Surgical Ventricular Restoration

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.

Background

The surgical ventricular restoration (SVR) procedure may also be referred to as ventricular remodeling, surgical anterior ventricular endocardial restoration (SAVER), left ventricular reconstructive surgery, left ventricular aneurysmectomy reconstruction, endoventricular circular plasty, or the Dor procedure after Vincent Dor, MD. Dr. Dor pioneered the expansion of techniques for ventricular reconstruction and is credited with treating heart failure patients with SVR in conjunction with coronary artery bypass grafting (CABG).

The SVR procedure is usually performed after CABG and may proceed 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 SVR 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. In addition, 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.

Regulatory Status

The CorRestore™ Patch System is a device approved by the U.S. Food and Drug Administration (FDA) 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. Product code: DXZ.
Surgical ventricular restoration is considered **not medically necessary** for the treatment of ischemic dilated cardiomyopathy or post-infarction left ventricular aneurysm.

**Benefit Application**

The BCBS FEP contract stipulates that FDA-approved biologics, drugs and certain devices may not be considered investigational when used for their intended purpose and thus these products may only be assessed based on medical necessity.

**Policy Guidelines**

Surgical ventricular restoration involves increased physician work compared with standard ventriculectomy. For example, the procedure includes evaluation of the ventricular septum and reshaping of the geometry of the heart. Surgical ventricular restoration is described as a global treatment of left ventricular failure, while conventional left ventricular aneurysmectomy represents a local treatment of a transmural infarct.

**Rationale**

**Randomized Controlled Trials**

In 2002, a randomized international clinical trial on the Surgical Treatment of Ischemic Heart Failure (STICH) was initiated to compare medical therapy with coronary artery bypass grafting (CABG) and/or surgical ventricular restoration (SVR) for patients with heart failure and coronary heart disease (NCT00023595). The STICH trial was sponsored by the National Heart, Lung, and Blood Institute. Results of the STICH trial were published in 2009. (1) This unblinded study was performed at 127 clinical sites from 26 countries. A total of 1000 patients with coronary artery disease and ejection fraction of 35% or less were randomized to CABG alone (n=499) or CABG plus SVR (n=501). The primary outcome was a composite of death from any cause and hospitalization for cardiac reasons. While SVR reduced the end-systolic volume index by 19% compared with 6% with CABG alone, there was no difference between groups in the primary outcome, which occurred in 292 of 499 (59%) of the CABG alone group compared with 289 of 501 (58%) of the CABG plus SVR group (hazard ratio [HR], 0.99; 95% confidence interval [CI], 0.84 to 1.17; p=0.90). Death from any cause occurred in 141 of 499 (28%) in the CABG alone group compared with 138 of 501 (28%) in the CABG plus SVR group (HR=1.00; 95% CI, 0.79 to 1.26; p=0.98). Cardiac symptoms and exercise tolerance also improved to similar degrees between groups. Other secondary outcomes, such as stroke, myocardial infarction (MI), and subsequent procedures, did not differ between groups. Subgroup analysis did not reveal any patient groups that benefited from SVR significantly more than the entire group.
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. A 2014 analysis evaluated whether, in the STICH study, myocardial viability was associated with patient outcomes. A total of 267 patients in the study underwent single-photon emission computed tomography viability studies, and 191 were found to have myocardial viability. The investigators found no significant interaction between myocardial viability status and treatment group for the outcomes mortality (p=0.36), or mortality plus cardiac hospitalization (p=0.55).

Subgroup analyses published in 2012 and 2013 did not found significantly better outcomes in 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. (3, 4) A 2015 subanalysis found that patients with moderate-to-severe preoperative right ventricular dysfunction had worse outcomes when they underwent SVR and CABG compared with CABG alone. (5) In an analysis adjusting for other prognostic factors, the interaction between right ventricular function and treatment group was statistically significant for all-cause mortality (p=0.022). Because subgroup analyses were performed post hoc, they are considered hypothesis generating, and any findings would need to be confirmed in prospective trials.

A separate publication from the STICH trial reported on quality-of-life (QOL) outcomes. (6) The main QOL outcome measure used was the Kansas City Cardiomyopathy Questionnaire (KCCQ), which is a 23-item scale meant to measure the effect of heart failure symptoms on QOL. Secondary QOL measures included the Seattle Angina Questionnaire, the 12-Item Short-Form Health Survey, the Center for Epidemiologic Studies Depression Scale, the Cardiac Self-Efficacy Questionnaire, and the EuroQoL 5-D. The questionnaires were administered at baseline and 4, 12, 24, and 36 months postrandomization. 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 with the CABG alone group. Similarly, there were no group differences noted on any of the secondary QOL measures.

A second RCT was published in 2011 by Marchenko et al. (7) This was a study performed in Russia of 236 patients with ischemic heart failure who were randomized to CABG alone or CABG plus SVR. The mean follow-up was 31±13 months. Outcome measures reported were perioperative mortality and survival at 1-, 2-, and 3-year follow-up. Perioperative mortality was 5.8% in the CABG alone group compared with 3.5% in the CABG plus SVR group (p=NS, statistical tests not reported). Survival at 1 and 3 years was 95% and 78%, respectively, in the CABG plus SVR group, compared with 83% and 78%, respectively, in the CABG alone group (statistical tests not reported). There were reductions in New York Heart Association (NYHA) functional class and angina class for both groups after surgery, but between-group statistical testing was not reported. For example, NYHA functional class decreased in the CABG plus SVR group from 3.1±0.4 at baseline to 2.2±0.6 at 3 years, compared with a decrease in the CABG alone group from 2.9±0.5 to 2.4±0.9.

Uncontrolled Studies

The returning Torsion Original Radius Elliptical Shape to the Left Ventricle (RESTORE) Group is an international group of cardiologists and surgeons from 13 centers that had investigated SVR for the past 20 years in more than 1000 patients with ischemic cardiomyopathy following anterior infarction.
Athanasuleas et al from the RESTORE Group, reported on early and 3-year outcomes in 662 patients who underwent SVR following anterior MI during the period of January 1998 to July 2000. (8) In addition to SVR, patients also concomitantly underwent CABG (92%), mitral repair (22%), and mitral replacement (3%). The authors reported that 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 3 years was 89.4±1.3% and 88.7%, respectively. In a separate publication on 439 patients from the RESTORE Group, Athanasuleas et al reported outcomes improved in patients with lower patient age, higher ejection factions, and lack of need for mitral valve replacement. (9)

Mickleborough et al reported on 285 patients who underwent SVR by a single surgeon for class III or IV heart failure, angina, or ventricular tachyarrhythmia during the period of 1983 to 2002. (10) 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%±9% from 24%±11% (p<0.000), and symptom class in 140 patients improved 1.3±1.1 functional classes per patient. Patients were followed for up to 19 years (mean, 63±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 et al reported on 157 patients who underwent SVR by a single surgeon for class III or IV heart failure, angina, ventricular tachyarrhythmia, or MI using 3 operative methods during the period of 1979 to 2000. (11) SVR procedures consisted of radical aneurysm resection and linear closure (n=65), septal dyskinesia 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%±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.

Sartipy et al reported on 101 patients who underwent SVR using the Dor procedure at a single center for class III or IV heart failure, angina, and ventricular tachyarrhythmia during the period of 1994 to 2004. (12) 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%; LVEF increased from 27%±9.9% to 33%±9.3% postoperatively. Patients were followed up 4.4±2.8 years, and overall actuarial survival was reported as 88%, 79%, and 65% at 1, 3, and 5 years, respectively.

In 2006, Hernandez et al reported on the contemporary performance of SVR based on data from the Society of Thoracic Surgeons’ database. (13) 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. Tulner et al reported on 6-month follow-up on 21 patients with ischemic dilated cardiomyopathy who underwent SVR and bypass grafting; some also had valve annuloplasty. (14) Improvement in a number of clinical variables was noted, including
decreased left-ventricular dyssynchrony, reduced tricuspid regurgitation, and improved ejection fraction (27%-36%).

Searches of the MEDLINE database have found that the published studies continue to primarily report on case series. In many, SVR was performed in conjunction with additional cardiac procedures. For example, Tulner et al reported on 6-month outcomes on 33 patients with class III/IV heart failure who underwent SVR and/or restrictive mitral annuloplasty. (15) Operative mortality was 3%, and additional in-hospital mortality was 9%. QOL scores improved, as did 6-minute walking distance (248-422 meters). Williams et al reported on a retrospective review of outcomes following SVR in a series of 34 patients with NYHA class IV heart failure and 44 patients with class II/III who had surgery between January 2002 and December 2005. (16) There were 3 operative deaths in each group. While there was symptomatic improvement in both groups, there was a trend toward reduced survival at 32 months in those with class IV versus class II/III disease (68% vs 88%, respectively). A nonrandomized 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% was published in 2009. (17) In this nonrandomized study, the authors concluded that patients in whom SVR was possible experienced more perioperative complications but had improved early and midterm outcomes. While these and similar studies show that some clinical improvement occurs following this surgery, the nonrandomized nature of these studies limits the ability to draw conclusions. Controlled trials are needed to compare the outcomes of SVR to other alternatives.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<thead>
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<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td>Ongoing</td>
<td>NCT00023595 Surgical Treatment for Ischemic Heart Failure</td>
<td>2136</td>
<td>Apr 2016</td>
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NCT: national clinical trial.

Practice Guidelines and Position Statements

In 2010, a Task Force of the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery developed guidelines on myocardial revascularization. (18) These guidelines consider SVR combined with CABG to be a surgical option for patients with ischemic heart failure and left ventricular ejection fraction 35% or less (based on opinion and evidence that is not well-established). The guidelines also recommend SVR with CABG only be performed in centers with a high level of surgical expertise.

The 2014 ESC/EACTS guidelines on myocardial revascularization did not discuss surgical ventricular restoration (19)

U.S. Preventive Services Task Force Recommendations

Not applicable.
Summary

The evidence for use of surgical ventricular restoration (SVR) in patients with ischemic cardiomyopathy includes a single randomized controlled trial (RCT) and a number of uncontrolled studies. Relevant outcomes are survival, quality of life (QOL), and others. The RCT, the Surgical Treatment of Ischemic Heart Failure (STICH) trial, did not report significant improvements in clinical outcomes QOL measures for patients undergoing SVR in addition to standard coronary artery bypass grafting (CABG) surgery. Several uncontrolled studies have suggested that SVR can improve the hemodynamic functioning in selected patients with ischemic cardiomyopathy; however, these studies are uncontrolled and thus are considered lower quality evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

Medicare National Coverage

There is no national coverage determination.

References

RESTORE group. Reconstructive Endoventricular Surgery, returning Torsion Original Radius Elliptical Shape to the LV. J Am Coll Cardiol. Apr 2001;37(5):1199-1209. PMID 11300423


Policy History

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<th>Date</th>
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<tr>
<td>June 2012</td>
<td>New Policy</td>
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<td>December 2012</td>
<td>Update Policy</td>
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<tr>
<td>December 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 9 and 10 added; “or post-infarction left ventricular aneurysm” added to policy statement.</td>
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<td>December 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review, adding references 2, 19. Policy statement is unchanged.</td>
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## Keywords

DOR Procedure  
Surgical Anterior Endocardial Restoration (SAVER)  
Surgical Ventricular Restoration (SVR)  
Ventricular Restoration or Remodeling

This policy was approved by the FEP Pharmacy and Medical Policy Committee on December 2, 2016 and is effective January 15, 2017.

Signature on File  
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