Paravalvular Leak After Mitral Valve Replacement: 20-Year Follow-Up

Ho Young Hwang, MD, PhD, Jae-Woong Choi, MD, Hyung-Kwan Kim, MD, PhD, Kyung-Hwan Kim, MD, PhD, Ki-Bong Kim, MD, PhD, and Hyuk Ahn, MD, PhD

Department of Thoracic and Cardiovascular Surgery, and Division of Cardiology, Department of Internal Medicine, Seoul National University Hospital, Seoul, Korea

Background. We evaluated the incidence of paravalvular leak (PVL) after mitral valve replacement (MVR) and analyzed factors associated with early and late PVL during more than 20 years of follow-up.

Methods. We studied 1,202 patients (50.4 ± 12.2 years; male/female, 456:746) who underwent MVR between 1992 and 2008. Follow-up duration was 134 months (range, 1 to 272 months). Incidence of early and late PVL was evaluated. The PVL was regarded as major if it caused hemolysis requiring multiple transfusions or regurgitant jet inducing heart failure symptoms.

Results. In-hospital mortality rate was 4.5%. Early mitral PVL was found in 23 patients (1.9%), including 7 patients with major PVL. Late mitral PVL without obvious infection occurred in 75 patients (major PVL in 55 patients). Median interval between the index operation and major PVL was 136 months (range, 6 to 250 months). Among 55 patients with major PVL, 50 patients underwent reoperations and 5 patients were treated medically. Ten- and 20-year late mitral PVL-free rates were 96.2% and 86.9%, respectively. Ten- and 20-year major mitral PVL-free rates were 98.0% and 89.3%, respectively. Cox proportional hazard analysis revealed that age (hazard ratio, 1.052; 95% confidence interval, 1.024 to 1.079), male sex (hazard ratio, 2.804; 95% confidence interval, 1.629 to 4.828), and redo MVR (hazard ratio, 5.193; 95% confidence interval, 2.930 to 9.112) were associated with major mitral PVL during the follow-up.

Conclusions. Major PVL without obvious infection occurs even 20 years after MVR with 10- and 20-year major PVL-free rates of 96.2% and 86.9%, respectively. Occurrence of major PVL after MVR is more frequent in elderly, male patients and those who undergo redo MVR.

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Paravalvular leak (PVL), which is characterized by eccentric jets originating from outside of the sewing ring, is a nonstructural valve dysfunction that occurs early and late after prosthetic valve replacement. The reported incidence of PVL after mitral valve replacement (MVR) ranges from 5% to 32% [1–4]. The PVL can result from technical failure, which can be identified intraoperatively or by early postoperative echocardiography. It also occurs late after MVR, even several years to a decade after surgery, without any evidence of overt endocarditis [5]. The aims of this study were (1) to evaluate the incidence of early and late PVL, and (2) to analyze factors associated with PVL after MVR during more than 20 years of follow-up.

Material and Methods

Study Population

The study protocol was reviewed by the institutional review board and approved as a minimal risk retrospective study (approval number H-1405-054-597) that did not require individual consent based on the institutional guidelines for waiving consent. From January 1992 to December 2008, 1,226 patients underwent MVR at our institution. Twenty patients who underwent index MVR because of PVL after previous operations and 4 patients who had no medical records were excluded. Finally, 1,202 patients (50.4 ± 12.2 years; male:female, 456:746) were enrolled in the present study (Table 1).

Surgical Procedures

All operations were performed under aortobicaval cannulation, moderate systemic hypothermia, and cold cardioplegic arrest through median sternotomy. Mitral valve replacement was performed using the everted mattress sutures buttress reinforced with polytetrafluoroethylene as a pledget or a tubule. Use of simple interrupted sutures or continuous suture technique was avoided. Three types of mechanical valves (n = 1,024: Carbomedics; Sulzer Carbomedics Inc, Austin, TX, in 444 patients; On-X valve; On-X Life Technology Inc, Austin, TX, in 392 patients; and St. Jude valve; St. Jude Medical Inc, Minneapolis, MN, in 188 patients) and two types of bioprostheses (n = 165: Carpentier-Edwards Perimount; Edwards Lifesciences LLC, Irvine, CA, in 126 patients; and Hancock II; Medtronic Inc, Minneapolis, MN, in 39 patients) were used in most patients (1,189 of 1,202). Six hundred eighty-four

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Address correspondence to Dr Ahn, Department of Thoracic and Cardiovascular Surgery, Seoul National University Hospital, 101 Daehak-ro, Jongno-gu, Seoul 110-744, Korea; e-mail: ahnhyuk@snu.ac.kr.

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Table 1. Preoperative Characteristics of the Study Patients

Variable	n = 1,202
Age (y)	50.4 ± 12.2
Male:female	456:746
Body surface area (m^2)	1.57 ± 0.16
Body mass index (kg/m^2)	21.6 ± 3.1
Risk factors, n (%)	
Smoking	136 (11.3)
Hypertension	93 (7.7)
Diabetes mellitus	74 (6.2)
History of stroke	138 (11.5)
NYHA class ≥3	566 (47.0)
Atrial fibrillation	885 (73.6)
LV dysfunction (EF <0.50)	291 (24.2)
Infective endocarditis, n (%)	88 (6.7)
Etiology of mitral valve disease, n (%)	
Rheumatic	1,054 (87.7)
Degenerative	87 (7.2)
Other	61 (5.1)
Mitral annular calcification, n (%)	315 (26.2)
History of MVR	330 (27.5)
History of AVR	74 (6.2)
History of TVR	8 (0.7)

AVR = aortic valve replacement; EF = ejection fraction; LV = left ventricle; MVR = mitral valve replacement; NYHA = New York Heart Association; TVR = tricuspid valve replacement.

patients underwent concomitant procedures including aortic valve surgery (n = 420), tricuspid valve operation (n = 335), and arrhythmia surgery (n = 410; Table 2). Mean cardiopulmonary bypass and aortic cross-clamp times were 178 ± 73 min and 117 ± 49 min, respectively. Patients underwent first time (n = 872), redo (n = 322), or second redo MVR (n = 8).

Evaluation of Mitral Paravalvular Leak

Comprehensive echocardiographic evaluation was performed by experienced echocardiographers. Great care was taken to assess the competence of prosthetic valves,

Table 2. Operative Data of the Study Patients

Variable	n = 1,202
CPB time (min)	178 ± 73
ACC time (min)	117 ± 49
Type of mitral valve replacement, n (%)	
Mechanical valve	1,035 (84.1)
Bioprosthesis	167 (15.9)
Concomitant procedures, n (%)	684 (56.9)
Aortic valve surgery	420 (34.9)
Tricuspid valve surgery	335 (27.9)
Arrhythmia surgery	410 (34.1)
Coronary artery bypass grafting	38 (3.2)
Aorta replacement	17 (1.4)

ACC = aortic cross clamp; CPB = cardiopulmonary bypass.

Table 3. Early Clinical Results

Variable	n = 1,202
Mortality, n (%)	54 (4.5)
Complications, n (%)	
Low cardiac output syndrome	152 (12.6)
Respiratory complication	86 (7.2)
Bleeding reoperation	61 (5.1)
Acute renal failure	40 (3.3)
Stroke	35 (2.9)
Mediastinitis	16 (1.3)

especially using color Doppler echocardiography. The normal bileaflet prosthetic valve shows a characteristic regurgitant flow pattern along the closure line of the discs. These regurgitant jets usually arise peripherally and converge with an inverted V shape, or originate from the center of the valve and diverge with a V pattern [6]. A flow within the orifice of the bioprosthesis was considered transvalvular or physiologic regurgitation. Deviations from the patterns described above (ie, large, asymmetric, or eccentric jets originating from outside of the sewing ring) were considered PVL. To delineate regurgitation flow in the left atrium, three apical, parasternal, off-axis, and subcostal views were carefully evaluated with the help of color Doppler imaging.

Early mitral PVL was defined as PVL detected by intraoperative or early postoperative echocardiograms. Late mitral PVL was defined as PVL newly diagnosed at the follow-up echocardiography after confirming the absence of PVL on early postoperative echocardiograms. Late PVLs associated with prosthetic valve endocarditis were demonstrated but treated as censored in the subsequent analyses. Mitral PVL was regarded as major if it

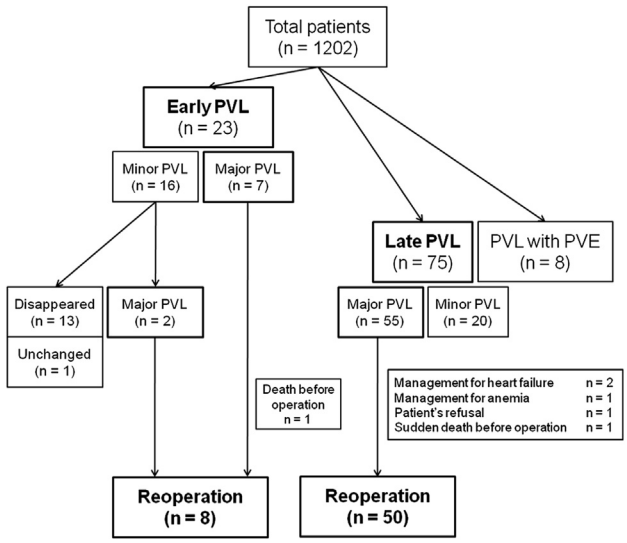

Fig 1. Flow diagram showing occurrence of early and late paravalvular leak (PVL) and subsequent reoperations after mitral valve replacement. (PVE = prosthetic valve endocarditis.)