventricular restoration (SVR) affects early and late survival in a registry of 1,198 post-anterior infarction congestive heart failure (CHF)
BACKGROUND	patients treated by the international Reconstructive Endoventricular Surgery returning Torsion Original Radius Elliptical shape to the left ventricle (RESTORE) team. Congestive heart failure may be caused by late left ventricular (LV) dilation after anterior infarction. The infarcted segment is often akinetic rather than dyskinetic because early reperfusion prevents transmural necrosis. Previously, only dyskinetic areas were treated by operation. Surgical ventricular restoration reduces LV volume and creates a more elliptical
	chamber by excluding scar in either akinetic or dyskinetic segments.
METHODS	The RESTORE group applied SVR to 1,198 post-infarction patients between 1998 and
	2003. Early and late outcomes were examined, and risk factors were identified.
RESULTS	Concomitant procedures included coronary artery bypass grafting in 95%, mitral valve repair in 22%, and mitral valve replacement in 1%. Overall 30-day mortality after SVR was 5.3% (8.7% with mitral repair vs. 4.0% without repair; $p < 0.001$). Perioperative mechanical support was uncommon (<9%). Global systolic function improved postoperatively. Ejection fraction (EF) increased from 29.6 ± 11.0% preoperatively to 39.5 ± 12.3% postoperatively ($p < 0.001$). The left ventricular end-systolic volume index (LVESVI) decreased from 80.4 ± 51.4 ml/m ² preoperatively to 56.6 ± 34.3 ml/m ² postoperatively ($p < 0.001$). Overall five-year survival was 68.6 ± 2.8%. Logistic regression analysis identified EF ≤30%, LVESVI ≥80 ml/m ² , advanced New York Heart Association (NYHA) functional class, and age ≥75 years as risk factors for death. Five-year freedom from hospital readmission for CHF was 78%. Preoperatively, 67% of patients were NYHA functional class III or IV and
CONCLUSIONS	postoperatively, 85% were class I or II. Surgical ventricular restoration improves ventricular function and is highly effective therapy in the treatment of ischemic cardiomyopathy with excellent five-year outcome. (J Am Coll Cardiol 2004;44:1439-45) © 2004 by the American College of Cardiology Foundation

The etiology of congestive heart failure (CHF) is coronary artery disease in approximately two-thirds of cases. The majority of these patients have experienced myocardial infarction (1). Despite successful early reperfusion, late left ventricular (LV) dilation develops in 20% of patients and leads to CHF (2,3). Myocardial necrosis progresses sequentially in the untreated transmural infarction from endocardium to epicardium (4). Early reperfusion alters the infarction process by sparing the epicardial layer and preventing thin-walled dyskinetic aneurysm formation. The reperfused infarcted myocardium retains its thickness and normal epicardial appearance, resulting in an akinetic segment with varying degrees of mid-myocardial and epicardial fibrosis. The remote non-infarcted myocardium undergoes changes in volume and shape during the course of "ventricular remodeling." As the ventricle enlarges, its normal elliptical shape becomes spherical and global systolic function worsens, resulting in CHF (5). The prognosis of patients with

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Abbreviations and Acronyms							
ACE	= angiotensin-converting enzyme						
CABG	= coronary artery bypass grafting						
CHF	= congestive heart failure						
EF	= ejection fraction						
LV	= left ventricular						
LVAD	= left ventricular assist device						
LVESVI	= left ventricular end-systolic volume index						
NYHA	= New York Heart Association						
SVR	= surgical ventricular restoration						

ischemic cardiomyopathy is more closely related to LV volume rather than to ejection fraction (EF) (6).

The new term "surgical ventricular restoration" (SVR) includes operative methods that reduce LV volume and "restore" ventricular elliptical shape (7-9). Excision of a thin-walled aneurysm with direct closure is an early method of SVR first described by Cooley et al. (10,11) and modified over the years. This operation is rarely performed currently because early reperfusion spares epicardial muscle, resulting in regional thick-walled akinesia rather than thin-walled dyskinesia. Dor (12) recognized that the adverse effects of remodeling on the remote non-infarcted myocardium were similar for akinesia and dyskinesia and was the first to utilize the endocardial patch plasty procedure for both morphologies. Dor's (12) operation improves systolic function and New York Heart Association (NYHA) functional class (13). However, the operation is not widespread because surgeons have been unwilling to exclude the akinetic normalappearing segments often encountered after early reperfusion. Instead, coronary artery bypass grafting (CABG) is performed and the non-functioning akinetic muscle segment containing deeper scar is left undisturbed.

The Reconstructive Endoventricular Surgery returning Torsion Original Radius Elliptical shape to the left ventricle (RESTORE) group is a team of cardiologists and surgeons from 12 centers on four continents: six in the U.S., four in Europe, one in South America, and one in Asia (Appendix). The following sections report on the RESTORE SVR registry with five-year follow-up and provide an update of our previous three-year findings in 439 patients (14).

METHODS

The SVR was performed in 1,198 patients between 1998 and 2003. Inclusion criteria were previous anterior myocardial infarction, significant ventricular dilation (left ventricular end-systolic volume index [LVESVI] $\geq 60 \text{ ml/m}^2$), and a regional asynergic (non-contractile) LV circumference of $\geq 35\%$. Patients were in NYHA functional class I in 9%, class II in 22%, class III in 40%, and class IV in 29% of cases. The small percentage of patients in class I underwent SVR while undergoing CABG or mitral repair as the primary operative indication, because LV volume exceeded 60 ml/m^2 . Echocardiography, ventriculography, or magnetic resonance imaging was used to confirm the asynergic segment and calculate EF. The LVESVI was determined by ventriculography or magnetic resonance imaging. Institutional review board approval was not obtained because the investigators considered the operation an established therapy based on the acceptance of endoventricular circular patch plasty and the reported outcomes of Dor et al. (15).

Anteroseptal, apical, and anterolateral LV scarred segments were identified and excluded by an intracardiac patch or direct closure. The operation is illustrated in Figure 1. Patients were placed on cardiopulmonary bypass with moderate hypothermia (approximately 34°C). Hearts were protected with warm and cold-blood cardioplegia during coronary grafting and/or mitral procedures. The ventricular restoration portion of the operation was performed during cardioplegia-arrested heart by about half of the surgeons, and in the open-beating heart by the others. Postoperative EF and volumes were obtained before hospital discharge. Follow-up NYHA functional class was obtained during physician visit or by telephone interview.

Statistics. Analysis of survival and readmission probabilities versus volume, EF, and age were carried out using Kaplan-Meier survival analysis to properly account for patients lost to follow-up. A similar analysis was used to determine the effect of mitral valve repair, replacement, and readmission. Times were taken as times to first readmission for readmitted patients, time to death for non-readmitted patients who died, and time to last follow-up for all others. Patients lost to follow-up were removed from the study (censored) for Kaplan-Meier survival analysis as of the date of last follow-up. Data comparisons used the general linear model for numeric data and logistic regression for categorical data. The SAS Institute JMP 4.0 statistical package was used for all tests.

RESULTS

Baseline characteristics. Patient age ranged from 25 to 89 years with a mean of 63 ± 11 years. The interval between anterior infarction and SVR procedure averaged 4.4 years. Mean NYHA functional class was 2.9 preoperatively with 9% of patients in class I, 22% in class II, 40% in class III, and 29% in class IV. Akinesia was present in 66% of cases and dyskinesia in 34%. Larger ventricular volumes were noted in patients with akinetic segments. Among the ventricles with LVESVI \geq 80 ml/m², akinesia was present in 73.3% and dyskinesia in 26.7%.

Concomitant procedures included CABG in 95%, mitral valve repair in 22%, and mitral valve replacement in 1%. Patients undergoing mitral valve procedures had reduced EF and larger ventricles compared with patients in whom no mitral procedure was performed. If EF was \leq 30%, mitral valve procedures were performed in 33.3% versus 15.0% in patients whose EF was >30% (p < 0.0001). Among patients with LVESVI \geq 80 ml/m², mitral procedures were more common as compared with patients with smaller volumes (34.1% vs. 21.1%, p < 0.0001).



Figure 1. (A) Incision into the scar of the dilated ventricle. (B) Placement of a suture to exclude the scarred segment. (C) Completed repair with endocardial patch. LV = left ventricle.

Early outcome. Global systolic function improved postoperatively. The EF, measured in 1,118 patients before discharge from the hospital, increased from 29.6 \pm 11.0% preoperatively to 39.5 \pm 12.3% postoperatively (p < 0.001). Both preoperative and postoperative EF were significantly less for patients undergoing mitral valve repair. There was no difference between the groups in improvement in EF (Table 1).

The LVESVI, obtained in 671 patients, was reduced from 80.4 \pm 51.4 ml/m² preoperatively to 56.6 \pm 34.3 ml/m² postoperatively (p < 0.001). Normal LVESVI is 24 \pm 10 ml/m² (16). Patients undergoing mitral valve repair had significantly larger hearts preoperatively than those with no mitral valve repair. There was no difference in postoperative LVESVI between the groups. Improvement in LVESVI was significantly greater in patients undergoing mitral valve repair (Table 2).

Thirty-day mortality after SVR was 5.3%, and it was higher among patients undergoing concomitant mitral valve repair (8.7%) versus patients in whom no mitral valve procedure was required (4.0%, p < 0.001). Perioperative mechanical support was uncommon; intra-aortic balloon pumping was used in 8.2%, left ventricular assist device

Table 1. LVESVI (ml/m²) and Mitral Valve Repair

	No Mitral Repair	Mitral Repair	p Value	
Preoperative	76.3	89.4	< 0.006	
Postoperative	56.0	55.8	NS	
Change	20.3	33.6	< 0.002	

LVESVI = left ventricular end-systolic volume index.

(LVAD) in 0.7%, and extracorporeal membrane oxygenation in 0.3%.

To assess inter-institutional differences in outcome, the centers were arranged in order of increasing preoperative risk, as determined by logistic regression of a combination of preoperative NYHA functional class, EF, LVESVI, and age on survival. Incomplete data excluded some patients from this analysis. There was a nearly linear relationship between risk and five-year survival for all centers for which meaningful risks could be calculated.

Late outcome. Overall five-year survival was $68.6 \pm 2.8\%$, calculated by the Kaplan-Meier product-limit method (Fig. 2). Mean time to death or loss to follow-up was 1.85 ± 1.45 years; at the end of five years, 22 patients remained in the study. Survival at five years was better in the group of patients that had dyskinetic as compared with akinetic morphology (80% vs. 65%; p < 0.001) (Fig. 3). Logistic regression analysis identified risk factors for death at any time after surgery. These included preoperative EF $\leq 30\%$, LVESVI ≥ 80 ml/m², advanced NYHA functional class, and age ≥ 75 years. Patients with EF $\geq 30\%$ had survival 76.7 \pm 3.2% as compared with 63.8 \pm 3.9% for those with EF $\leq 30\%$ (Fig. 4). Patients with EF $\geq 40\%$ had survival

Table 2. EF (%) and Mitral Valve Rep

	No Mitral Repair	Mitral Repair	p Value
Preoperative	31.0	25.4	< 0.0001
Postoperative	41.3	34.0	< 0.0001
Change	10.3	9.3	NS

EF = ejection fraction.



Figure 2. Overall five-year survival.

83.0 ± 4.0% as compared with 67.4 ± 3.0% for those with EF \leq 40% (p < 0.001). Patients with LVESVI <80 ml/m² had survival 79.4 ± 3.3% as compared with 67.2 ± 3.2% for those with hearts >120 ml/m² (p < 0.001) (Fig. 5). Preoperative NYHA functional class was associated with long-term survival. At five years, survival was 94.5 ± 2.7% in NYHA functional class I, 87.2 ± 3.3% in class II, 69.9 ± 4.7% in class III, and 49.7 ± 5.8% in class IV (p < 0.001) (Fig. 6).

Mitral valve procedures were performed more commonly in patients with larger ventricles and reduced EF. Mortality at 30 days was higher in patients who underwent concomitant mitral repair (9.1%) as compared with those in whom no mitral valve procedure was performed (4%; p < 0.001). However, at five years, the survival curves were not different between patients who underwent repair and those who did not (68.7 ± 3.9% vs. 70.8 ± 3.3%). Mitral valve replacement was rare (30 patients, <1%) and was performed early in the registry. These patients had extensive areas of remote muscle scar precluding simple annuloplasty to correct mitral regurgitation.

Freedom from readmission to the hospital for CHF was 78%. The NYHA functional class improved from a mean of 2.9 preoperatively to 1.7 postoperatively. Preoperatively, 67% of patients had NYHA functional class III or IV symptoms (39% class III, 28% class IV). Postoperatively, 85% were functional class I or II (48% class I, 37% class II). **SVR in the elderly.** Age was also a risk factor. Among all patients operated on, 12.4% (149) were \geq 75 years old.



Figure 3. Survival based upon chamber morphology: dyskinesia versus akinesia.





Figure 4. Survival based upon preoperative ejection fraction.

Concomitant procedures included coronary bypass in 98%, mitral valve repair in 17%, and replacement in 4%. Mortality 30 days after operation was 13% and higher than in younger patients. Postoperative hemodynamic support with intraaortic balloon pumping was required in 13%. The EF improved from 31% preoperatively to 39% postoperatively (p < 0.001). The LVESVI was reduced from 88 ml/m² to 60 ml/m² (p < 0.001). Overall five-year survival in the elderly was 63% and related to preoperative EF (50% if preoperative EF <30% and 73% if EF \ge 30%; p < 0.001). Among elderly patients undergoing concomitant CABG, the five-year survival was 71% compared with 55% among patients undergoing simultaneous mitral valve procedures. The NYHA functional class III and IV was present in 70% of patients preoperatively and in 20% postoperatively. Mean NYHA functional class improved from 3.0 to 1.9. Hospital readmission for CHF at five years was 15%.

DISCUSSION

Remodeling after infarction enlarges chamber diameter and increases wall tension by Laplace's law. The augmented wall stress results in increased oxygen consumption, decreased subendocardial blood flow, and reduced systolic shortening. White et al. reported that LV volume was more predictive of survival than EF after infarction (6). Investigators in the Global Utilization of Streptokinase and t-PA for Occluded Coronary Arteries (GUSTO I) trial confirmed this and showed that LVESVI \geq 40 ml/m² after infarction was associated with high CHF rates and poor long-term survival (3). The SVR reshapes the remodeled LV and significantly reduces chamber volume.

Ventricular shape in dilated cardiomyopathy is also an important determinant of function. As the enlarging LV changes from elliptical to spherical, normal systolic torsion is reduced. The myofibrils of the spherical LV are shifted away from their normal oblique axis toward a more transverse direction. The normal myofibril shortening of 15% generates a global EF of only 30% in spherical ventricles, as compared with an EF of 60% in elliptical ventricles with natural torsion (17). The circumferential radius of curvature increases after infarction with loss of regional EF in the remote non-infarcted myocardium (18). The Dor procedure



Figure 5. Survival based upon preoperative left ventricular end-systolic volume index.

improves global systolic function by increasing regional function in remote non-infarcted segments (19). Postoperatively, LV shape becomes more elliptical in systole than it was in diastole (20).

In this RESTORE registry, SVR was used to correct LV geometry in all cases. Concomitant procedures included CABG in 95% and mitral valve intervention in 23%. Thus, the three pathologic components contributing to CHF— the ventricle, vessel, and valve—were all surgically corrected. Our integrated approach resulted in an overall five-year survival of approximately 70% and a rehospitalization for CHF of 22%. These results can be contrasted to current approaches including medical therapy, CABG alone, CABG with mitral intervention, ventricular assist devices, and transplantation.

Medical therapy. Angiotensin-converting enzyme (ACE) inhibitors increase survival among NYHA functional class IV CHF patients as shown in the Cooperative North Scandinavian Enalapril Survival Study (CONSENSUS) trial; however, only 64% survived to one year (21). Although the Carvedilol Prospective Randomized Cumulative Survival (COPERNICUS) trial demonstrated an advantage of adding carvedilol to ACE drugs in patients with EF <25%, survival at 28 months was 72% (22). Recently, the Carvedilol or Metoprolol European Trial (COMET) trial examined the efficacy of carvedilol in NYHA functional class III (48%) and IV (3%) patients with a mean EF of 26%. Survival at five years was 66% in the carvedilol treated group (23). In the Carvedilol and ACE Inhibitor Remodeling Mild Heart Failure EvaluatioN (CARMEN) trial, the majority of patients were NYHA functional class II (60% to 70%) and there were none in class IV. Event-free mortality or hospitalization was approximately 75% at two years with marginal reduction of LVESVI (7 ml/m²) and EF improvement of 3.5% (24). Recently, spironolactone was added to ACE and beta-blocker therapy in the Randomized Aldactone Evaluation Study (RALES) trial among patients with EF \leq 35%. Pre-treatment class was not reported, but the two-year survival was 65% in the treated group versus 54% in the placebo group (25).

In contrast to the above-cited trials, our RESTORE



Figure 6. Survival based upon preoperative New York Heart Association functional class.

registry provides five-year follow-up in patients whose NYHA functional class was III or IV in 67% of cases. Systolic function was measured by EF and ventricular volume. Both showed dramatic improvement. Rehospitalization was very low in a high-risk patient population.

Coronary revascularization. Coronary artery bypass grafting can be safely carried out in patients with reduced systolic function because of improved methods of myocardial protection; however, the five-year survival of patients with EF \leq 35% is 50% to 65% (26–29). The CABG alone is not very effective when ventricular dilation occurs. In one study, CABG mortality was 27% if LV end-diastolic diameter was \geq 81 mm (30). Moreover, CHF symptoms are common after CABG for ischemic cardiomyopathy. Yamaguchi's analysis of CABG for patients with $EF \leq 30\%$ showed that outcome correlated with preoperative LVESVI. The fiveyear survival was 54% if the preoperative LVESVI was \geq 100 ml/m² compared with 85% if LVESVI was \leq 100 ml/m². Congestive heart failure at five years was seen in 69% of patients with the larger hearts versus 15% with the smaller ones (31). Luciani et al. reviewed 167 patients who underwent CABG with a mean EF of 28%. Among these patients, 40% were functional class III or IV. At five years, 60% of patients continued to have signs and symptoms of CHF, demonstrating the limitations of CABG surgery alone (32). Another study of CABG for ischemic cardiomyopathy confirmed that recurrent CHF was the most common cause of death postoperatively (27).

Mitral valve repair or replacement. Functional mitral regurgitation often accompanies ventricular dilation (33). Patients with ischemic cardiomyopathy undergoing mitral procedures have a five-year mortality of approximately 50% (27,34). Recurrence of CHF occurs in one-third of patients by five years and is the most common cause of death, presumably related to continuing dysfunction of the unmodified ventricle (27,35). Mitral valve repair is an integral part of the SVR procedure in addition to volume reduction and revascularization.

Ventricular assist or replacement. Other surgical approaches in the treatment of ischemic cardiomyopathy include LVAD and transplantation. The Randomized Evaluation of Mechanical Assistance for the Treatment of

Congestive Heart Failure (REMATCH) trial examined LVAD use as long-term myocardial replacement therapy in patients who were ineligible for cardiac transplantation. Less than 10% of patients survived to three years in the LVAD group, compared with no survivors among patients treated medically (36). The five-year survival after cardiac transplantation is 70%, but few patients receive a heart owing to donor shortage (37). The five-year survival of NYHA functional class IV patients undergoing SVR in our registry was approximately 50%. Surgical ventricular restoration should be considered as a therapeutic option because it can be more readily applied compared with LVAD or transplantation.

SVR. The SVR was applied to patients with previous infarctions primarily as therapy for advanced heart failure. The few patients with less advanced symptoms of CHF, namely NYHA functional class I or II, underwent SVR as a concomitant procedure to CABG or mitral valve repair based on the important recognition that volume, not EF, is the major determinant of survival after myocardial infarction. White et al. showed that patients with LVESVI >60ml/m² have approximately a fivefold increase in mortality compared with those with normal volumes after infarction (6). The GUSTO I trial similarly demonstrated the importance of ventricular volume on outcome. Among infarction patients with successful thrombolysis, 17% had progressive LV enlargement above 40 ml/m². Mortality at one year was 16% among those with LVESVI 40 to 50 ml/m², 21% with LVESVI 50 to 60 ml/m², and 33% with LVESVI >60 ml/m² (3). A small number of patients (9%) in functional class I underwent restoration as an adjunct to CABG because ventricular dilation (LVESVI >60 ml/m²) is a precursor of late development of CHF and early death (3). More importantly, the low five-year mortality of patients with NYHA functional class II and III symptoms of CHF, and LVESVI <120 ml/m² further define the importance of using volume measurement to gauge the progression of CHF and how LVESVI helps determine prognosis.

Our multivariate analysis of SVR shows that major risk factors were age, preoperative EF, LVESVI, and NYHA functional class. The five-year survival of 63% among patients \geq 75 years old is a gratifying result in view of the fact that CHF is common in the elderly. Mitral valve procedures were performed in over 20% of patients in this series and were more common in patients with severely depressed systolic function and extensive ventricular dilation. Regurgitation was usually central and thus amenable to ring annuloplasty. Subgroup analysis showed patients with mitral repair had larger hearts from secondary mitral regurgitation, and sustained greater improvement in LVESVI when valve repair was added to CABG and SVR. The rare use (<1%) of mitral valve replacement was indicated because of previous infarcted segments in sites other than the antero-apical or antero-septal regions. These patients were a high-risk group, and our findings are consistent with the report by Di Donato et al. (38) of decreased survival at two

years (52%) if the muscle remote from the anterior scar was asynergic. These findings illustrate the importance of preoperative assessment of the non-infarcted segments supplied by the right and circumflex arteries. Imaging of the remote muscle is crucial, and SVR should be avoided if the inferior and lateral wall segments are infarcted and asynergic (19). Hypokinesia, however, is not a contraindication to operation, because local contractility may improve with revascularization. Viability of remote segments is helpful in determining operability.

Study limitations. This was a non-randomized registry of patients who underwent the SVR procedure. Drug regimens were not standardized or reported. Quality of life was based on NYHA functional class. Criteria for CHF hospital admission may have varied among centers.

Although the overall geometric objective was similar, some centers used direct closure in selected cases, and others placed an endocardial patch in all patients. Myocardial protection varied. The indication for intra-aortic balloon pumping use was not specified. Measurements of EF and LVESVI were performed by the same method in each patient before hospital discharge; however, the interval between operation and these measurements was not standardized. Implantable defibrillators were not routinely placed in these patients, and arrhythmia management in the RESTORE registry varied. In most instances, preoperative electrophysiologic testing was not performed.

Conclusions. Surgical ventricular restoration reduces volume and "restores" a more normal elliptical ventricular shape in dilated hearts after anterior infarction. Our data demonstrate a low operative mortality, improved systolic function, a gratifying five-year survival, and a low rate of rehospitalization for CHF.

Our previous results were instrumental in the design of the current Surgical Treatment for Ischemic Heart Failure (STICH) trial that randomizes patients with ischemic cardiomyopathy to medical therapy, CABG alone, or CABG with SVR. The RESTORE groups' outcomes serve as a benchmark for this trial, which should further define the optimal indications for ventricular restoration.

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APPENDIX

For a list of the RESTORE group members, please see the October 6, 2004, issue of *JACC* at http://www.cardiosource.com/jacc.html.