

## Surgical treatment of paravalvular leak: Long-term results in a single-center experience (up to 14 years)

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**Objectives:** The aim of this study is to report the long-term outcomes (median follow-up time, 7 years; range, 1 month to 14 years) of patients who underwent surgery for paravalvular leak in our single-center experience.

**Methods:** From October 2000 to November 2007, 122 consecutive patients underwent surgery for symptomatic paravalvular leak (40 patients with aortic paravalvular leak; 82 with mitral paravalvular leak). In 7 patients (5.7%, all mitral), surgery was performed on the beating heart through a right thoracotomy. In 35% of patients, multiple paravalvular leaks were present.

**Results:** The mean age of patients was  $62 \pm 11$  years, and European System for Cardiac Operative Risk Evaluation II was  $7.2\% \pm 6\%$ . Most of the patients were in New York Heart Association functional class III or IV (60%). Symptomatic hemolysis was present in 31% of the patients, and 41% of the patients had more than 1 previous cardiac operation. Paravalvular leak repair was feasible in 79 patients (65%), whereas in 43 patients (35%) prosthesis re-replacement was required. Thirty-day mortality was 10.7% (13/122 patients; 5% for aortic paravalvular leak and 13% for mitral paravalvular leak;  $P = .1$ ); 2 patients (1.6%) with residual severe mitral paravalvular leak underwent successful redo surgery before discharge. Median length of stay was 7 days. Overall actuarial survival was  $39\% \pm 6\%$  at 12 years; freedom from cardiac death was  $54\% \pm 7\%$  at 12 years. Only 1 patient underwent redo surgery during follow-up. Multivariable analysis identified preoperative chronic renal failure (hazard ratio, 2.6; 95% confidence interval, 1.4-4.9;  $P = .03$ ) and more than 1 previous cardiac reoperation (hazard ratio, 2.3; 95% confidence interval, 1.3-4;  $P = .03$ ) as independent predictors of death at follow-up.

**Conclusions:** The operative mortality of surgical treatment of paravalvular leak is still high. Long-term outcomes remain suboptimal in these challenging patients, especially in the presence of multiple previous cardiac operations and associated co-pathologies. These results support the importance of alternative therapeutic options. (J Thorac Cardiovasc Surg 2015;149:1270-5)

See related commentary pages 1276-7.

Paravalvular leak (PVL) is a common complication after surgical valve replacement, with reported incidences at follow-up of 2% to 17% in both mitral and aortic positions.<sup>1-3</sup> Among patients in whom PVL develops after surgery, approximately 3% require reoperations because of heart failure, hemolysis, or a combination of both.<sup>4-6</sup> In symptomatic patients, surgical treatment is associated with improved event-free survival compared with conservative management.<sup>3</sup> The standard therapy for these defects is

surgical closure of PVL or valve re-replacement. However, redo surgery in this context is often associated with high morbidity and mortality rates, as well as a high risk of leak recurrence.<sup>1,7</sup> Limited data exist on the long-term outcomes of surgical treatment of PVLs.

We recently reported the acute results of surgical treatment of PVLs compared with transapical transcatheter closure.<sup>8</sup> The aim of this study is to report the long-term results (up to 14 years) of the surgical treatment of PVLs in our single-center experience.

### MATERIALS AND METHODS

We retrospectively analyzed the clinical and echocardiographic data of a cohort of consecutive patients who underwent surgery for symptomatic PVL, without associated procedures, between October 2000 and November 2007. Clinical, echocardiographic, operative, and outcome data were collected prospectively. All patients underwent preoperative coronary angiography and transesophageal Doppler echocardiography. Periprosthetic PVL was defined as a regurgitant jet, demonstrated by transesophageal echocardiography, originating between the outer margin of the prosthetic sewing ring and the native tissues around the valve. The severity of the PVL was defined as mild (1+/4+), moderate (2+/4+), moderate to severe (3+/4+), and severe (4+/4+) using an integrative approach, as recommended by the current guidelines.<sup>9</sup> All patients included in the study had preoperative moderate-to-severe or severe PVL.

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**Abbreviations and Acronyms**

NYHA = New York Heart Association  
 PVL = paravalvular leak

Patients were considered for surgery if 1 or more of the following criteria were met: severe symptoms of heart failure (New York Heart Association [NYHA] class III-IV or class II with significant lifestyle impairment), clinically significant hemolytic anemia, and moderately severe or severe paravalvular prosthetic regurgitation. Symptomatic hemolysis was defined as hemolytic anemia (hemoglobin  $\leq 10$  g/dL, lactate dehydrogenase  $\geq 600$  mg/dL, haptoglobin  $\leq 10$  mg/dL) requiring more than 2 units of blood transfusions or erythropoietin injections within 90 days to maintain hemoglobin 10 g/dL or greater, without any other source of blood loss.<sup>10</sup> Patients with associated prosthetic dysfunction and patients with active acute endocarditis were excluded from this study. Figure 1 shows the patient flow and final study population.

The study protocol was performed in accordance with the institutional ethics committee, and all patients gave informed written consent for the procedures. The need for consent to participate in this research study was waived in view of its observational, retrospective, and anonymous nature.

**Patient Characteristics**

A total of 122 patients were treated; 82 patients had mitral PLV (67.2%) and 40 patients (32.8%) had aortic PVL. In 35 patients (28.7%), multiple PVLs were present.

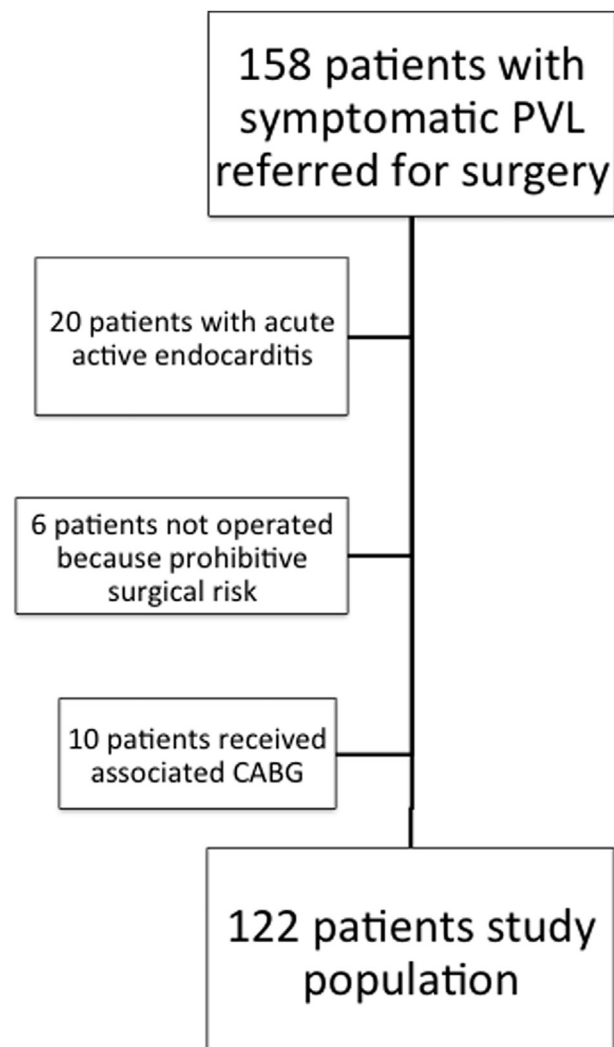
The mean age of the overall study population was  $62 \pm 11$  years. Predicted surgical risk with European System for Cardiac Operative Risk Evaluation II was  $7.2\% \pm 6\%$ . Most of the patients were in NYHA functional class III or IV (overall 60%; 66% with mitral PVL and 45% with aortic PVL;  $P = .02$ ). Patients with mitral PVL have a higher prevalence of atrial fibrillation ( $P = .001$ ). Symptomatic hemolysis was present in 37 patients (30.3%) and was particularly frequent in patients with mitral PVL (41% vs 13%;  $P = .0009$ ). Many patients had more than 1 previous cardiac operation (40.9% overall; 50% for mitral PVL and 22% for aortic PVL;  $P = .003$ ). Demographic and clinical features of the patients are detailed in Table 1.

**Surgical Treatment**

The majority of the patients underwent surgery through a midline sternotomy and moderate hypothermic cardiopulmonary bypass. A minority of the patients with isolated mitral PVL underwent mitral surgery on the beating heart via a right thoracotomy (7 patients). In case of mitral PVL, the mitral prosthesis was approached through a conventional left atriotomy in all patients; in case of aortic PVL, the aortic prosthesis was approached through a transversal aortotomy. After the inspection of the prosthesis and the identification of the PVL, repair was performed with interrupted Ticron 2-0 sutures with pledgets. If repair was judged unfeasible by the surgeon, replacement of the prosthesis was performed. The use of interrupted over running suture for valve replacement depended on the surgeon's preference.

**Statistical Analysis**

Statistical analysis was conducted using SPSS 22.0 software (IBM SPSS Statistics for Macintosh, Version 22.0. IBM Corp, Armonk, NY). Continuous variables are presented as mean  $\pm$  standard deviation, and categorical variables are expressed as percentages. Univariable comparisons have been performed with the Student unpaired *t* test for continuous normally distributed data, which have been tested by the Shapiro-Wilk normality test; the Mann-Whitney rank-sum test was used for comparisons of non-normally distributed data, and the chi-square test was used for categorical data. Long-term survival was presented using the Kaplan-Meier



**FIGURE 1.** Diagram showing patient flow and final study populations. CABG, Coronary artery bypass grafting; PVL, paravalvular leak.

method; comparisons were performed with the log-rank test. Multivariable Cox proportional-hazards regression modeling was performed to determine the independent predictors of mortality at follow-up using purposeful selection of covariates. Variables associated at univariate analysis with death at follow-up (all with a  $P < .1$ ) and those judged to be of clinical importance from previous published literature were eligible for inclusion in the multivariable model-building process.

**RESULTS****Procedural and In-Hospital Outcomes**

Acute procedural success was 98% (120/122 patients; 2 patients had residual severe mitral PVL and required redo-surgery before discharge). PVL repair was feasible in 79 patients (65%), and prosthesis re-replacement was required in 43 patients (35%).

Thirty-day mortality was 10.7% (13/122 patients; 7 patients died of acute cardiogenic shock, 4 patients died of multiorgan failure secondary to sepsis, 1 patient died of

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