Journal of the American College of Cardiology
© 2011 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 58, No. 21, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.03.074



# 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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Manuscript received October 29, 2010; revised manuscript received February 10, 2011, accepted March 10, 2011.

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.

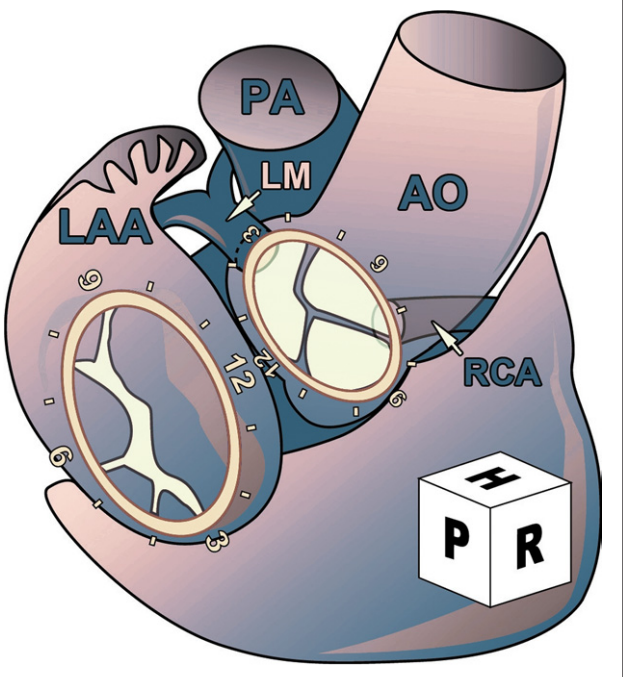


**Figure 1** Left Atrial Perspective View: Surgical View

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.

**Table 1** Patient Demographics and Medical History

| | |
|---|---|
| Patients intended to treat | 43 |
| Male | 29 (67.4) |
| Age | 69.4 ± 11.7 |
| Time since last valve replacement, months | 23.5 (2–322) |
| Patients with 1 prosthetic valve | 28 (65) |
| Patients with 2 prosthetic valves | 15 (35) |
| Number of thoracotomies per patient | 1.8 ± 1.2 |
| Indication for procedure, hemolysis only | 8 (14) |
| Indication for procedure, CHF only | 9 (16) |
| Indication for procedure, hemolysis and CHF | 40 (70) |
| Comorbidities | |
| Pulmonary hypertension | 14 (33) |
| Congestive heart failure | 36 (84) |
| Systemic hypertension | 26 (60) |
| Atrial fibrillation | 10 (23) |
| Extensive coronary artery disease | 18 (42) |
| Patients with coronary artery bypass grafts | 14 (33) |
| Chronic renal insufficiency, creatinine >1.5 mg/dl | 14 (33) |
| Permanent pacemaker | 14 (33) |

Values are n, n (%), mean ± SD, or median (range).

Patients were advised of the procedural risks and options as well as the off-label use of all closure devices, and all signed the informed consent. All procedures were performed in the biplane structural heart catheterization laboratory under general anesthesia. The study was approved by Lenox Hill Hospital's institutional review board.

**Imaging.** Pre-procedure, each patient underwent complete diagnostic transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE). Special attention was paid to the morphology and the function of the native and prosthetic valves. Initially, the size, location, and shape of each paravalvular leak orifice were imaged, analyzed, and measured. The location of the defects was determined by our own modification (Fig. 1) of the clock-face system in the "surgical view," as previously described (12,13). Electrocardiography-gated computed tomographic angiography (CTA) with 3-dimensional (3D) and 4-dimensional (4D) reconstruction using volume-rendering techniques (TeraRecon, San Mateo, California) was also performed in all but 1 patient to plan the best approach depending on the position of the defect. The 64-slice Brilliance iCT scanner (until 2008) and the 256-slice Brilliance iCT scanner (Philips Healthcare, Cleveland, Ohio) were used to perform the CTAs. The dehiscence length, width, and area, as identified by echocardiography and CTA, permitted the selection of the closure device best suited to close the paravalvular leak while trying to avoid embolization or interference with valve prosthesis function.

When applicable, the degree of valvular regurgitation and stenosis was evaluated by Doppler echocardiography using the guidelines recommended by the American Society of Echocardiography (14). Two-dimensional TEE (and real-time 3D TEE when it became available in April 2008) was performed throughout each procedure, using the IE-33 with the x7-2T 3D TEE probe (Philips, Andover, Massachusetts). Three-dimensional modalities included live real

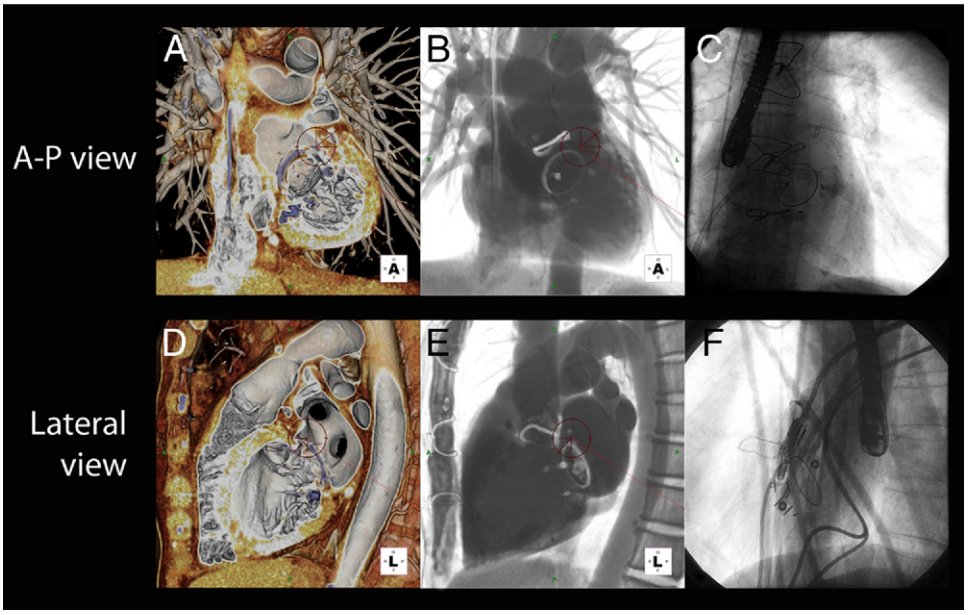


**Figure 2** 3D CTA Guidance During Paravalvular Leak Closure Procedure

A-P view: **(A)** 3-dimensional (3D) volume-rendered computed tomography angiography (CTA) for paravalvular leak localization and marking with the "target" cursor; **(B)** "fluoro-like" view with the "target" remaining at the leak location; **(C)** live fluoroscopy. Lateral View: **(D)** 3D CTA; **(E)** "fluoro-like" view; **(F)** live fluoroscopy. A = anterior; I = Left.

time, real-time 3D zoom, and full volume acquisition with or without color Doppler.

During the procedure, 4D volume rendering of pre-acquired CTA images were displayed in the catheterization laboratory adjacent to the fluoroscopy image, using a gray scale pre-set that simulates the live fluoroscopy image (Fig. 2). The C-arm was rotated and angulated to correspond to the angulations determined by the 3D CTA to best profile the defect. The paravalvular leak was "targeted" on the reconstructed image to facilitate crossing with the guidewire.

Multiple imaging modalities were used during the procedures including 2D and 3D transthoracic echocardiography, fluoroscopy, and CTA. Images were obtained and recorded during each stage of the procedure. The operator used the simultaneously displayed information to select the approach and to guide the catheters and devices. That included selection of the transseptal puncture site and the demonstration of the wires and catheters across the paravalvular leak, avoiding the valve orifice. Successful crossing of the defect was confirmed by real-time 3D TEE (Fig. 3). Before deployment and release of the occlusion device, the valve was interrogated with Doppler echocardiography, before release, to ensure the absence of interference with prosthetic valve function (resulting in regurgitation and/or stenosis).

At the end of the procedure, careful echocardiographic evaluation was performed to review the presence of residual leak, and to exclude complications such as pericardial effusion, intracardiac clot, and possible new intracardiac shunt.

**Paravalvular leak closure techniques.** Aortic paravalvular leaks were approached retrograde in all but 1 case, using different coronary catheters over hydrophilic guidewires as previously described (15). In 1 patient with both aortic and mitral paravalvular leaks, the aortic leak was closed antegradely. All leaks were closed using Amplatzer-type occluder devices (AGA Medical, Plymouth, Minnesota).

Mitral paravalvular leaks closures were performed using 3 different approaches depending on the location of the leaks, as previously described (15) The transseptal-antegrade technique was used mostly for leaks located between 6 o'clock and 9 o'clock. The retrograde (retroaortic) technique was often used for leaks located between 10 and 2 o'clock. The transapical approach was used most often over the past 2 years for the majority of mitral paravalvular leaks, especially if located between 10 and 6 o'clock. The transapical approach was accomplished by carefully planning the point of entry into the left ventricle on the basis of a pre-acquired CT angiogram. The transapical access was closed using 0.052-inch Gianturco Coils (Cook Medical, Bloomington, Indiana) in 1 patient (16), a 6-mm Amplatzer Muscular VSD Occluder (AGA Medical) in another patient, and a 6-mm to 4-mm Amplatzer Duct Occluder (AGA Medical) in the remainder. Surgiflo (Ethicon, Somerville, New Jersey) was also injected in the delivery sheath after release of the closure device to fill the track to the skin.

**Follow-up.** All patients were evaluated post-procedure with transthoracic echocardiography and 4D CTA. All patients were either seen in our clinic or contacted by telephone for ascertainment of clinical status (NYHA functional class), requirements of blood transfusion, further surgical or catheter-based intervention related to the paravalvular leaks, occurrence of transient or permanent cerebrovascular accidents, myocardial infarction, and bacterial endocarditis post-paravalvular leak closure. For deceased patients, review of death certificates or contact with referring physician and family was performed, to ascertain the cause of death.

**Data analysis.** All demographic, valve-related, procedural and outcome data, and clinical and anatomic data were obtained from retrospective review of patient charts and pro-

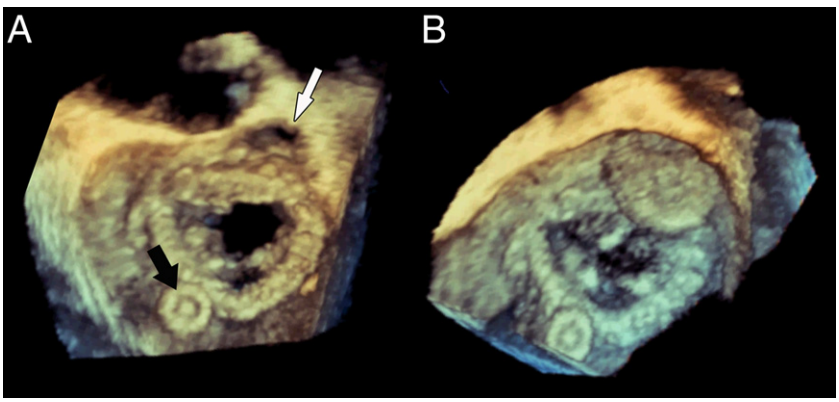


**Figure 3** Real-Time 3D TEE (Zoom Mode) Monitoring and Guidance During Paravalvular Leak Closing Procedure

The mitral valve is visualized from the left atrial perspective, and the image rotated to provide the "surgical view". **(A)** A deployed Amplatzer Duct Occluder closure device is noted in the 7 o'clock position of the mitral valve **(black arrow)**. There is a new 8-mm paravalvular dehiscence at 1 o'clock **(white arrow)**. **(B)** A new Amplatzer Muscular VSD Occluder device is delivered to occlude the 1 o'clock dehiscence. Now, there are 2 occluding devices, the one at 1 o'clock and the other at 7 o'clock. 3D = 3-dimensional.

cedural records. Statistical analyses were performed using the SPSS statistical package (version 17.0, SPSS, Chicago, Illinois). Continuous variables were reported as mean ± SD or as a median and range when appropriate. Events are reported in a nonhierarchical fashion. A Kaplan-Meier plot for survival function was built using both phone visit data and data obtained from chart review.

## Results

There were 57 procedures performed in 43 patients with leaks in biological valve prosthesis (65.3%) and mechanical valve prosthesis (34.7%). Twelve patients had multiple procedures: 10 had 2 procedures and 2 patients had 3 procedures (Figure 4). Using the clock-face diagram, the locations of the leaks treated at the mitral valve were 18% located between 2 and 6 o'clock, 37% between 6 and 10 o'clock, and 45% between 10 and 2 o'clock; at the aortic valve, there were 36% between 11 and 3 o'clock (left coronary cusp), 18% between 3 and 7 o'clock (right coronary cusp), and 46% between 7 and 11 o'clock (noncoronary cusp).

**Technical success.** Successful deployment was achieved in 86% (42 of 49) of leaks and 86% (37 of 43) of patients. Worsening or development of new hemolysis, determined by increase in lactate dehydrogenase level, was documented in 13 of 37 patients in whom the procedure was successful.

There were 12 procedural failures to deploy the occlusive devices, 8 due to inability to cross the defect with the delivery system, 3 due to device interference with the mechanical function of the valve prosthesis, and 1 due to wire entrapment during the attempt to cross the aortic paravalvular leak.

As shown in Table 2, there were 36 mitral paravalvular leaks treated in 32 patients, 9 aortic paravalvular leaks treated in 8 patients, and 2 patients with paravalvular leaks treated in both valves. Four patients had 2 different paravalvular leaks closed during the same procedure: 3 had 2 mitral paravalvular leaks closed and the other had 1 paravalvular leak closed in both the aortic and mitral valves. The Amplatzer Duct Occluder was used in 68.9% of the procedures, the Amplatzer Muscular VSD Occluder in 18.7%, the Amplatzer Vascular Plug II in 8.3%, and the Amplatzer Septal Occluder in 4.1%. Average fluoroscopy time was 39.0 ± 28.8 min for all procedures, 42.6 ± 29.9 min for mitral paravalvular leaks procedures and 29.9 ± 24.5 min for aortic paravalvular leaks procedures.

**Complications.** Six patients experienced complications during the paravalvular leak closure. Two patients had an acute embolization of an occlusion device. The first patient had embolization of the closure device during the attempted closure of a crescent-shaped mitral paravalvular leak with simultaneous deployment of 2 Amplatzer Duct Occluder devices. The device initially embolized to the left atrium, then to the left ventricle, and subsequently to the aortic bifurcation. The device was percutaneously retrieved, and the paravalvular leak was successfully closed by utilizing a larger second device during the same procedure. A second patient had an embolization of the

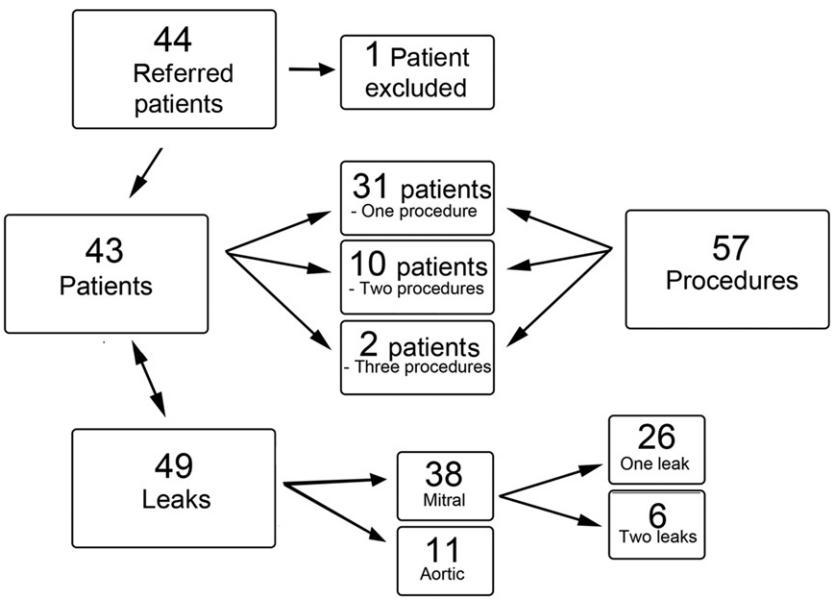


**Figure 4** Study Group Profile

Forty-four patients were referred to our structural heart disease center. One patient was excluded, and all remaining 43 patients underwent 57 percutaneous paravalvular leak closure procedures. Thirty-one patients underwent 1 procedure, 10 patients underwent 2 procedures, and 2 patients underwent 3 procedures. In all, 49 paravalvular leaks closures were attempted: 38 mitral paravalvular leaks and 11 aortic paravalvular leaks. Twenty-six patients had 1 mitral paravalvular leak, and 6 patients had 2 mitral paravalvular leaks.

**Table 2 Procedural Outcomes**

| | |
|---|---|
| Total number of procedures | 57 |
| Number of patients with mitral PVL | 32 (74) |
| Number of patients with aortic PVL | 9 (21) |
| Number of patients with aortic PVL and mitral PVL | 2 (5) |
| Mitral PVL leak locations* | |
| 2–6 | 7 (18) |
| 6–10 | 14 (37) |
| 10–2 | 17 (45) |
| Aortic PVL leak locations* | |
| 11–3 | 4 (36) |
| 3–7 | 2 (18) |
| 7–11 | 5 (46) |
| Mitral PVLs intended to treat | 38 |
| Mitral PVLs successfully treated | 34 (89) |
| Mitral PVLs requiring a second procedure to close | 5 (14) |
| Mitral PVLs in biological valves | 26 (68) |
| Mitral PVLs in mechanical valves | 12 (32) |
| Aortic PVLs intended to treat | 11 |
| Aortic PVLs successfully treated | 8 (73) |
| Aortic PVLs requiring a second procedure to close | 3 (27) |
| Aortic PVLs in biological valves | 6 (55) |
| Aortic PVLs in mechanical valves | 5 (45) |
| Procedural failures | |
| Valve interference, device withdrawal | 3 (5) |
| Failure to cross with delivery system | 8 (14) |
| Wire entrapment, conversion to surgery | 1 (2) |
| Fluoroscopy time, min | 39.0 ± 28.8 |
| Mitral PVL | 42.6 ± 29.9 |
| Aortic PVL | 29.9 ± 24.5 |
| Complications | |
| Acute embolization | 2 (4) |
| Wire entrapped, conversion to surgery | 1 (2) |
| Cardiac perforation | 2 (4) |
| Iliac artery dissection | 1 (2) |
| Procedure-related death | 1 (2) |

Values are n, n (%), or mean ± SD. *See Figure 1.
PVL = paravalvular leak.

Amplatzer Duct Occluder device, placed in an aortic paravalvular leak, in the left ventricle detected by echocardiography a few hours after the procedure. A second larger device was then placed during the same hospitalization to successfully close the leak. The embolized device was firmly imbedded behind the papillary muscle and remains in a stable position by 2D echocardiography and CTA 6 months post-procedure. The third complication occurred in a patient who had an entrapped wire during the procedure that required surgical removal (17). A fourth patient experienced a non–flow-limiting external iliac artery dissection requiring no intervention. Two additional patients had minor cardiac perforations that occurred during the transseptal procedures. Both were associated with pericardial effusions that required no intervention.

There was 1 procedure-related death in a patient with suprasystemic pulmonary hypertension who experienced pulseless electrical activity (electromechanical dissociation) after a successful PVL closure. The patient had no tamponade, as confirmed by echocardiography and an emergency thoracotomy. There was 1 non–procedure-related death due to an intracerebral bleed 5 days after the procedure.

**Clinical success.** Clinical success was achieved in 89% (33 of 37 patients) with successful closure of the paravalvular leak. Eighteen patients improved by 1 NYHA functional class, 8 patients improved by 2 functional classes, and 2 patients improved by 3 functional classes (Fig. 5). Seven patients did not improve in NYHA functional class, but 5 of them had resolution of hemolysis, and therefore were considered a clinical success. The percentage of patients requiring blood transfusions or erythropoietin injections decreased from 56% pre-procedure to 5% at follow-up.

**Follow-up.** On the basis of the follow-up of 37 patients in whom the procedure was successful, 28 have had an improvement in NYHA functional class by at least 1 class, and 33 patients have not required any blood transfusions or erythropoietin injections after the procedure.

The survival rates for patients at 6, 12, and 18 months after undergoing paravalvular leak closures are 91.9%, 89.2%, and 86.5%, respectively (Fig. 6). These rates include 2 non–cardiac-related deaths that occurred at 11 months (head trauma) and 13 months (bronchopneumonia and sepsis) post-procedure, with both patients exhibiting clinical improvement. A third patient, with persistent residual leak, underwent surgical repair in spite of clinical improvement but died during surgery. Freedom from cardiac-related death after 6, 12, and 18 months was 91.9%.

## Discussion

This analysis represents the largest series of percutaneous paravalvular leak closures yet reported. In this study, patients demonstrated significant and marked improvement in

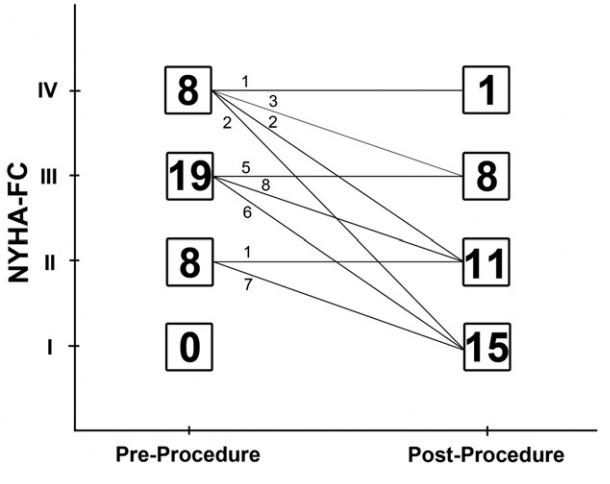


**Figure 5 NYHA-Functional Class in 35 Patients Before and After Technically Successful Procedure**

Figure does not include 2 patients who underwent technically successful procedure but who died within 30 days of the procedure. NYHA-FC = New York Heart Association functional class.

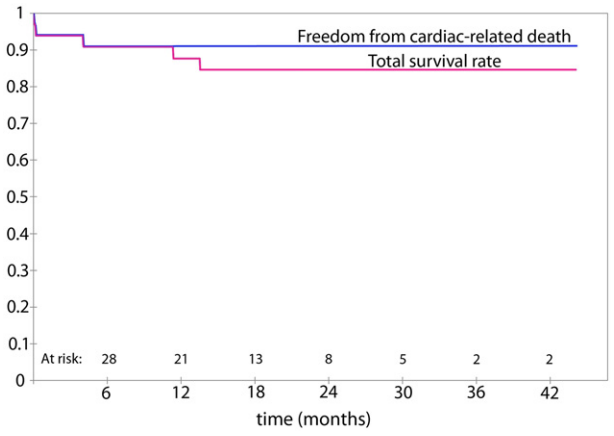


**Figure 6** Kaplan-Meier Plot of Survival Function for 42 Months Post-Procedure

**Red line** = total survival rate; **blue line** = freedom from cardiac-related death.

both CHF symptoms and the need for blood transfusions for ongoing hemolysis.

Hein et al. (18) observed that 33% of patients requiring transfusions had worsening hemolysis after the procedure, and there was newly developed hemolysis in 10% of all patients. This series had similar results immediately after the procedure. It has been determined best to wait 6 months, while minimizing blood transfusions using erythropoietin injections as needed, to ascertain whether severe hemolysis was ongoing and a second closing procedure was indeed needed (i.e., second percutaneous procedure or surgery).

The 30-day all cause mortality rate of 5.4% appears to be lower than that of 1 large surgical series (12%) (3). Percutaneous paravalvular leaks closure may become increasingly favorable after 1 reoperation as surgical mortality rates as high as 22% have been reported (3,5). The cardiac-related mortality rate at 6 months of 8.1% also appears to be considerably lower than that of conservative medical management (26%) (3).

As previously reported (10,11,18–22) (Table 3), the percutaneous paravalvular leak closure outcomes with the current available technology still leave a lot to be desired, owing to several issues. 1) There are no devices that are specifically designed to treat this problem; the devices that are currently employed are being utilized "off-label." 2) Paravalvular leaks may be difficult to cross because of their position and/or because of the anatomic configuration of the defects that may be serpiginous and/or rigid due to annular calcification or to the valve ring per se. At times, the defect can be crossed with a guidewire, but crossing with an available delivery sheath or catheter may be impossible (8 of 12 of our failures). 3) The defect may be crossed and closed but the closure device may interfere with the function of the prosthetic valve, prohibiting release of the device (3 of 12 of our failures). However, with this limited number of patients, we cannot determine if the type of prosthesis and the type of closure devices used can influence the outcome. The development of newer low profile and largely adaptive devices that can conform to the variety of shapes of these defects and are specifically designed for this application will undoubtedly improve the current results.

In the current study, procedural and clinical success as well as complications rate appear acceptable. This series incorporates the use of multiple imaging modalities to facilitate the planning and performance of the procedure. The relatively high rate of procedural success may have been related to the close collaboration and communication between the 4D CTA reconstruction specialist, the transesophageal echocardiography specialist, and the interventional cardiologist, both before the procedure to plan the approach and during the procedure to confirm the course of wires and catheters in the 3D space within the heart. Targeting the paravalvular leak on the 4D CTA reconstructed image adjacent to the fluoroscopic image greatly enhanced the ability to cross the defect in an expeditious fashion. These procedures can be challenging and technically demanding, but are clearly facilitated by a "team

**Table 3** Current Publications

| First Author (Ref. #) | Year | Type (n) | Patients (n) | Leaks (n) | Technical Success | Clinical Success | Repeat Procedures | Mean Fluoroscopy Time (min) |
|---|---|---|---|---|---|---|---|---|
| Hourihan et al. (10) | 1992 | A | 3 | 3 | 3 (100%) | 2 (67%) | 1 (33%) | n/a |
| Pate et al. (20) | 2006 | M (9)<br>A (1) | 10 | 10 | 7 (70%) | 4 (57%) | 4 (40%) | 62 |
| Hein et al. (18) | 2006 | M (13)<br>A (8) | 21 | 26 | 24 (92%) | 14 (67%) | 9 (43%) | 31 |
| Shapira et al. (21) | 2007 | M (9)<br>A (2) | 11 | 13 | 11 (85%) | 6 (54%) | 1 (8%) | 60 |
| Sorajja et al. (22) | 2007 | M (14)<br>A (2) | 16 | 19 | 17 (89%) | 12 (75%) | 0 (0%) | 55 |
| Cortes et al. (19) | 2008 | M | 27 | 27 | 17 (63%) | 10 (59%) | 0 (0%) | n/a |
| García-Borbolla Fernández et al. (11) | 2009 | M | 8 | 8 | 5 (63%) | 4 (80%) | 0 (0%) | n/a |
| Nietlispach et al. (25) | 2010 | A (1)<br>M (4) | 5 | 5 | 5 (100%) | 5 (100%) | 0 (0%) | 15 |

A = aortic paravalvular leak; M = mitral paravalvular leak; n/a = not available.

approach." Even so, the procedures may be lengthy, as evidenced by the relatively long fluoroscopy times of 42.6 min for mitral and 29.9 min for aortic paravalvular leaks closures.

Continued careful long-term follow-up by the clinical cardiologist is warranted in view of the possibility of additional paravalvular leaks developing as well as continued CHF and/or hemolysis requiring transfusion resulting from incomplete closure. Late embolization of the closure device has also been reported (23,24), although this event was not observed in this series. In some cases, hemolysis may temporarily worsen before improving because of increased shear stress through the device before it has a chance to endothelialize.

## Conclusions

Percutaneous closure of symptomatic paravalvular leaks requires multiple imaging modalities and the ability to visualize the 3D relationships of intracardiac structures. A collaborative effort with a skilled interventional team consisting of a structural heart disease interventionalist, an echocardiographer skilled in 3D echo reconstruction, and a CT specialist skilled in 4D reconstruction can result in successful outcomes with improvements in functional class and hemolysis, and with apparently lower morbidity and mortality rates in comparison to surgical series.

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**Key Words:** device closure ■ paravalvular leak ■ prosthetic valve.