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STRUCTURAL

Techniques and Outcomes of Percutaneous Aortic Paravalvular Leak Closure

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ABSTRACT

OBJECTIVES The aim of this study is to provide a summary of the currently applied aortic paravalvular leak (PVL) closure techniques and describe the procedural and long-term outcomes in a large consecutive cohort of patients.

BACKGROUND Percutaneous repair has emerged as an effective therapy for patients with PVL. To date, clinical outcome data on percutaneous closure of aortic PVL are limited.

METHODS All patients who underwent catheter-based treatment of aortic PVL between 2006 and 2015 were identified. Procedural and short-term results were assessed. Patients were contacted for clinical events and symptoms.

RESULTS Eighty-six procedures were performed in 80 patients. The mean age was 68 ± 15 years, and 70% were men. The primary indications for PVL closure were symptoms of heart failure, hemolysis, and both in 83%, 5%, and 12%, respectively. Successful device deployment was accomplished in 94 defects (90%). Reduction in PVL to mild or less was achieved in 62% of patients. In-hospital major adverse events occurred in 8% of procedures. Symptomatic improvement at 30 days was achieved in 64% of patients. Patients who had reduction in the PVL grade to mild or less experienced more improvement in New York Heart Association functional class (from 2.93 ± 0.62 to 1.72 ± 0.73) compared with those with mild or greater residual leak (from 3.03 ± 0.57 to 2.52 ± 0.74) ($p < 0.001$). In patients with severe hemolysis ($n = 8$), transfusion requirements were eliminated in 7 (88%) after PVL closure. Kaplan-Meier survival analysis showed that the cumulative probability of freedom from repeat surgery at 2 years was 98 ± 2% in patients who had mild or less residual leak compared with 68 ± 10% in patients with higher grades of residual PVL (log-rank $p = 0.004$).

CONCLUSIONS Percutaneous reduction of aortic PVL is associated with durable symptom relief and lower rates of repeat cardiac surgery. The magnitude of benefit is greatest with PVL reduction to a grade of mild or less. Therefore, attempts should be made to reduce PVL as much as possible. (J Am Coll Cardiol Intv 2016;9:2416–26)

Paravalvular leak (PVL) occurs in 5% to 17% of patients after valve replacement surgery (1–4). For symptomatic patients, repeat surgery has been the traditional treatment of choice, but it is associated with high operative mortality and variable results even in the modern era (1,4–7). Percutaneous repair has emerged as an effective therapy for patients with PVL, with feasibility and efficacy demonstrated in multiple studies (8–12). Although the principles of transcatheter closure of mitral and aortic PVL are similar, the techniques and procedural complexity differ significantly (13). Mitral PVL closure

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is more intricate than aortic PVL because of some procedural and leak-specific characteristics. To date, the largest series examining the outcomes of percutaneous PVL closure included only a small number of patients with aortic PVL (10,12,13).

We hypothesized that aortic PVL closure can be achieved with high success and low complications rates and that the degree of PVL reduction correlates with symptomatic improvement and clinical outcomes. In this report, we review the commonly applied techniques in aortic PVL closure and provide comprehensive data on the procedural and long-term outcomes of a large consecutive cohort of patients referred for aortic PVL closure.

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METHODS

STUDY POPULATION. The Mayo Clinic Institutional Review Board approved this investigation. We retrospectively identified patients who underwent percutaneous repair of aortic PVL at the Mayo Clinic (Rochester, Minnesota) before January 10, 2016. The indications for percutaneous repair were moderate or severe PVL with severe or life-style-limiting dyspnea (New York Heart Association [NYHA] functional class III or IV or class II with significant life-style or occupational impairment) or clinically significant hemolytic anemia. Patients who had active endocarditis and those who had large leaks involving more than one-half of the circumference of the sewing ring, or rocking motion of the valve, were referred for surgical repair. Clinically significant hemolytic anemia was defined as symptomatic anemia (hemoglobin <11 g/dl in women and <12.5 g/dl in men), with laboratory evidence of intravascular hemolysis.

GRADING OF AORTIC PVL. The assessment of the severity of aortic PVL incorporated a multifaceted approach. This included echocardiographic, invasive hemodynamic, and angiographic measures. Semiquantitative echocardiographic parameters were used in all cases to grade the PVL as mild, mild to

ABBREVIATIONS AND ACRONYMS

AVPII = Amplatzer Vascular Plug II

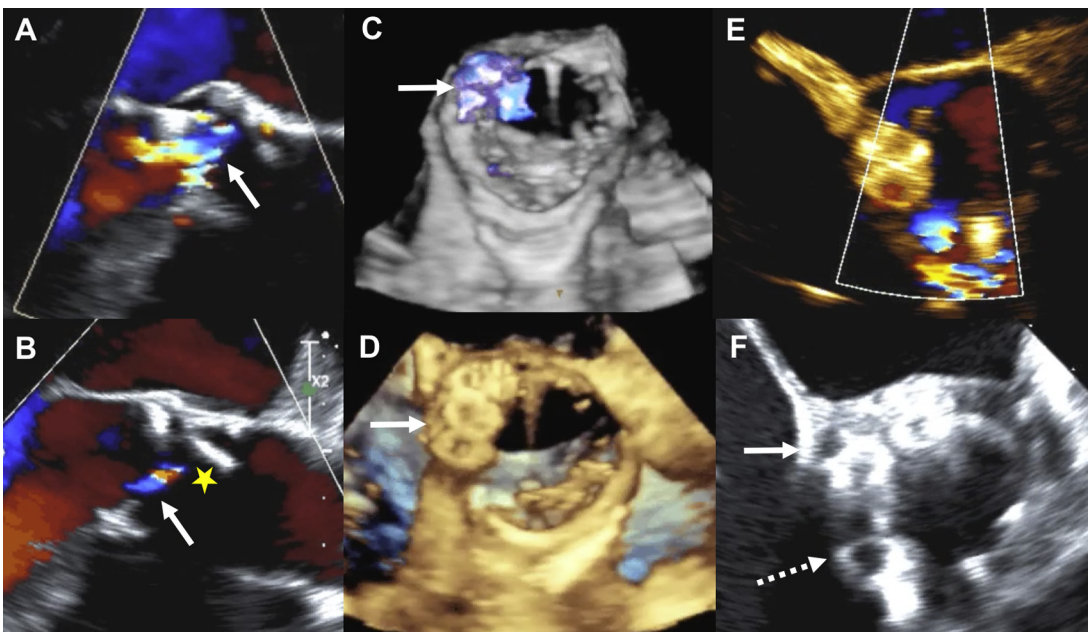
IE = infective endocarditis

NYHA = New York Heart Association

PVL = paravalvular leak

TAVR = transcatheter aortic valve replacement

FIGURE 1 Utility of Echocardiography in Aortic Paravalvular Leak Closure



Transeophageal echocardiography (TEE) revealing significant para-aortic leak in 2 patients (Patient#1, **A, B**) and (Patient#2, **C to F**). **(A)** Moderate posterior para-aortic leak pre-closure **(arrow)**. **(B)** Trivial residual leak after deployment with a 12-mm Amplatzer Vascular Plug II (AVPII) device **(arrow)**. The star indicates the delivery cable before device release. **(C)** 3-dimensional TEE showing severe anteriomedial para-aortic leak pre-closure **(arrow)**. **(D)** 3-dimensional TEE showing successful closure of the leak with 3 AVPII devices **(arrow)**. **(E)** 3D-dimensional TEE in the same patient showing an interval development of a de novo leak at a different anterior location 9 months after the index procedure. **(F)** 3D-dimensional TEE showing successful closure of the leak with 1 AVPII device **(dashed arrow)**. The plugs from the prior closure procedure are indicated by the **arrow**.