Surgical Ventricular Restoration (SVR) for Ischemic Cardiomyopathy: Is the SVR Alternative Treatment to Heart Transplantation?

Tadashi Isomura, Yasuhisa Fukuda, Takuya Miyazaki, Minoru Yoshida, Akimasa Morisaki, Masahiro Endo and Masanori Hirota

Objectives: Ischemic cardiomyopathy (ICM) is defined as the end-stage of ischemic heart disease. The treatment for ICM is not only medication or heart transplantation, but also non-transplant surgery including surgical ventricular restoration (SVR). We studied the effectiveness of the SVR for ICM and the possibility of alternative treatment to heart transplantation. Methods: Since May 2000, SVR for ICM were performed in 186 patients. There were 163 men and 23 women with a mean age of 62±10 years old. There were 164 elective operations and 22 emergent operations. In addition to routine echocardiogram, speckle tracking echocardiogram was introduced to detect the lesion of LV since 2005. After cardioplegic arrest, complete coronary revascularization, and/or mitral or tricuspid surgery was performed, followed by SVR of either anteroseptal or posterior exclusion. The patients were followed up by transthoracic echocardiography. Results: The procedures of SVR was endoventricular circular patch plasty (EVCPP) in 66, septal anterior ventricular exclusion (SAVE) in 94, and posterior restoration procedure (PRP) in 26 patients. In addition to SVR, CABG was performed in 159, mitral surgery in 121 (plasty 105, replacement 16), and tricuspid annuloplasty in 48. Perioperative intra-aortic balloon pumping (IABP) was required in 46 and the hospital mortality was 4.3 % in elective and 18% in emergent operation. After the operation, 132 patients (75%) improved their functional class to class I or II. In the late follow-up, there were 17 cardiac deaths (congestive heart failure 11, ventricular arrhythmia 6). After 2005, the eight-year survival rates were 76.2% in elective operation. Conclusions: Our results demonstrated that the eight-year survival rate was equivalent to that after heart transplantation and 71% of the indicated patients for SVR could avoid heart transplantation with relief of their symptoms. KEY WORDS: coronary artery bypass grafting, ischemic cardiomyopathy, non-transplant surgery, speckle-tracking echocardiography, surgical ventricular restoration

I. Introduction

The first choice of surgical treatment for end-stage ischemic heart failure is heart transplantation, however, as the non-transplant surgery, surgical ventricular restoration (SVR) has been believed to be beneficial for indicated patients with ischemic cardiomyopathy (ICM)\(^1\). In contrast, surgical treatment for ischemic heart failure (STICH) trial\(^2\) concluded that SVR in addition to coronary artery bypass grafting (CABG) had no further beneficial effect on survival compared with CABG alone. However, the results of the STICH trial are controversial because the study design and operative procedures are not correctly performed. Therefore, recent repeated analysis of the STICH trial data showed a survival benefits was realized in patients with CABG plus SVR compared with CABG alone, with the achievement of a postoperative end-systolic volume index (ESVI) of 70 ml/m\(^2\) or less\(^3\). In another option, implantable ventricular assist devices (VAD) have become more common in the treatment for severe congestive heart failure (CHF) because of the improvement of the mid-term results after VAD implantation\(^4\). However, VAD implantation has inherent unresolved problems due to thromboembolism, bleeding, or infection of the device. Therefore, if the SVR is effective in indicated patients with ICM in the long term results, the SVR contributes to one of the best choice of surgical treatment for ICM. We retrospectively studied surgical results in late follow up after SVR with developed procedures and examination method in patients with ICM.

II. Patients and Methods

1. Patients

Since May 2000, 248 patients with ischemic heart disease received SVR and among them 186 patients were diagnosed as
ICM which showed diffuse akinesis of left ventricle (LV) with LV ejection fraction (LVEF) less than 30% by echocardiogram. There were 163 men and 23 women and the mean age was 62±10 years (range, 29–85 years) with 83 patients over the age of 65 years. The preoperative New York Heart Association (NYHA) functional class was class-III in 111 patients and class-IV in 75 patients. Preoperative inotrope support was required in 78 patients (Table 1).

Two-dimensional echocardiography was used to evaluate cardiac geometry, including dimensions and LV volume, valvular morphology and the subvalvular apparatus. Geometric parameters such as LV end-diastolic and end-systolic diameter (LVEDD and LVESD), and LVED- and LVES volume indices (LVEDVI and LVESVI) were calculated by the modified Simpson method. Since July 2005, the findings of LV wall lesion were detected based on the preoperative findings of speckle-tracking echocardiography, which showed severe akinetic or dyskinetic lesion and dys synchrony at the anteroseptal or posterior wall of the dilated LV. LVESVI >100ml/m² as determined by echocardiography was a prerequisite for LV restoration.

2. Surgical procedures
Using ordinary cardiopulmonary bypass (CPB) with tepid warm blood (34 degrees Celsius) cardioplegic heart arrest, CABG first, and then mitral or tricuspid surgery, if indicated, was performed, followed by SVR. As previously reported, details of SVR were described and the similar techniques were performed. The endoventricular circular patch plasty (EVCP) procedure was done in the traditional way with use of only the akinetic lesion to define site of patch placement. The LV was incised along to the left anterior descending artery (LAD) for 4–5cm and then the LV was excluded with 2–0 Prolene monofilament suture (Ethicon, Inc., Somerville, N.J.) continuous sutures. The suture was tied and the defect was closed with 3 × 4 cm oval Dacron patch. The incised left ventricle was closed with double layers of mattress sutures and then over sewn with a running over-and-over suture. For the septal anterior ventricular exclusion (SAVE) operation, multiple mattress stitches with 0-Ticron were placed along to the exclusion line of the septum, with a direction that proceeded from the apex to a septal site 2–3 cm below the aortic valve. Sutures were placed above the akinetic lesion. The anterior lateral wall exclusion was also performed in similar fashion with multiple mattress sutures. The Dacron patch was trimmed to create a longitudinal shape, approximately 3 cm × 8 cm, and placed along the site of the exclusion, with sutures placed 1 cm from the patch edge to leave a patch rim outside these sutures (Fig. 1).

The posterior restoration procedure (PRP) consisted of posterior restoration with preservation of bilateral papillary muscle and the LV apex, and the prevention of late occurrence of ventricular arrhythmia. The LV was incised for 1–2 cm at the left side of the LAD and the bilateral papillary muscles were carefully inspected. The incision was then extended forwards between bilateral papillary muscles to the mitral annulus before reaching 1–2 cm from the mitral annulus. The posterior wall of the LV between both papillary muscles was then resected. Cryoablation was performed inside the LV muscle between the edge of the incision and the mitral annulus. The bilateral papillary muscle was re-approximated during closure of the LV (Fig. 2). The incised LV wall was closed in two layers to secure hemostasis.

3. Medical treatment and follow-up
Optimnal medical therapy for heart failure was re-instituted as soon as possible after surgery.
Cardiac echocardiography was performed before discharge and the patients were followed up every 6–12 months. The regular follow-up was made by the outpatient clinic, and by telephone calls or mailed questionnaires. The follow-up completion rate was 91.4% and the mean follow-up was 51 ± 38 months. The longest follow-up extended to 12.7 years.

4. Statistical analysis
Continuous variables are expressed as the mean ± standard error. Cumulative survivals were calculated by the Kaplan-Meier
procedures included mitral surgery in 121 patients (65%) and the procedures consisted of mitral valve plasty (MVP) in 105 patients and mitral valve replacement (MVR) in 16 patients. Tricuspid surgery with annuloplasty ring was in 48 patients with preoperative tricuspid regurgitation (TR) greater than grade II. In 92 patients with a history of ventricular tachycardia (VT) and/or presence of scar area inside of the LV at the operative findings, cryoablation was performed.

SVR was performed based on the lesion of LV. EVCPP was performed in 66 (35%) with anteroseptal lesion and SA VE was in 94 patients (51%) with large anteroseptal akinetic lesion to make large exclusion of LV. In contrast, 26 patients (14%) with inferior or posterior lesion received PRP for the exclusion of the lesion. Perioperative intra-aortic balloon pumping (IABP) was used in 46 patients and LV AD was implanted in two patients with preoperative shock (Table 2). After the operation, hospital mortality was in 11 patients. In 164 patients with elective operation, the mortality was in 7 patients (4.3%) and in 22 patients with emergent operation, 4 patients (18%) died of CHF after operation.

After the operation, 175 patients were discharged from hospital. During the follow-up period of a mean of 51±38 months, 19 patients died. Cardiac related deaths were in 17 consisted of CHF in 11 and VT in 6.

Re-admission for CHF was in 24 patients, however, 132 patients (71%) were in NYHA class 1 or 2 after the operation (Table 3).

Before May in 2005, the procedures of SVR was selected by estimation with the dates of the operation and of the most recent follow up. P-values were obtained by paired or unpaired Student’s t-test, Wilcoxon’s signed-rank test, the Mann–Whitney test and one-way analysis of variance followed by Tukey-Kramer’s post hoc test. The differences in the survival rate were determined by log-rank analysis. A p-value of < 0.05 was considered statistically significant.

### III. Results

CABG was performed in 159 patients (85%) with a mean number of distal anastomosis of 2.7 per patient. Concomitant procedures included mitral surgery in 121 patients (65%) and the procedures consisted of mitral valve plasty (MVP) in 105 patients and mitral valve replacement (MVR) in 16 patients. Tricuspid surgery with annuloplasty ring was in 48 patients with preoperative tricuspid regurgitation (TR) greater than grade II. In 92 patients with a history of ventricular tachycardia (VT) and/or presence of scar area inside of the LV at the operative findings, cryoablation was performed.

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**Table 2** Operative characteristics

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
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<tr>
<td>Anterior : EVCPP</td>
<td>66 (35%)</td>
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<tr>
<td>Anterior : SAVE</td>
<td>94 (51%)</td>
</tr>
<tr>
<td>Posterior : PRP</td>
<td>26 (14%)</td>
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<tr>
<td>CABG</td>
<td>159 (85%)</td>
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<td></td>
<td>2.7 ± 1.3/patient</td>
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<tr>
<td>Mitral</td>
<td>121 (65%)</td>
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<tr>
<td>MVR/MVP</td>
<td>16/105</td>
</tr>
<tr>
<td>Tricuspid</td>
<td>48 (26%)</td>
</tr>
<tr>
<td>Cryoablation</td>
<td>92 (49%)</td>
</tr>
<tr>
<td>IABP/LVAD</td>
<td>46 (25%)/2 (1.1%)</td>
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preoperative routine trans-thoracic echocardiogram and intraoperative gross findings. The speckle tracking echocardiogram was preoperatively introduced in all since 2005, and more precise lesion of LV was detected to make a plan of procedures for SVR before surgery.

With regard to survival according to the operative period, the cumulative survival rate in 164 elective cases at five or eight years after the operation was 68.3 or 55.8% before 2005, and 76.2% or 76.2% after 2005, respectively (Fig. 3).

IV. Discussion

The end-stage heart failure of ischemic heart disease is called ischemic cardiomyopathy (ICM) and the heart transplantation is indicated in young patients with ICM. Several treatment options can be selected for ischemic heart failure depending on the patient’s status: medication, revascularization, SVR, VAD, and heart transplantation. Because medication alone or CABG alone has reported unsatisfactory results in those with severe LV dilatation, acute reverse remodeling by SVR was expected to benefit such patients by reducing LV volume and restoring LV shape.

In 1998, Dor et al. reported SVR as EVCPP in patients with ICM and showed the excellent long-term results for EVCPP for not only LV aneurysm as LV dyskinesis but also ICM as diffuse akinesis of LV. Based on the long-term results, they concluded that the EVCPP for ICM could be considered as an alternative to heart transplantation.

In our reported 186 patients with ICM, all patients had received maximal medical treatment including, full medication, catheter intervention, and resynchronization treatment if indicated. 103 patients were less than 65 years old and among them, 45 patients required inotropic support before operation. In 61 patients without inotropic support, two third of the patients had repeated CHF with medical treatment and they had been suggested to consider heart transplantation during medical treatment. However, they were not candidates for heart transplantation because of hepatic or renal failure, pulmonary hypertension, or other limitations.

Although we did not conduct a prospective study that compares different treatment sets such as heart transplantation or VAD implantation, the results of the late survival rate after the operation showed that SVR was effective to improve late outcome similar to the report by Dor et al.

In the end-stage heart failure with dilated heart, functional MR is associated with deterioration of CHF symptom. The etiology of functional MR is the mitral annular dilatation and leaflet tethering due to dilated LV as spherical shape. The small ring annuloplasty alone, as suggested by Bolling et al., was not the choice for the functional MR and showed the recurrence of MR after small ring annuloplasty. Therefore, SVR for the reduction of LV volume, or re-shape the LV (SVR) or papillary muscle plication (PMP) or chordal plication as additional surgical procedure is required to reduce the recurrence of functional MR after ring annuloplasty. After the EVCPP progression or occurrence of MR was reported as high as 30% in patients with EVCPP because the shape of LV usually became spherical after the surgery. We developed SAVE procedure for SVR to make the LV shape elliptical after the procedure.

With regard to LV volume and prognosis, Yamaguchi et al. showed that the actuarial survival rate during follow-up in patients who had a preoperative LVESVI of less than 100 ml/m² was significantly greater than that in patients who had a preoperative LVESVI of greater than 100 ml/m². They concluded that after the CABG alone, the preoperative LVESVI predicted the development of postoperative CHF and the poor survival rate in patients with ICM.

The adverse effects of LV dilatation were reported by White et al., who showed that increased ventricular volume rather than altered ejection fraction became the principal surrogate for mortality. In this study, preoperative ESVI more than 100ml/m² was indicated for the SVR procedures, and the postoperative volume was tried to decrease less than 80 to 100ml/m² of ESVI.

After the report of SVR as EVCPP by Dor et al. in 1998, more

<table>
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<th>Table 3 Operative results</th>
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<td>Hospital death</td>
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<tr>
<td>Elective</td>
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<td>Emergent</td>
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<td>Late follow up</td>
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<td>NYHA class 1-2</td>
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<tr>
<td>NYHA class 3-4</td>
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<tr>
<td>Late death</td>
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CHF: congestive heart failure, VT: ventricular tachycardia

Fig. 3 Survival of patients in elective operation (n=164)
than 5,000 patients on an international database\textsuperscript{19–21} have been reported and the database demonstrated favorable survival compared to CHF natural history studies\textsuperscript{22} and a CABG patient cohort with poor LVEF and CHF\textsuperscript{20,29}.

However, in 2009, STICH for SVR found there was no beneficial effect on survival in SVR plus CABG compared with CABG alone. However, the validity of the STICH results is controversial\textsuperscript{24,25}. Specifically, STICH seemed to enroll a CABG-preferable population, considering the reported risk factors related to CABG alone, such as an extensively dilated LV and increased number of nonviable segments\textsuperscript{26}, as well as severe LV systolic dysfunction\textsuperscript{27}. CABG alone or SVR plus CABG may be appropriate for different populations with a small overlap between them. For SVR, favorable clinical results followed approximately 40% volume reduction below control levels in more than 1,500 cases in 12 worldwide centers. In contrast, STICH reduced ventricular volume 19% in 161 patients, and 96 centers were required to achieve this end point. The volume studies were not shown in 66% of patients and an invalid echo-based monitoring method was used in the others. Furthermore, 18.5% of the patients undergoing SVR had no left ventricular volume reduction. Without postoperative volumes, all STICH data should be skeptically viewed. Base on the controversial comments to STICH trial and widespread discussion\textsuperscript{28–30}, Michler et al.\textsuperscript{3} evaluated the distribution of LV volumes at baseline and 4 months postoperatively and the individual reductions in LV volume with surgery to determine whether a threshold postoperative LVESVI, or any magnitude of postoperative reduction in LVESVI, affected survival after CABG plus SVR compared with CABG alone. They\textsuperscript{3} reported that 44% of patients in the STICH data did not have adequate volume data for preoperative and postoperative analysis. They concluded that in patients undergoing CABG plus SVR, a survival benefit was realized compared with bypass alone, with the achievement of a postoperative ESVI of 70 ml/m\textsuperscript{2} or less. Extensive ventricular remodeling at baseline might limit the ability of ventricular reconstruction to achieve a sufficient reduction in volume and clinical benefit. However, favorable results of SVR for those excluded from STICH were also reported\textsuperscript{31,32}. In Japanese multicenter study\textsuperscript{33}, the results suggested that the patient’s condition (heart failure status) and MR severity were more important predictors than LV size. Even for patients with an extremely large LV, SVR can be indicated if heart failure is well controlled and MR is not severe.

The extent of left ventricular volume reduction is thought to be crucial for an optimal outcome\textsuperscript{26}. We previously\textsuperscript{33} reported an 84% of five-year survival when LVESVI was reduced to less than 90 ml/m\textsuperscript{2} and volume reduction was greater than 30%, especially when the elliptical, conical shape of the heart was restored after the SVR operation. Excellent survival has been achieved when residual volume is less than 60 ml/m\textsuperscript{2}.

In this study, SVR was indicated in patients with ICM and LVESVI more than 100ml/m\textsuperscript{2} and the operative procedures were selected according to the lesion of LV. The SVR was anterosetal restoration in 87% consisted of EVCPP in 36% and SAV in 51%, and PRP for posterior lesion in 13%. Since 2005, the lesion of LV was detected by speckle tracking echocardiogram and the postoperative long term results were compared before and after 2005. The cumulative survival rate in elective cases improved to 76.2% at eight years after SVR in patients with SVR after 2005.

\textbf{Study limitations}

First, the results of initial surgery between 2000 and 2005, and late surgery for SVR since 2005 might be influenced by learning curve for SVR procedures.

Second, in this reported data, the LV volume study by left ventriculogram or scintigram in addition to echocardiogram was not measured in all patients. However, we used the data of the volume and the results of surgical outcome in our previous report in this discussion. The procedures of the volume reduction surgery for SVR was similar to those in the previous report for volume study\textsuperscript{35}.

In this report regarding SVR in 186 patients, we included the previous report from 90 patients who underwent accurate preand post-operative assessment of LV volumes by left ventriculogram or scintigram. Before surgery, the mean ESVI was 123.5 ± 53.2 ml/m\textsuperscript{2} (range 92–310 ml/m\textsuperscript{2}) and exceeded 80 ml/m\textsuperscript{2} in all patients. SVR reduced the mean ESVI to 95.0 ± 42.7 ml/m\textsuperscript{2}, an overall 23% reduction in mean LV volume. However, 30 patients (33%) with SVR retained an ESVI > 100 ml/m\textsuperscript{2} despite LV rebuilding. The post-operative ESVI was <90 ml/m\textsuperscript{2} (Group-S) in 54 patients, 90–120 ml/m\textsuperscript{2} (Group-M) in 16, and >120 ml/m\textsuperscript{2} (Group-L) in 20 patients. The 8-year survival rate was 82.4% in Group-S following a >33% LV volume reduction. In contrast, in Group-M and Group-L, the volume reduction was −15%, and 100% of patients died within 7 years following the SVR procedure (or 0% of 8-year survival). The report showed a >33% ESVI reduction to be the most important SVR objective; 82.4% 8-year survival resulted when an ESVI <90 ml/m\textsuperscript{2} was achieved. Conversely, 100% 8-year mortality followed a −15% volume reduction rate and ESVI > 90 ml/m\textsuperscript{2}. Our report\textsuperscript{35} defined the prognostic role of inadequate volume reduction.

Finally, this is a retrospective and non-comparative study. The results of SVR were not compared with other treatments (eg, CABG alone, medication, and VAD). Thus, a prospective study that compares different treatments is required to choose the best choice of the treatment. However, in the late follow-up up to eight years after surgery since 2005, the survival rate was equivalent to the survival rate after heart transplantation and 71% of
the patients could avoid heart transplantation with relief of their symptoms.

V. Conclusion

Based on the results the selected patients for SVR showed favorable outcome if the operative procedure is selected properly and the volume reduction is sufficiently performed for SVR. Our reported findings and those in several literatures suggest that the SVR in patients with sufficient reduction of dilated LV may be an alternative surgery to heart transplantation.

All authors declare no conflict of interest.

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