

# Regence

Medical Policy Manual

Surgery, Policy No. 149

## ***Surgical Ventricular Restoration***

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**Next Review:** July 2024

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### **IMPORTANT REMINDER**

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Surgical ventricular restoration (SVR) is a procedure designed to restore or remodel the left ventricle to its normal, spherical shape and size in patients with akinetic segments of the heart, secondary to either dilated cardiomyopathy or post infarction left ventricular aneurysm.

### **MEDICAL POLICY CRITERIA**

Surgical ventricular restoration is considered **investigational** for the treatment of all indications, including but not limited to ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

### **CROSS REFERENCES**

1. [Ventricular Assist Devices and Total Artificial Hearts](#), Surgery, Policy No. 52

### **BACKGROUND**

The surgical ventricular restoration (SVR) procedure is usually performed after coronary artery bypass grafting (CABG) and may precede or be followed by mitral valve repair or replacement

and other procedures such as endocardectomy and cryoablation for treatment of ventricular tachycardia. A key difference between surgical ventricular restoration and ventriculectomy (i.e., for aneurysm removal) is that in SVR circular “purse string” suturing is used around the border of the aneurysmal scar tissue. Tightening of this suture is believed to isolate the akinetic or dyskinetic scar, bring the healthy portion of the ventricular walls together, and restore a more normal ventricular contour. If the defect is large (i.e., an opening >3 cm), the ventricle may also be reconstructed using patches of autologous or artificial material to maintain the desired ventricular volume and contour during closure of the ventriculotomy. Additionally, SVR is distinct from partial left ventriculectomy (i.e., the Batista procedure) which does not attempt to specifically resect akinetic segments and restore ventricular contour.

The SVR procedure may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER) or the Dor procedure after Vincent Dor, MD. Dr. Dor pioneered expansion of techniques for ventricular reconstruction and is credited with treating congestive heart failure patients with SVR in conjunction with CABG.

## **REGULATORY STATUS**

The CorRestore™ Patch System is a device FDA approved through the 510(k) process that is specifically labeled for use “as an intracardiac patch for cardiac reconstruction and repair.” The device consists of an oval tissue patch made from glutaraldehyde-fixed bovine pericardium. It is identical to other marketed bovine pericardial patches except that it incorporates an integral suture bolster in the shape of a ring that is used along with ventricular sizing devices, to restore the normal ventricular contour.

In 2020, Ancora Heart announced that it received an FDA investigational device exemption for its AccuCinch® ventricular restoration system. This exemption allows Ancora Heart to proceed with an initial efficacy and safety study in patients with heart failure and reduced ejection fraction.

## **EVIDENCE SUMMARY**

Reliable randomized controlled trials (RCTs) that compare patients managed with versus without surgical ventricular restoration (SVR) and that report on relevant clinical outcomes (as opposed to intermediate or physiologic outcomes) are necessary in order to establish whether SVR is efficacious and whether it is at least as good as alternative interventions. In order to evaluate the contribution of SVR to other components of care (such as coronary artery bypass [CABG]), RCTs comparing outcomes of patients treated with and without SVR as an adjunct to surgery with CABG, are needed. Where SVR is proposed as an alternative to heart transplantation, outcomes from patients treated with SVR versus those treated with transplantation are needed.

The focus of this literature appraisal is on data from several RCTs, although examples of nonrandomized trials are also presented below.

## **RANDOMIZED CONTROLLED TRIALS**

Jones (2009) reported results of the National Heart, Lung, and Blood Institute-sponsored STICH trial, which randomized 1,000 patients with coronary artery disease and ejection fraction of 35% or less to either CABG alone (n=499) or CABG with SVR (n=501).<sup>[1]</sup> At median follow-up of 48 months, reduction in end-systolic volume index remained significantly greater in

the SVR group than in the CABG alone group (19% and 6%, respectively). There was no between-group difference for the primary endpoint, which was a composite of death from any cause and hospitalization for cardiac causes.

STICH investigators have subsequently conducted additional analyses in attempts to identify patient groups that might have improved outcomes with CABG and SVR over CABG alone.<sup>[2-4]</sup> Subgroup analyses reported a trend suggesting patients with better preoperative left ventricular function, using measures such as left-ventricular ejection fraction (LVEF), end-systolic volume index and/or end-diastolic volume index might benefit from SVR, but subgroup differences did not reach statistical significance. For example, in the subgroup of patients with an LVEF of 33% or higher, the hazard ratio for the primary outcome was 0.77 (95% CI 0.55 to 1.08), while in patients with an LVEF of 25% or less, the hazard ratio was 1.42 (95% CI 1.02 to 1.98). Since these subgroup analyses were performed post-hoc and no statistically significant differences were reported, the results are inconclusive.

Goh (2013) investigated how SVR improved hemodynamic and clinical outcomes in ischemic cardiomyopathy in patients from the Surgical Treatment for Ischemic Heart Failure (STICH) trial.<sup>[5]</sup> Nine non-STICH SVR (NSSVR) patients were compared with 12 STICH SVR (SSVR) patients). The NSSVR group had more anterior wall asynergy (60% vs. 45%,  $p < 0.001$ ), larger preoperative heart volumes (left ventricular end-diastolic volume index 108 mL/m<sup>2</sup>) vs 69 mL/m<sup>2</sup>,  $p < 0.05$ ) and larger volume reductions (34% vs. 11%,  $p = 0.06$ ) compared to SSVR patients. At 6.5-year follow-up, 83% SSVR and 89% NSSVR patients were alive. Authors concluded that patients eligible but not randomized into the STICH trial, had larger preoperative heart volumes and larger volume reduction with SVR.

A separate publication from the STICH trial reported on quality-of-life (QOL) outcomes.<sup>[6]</sup> The main QOL outcome measure used was the Kansas City Cardiomyopathy Questionnaire (KCCQ). Secondary QOL measures included the Seattle Angina Questionnaire, the short form (SF)-12, the CES-D depression measure, the Cardiac Self-Efficacy Questionnaire, and the EuroQoL 5-D. The questionnaires were administered at baseline and 4, 12, 24, and 36 months post-randomization. Available numbers of patients at each time point were 991, 897, 828, 751, and 669, respectively. Scores on the KCCQ QOL measures improved for both groups to a similar degree; there was no incremental benefit for the SVR group compared to CABG alone group. Similarly, there were no group differences noted on any of the secondary QOL measures. Although the per-protocol analysis is associated with increased risk of bias, such bias would tend to favor the treatment group. Nevertheless, replication of such results from a long-term randomized controlled trial, using an intent-to-treat analysis, is needed.

Marchenko (2011) reported results from an RCT performed in Russia of 236 patients with ischemic heart failure who were randomized to CABG alone or CABG and SVR.<sup>[7]</sup> The mean follow-up was 31 months. Outcome measures included perioperative mortality and survival at one-, two-, and three-year follow-up; however statistical tests were not reported on between-group differences in perioperative mortality, survival at one and three years, and reductions in NYHA functional class and angina class for both groups after surgery. Therefore, interpretation of these results is not possible.

Aguiar Ribeiro (2006) randomized 74 patients with viable anterior wall myocardium following anterior myocardial infarction to CABG alone or CABG plus SVR.<sup>[8]</sup> Indications for revascularization included angina, heart failure or both. Patients were randomized on a 1:1 ratio. Two-year survival rates did not differ between groups. The CABG+SVR group had

significantly improved freedom from heart failure compared with the CABG only group ( $p=0.016$ ). As the authors noted in their discussion and as noted in an accompanying editorial,<sup>[9, 10]</sup> while SVR provided significant improvement in left ventricular volumes compared to CABG alone, the number of patients was small and the follow-up short term. Recurrence of heart failure is likely to occur at higher rates after more time has passed. The authors further stated that it is not clear whether SVR can revert or stop the remodeling processes after myocardial infarction.

## Section Summary

While evidence from these trials add to the body of literature on SVR, the lack of significant treatment differences in rates of heart failure and long-term overall survival limits the interpretation of these findings. Additional trials, with clear patient selection criteria, are needed to evaluate the safety and effectiveness of SVR for restoration of normal heart size and shape.

## NONRANDOMIZED TRIALS

The following discussion summarizes a representative sample of some of the reports on SVR, which consists primarily of case series reports and retrospective reviews from single centers and publications from the multi-center RESTORE Group (Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the Left Ventricular).

Stefanelli (2020) reported short- and long-term outcomes for 62 patients who underwent SVR between 2002 and 2016 at a single center. During follow-up, 36 patients died, included 15 who died from cardiac causes.<sup>[11]</sup>

Ohira (2017) reported on 44 consecutive patients who underwent a modified SVR procedure, many done in conjunction with CABG (93%) or mitral valve repair or replacement (58%). Operative mortality was 11%. Patients demonstrated improvements in ejection fraction as well as end-systolic left ventricle (LV) volume index after the procedure.<sup>[12]</sup>

Wang (2017) carried out a retrospective analysis on 30 (18 dyskinetic, 12 akinetic) patients with a postinfarction LV anterior aneurysm who underwent SVR. <sup>[13]</sup> A beneficial effect was seen on LV shape, size, and ejection fraction within one week after SVR, but the LV is more spherical and enlarged in the akinetic group at least one year post-op. The retrospective design and small sample size in this study preclude the findings from being applied to the general population of patients with LV aneurysms.

Furukawa (2017) published an analysis on outcomes in 19 patients who underwent SVR for ischemic cardiomyopathy. <sup>[14]</sup> The early to late mitral valve flow ratio (E/A) was the only significant predictor of major adverse cardiac events in this sample. The authors concluded that patients with an E/A of greater than or equal to 2 may not be good candidates for SVR.

Shen (2016) published a retrospective analysis on a non-randomized comparative study from China involving 64 patients with left ventricular aneurysms who underwent CABG or CABG plus SVR.<sup>[15]</sup> The patients were compared for survival rates, major adverse cardiac or cerebrovascular events (MACCEs), left ventricular geometry and function at one, three and five years of follow-up. At five year follow-up, improvements in echocardiographic parameters and NYHA functional class were similar between groups, as were long-term survival and the incidence of major adverse cardiac or cerebrovascular events.

A non-randomized comparative study from Europe involving patients with coronary artery disease who underwent CABG or CABG plus SVR and had an ejection fraction of 30% to 40% has also been published.<sup>[16]</sup> In this non-randomized study, the authors concluded that patients in whom SVR was possible experienced more peri-operative complications but had improved early and midterm outcomes. However, the non-randomized nature of this study limits its conclusions.

Another article reported on the contemporary performance of SVR based on data from the Society of Thoracic Surgeons' Database.<sup>[10]</sup> From January 2002 to June 2004, 731 patients underwent procedures at 141 hospitals. The operative mortality was 9.3%; combined death or major complications occurred in 33.5%. The authors commented that further studies of SVR are needed to improve patient selection and procedural performance.

Sartipy (2005) reported on 101 patients who underwent SVR using the Dor procedure at a single center for class III or IV congestive heart failure, angina and ventricular tachyarrhythmia during the period of 1994 to 2004.<sup>[9]</sup> In addition to SVR, patients also concomitantly underwent CABG (98%), arrhythmia ablation (52%) and mitral valve procedure (29%). The authors reported early mortality (within 30 days of operation) was 7.9%; left ventricular ejection fraction increased from  $27\% \pm 9.9\%$  to  $33\% \pm 9.3\%$  postoperatively. Patients were followed up  $4.4 \pm 2.8$  years and overall actuarial survival was reported as 88%, 79%, and 65% at one, three and five years respectively.

Mickleborough (2004) reported on 285 patients who underwent SVR by a single surgeon for class III or IV congestive heart failure, angina or ventricular tachyarrhythmia during the period of 1983 to 2002.<sup>[17]</sup> In addition to SVR, patients also concomitantly underwent CABG (93%), patch septoplasty (22%), arrhythmia ablation (41%), mitral repair (3%), and mitral replacement (3%). SVR was performed on the beating heart in 7% of patients. The authors reported hospital mortality of 2.8%; postoperative ejection fractions increased  $10\% \pm 9\%$  from  $24\% \pm 11\%$  ( $p < .000$ ) and symptom class in 140 patients improved  $1.3 \pm 1.1$  functional class per patient. Patients were followed up for up to 19 years (mean,  $63 \pm 48$  months) and overall actuarial survival was reported as 92%, 82%, and 62% at 1, 5 and 10 years respectively. The authors suggested wall-thinning should be used as a criterion for patient selection.

Bolooki (2003) reported on 157 patients that underwent SVR by a single surgeon for class III or IV congestive heart failure, angina, ventricular tachyarrhythmia or myocardial infarction using three operative methods during the period of 1979 to 2000.<sup>[18]</sup> SVR procedures consisted of radical aneurysm resection and linear closure ( $n=65$ ), septal dyskinesis reinforced with patch septoplasty ( $n=70$ ), or ventriculotomy closure with an intracavitary oval patch ( $n=22$ ). The authors reported hospital mortality of 16%. The mean preoperative ejection fraction was  $28\% \pm 0.9\%$ . Patients were followed up for up to 22 years and overall actuarial survival was reported as 53%, 30%, and 18% at 5, 10 and 15 years respectively. The authors found factors improving long term survival included SVR with intraventricular patch repair and ejection fraction of 26% or greater preoperatively.

The RESTORE Group is an international group of cardiologists and surgeons from 13 centers that has investigated SVR in over 1,000 patients with ischemic cardiomyopathy following anterior infarction in the past 20 years.<sup>[17, 19-25]</sup> For example, Athanasuleas from the RESTORE Group, reported on early and three-year outcomes in 662 patients who underwent SVR following anterior myocardial infarction during the period of January 1998 to July 2000.<sup>[24]</sup> In addition to SVR, concomitant (uncontrolled) procedures included CABG (92%), mitral repair

(22%), and mitral replacement (3%). The authors reported overall mortality during hospitalization was 7.7%; postoperative ejection fractions increased from 29.7% ± 11.3% to 40.0% ± 12.3% (p <0.05). The survival rate and freedom from hospitalization for heart failure at three years was 89.4% ± 1.3% and 88.7% respectively. In a separate publication on 439 patients from the RESTORE Group, Athanasuleas reported that improved outcomes were associated with lower patient age, higher ejection fractions and lack of need for mitral valve replacement.<sup>[25]</sup>

## Section Summary

Interpretation of results from the above studies is limited by lack of randomization to controlled treatment groups. Non-randomized treatment allocation along with uncontrolled co-treatment with CABG, or other surgical interventions precludes the ability to isolate any reported treatment effects specifically to SVR.

## PRACTICE GUIDELINE SUMMARY

No evidence-based clinical practice guidelines were identified which recommend the use of SVR for any indication.

### AMERICAN COLLEGE OF CARDIOLOGY AND AMERICAN HEART ASSOCIATION (ACC/AHA)

The 2013 joint guidelines from the ACC/AHA for the Management of Heart Failure state that SVR “does not appear to be of benefit but may be considered in carefully selected patients with [heart failure with reduced ejection fraction] for specified indications, including retractable HF and ventricular arrhythmias”.<sup>[26]</sup> Although other medical and surgical interventions were evaluated with a formal recommendation (including strength of recommendation and level of evidence), the guidelines do not include a formal recommendation regarding the use of SVR.

## SUMMARY

There is not enough research to show that surgical ventricular restoration (SVR) improves long term survival or health outcomes. No clinical practice guidelines based on research recommend SVR. Therefore, the use of this procedure is considered investigational for all indications.

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## CODES

Codes	Number	Description
CPT	0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach
	33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (eg, ventricular remodeling, SVR, SAVER, DOR procedure)
HCPCS	None	

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