Restrictive Mitral Annuloplasty for Functional Mitral Regurgitation
– Acute Hemodynamics and Serial Echocardiography –
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**Background:** Long-term effects of restrictive mitral annuloplasty (RMA), especially on hemodynamics and left ventricular (LV) function in patients with functional mitral regurgitation (MR), have not been fully investigated.

**Methods and Results:** From 1999 to 2008, 44 patients with refractory heart failure and functional MR underwent RMA with stringent downsizing of the mitral annulus. Serial echocardiography was performed to evaluate LV function (reverse remodeling), estimated systolic pulmonary artery pressure (PAP) and mitral valve geometry at baseline and at discharge, and annually thereafter. Cardiac catheterization was performed at baseline, and at discharge to evaluate acute hemodynamic change. There were 3 early deaths, and the 5-year survival rate was 78±8%. In 41 survivors the clinical symptoms, stratified according to New York Heart Association class, significantly improved after surgery. Postoperative cardiac catheterization showed significant unloading for left ventricle, as well as improvement in LV systolic function. Serial echocardiography showed that improvements in LV function and systolic PAP were sustained in the majority of patients. Multivariate Cox regression analysis identified preoperative pulmonary hypertension (systolic PAP > 60 mmHg) as the significant predictor for postoperative adverse cardiac events.

**Conclusions:** RMA for functional MR resulted in sustained improvement of hemodynamics and LV function over time. Additional studies are needed to define the negative impact of preoperative pulmonary hypertension in patients with this condition. *(Circ J 2011; 75: 571–579)*

**Key Words:** Cardiomyopathy; Mitral valve; Pulmonary arterial hypertension; Surgery

Functional mitral regurgitation (MR), frequently observed in patients with advanced dilated cardiomyopathy and heart failure, is associated with poor prognosis. It is well known that β-blockers and cardiac resynchronization therapy diminish functional MR, partially reverse left ventricular (LV) remodeling, and improve LV function, leading to improved long-term survival. Restrictive Mitral Annuloplasty (RMA), in which the mitral valve is repaired by implanting an undersized annuloplasty ring, has become the preferred surgical treatment for this condition. Some studies have demonstrated satisfactory short- and midterm outcomes following RMA, but the long-term effects on survival, symptomatic status, and LV remodeling have not been fully investigated. Furthermore, whether the benefits from RMA persist over time is uncertain and controversial.

To address these issues, we investigated long-term clinical, acute hemodynamics and serial echocardiography following RMA in patients with advanced cardiomyopathy and refractory MR. We also attempted to identify preoperative predictors for and correlating factors with postoperative adverse outcomes.
Patients

We examined the records of 56 consecutive patients who underwent RMA for functional MR at Osaka Rosai Hospital between August 1998 and December 2008. Of these, 44 were chosen as study subjects, based on the following inclusion criteria: (1) end-stage cardiomyopathy with New York Heart Association (NYHA) functional class III or IV; (2) history of hospitalization for heart failure in the previous 6 months (at least once) despite maximum medical treatment; (3) advanced LV remodeling defined as LV ejection fraction (LVEF) <35% and LV end-systolic volume (LVESV) >100 ml on left ventriculography; and (4) severe or moderate–severe MR caused by restrictive leaflet motion secondary to global severe LV dilatation. The underlying etiology was idiopathic dilated cardiomyopathy in 19 patients, ischemic cardiomyopathy in 23, and unknown in 2. Patients with less LV remodeling and ischemic MR secondary to a regional LV deformity, due to inferior/posterior myocardial infarction were excluded from the study. Patients with type I LV aneurysm,7 recent myocardial infarction (<3 months), organic MR, rheumatic mitral disease, or aortic valve disease were also excluded. Prior to surgical referral, all patients had been treated with optimized medical regimens by an attending cardiologist (M.N.), including angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers, β-blockers, and diuretics.

The institutional ethics committee approved this study and waived individual consent for this retrospective analysis. Written informed consent for the procedure was obtained from each patient before surgery. Patient baseline characteristics and all relevant surgical data are presented in Table 1.

Echocardiography

Two-dimensional (D) and Doppler transthoracic echocardiography (TTE) were performed at baseline, at discharge (14–28 days after surgery; mean 21±5 days), and annually thereafter. Preoperative (baseline) and postoperative TTE at discharge were performed within 1 day of cardiac catheterizations. All echocardiography was done using commercially available 3.75-MHz transducers (Toshiba, Tokyo, Japan, and Hewlett-Packard Sonos) by the same echocardiography expert examiner (S.F.), who was blinded to the clinical status of the patients.

LV Function and Left Atrial Dimensions (LAD)

The LV end-diastolic dimension (LVESD), the LV end-systolic dimension (LVESV), and the LAD were determined from 2-D TTE images in parasternal long-axis views. The LVEF was calculated by means of Simpson’s method with 2 apical views.

Doppler-Derived Systolic Pulmonary Artery Pressure (PAP)

Systolic PAP was calculated by adding the systolic pressure gradient across the tricuspid valve derived from the tricuspid regurgitation (TR) to the estimated right atrial pressure.8,9 Right atrial pressure was estimated using the diameter of the inferior vena cava and the response to changes in respiration.

Mitril and Tricuspid Valve Measurements

The severity of MR and TR was graded semi-quantitatively from color-flow Doppler data. In our routine assessment, MR severity was characterized as none (0), trivial (1+), mild (2+), moderate (3+), or severe (4+). The tenting height, coaptation length and effective orifice area of the mitral valve, and mean transmural diastolic pressure gradient were also measured. The coaptation length was calculated using the following formula: Ad–Ac, where Ad equals the whole length of the anterior leaflet during the diastolic phase and Ac equals the
length of the non-coaptation free portion of the anterior leaflet at mid-systole.

Cardiac Catheterization and Hemodynamics
Cardiac catheterization was performed at baseline (within 1 week before the operation) and 1 month after the operation (at discharge). Quantitative LV cineangiography and pressure measurements were performed during all examinations. Using right heart catheterization, the pulmonary capillary wedge pressure (PCWP), systolic, diastolic, and mean PAP, transpulmonary gradient (mean PAP–PCWP), transmitral diastolic gradient (PCWP–LV end-diastolic pressure), systemic vascular resistance ([mean arterial pressure–right atrial pressure] × 80/cardiac output) and pulmonary vascular resistance ([mean PAP–PCWP] × 80/cardiac output) were calculated.

Surgical Procedures
Surgical data are given in Table 1. A median sternotomy was performed under mild hypothermic cardiopulmonary bypass with intermittent cold blood cardioplegia. The mitral valve was exposed through a trans-septal superior approach. A stringent RMA (downsizing by 2–4 ring sizes) was performed in all patients. Early in the series (1998–2003), the Cosgrove-Edwards annuloplasty system (Cosgrove band; Edwards Lifesciences, Irvine, CA, USA) was used (n=8). Beginning in 2004, the Carpentier-Edwards Physio ring (n=36; Carpentier ring; Edwards Lifesciences) was used consistently. Of the 23 patients with ischemic etiology, 13 underwent a mitral annular repair with RMA alone and the remaining 10 underwent RMA and additional surgical ventricular reconstruction (SVR), which has been described previously.11,12 SVR was performed when a broad anterolateral or anteroseptal asynergy (akinesis or dyskinesis) was demonstrated on left ventriculography and a postoperative LV end-diastolic volume index >90 ml/m² could be anticipated. Our criteria for adding SVR to RMA were mainly based on the previous 2 investigations.13,14

Clinical Follow-up
Clinical follow-up was completed for the 41 survivors, with a mean duration of 48±33 months (range, 5–134 months). Every 6 months–1 year, they were assessed in Department of Cardiovascular Surgery as well as by their primary cardiologist. Functional status was assessed according to the NYHA criteria (for symptoms of heart failure) and serum brain natriuretic peptide (BNP) level. A retrospective review of the medical records of these patients was performed for the preoperative and postoperative data, and the current information was obtained by calling the patient or the referring cardiologists. Postoperative adverse cardiac events included cardiac deaths, readmission for heart failure, myocardial infarction, endocarditis, thromboembolism and reoperation for recurrent MR.

Statistical Analysis
Continuous variables are expressed as mean±SD and were compared using the Student’s t-test for paired and unpaired data when appropriate. Categorical variables were compared using chi-square test and Fisher’s exact test. The functional and echocardiographic variables over time were compared using repeated-measures analysis of variance, followed by paired t-test with Bonferroni α-adjustment method for individual significant differences. Correlations between variables were tested using Spearman’s rank correlation. Predictors of postoperative adverse cardiac events were analyzed using a Cox proportional hazards model (Appendix 1). Univariate analysis was first applied and factors having P<0.1 were then entered appropriately into a multivariate model. Multiple regression analysis was also performed to identify the correlating postoperative factors with postoperative cardiac events. The highest values of LVEDD, LVESD, LAD, systolic PAP, degree of MR and TR and lowest EF detected during
the follow-up period were included for the potential correlat-
ing factors. Actuarial survival was obtained using the Kaplan–
Meyer method. Statistical significance was defined as \( P < 0.05 \).
Statistical analyses were performed using JMP 7.0 (SAS
Institute, Cary, NC, USA).

**Results**

**Clinical Outcomes**

There were 3 (6.8\%) early deaths (within 30 days and in-
hospital). One death was due to cardiac tamponade and 1 to
low-output syndrome. The third patient had good recovery
from surgery, but developed biliary sepsis from acute necro-
tizing cholecystitis and died of cerebral hemorrhage on the
24th postoperative day.

There were 5 late deaths: 4 from cardiac and 1 from
non-cardiac causes. Actuarial survival rates were 91 ± 4\%,
84 ± 6\% and 78 ± 8\% at 1 year, 3 years, and 5 years, respectively
(Figure 1A). Five patients required hospitalization for heart
failure; one of these patients had recurrent MR (>3+). This
patient received a biventricular pacemaker, after which the
patient’s MR and clinical symptoms improved. The other 4
received medical treatment, and their symptoms improved.
None of the patients needed re-operation for recurrent MR
or endocarditis, or experienced postoperative myocardial
infarction. Adverse cardiac event-free rates at 1 year, 3 years

![Figure 2. Serial changes in New York Heart Association (NYHA) clinical symptoms and serum brain natriuretic peptide (BNP) level in patients undergoing restrictive mitral annuloplasty for functional mitral regurgitation.](image)

<table>
<thead>
<tr>
<th>Table 2. Acute Hemodynamic Changes in Cardiac Catheterization</th>
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<tr>
<td>Baseline (n=44)</td>
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<tr>
<td>LV end-diastolic volume (ml)</td>
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<tr>
<td>LV end-systolic volume (ml)</td>
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<tr>
<td>LV ejection fraction (%)</td>
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<tr>
<td>LV systolic pressure (mmHg)</td>
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<tr>
<td>LV end-diastolic pressure (mmHg)</td>
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<tr>
<td>Pulmonary capillary wedge pressure (mmHg)</td>
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<tr>
<td>Systolic pulmonary artery pressure (mmHg)</td>
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<td>Mean pulmonary artery pressure (mmHg)</td>
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<tr>
<td>Right atrial pressure (mmHg)</td>
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<td>Cardiac index (L·min⁻¹·m⁻²)</td>
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<tr>
<td>Stroke volume (ml/beat)</td>
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<tr>
<td>Transmirtal diastolic gradient (mmHg)</td>
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<tr>
<td>Transpulmonary gradient (mmHg)</td>
</tr>
<tr>
<td>Systemic vascular resistance (dynes sec cm⁻⁵ m²)</td>
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<tr>
<td>Pulmonary vascular resistance (dynes sec cm⁻⁵ m²)</td>
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<td>PVR/SVR ratio</td>
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*\( P < 0.05 \) vs. variables at baseline.
LV, left ventricular; PVR, pulmonary vascular resistance; SVR, systemic vascular resistance.
Restrictive Mitral Annuloplasty for Cardiomyopathy

The NYHA class for the survivors improved from 3.0 ± 0.2 at baseline to 2.0 ± 0.5 at 1 year (n=40) and 1.9 ± 0.7 at 3 years (n=23), and 2.0 ± 0.7 at 5 years after surgery (n=12), respectively (P<0.01; Figure 2A). The BNP level decreased from 552 ± 305 pg/ml at baseline to 223 ± 223 pg/ml at 1 year, 158 ± 179 pg/ml at 3 years, 134 ± 149 pg/ml at 5 years, respectively (P<0.01; Figure 2B).

Acute Hemodynamic Changes

These data are summarized in Table 2. On postoperative cardiac catheterization there was a significant decrease in LV volume and improvement in LVEF. LV peak systolic pressure did not change, whereas LV end-diastolic pressure and PCWP significantly decreased. The systolic and mean PAP also decreased significantly. The cardiac index tended to increase, but this change did not reach statistical significance. The mean postoperative transmural diastolic pressure gradient was 3.3±3.1 mmHg, indicating the absence of significant functional mitral stenosis. The ratio of pulmonary vascular resistance to systemic vascular resistance was unchanged, indicating the absence of obvious progression of pulmonary vascular disease.

Correlations Between Doppler-Derived Systolic PAP and Catheter-Measured Pulmonary Hemodynamic Variables

Spearman’s rank correlation analysis showed that the systolic PAP estimated on Doppler-echocardiography was significantly correlated with the catheter-measured LV end-diastolic pressure (r=0.549, P<0.01), PCWP (r=0.725, P<0.01), systolic PAP (r=0.833, P<0.01; Figure 3A), diastolic PAP (r=0.702, P<0.01), mean PAP (r=0.797, P<0.01), and transpulmonary gradient pressure (r=0.481, P<0.01), but not with...
the LV systolic pressure or cardiac index. Furthermore, Bland-Altman analysis indicated that the 2 modalities had good agreement in measuring systolic PAP, and it was slightly overestimated on Doppler echocardiography (mean bias ± SD, 1.5 ± 8.4 mmHg; Figure 3B).

Serial Echocardiography

LV Function and LAD All echocardiography results are summarized in Table 3. Postoperative echocardiography at discharge indicated that the LVEDD, LVESD and LAD decreased, on a parallel with significant improvement in LVEF, and these improvements were sustained during the entire follow-up period. These variables, however, never returned to the normal range in the majority of cases, suggesting that only a partial reversal of LV remodeling occurred (Figure 4).

When a 10% reduction in LVEDD (compatible with a 20% reduction in end-diastolic volume) was defined as significant reverse LV remodeling, 44% of patients demonstrated reverse remodeling at 1 month after operation, 53% at 1 year, 70% at 3 years and 58% at 5 years, respectively. Doppler-Derived Systolic PAP Postoperative echocardiography also showed that the mean value of systolic PAP significantly decreased, and the improvement was sustained in the majority of patients (Figure 4). During the postoperative follow-up period, 8 of the 41 survivors had persistence or deterioration of pulmonary hypertension (defined as systolic PAP > 40 mmHg). Postoperative adverse cardiac events occurred in 6 out of these 8 patients (75%) with postoperative PAP > 40 mmHg (75%), whereas these occurred in 3 out of the 33 patients (9.1%) with systolic PAP < 40 mmHg (P = 0.015).

Mitral Valve Performance For all patients, the MR grade significantly improved after surgery, with no further significant changes at subsequent examinations. Postoperatively, the tenting height was significantly decreased and the coaptation length also increased concomitantly at follow-up. The interval changes of these variables were not significant, indicating that no significant deterioration in valve performance occurred. The mean transmitral diastolic pressure gradient was < 5 mmHg at discharge in the majority of patients and had remained stable during follow-up. Furthermore, the effective orifice area of the mitral valve did not change. Thus, improvements in mitral valve geometry and performance were sustained during the entire follow-up period.

Predictors for and Correlating Factors With Postoperative Adverse Cardiac Events

In univariate analysis, history of ventricular arrhythmia, longer duration of heart failure, lower LVEF, higher tenting height, higher systolic PAP and severe pulmonary hypertension (Doppler-derived systolic PAP > 60 mmHg) were significantly associated with postoperative adverse cardiac events. The type (Cosgrove/Physio) or size of annuloplasty ring were not identified to be predictors of poor outcome. In the multivariate analysis, only severe pulmonary hypertension and

![Figure 4](https://example.com/f4.png)

Figure 4. Individual changes in (A) left ventricular end-diastolic dimension (LVEDD), (B) left ventricular end-systolic dimension (LVESD), (C) left ventricular ejection fraction (LVEF) and (D) systolic pulmonary artery pressure (PAP) at baseline, discharge, 1, 3 and 5 years after surgery. Red circles, mean data; black circles, individual data.
Table 4. Predictors of Postoperative Major Adverse Cardiac Events

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<tr>
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<th>Univariate</th>
<th>Multivariate</th>
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<tr>
<td></td>
<td>P value</td>
<td>HR (95%CI)</td>
</tr>
<tr>
<td>History of VT</td>
<td>0.02</td>
<td>4.0 (1.2–13.1)</td>
</tr>
<tr>
<td>Duration of HF (months)</td>
<td>&lt;0.01</td>
<td>1.02 (1.008–1.033)</td>
</tr>
<tr>
<td>LVESD (mm)</td>
<td>0.09</td>
<td>NS</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>&lt;0.01</td>
<td>0.8 (0.72–0.9)</td>
</tr>
<tr>
<td>Tenting height (mm)</td>
<td>&lt;0.01</td>
<td>1.36 (1.1–1.6)</td>
</tr>
<tr>
<td>Systolic PAP (mmHg)</td>
<td>&lt;0.01</td>
<td>1.05 (1.02–1.09)</td>
</tr>
<tr>
<td>Severe PH†</td>
<td>&lt;0.01</td>
<td>12.6 (3.2–50.4)</td>
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1 Systolic pulmonary artery pressure >60 mmHg.

HR, hazard ratio; CI, confidence interval; VT, ventricular tachycardia; HF, heart failure; LVESD, left ventricular end-systolic dimension; LVEF, left ventricular ejection fraction; PAP, pulmonary artery pressure; PH, pulmonary hypertension.

longer duration of heart failure were identified as significant predictors of postoperative adverse cardiac events (Table 4). Moreover, multiple regression analysis identified that among postoperative echocardiographic variables at their worst conditions, only systolic PAP independently correlated with adverse cardiac events (r=0.69, P<0.01).

Discussion

A novel aspect of the present study is the acute hemodynamic assessment and serial Doppler echocardiography of systolic PAP after RMA. The present results suggest that stringent RMA could effectively eliminate functional MR and prevent its recurrence in the majority of patients. That is, RMA abolished LV volume overload and partially reversed LV remodeling, and decreased systolic PAP in such failing hearts. The significant decrease in systolic PAP and LV partial reverse remodeling could be detectable at early follow-up after RMA and persisted during the entire follow-up period, and these changes were accompanied by improvement in NYHA functional class in parallel with reduced serum BNP levels.

Other important findings suggest that preoperative pulmonary hypertension (systolic PAP >60 mmHg) was a meaningful echocardiographic predictor of adverse cardiac events, and that postoperative systolic PAP was also significantly correlated with poor outcome.

Early and Long-Term Survival

The present findings demonstrate that RMA could be performed in patients with advanced cardiomyopathy and severe MR with an acceptable rate of operative mortality and satisfactory long-term survival. The present encouraging results confirm those of other recent studies. Notably, the present patients had a higher EF and 5-year survival rate than those reported by Romano and Bolling, and the present actuarial 5-year survival was substantially better than that of several medical treatment series. Although a recent report showed no survival advantage for patients treated surgically, the present data support the use of RMA for selected patients with reduced EF and refractory MR.

Acute Hemodynamic Changes and Long-Term Serial Echocardiography

Despite increasing experience with RMA for functional MR, information regarding acute hemodynamic changes remains scarce. The present data showing decreased LV volumes and improved EF are in accordance with those of a previous report. In addition, we found that LV end-diastolic pressure, PCWP, systolic and mean PAP, and pulmonary vascular resistance substantially decreased. Despite the use of small annuloplasty rings, no significant transmural diastolic pressure gradient was observed. These favorable hemodynamic changes after RMA probably caused the improvement in heart failure symptoms.

The present serial echocardiography data on LV reverse remodeling and mitral valve performance were also largely consistent with previous reports. Gelsomino et al observed significant LV reverse remodeling (responders) in 44% of 251 patients who underwent RMA for ischemic MR, and continued or progressive LV remodeling (non-responders) in 56%, including 10% who exceeded their preoperative level after 5 years. Braun et al noted 60.5% of responders and 39.5% of non-responders among 87 consecutive patients with ischemic MR undergoing RMA at 18-month follow-up. We noted significant reverse remodeling in 58% of the present patients at 5 years after surgery. Non-responders comprised the remaining 42%, and only a few of them had LV remodeling that exceeded the preoperative level. The variable percentages of LV reverse remodeling in these studies are probably due to differences in the patient characteristics, size or type of prosthetic ring implanted, incidence of recurrent MR, and/or criteria used to designate significant LV remodeling. We consider that although RMA can partially reverse LV remodeling or slow its progression, it cannot completely repair or permanently halt these processes.

The present findings include serial postoperative changes in the systolic PAP, which was determined non-invasively on Doppler echocardiography. In the present study a highly significant correlation could be identified between the catheter-measured systolic PAP and that obtained by the non-invasive Doppler technique. Thus, the present Doppler-derived systolic PAP data support the conclusion that the partially reversed LV remodeling and improved hemodynamic function induced by RMA persist for 5 years postoperatively.

Recurrence of MR and Functional Mitral Stenosis

Relatively high frequencies of residual or recurrent MR were reported in earlier series of conventional annuloplasty with a flexible or normal-sized ring. In a large series of patients treated at the Cleveland Clinic with a 30-mm (median ring size) rigid ring (Carpentier-Edwards Classic annuloplasty ring), high grade (3+ or 4+) MR occurred in approximately 25% during the first 6 months and was stable thereafter. In a series reported by Gelsomino et al, who used 28-mm rings (median ring size), the MR recurrence rate was 44% after 5

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end-systolic volume from 163±45 ml to 127±49 ml (P<0.01, respectively), whereas the LVEF improved from 24±6% to 33±1% (P<0.01). Furthermore, similar hemodynamic improvements are also demonstrated as a result of RMA alone and it is therefore unlikely that the inclusion of those patients with SVR would have led to different conclusions.

Third, quantitative grading of MR severity (eg, effective regurgitation orifice area and regurgitant volume) rather than the traditional semiquantitative measurement is a more objective evaluation. We believe, however, that the conclusions with respect to serial echocardiographic results are not significantly altered by such a more precise method for grading of MR severity.

Finally, the lack of an untreated control group did not allow us to evaluate the impact of correcting MR on the prognosis. Certainly, further randomized studies with higher numbers of patients and longer follow-up periods are necessary.

Conclusions

Acute hemodynamics and serial echocardiography have demonstrated the beneficial effects of stringent RMA, as evidenced by reverse LV remodeling, improvement of systolic function, and reduction of systolic PAP, which occurred within 1 month after surgery and persisted for up to 5 years. This sustained reverse remodeling is probably responsible for the improved long-term survival, reduced NYHA symptoms, and reduced serum BNP level in our patients with functional MR and advanced cardiomyopathy.

Additional studies are needed to define the mechanism and negative impact of pulmonary hypertension in patients with cardiomyopathy with regard to clinical outcome, and to establish new treatment strategies.

Acknowledgments

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References


Study Limitations

The main limitations of the present study are its retrospective nature and the number of subjects. The present study population, however, consisted only of patients with advanced or end-stage cardiomyopathy, which is the most difficult to treat with RMA. The patients with less LV remodeling and ischemic MR due to predominant inferior/posterior myocardial infarction, who were often included in the previous studies, were excluded from the present study. Second, the inclusion of patients with different etiologies of cardiomyopathy, as well as those with concomitant surgical procedures, may also have influenced the results. In particular, as noted, some patients underwent SVR, which is a specific surgical procedure to reduce the LV volume. However, even if those patients undergoing SVR are completely excluded from the cohort, LV end-diastolic volume significantly decreased from 221±53 ml to 188±51 ml, and LV


Appendix 1

Tested Variables

Age, gender, body surface area, NYHA functional class, ischemic etiology, hypertension, diabetes, hyperlipidemia, chronic obstructive pulmonary disease, chronic renal failure, peripheral vascular disease, cerebral vascular disease, atrial fibrillation, duration of heart failure (months), multivessel coronary artery disease, previous percutaneous coronary intervention, β-blockers, ACE inhibitors, ARB, diuretics, type and size of ring used, coronary artery bypass grafting, tricuspid annuloplasty, maze procedure, LVEDD (continuous), LVESD (>65 mm), LVEF (continuous), LVESD (continuous), LVEDV (>50 ml), LAD, LVEF, tenting height, coaptation length, MR grade, TR grade, systolic PAP (continuous) and pulmonary hypertension (systolic PAP>60 mmHg).