Original Article

Mitral valve repair using a semi-rigid posterior band: a 10-year Japanese single-center experience of 244 patients

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Background: Mitral valve repair (MVr) is an established procedure for patients who require surgery for primary mitral regurgitation (PMR). The Colvin-Galloway Future Band (CGFB) is a semi-rigid posterior band expected to improve the clinical outcomes of MVr. However, information on the hemodynamic and functional performance and long-term outcomes of CGFB is limited. We evaluated the quality, durability, and clinical performance after MVr using CGFB for PMR as the cohort study.

Methods: A total of 244 patients who underwent MVr with CGFB were enrolled. Clinical and echocardiographic assessments were performed (mean follow-up period, 4.0±2.4 years).

Results: Posterior mitral leaflet resection was the most common MVr procedure. CGFBs measuring 28 mm (35.2%) and 30 mm (36.5%) were used. The incidence of systolic anterior motion (SAM) was 1.6%. A total of 93.4% of the patients had no or trace MR at discharge. Over 90% of patients had no or mild MR at the last follow-up. The mean pressure gradient and mitral valve orifice area one year after MVr ranged between 2.6 and 3.6 mmHg and 2.3 and 3.4 cm^2, respectively. At follow-up, 85.4% of the patients were New York Heart Association class I. Three patients underwent repeat mitral valve surgery.

Conclusions: The CGFB demonstrates satisfactory quality and durability in MVr for PMR. Other advantages include a low occurrence of SAM and acceptable hemodynamic outcomes, particularly in patients requiring a smaller annuloplasty device.

Keywords: Mitral valve repair (MVr); primary mitral regurgitation (PMR); semi-rigid partial band; outcome

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Introduction

Mitral valve repair (MVr) is an established procedure for patients requiring surgical intervention for primary mitral regurgitation (PMR) (1-6). Although excellent long-term durability and positive outcomes of various MVr techniques, such as Carpentier's technique and artificial chordal replacement for PMR, have been reported (1-6), valve reconstruction alone might not be sufficient. Mitral annuloplasty is essential in improving the durability of MVr because annular dilatation occurs in most patients with

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PMR (7,8). Annuloplasty devices have been developed to maintain normal mitral annular size, shape, and flexibility. The use of an annuloplasty device is the most common, reproducible, and durable approach (1,7,8). Many devices, such as complete or partial, rigid, semi-rigid, or flexible rings or bands, are available today (9,10).

The Colvin-Galloway Future Band (CGFB) (Medtronic, Inc., Minneapolis, MN, USA) was designed using a semi-rigid material in a partial band. The CGFB remodels the anterior-posterior diameter of the mitral annulus and maintains the physiological motion of the inter-trigonal distance during the cardiac cycle (10). Several European studies have demonstrated satisfactory early results of CGFB in MVr (11-14), and only good long-term results of MVr with CGFB have been reported (15). However, there is no evidence regarding the clinical efficacy and hemodynamic performance of CGFB in Asian populations with smaller body surface area (BSA), which might necessitate the use of smaller-sized CGFBs.

This study reports the late outcomes of MVr using CGFB in a large cohort of Japanese patients evaluating the quality and durability of the repair, hemodynamic status, major adverse events, and functional status through a complete follow-up. We present this article in accordance with the STROBE reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1486/rc).

Highlight box

Key findings

- The Colvin-Galloway Future Band (CGFB) has exhibited satisfactory quality and durability in addressing mitral valve repair (MVr) for primary mitral regurgitation. Additional advantages of CGFB include a reduced incidence of systolic anterior motion (SAM) and favorable hemodynamic outcomes, especially among patients requiring a smaller annuloplasty device.

What is known and what is new?

- Several European studies have demonstrated favorable early and long-term outcomes associated with CGFB employment in MVr. However, there is a lack of evidence regarding the clinical efficacy and hemodynamic performance of CGFB within Asian populations characterized by smaller body surface area, potentially necessitating the use of smaller-sized CGFBs.
- This study illustrates the satisfactory quality and durability of CGFB in MVr, highlighting acceptable hemodynamic outcomes, particularly among Asian populations utilizing smaller-sized CGFBs. In addition, CGFB showed a low incidence in SAM high-risk cases.

What is the implication, and what should change now?

- CGFB not only exhibits satisfactory quality and durability in MVr but also represents a potentially valuable option for enhancing outcomes in MVr among patients necessitating small-sized annuloplasty devices and those at high risk for SAM.

Methods

Patients

A total of 244 patients underwent MVr using CGFB for PMR between October 2012 and December 2021 at the Kurume University Hospital in Kurume, Japan. During this period, a Carpentier-Edwards (CE) Physio II ring (Edwards Lifesciences LLC, Irvine, CA, USA) was implanted in five patients according to surgeon preference; these patients were excluded from the study. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). Informed consent was obtained from all patients to analyze the clinical data for retrospective studies. The institutional ethics committee approved this retrospective study on April 20, 2021 (Kurume University IRB No. 21001).

Operative technique

The operation was performed through a complete median sternotomy in 80% of the patients and a minimally invasive right thoracotomy in 20% of the patients. A minimally invasive approach was applied for patients with simple mitral valve pathology, maintaining left ventricular ejection fraction (LVEF) (>50%), and without concomitant surgery, pulmonary hypertension (>50 mmHg), obesity (body mass index >35 kg/m^2), chest wall deformities, severe peripheral disease, and atherosclerosis in this study period. Cardiopulmonary bypass (CPB) was performed through the superior vena cava, inferior vena cava, and ascending aorta in cases of median sternotomy. CPB was established between the superior vena cava and the right femoral vein and artery in the case of right thoracotomy. Mild-to-moderate hypothermia (28–32 ℃) was maintained in all cases. After aortic cross-clamping, antegrade cold blood or crystalloid cardioplegia was administered every 20 or 30 minutes. In most cases, the mitral valve was exposed using a left atrial approach. Systematic valve analysis was then performed to identify the etiology of valve dysfunction.

MVr was performed using standard reconstruction techniques. Our typical approach was as follows. Segmental resection (quadrangular or triangular) was performed to excess posterior mitral leaflet (PML) prolapse. Polytetrafluoroethylene

(PTFE) chordae were sometimes used to achieve greater coaptation depth. In cases of minimal PML prolapse or tissue, limited triangular resection with or without artificial chordae was performed. In anterior mitral leaflet (AML) prolapse, MVr using PTFE chordae was primarily performed, supplemented by triangular resection in selected cases. The commissure closure is often used in commissural mitral leaflet prolapse and segmental prolapse of AML and/or PML near the commissure. This technique was also used to reinforce MVr as an additional procedure after inspecting the closure line using a saline solution test. Our standard annuloplasty was a true-sized annuloplasty primarily based on the intertrigonal distance with a device sizer and we selected the smaller-sized device if the device size was in the middle. Saline solution testing and intraoperative transesophageal echocardiography (TEE) after weaning from CPB were performed in all patients to ensure the quality of MVr.

Postoperative management

Postoperative intensive care unit management was standardized for all patients. Our standard anticoagulation management after MVr was as follows. Continuous intravenous heparin was administered on the first postoperative day, aiming for an activated partial thromboplastin time of 1.5–2 times the control value. Patients received warfarin sodium after extubation to reach a target prothrombin time of international normalized ratio between 2.0 and 2.5, at which point heparin administration was suspended. Anticoagulation therapy was continued for three months after surgery. Anticoagulation therapy had to be continued permanently if the patients had atrial fibrillation (AF) or flutter. Patients who underwent concomitant coronary artery bypass surgery received antiplatelet agents.

Data collection and patient follow-up

Clinical, laboratory, echocardiographic, and procedural data were obtained retrospectively using hospital records. Follow-up data were obtained through outpatient visits, telephone interviews, and/or questionnaires filled by the patients, their families, or referring cardiologists. Major adverse events were defined according to the previous guideline as the following: valve-related mortality, thromboembolism (i.e., stroke, transient ischemic attack, systemic embolism), major bleeding, endocarditis, reoperation, and congestive heart failure (16). Transthoracic echocardiography (TTE) was performed on all surviving patients before discharge. The presence of MR, mean pressure gradient (MPG) across the mitral valve using continuous wave Doppler, and mitral valve orifice area (MVA) were evaluated by planimetry. TTE follow-up was performed at our institution or by referring cardiologists. The follow-up period was terminated on June 30, 2022. The mean follow-up period was 4.0±2.4 years, with a median of 3.9 [interquartile range (IQR), 1.9–6.1] years, and 97% of patients completed the follow-up. The follow-up rate was 98% at 1 year, 97% at 3 years, 95% at 5 years, and 91% at 8 years. Neither we nor the referring cardiologists were able to contact 3% of patients or their families for a complete follow-up. The most extended follow-up reached 9.5 years. The median TTE follow-up was 3.3 years (IQR, 1.1–5.3 years), and 92% were completed within one year before June 30, 2022. The TEE follow-up rate was 98% at 1 year, 97% at 3 years, 87% at 5 years, and 82% at 8 years.

In addition, We analyzed end-diastolic diameter (EDD), basal septal diameter (BSD), coaptation-septum distance (C-sept), AML length, PML length, and aortomitral angle (AMA) as the anatomical predictors of systolic anterior motion (SAM) using preoperative TEE in 182 patients.

Statistical analysis

Data analysis was performed using JMP Pro 16 software (SAS Institute Inc., Cary, NC, USA). Continuous data are reported as the mean ± standard deviation or median (IQR). Categorical data are expressed as numbers and percentages. The Kaplan-Meier method estimated freedom from time-dependent outcomes and late survival probabilities.

Results

Preoperative patient characteristics and echocardiography

The mean age of the patients was 65.0±12.7 (range, 19–90) years. The mean BSA was 1.58±0.18 m^2. Over 70% of the patients had a history of clinical symptoms, and 102 (41.8%) had pulmonary hypertension. The preoperative patient characteristics are listed in *Table 1*. Two hundred and twenty-two (91%) patients had degenerative mitral disease with isolated PML (56.6%) and AML prolapse (23.3%). The mean LVEF was 65.7%±9.3%, and over 80% of patients showed LVEF >60%. The preoperative echocardiography results are summarized in *Table 2*. Thirty-

Table 1 Preoperative patient characteristics

Variables	Value (N=244)
Age (years)	
Mean age at surgery	65.0±12.7 [19–90]
<45	14 (5.7)
45–60	67 (27.5)
61–75	103 (42.2)
>75	60 (24.6)
BSA (m^2)	1.58±0.18 [1.18–2.11]
Male sex	141 (57.8)
Associated diseases	
Hypertension	143 (58.6)
Diabetes	38 (15.6)
Chronic kidney disease (eGFR <60)	79 (32.4)
Chronic obstructive pulmonary disease	41 (16.8)
Peripheral vascular disease	5 (2.0)
Previous stroke	22 (9.0)
Previous myocardial infarction	2 (0.8)
Previous infective endocarditis	17 (7.0)
Electrocardiogram at admission	
Sinus rhythm	172 (70.5)
Atrial fibrillation or flutter	68 (27.9)
Permanent pacemaker	4 (1.6)
History of clinical symptoms	175 (71.7)
New York Heart Association functional class	
I	68 (27.9)
II	151 (61.9)
III	21 (8.6)
IV	4 (1.6)
Pulmonary hypertension >31 mmHg	102 (41.8)
Previous cardiac surgery	9 (3.7)
Timing of surgery	
Elective	236 (96.7)
Emergent	8 (3.3)

Values are presented as mean ± standard deviation [range] or n (%). BSA, body surface area; eGFR, estimated glomerular filtration rate (mL/min/1.73 m^2).

Table 2 Preoperative echocardiography

Variables	Value (N=244)
Cause of primary MR	
1. Degenerative	
Anterior leaflet prolapse	57 (23.4)
Posterior leaflet prolapse	138 (56.6)
Bileaflet prolapse	17 (7.0)
Commissural leaflet prolapse	10 (4.1)
2. Infective endocarditis	17 (7.0)
Active	8 (3.3)
Healed	9 (3.7)
3. Others	
Rheumatic	2 (0.8)
Congenital	2 (0.8)
Traumatic	1 (0.4)
Left ventricle ejection fraction (%)	65.7±9.3 [25–85]
≥60%	196 (80.3)
40–59%	44 (18.0)
20–39%	4 (1.6)
Left atrium dimension (mm)	44.8±8.7 [24–82]
Left ventricle diameter at end-diastole (mm)	53.5±6.8
Left ventricle diameter at end-systole (mm)	33.7±6.4
Tricuspid valve regurgitation	
None, trace or mild	188 (77.0)
Moderate or severe	56 (23.0)

Values are presented as n (%) or mean ± standard deviation [range]. MR, mitral regurgitation.

two patients with moderate MR and 2 patients with mild MR underwent MVr (*Figure 1*). Surgical indications for these patients were concomitant surgeries in 24 cases, infective endocarditis (IE) in 3 cases, and a history of heart failure in 5 cases. We identified patients with the anatomical risk of SAM; 16 (8.8%) patients with EDD <45 mm, 15 (8.2%) patients with BSD >15 mm, 43 (23.6%) patients with C-sept <25 mm, 83 (45.6%) patients with AML length >25 mm, 78 (42.9%) patients with PML length >15 mm, and 96 (52.7%) patients with AMA <120°.

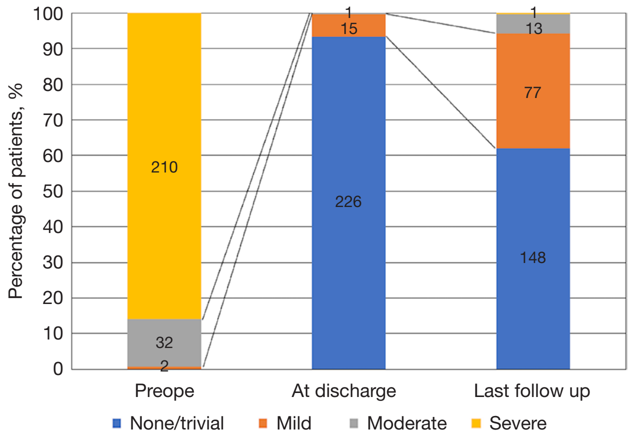


Figure 1 Mitral valve regurgitation preoperatively, predischarge, and at the last follow-up. Preope, preoperative.

Operative details

The most common MVr procedure was segmental PML resection. Only 6 patients underwent the PML height reduction to prevent SAM. Artificial chordal replacement with PTFE, and the commissure closure were frequently performed. The 28 mm (35.2%) and 30 mm (36.5%) sized CGFBs were commonly used. Tricuspid annuloplasty and the maze procedure were performed in 38.1% and 29.9% of patients. SAM was confirmed intraoperatively with TEE in 4 (1.6%) patients. SAM was managed medically using volume loading, reducing inotropes, and initiating β-blockers without any additional repairs in every patient. No recurrence of SAM was observed at discharge and during follow-up. The operative details are presented in *Table 3*.

Table 3 Operative details

Variables	N (%) (N=244)
Mitral valve repair technique	
PML segmental resection	136 (55.7)
AML segmental resection	16 (6.6)
BL segmental resection	7 (2.9)
Chordal replacement with PTFE suture	68 (27.9)
Commissure closure	66 (27.0)
Size of the semi-rigid posterior band	
26 mm	27 (11.1)
28 mm	86 (35.2)
30 mm	89 (36.5)
32 mm	36 (14.8)
34 mm	6 (2.5)
Combined procedures	
CABG	26 (10.7)
Aortic valve surgery	33 (13.5)
TAP	93 (38.1)
Maze procedure	73 (29.9)
Left atrium appendage closure/resection	16 (6.6)
Via right thoracotomy (MICS)	51 (20.1)
Intraoperative SAM	4 (1.6)

PML, posterior mitral leaflet; AML, anterior mitral leaflet; BL, both mitral leaflets; PTFE, polytetrafluoroethylene; CABG, coronary artery bypass grafting; TAP, tricuspid valve annuloplasty; MICS, minimally invasive cardiac surgery; SAM, systolic anterior motion.

Early mortality

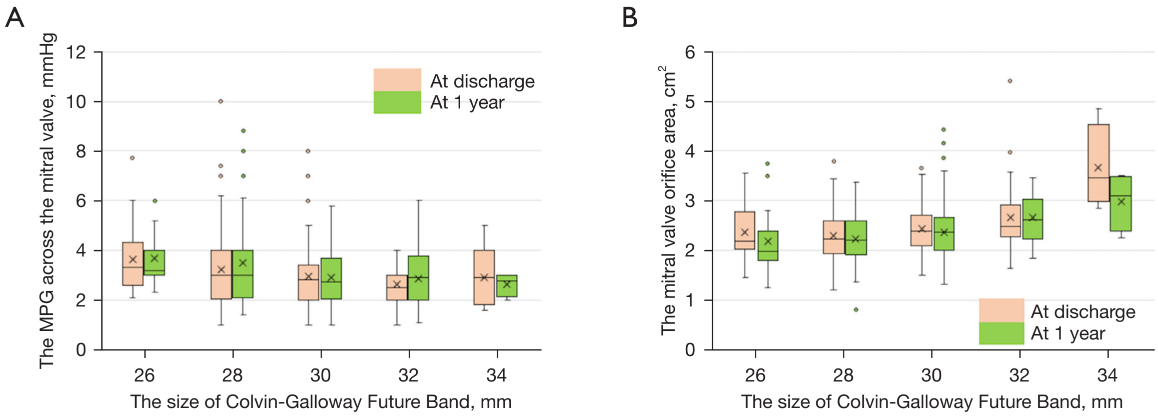
The overall 30-day mortality rate was 0.4% (n=1), and the overall hospital mortality rate was 1.6% (n=4). One patient died of postoperative low cardiac syndrome on the 21st postoperative day. One patient with liver cirrhosis died due to gastrointestinal complications, and another patient undergoing hemodialysis died due to mediastinitis. One patient with active IE and severe emaciation died of sepsis.

Quality of repair

Predischarge TTE was performed in 242 patients (99.2%). Two hundred twenty-six patients (93.4%) had no or trace MR, and 15 patients (6.2%) had mild MR. Only one patient showed moderate MR at discharge (*Figure 1*).

Hemodynamic status

The MPG and MVA at discharge and one year after surgery are shown in *Figure 2*. The MPG were 3.6±1.3 mmHg in 26 mm, 3.4±1.9 mmHg in 28 mm, 2.9±1.3 mmHg in 30 mm, 2.6±0.9 mmHg in 32 mm, and 2.9±1.3 mmHg in 34 mm sized CGFB at discharge. The MVA was 2.4±0.6 cm^2 in 26 mm, 2.3±0.5 cm^2 in 28 mm, 2.4±0.5 cm^2 in 30 mm, 2.7±0.7 cm^2 in 32 mm, and 3.7±0.8 cm^2 in 34 mm sized CGFB at discharge. The MPG and MVA had no significant differences at discharge and one year after



	26 mm	28 mm	30 mm	32 mm	34 mm
Discharge (n=242)	3.6±1.3	3.4±1.9	2.9±1.3	2.6±0.9	2.9±1.3
At 1 year (n=186)	3.7±1.0	3.5±2.2	3.2±2.4	2.9±1.2	2.6±0.5

	26 mm	28 mm	30 mm	32 mm	34 mm
Discharge (n=242)	2.4±0.6	2.3±0.5	2.4±0.5	2.7±0.7	3.7±0.8
At 1 year (n=186)	2.2±0.6	2.2±0.5	2.4±0.6	2.7±0.5	3.0±0.6

Figure 2 Postoperative hemodynamic performance of the mitral valve. MPG, mean pressure gradient.

surgery in all sizes of CGFBs (*Figure 2*). Patients with rest MPG >4.5 mmHg one year after surgery exhibited varying prosthesis sizes: 4 patients received a 26 mm prosthesis, 14 patients received a 28 mm prosthesis, 7 patients received a 30 mm prosthesis, and 3 patients received a 32 mm prosthesis.

Late mortality

The freedom from all-cause mortality at 1, 3, 5, 7, and 9 years was 97%, 94%, 91%, 86%, and 82%, respectively (*Figure 3A*). Seventeen patients died during the follow-up period for the following reasons (malignancy in seven, senility in two, stroke in three, subdural hematoma in one, sepsis in one, trauma in one, sudden death in one, and unknown in one). Cardiac- or valve-related death occurred in five of 240 patients.

Major adverse cardiocerebral events (MACCE)

Eight patients had cerebral infarction, five experienced intracranial hemorrhage, and seven had congestive heart failure [hypertensive heart disease in five elderly patients and two due to recurrent MR (reMR)]. Eighty percent of patients with intracranial hemorrhage and 50% of patients with cerebral infarction received anticoagulation therapy for AF. Eight patients underwent MVr with CGFB for active IE with no recurrence observed during the follow-up period. Freedom from MACCE at one, three, five, seven, and nine years was 97%, 92%, 88%, 86%, and 61%, respectively (*Figure 3B*).

reMR

One hundred forty-eight patients (60.6%) had no or trace MR, and 77 patients (31.6%) had mild MR at the last follow-up. One patient developed severe MR, and 13 developed moderate MR during follow-up. Moderate MR in five patients (AML prolapse in 3, PML prolapse in 1, commissural prolapse in 1) was reported within one year after surgery. One patient with severe reMR suffered from congestive heart failure; however, she rejected reoperation. One patient with moderate MR and hemolysis underwent reoperation. The other patients were treated with appropriate medications. Freedom from moderate MR at 1, 3, 5, 7, and 9 years was 98%, 94%, 93%, 90%, and 90%, respectively (*Figure 3C*).

Reoperation on the MV

Three patients underwent a re-MV surgery. The indication was reMR in one, IE in one, moderate mitral stenosis due

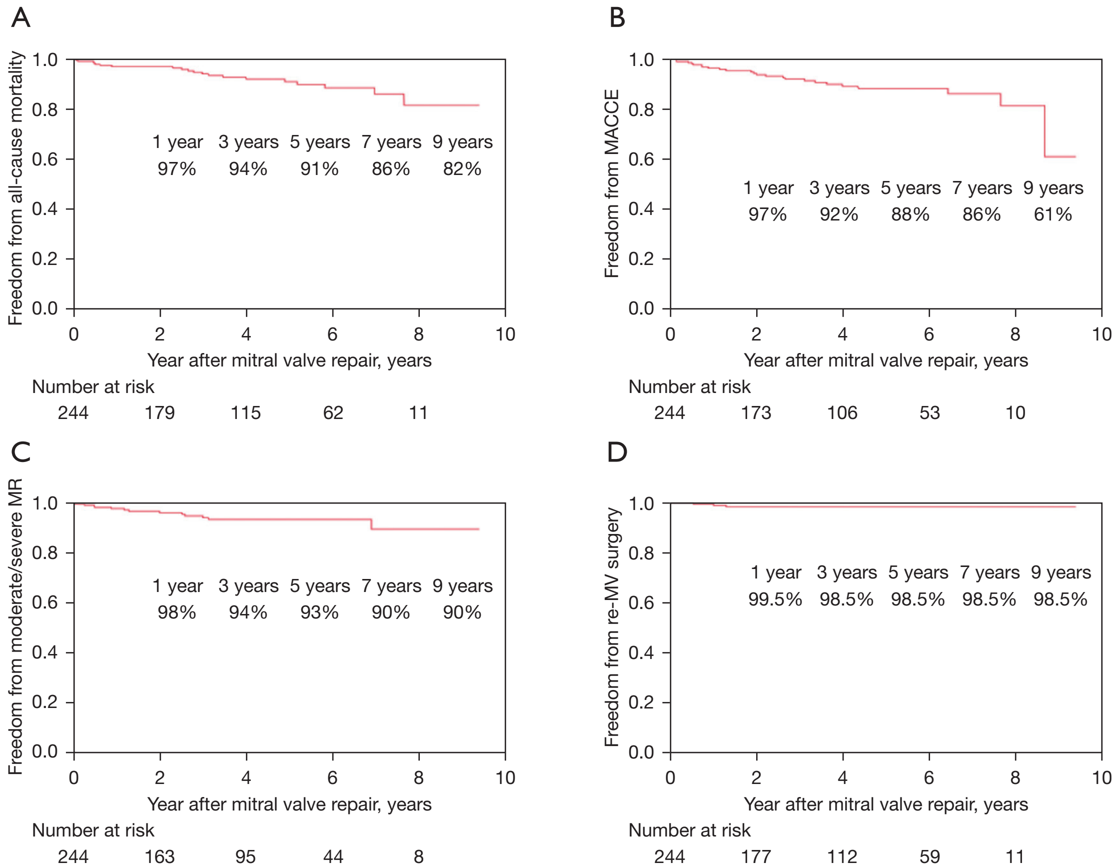


Figure 3 Long-term outcomes after mitral valve repair using Colvin-Galloway Future Band for PMR. (A) Freedom from all-cause mortality. (B) Freedom from MACCE. (C) Freedom from moderate or severe MR. (D) Freedom from re-MV surgery. MACCE, major adverse cardiac and cerebrovascular events; MR, mitral regurgitation; MV, mitral valve; PMR, primary mitral regurgitation.

to AML sclerosis with symptomatic severe aortic stenosis in one. CGFB dehiscence and fractures were not observed. Freedom from reoperation is shown in *Figure 3D*.

Functional status

The preoperative functional status of the patients was New York Heart Association (NYHA) class I (27.8%), class II (61.8%), class III (8.6%), and class IV (1.6%). At follow-up, 85.4%, 12.9%, and 1.7% of patients were class I, II, and III, respectively. Among the four patients with NYHA class III, one had severe MR, and two had moderate MR.

Discussion

This study has shown that CGFB exhibits satisfactory quality and durability following MVr in Japanese patients. The study also observed a low occurrence of SAM and noted acceptable hemodynamic and functional statuses after MVr using CGFB.

Quality and durability of MVr

In patients with mild residual MR in the operating theater, the relative risk for recurrence in the first year and after the first year was 3.9 and 4.0 times, respectively, compared to those without mild residual MR (17). The reMR significantly impacts adverse left ventricular remodeling and overall survival after MVr (17). Hence, the implementation of precise repair techniques and the use of annuloplasty devices play a pivotal role in maintaining the efficacy and endurance of MVr. While prior studies have indicated comparable outcomes between leaflet resection and chordal replacement (3-5), our preference veers toward segmental resection due to its reproducibility and simplified approach, especially in cases of PML prolapse.

A pertinent concern revolves around whether a semi-rigid partial band provides analogous quality and durability for MVr when compared to a complete ring. Castillo *et al.* reported no MR in 94.5% and mild MR in 5.5% of 744 patients at predischarge; 98% of patients were using a CE Physio I or II ring (3). Noack *et al.* have shown that 80% of no MR, 18% of mild MR at discharge, and the rate of not requiring re-MV operation at one and four years were 96.2% and 94.0%, respectively, after MVr with a CE Physio II in 486 patients (18). David *et al.* found only three patients (0.3%) with moderate MR among 840 patients who underwent MVr using various annuloplasty devices (4). Large reference centers have also revealed remarkable long-term outcomes for MVr (3-6). The probabilities of moderate to severe MR at 1, 5, 10, 15, and 20 years were 3.3%, 4.4%, 6.3%, 8.9%, and 12.5%, respectively (6). The incidence of reoperation at 1, 5, and 10 years was reported as 0.9%, 2.7%, and 4.1% (4). In this study, 99.6% of the patients showed no or mild MR at discharge. The freedom rates of reMR and re-MV surgery at 1, 5, and 9 years were 98%, 93%, 90%, and 99.5%, 98.5%, and 98.5%, respectively. These results clarified that the quality and durability of MVr using CGFB were acceptable compared to those of other similar studies. Cetinkaya *et al.* also reported comparable outcomes, such as reMR and LVEF after MVr between a flexible partial band and CE Physio I or II (19). The type of annuloplasty had no impact on reMR and re-MV surgery over 14 years in 482 patients who underwent MVr using the same procedure with a partial band or complete ring for PML prolapse (20). Although AML prolapse is considered a major risk factor for reMR and re-MV surgery after MVr (6,17), the incidence of reMR was not significantly different between AML and PML prolapse in this study (P=0.102).

Incidence of SAM

Intraoperative or postoperative SAM occurs in approximately 10% of cases after MVr (21,22). Thirteen percent of intraoperative residual MR is caused by SAM (23); in addition, about 8–50% of patients with SAM require reoperation (22). Varghese *et al.* described EDD <45 mm, BSD >15 mm, C-sept <25 mm, AML length >25 mm, PML length >15 mm, and AMA <120° were independent predictors of SAM (21). Loulmet *et al.* revealed that LVEF >60%, hypertrophic obstructive cardiomyopathy, and flail PML pathology were risk factors for the incidence of SAM, and using a semi-rigid partial band could decrease SAM by 38% than a complete rigid ring (22). Most of the patients in this study had one of the anatomical risk factors of SAM. We underwent additional surgical techniques to prevent SAM on only 6 patients, however, this study showed a very low incidence of SAM (n=4, 1.6%) in 80% of the patients with LVEF >60%. These results suggest that CGFB helps prevent postoperative SAM by maintaining the physiological motion of the anterior mitral annulus and avoiding the narrowing of the AMA and changes in left ventricular flow patterns (22). In the four cases with intraoperative SAM, all patients had some anatomical risk factors preoperatively as follows; four patients had maintained LVEF >65%, half of the patients showed EDD <45 mm, two patients who underwent quadrangular PML resection had excess PML tissue >15 mm, and three-quarters patients showed narrow AMA <120°. We believe that the prevention of SAM by additional surgical procedures was difficult in these patients. Thus, careful perioperative management is always needed to avoid SAM for these patients with anatomical risk factors.

Hemodynamic and functional performance

Postoperative hemodynamic performance is essential for preventing MACCE and maintaining functional performance (6,24-26). The MPG >4.5 mmHg was associated with late AF, leading to postoperative thromboembolic events (6,24). Moreover, functional mitral stenosis (FMS) due to elevated MPG after MVr is related to a higher B-type natriuretic peptide level, lower exercise capacity, and poorer quality of life (25). Hence, exploring potential disparities in postoperative hemodynamics between partial bands and full rings is an intriguing focal point, alongside evaluating the quality and durability of MVr and the incidence of SAM.

Previous studies have suggested that a partial band could decrease MPG after MVr because of dynamic mitral annular motion (6,25). An *in-vivo* echocardiography study has also demonstrated that the semi-rigid partial band had a larger MVA (6.14±0.37 *vs.* 4.12±0.15 cm^2 at end-diastole) and a lower MPG (4.0±0.3 *vs.* 5.0±0.3 mmHg) than the rigid complete ring (27). Conversely, a recent study has indicated that the type of annuloplasty device employed has no discernible impact on postoperative MPG and MVA (28). However, this finding is attributed to the predominant usage of larger rings (>32 mm) in over 80%

of cases involving patients with a mean BSA ranging from 1.83 to 1.90 m^2, which markedly differs from the patient demographics in this study.

Numerous studies have highlighted the suboptimal hemodynamic performance associated with smaller full rings. Tomšič *et al.* have demonstrated that the MPG after MVr using full-ring <28 mm was over 5 mmHg and the elevated postoperative MPG has a possible risk of mitral re-intervention (26). Previous study on *in vitro* echocardiographic characteristics after MVr employing full rings indicated that while resting MPG post-MVr is linked to the size of implanted full rings, median MPG with full rings under 28 mm was >5 mmHg, with a smaller full ring size under 28 mm being the primary contributor to elevated postoperative MPG (26). Hiraoka *et al.* delineated that the MPG and MVA achieved with a partial band were superior to those attained with a full ring in patients with smaller annuloplasty devices <30 mm (29). Their report indicated an MPG of 4.0 mmHg (ranging from 2.8 to 5.0 mmHg) and an MVA of 1.44 cm^2 (ranging from 1.23 to 1.79 cm^2) in patients with smaller full rings <30 mm. Another study also affirmed that the MPG and right ventricular systolic pressure, both at rest and during peak exercise, were more unfavorable with a complete ring in comparison to a partial band (30). In their investigation, resting MPG exceeded >5 mmHg in all patients with full rings <30 mm.

In this study, we used 30 mm or smaller-sized CGFB in 80% of patients, with a mean BSA of 1.58 m^2, and the mean of MPG and MVA even in 26 and 28 mm sized CGFB were 3.6±1.3 and 3.4±1.9 mmHg, and 2.4±0.6 and 2.3±0.5 cm^2, respectively, with a satisfactory postoperative NYHA functional status. These results clarified that acceptable hemodynamic performance is an important advantage of CGFB, especially in patients requiring a small annuloplasty device.

Yamazaki *et al.* assessed the hemodynamic performance and exercise capacity in 48 patients who underwent MVr using CGFB (31). They have described that the rest MPG was 2.8±1.1 mmHg in all patients, but only one-third of patients could achieve age and sex expected metabolic equivalents (eMETS), and more than half of patients had FMS during their exercise intensity to eMETS. In addition, an indexed device size (device size/BSA) >19.5 mm/m^2 was needed to obtain 100% eMETS exercise tolerance even in patients with CGFB. In this study, the mean indexed device size was 18.7±1.9 mm/m^2 which is a little bit small to obtain 100% eMETS, because we selected the smaller-sized device if the device size was in the middle. Although the most of patients showed satisfactory hemodynamics at rest, 28 patients (11.4%) showed the rest MPG >4.5 mmHg one year after MVr in this study. However functional status was declared as class I in 26 and class II in two patients. Yamazaki *et al.* also confirmed similar results (31). All of the patients who could not achieve eMETS declared their functional status was NYHA I and II in their study. They considered that most of these patients didn't need 100% exercise intensity in reality; thus they didn't feel inconvenienced in their daily life. This is the possible explanation for why the elevated MPG at one year has not affected the postoperative functional status in this study.

Major adverse events

Cerebrovascular accidents were the primary cause of MACCE after MVr in this cohort. Congestive heart failure, with or without reMR, was the second most common cause. Similar MACCE were reported in another large cohort study (6). Impaired LVEF and new-onset AF were associated with MACCE, and successful MVr could not guarantee freedom from cardiac and valve-related events (6). Therefore, appropriate medication and follow-up are needed, especially in patients with impaired LVEF, advanced age, advanced preoperative NYHA, and developing tricuspid regurgitation (6).

This study had some limitations. Firstly, this single-center retrospective study did not compare the partial band and complete ring using exercise stress tests. Therefore, the superiority of CGFB during functional performance can only be speculated based on previous studies. Additionally, the limitations include the number of patients involved and the specific etiology of mitral valve issues. Approximately 50% of the mitral valve lesions comprised degeneration of the PML, representing a subgroup with a lower risk for reMR. Second, echocardiography was not performed according to a scheduled protocol. In addition, not all patients have been followed up. Thus, this may have led to an underestimation of the freedom rate of reMR and MACCE. Third, it was not possible to verify the anatomical risks of SAM of all patients using preoperative TEE. Further study is needed to determine whether CGFB is truly beneficial to prevent SAM in patients with anatomical risks of SAM. Fourth, anticoagulation management and the incidence of late AF at follow-up could not be verified because part of the follow-up data was obtained by telephone interviews and/or questionnaires answered by families, especially for patients who had died.

Conclusions

In conclusion, CGFB exhibits satisfactory quality and durability of MVr for PMR. Acceptable hemodynamic stability with good functional status during long-term follow-up and a very low incidence of SAM are other advantages of CGFB. However, major adverse events often occur during long-term follow-up, regardless of successful MVr. Appropriate postoperative medication should be administered to improve patient outcomes.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The Institutional Ethical Committee approved this retrospective study on April 20, 2021 (Kurume University IRB No. 21001). Informed consent was obtained from all patients preoperatively to analyze their clinical data for retrospective studies.

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