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Clinical Outcomes in Patients Undergoing Percutaneous Closure of Periprosthetic Paravalvular Leaks

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Objectives The purpose of this study was to evaluate the feasibility and efficacy of the percutaneous device closure of a consecutive series of patients with periprosthetic paravalvular leaks referred to our structural heart disease center with congestive heart failure and hemolytic anemia.

Background Clinically significant periprosthetic paravalvular leak is an uncommon but serious complication after surgical valve replacement. Percutaneous closure has been utilized as an alternative to surgical repair of this defect in high-risk surgical patients.

Methods This is a retrospective review of 57 percutaneous paravalvular leak closures that were performed in 43 patients (67% male, mean age 69.4 ± 11.7 years) between April 2006 and September 2010. Integrated imaging modalities were used for the evaluation, planning, and guidance of the interventions.

Results Closure was successful in 86% of leaks and in 86% of patients. Twenty-eight of 35 patients improved by at least 1 New York Heart Association functional class. The percentage of patients requiring blood transfusions and/or erythropoietin injections post-procedure decreased from 56% to 5%. Clinical success was achieved in 89% of the patients in whom procedure was successful. The survival rates for patients at 6, 12, and 18 months after paravalvular leak closures were 91.9%, 89.2%, and 86.5%, respectively. Freedom from cardiac-related death at 42 months post-procedure was 91.9%.

Conclusions Percutaneous closure of symptomatic paravalvular leaks, facilitated by integrated imaging modalities has a high rate of acute and long-term success and appears to be effective in managing symptoms of heart failure and hemolytic anemia. (J Am Coll Cardiol 2011;58:2210–7) © 2011 by the American College of Cardiology Foundation

Paravalvular leak is a common complication after surgical valve replacement, with reported incidences at a follow-up of 2% to 10% for prosthetic valves in the aortic position (1,2) and 7% to 17% for prosthetic valves in the mitral position (1–3). Most paravalvular leaks remain clinically silent; however, 1% to 3% of patients with paravalvular leak require reoperations due to symptomatic paravalvular leak (4–6). Paravalvular leaks manifest with symptoms of congestive heart failure (CHF), hemolysis, or in most cases, the combination of both.

Surgical closure of paravalvular leaks remains the most common therapy for these defects; however, re-do surgery has some limitations, depending on the number of patient comorbidities, including a high recurrence rate (7) as well as high morbidity and mortality rates (7–9). Furthermore, mortality increases progressively with the number of reoperations: 13% after the first, 15% after the second, and 37% after the third (9).

Since first reported by Hourihan et al. (10) in 1992, percutaneous closure of periprosthetic paravalvular leaks has been proposed as an attractive alternative to surgical closure and has been found to alleviate the consequences and symptoms of paravalvular leaks in high-risk patients (11). This retrospective study was performed to review the feasibility and efficacy of the percutaneous device

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closure of a consecutive series of patients with paravalvular leaks referred to our Structural Heart Disease Center.

Methods

Definitions for this study of patients with paravalvular leaks. Periprosthetic paravalvular leak is defined as a regurgitant jet, demonstrated by Doppler echocardiography, originating between the outer margin of the prosthetic sewing ring and the native tissues around the valve. Congestive heart failure is defined as symptoms consistent with a New York Heart Association (NYHA) functional class greater than II. Symptomatic hemolysis is defined as hemolytic anemia (hemoglobin ≤10 g/dl, lactate dehydrogenase ≥600 mg/dl, haptoglobin ≤10 mg/dl) requiring >2 U of blood transfusions and/or erythropoietin injections within 90 days to maintain hemoglobin ≥10 g/dl, without any other source of blood loss. Anatomic location of the leaks is based on our own adaptation of the accepted surgical nomenclature using the clock-face reference (Fig. 1) (12,13). Technical success is defined as a successful deployment of an occlusive device across the paravalvular leak without any mechanical interference with the valve prosthesis, or acute conversion to surgery. Procedural outcome events are defined as events occurring during the procedure and within the subsequent 24 h; such events include procedure-related death, cardiovascular death, neurological events (i.e., transient ischemic attacks and stroke), myocardial infarction, cardiac tamponade, vascular access site bleeding requiring intervention and/or blood transfusions, and urgent conversion to conventional open-chest surgery. Procedural-related death was defined as any death that was adjudicated to be a result of an intraprocedural complication. Thirty-day outcome events, as assessed by telephone or during a clinic visit, include procedural outcome events and those occurring within 30 days of the procedure, including death from all causes, cardiovascular death, myocardial infarction, and neurological events (i.e., reversible transient ischemic attacks and irreversible stroke). Clinical success is defined as an improvement in NYHA functional class of at least 1 class within a period of 6 months and/or an improvement in mechanical hemolysis allowing the patient to become transfusion free.

Patient population. Between April 2006 and September 2010, 44 consecutive patients were referred to the Lenox Hill Hospital Structural and Congenital Heart Disease Center for possible percutaneous paravalvular leak closure. One patient was excluded because of the need for open-heart surgery for additional cardiac pathology. No patient was excluded on the basis of their risk, and all remaining 43 patients underwent 57 percutaneous paravalvular leaks closure procedures. Patient demographics and medical history are shown in Table 1. The group mean age was 69.4 ± 11.7 years (range 28 to 85 years), and 29 (67%) were male. Twenty-eight patients had 1 prosthetic valve and 15 had 2 prosthetic valves, in the mitral and/or aortic position. The median time since last valve replacement was 23.5 months and ranged from 2 to 322 months.

Abbreviations and Acronyms

CHF = congestive heart failure

CTA = computed tomographic angiography

D = dimensional

NYHA = New York Heart Association

TEE = transesophageal echocardiography

Patients exhibited a multitude of comorbidities: 36 (84%) had CHF, 26 (60%) had systemic hypertension, 18 (42%) had extensive coronary artery disease, 14 (33%) had pulmonary hypertension, 14 (33%) had a permanent pacemaker, 14 (33%) had prior cardiac bypass surgery, 14 (33%) had chronic renal insufficiency, and 10 (23%) had atrial fibrillation. All patients were symptomatic with severe heart failure and/or mechanical hemolytic anemia requiring multiple transfusions. Hemolysis alone was the indication for paravalvular leak closure in 8 (14%) procedures, CHF alone was the indication in 9 (16%) procedures, and both hemolysis and CHF were the indications in the other 40 (70%) procedures. There were no signs of active infection in any patient before device closure.

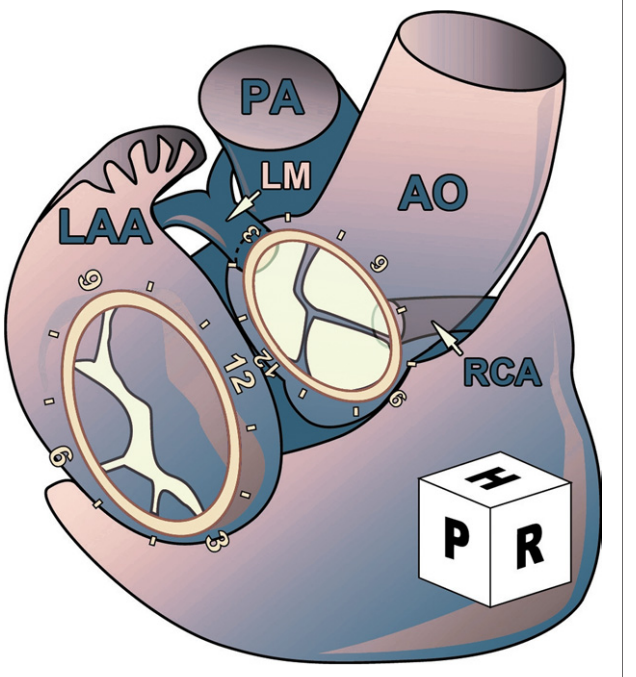

Figure 1 Left Atrial Perspective View: Surgical View

The mitral-aortic fibrous continuity corresponds to 12 o'clock in both clocks; the atrial septum corresponds to 3 o'clock, the posterolateral free wall corresponds to 6 o'clock, and the atrial appendage corresponds to 9 o'clock. For the aortic valve, the noncoronary cusp is between 7 o'clock and 11 o'clock, the left coronary cusp is between 11 o'clock and 3 o'clock, and the right coronary cusp is between 3 o'clock and 7 o'clock. Ao = aorta; H = head; LAA = left atrial appendage; LM = left main coronary artery; P = posterior; PA = pulmonary artery; R = right; RCA = right coronary artery.