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Clinical Research

Long-Term Follow-Up of Percutaneous Repair of Paravalvular Prosthetic Regurgitation

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Objectives The goal of this study was to determine the long-term clinical efficacy of percutaneous repair of paravalvular prosthetic regurgitation.

Background Percutaneous repair has emerged as an effective therapy for patients with paravalvular prosthetic regurgitation.

Methods We retrospectively identified 126 patients who underwent catheter-based treatment of symptomatic prosthetic paravalvular regurgitation. Patients were contacted for symptoms, clinical events, and vital status.

Results The 3-year estimate for survival was 64.3% (95% confidence interval: 52.1% to 76.8%). Mortality occurred due to cardiac, noncardiac, and unknown causes in 9.5%, 7.1%, and 5.6% of patients, respectively. Among survivors, 72% of patients who had presented with heart failure were free of severe symptoms and need for cardiac surgery. Severity of residual regurgitation was not related to overall survival but was an important determinant of other clinical events. For those with no, mild, or moderate or severe residual regurgitation, 3-year estimate of survival free of death or need for surgery was 63.3%, 58.3%, and 30.3% ($p = 0.01$), respectively.

Conclusions Percutaneous repair of paravalvular prosthetic regurgitation can lead to durable symptom relief in selected patients. Nonetheless, mortality remains significant in symptomatic patients with paravalvular prosthetic regurgitation. Long-term clinical efficacy is highly dependent on residual regurgitation. (J Am Coll Cardiol 2011;58:2218–24) © 2011 by the American College of Cardiology Foundation

Paravalvular prosthetic regurgitation occurs in 8% to 18% of patients after heart valve surgery (1). For symptomatic patients, repeat surgery has been the traditional treatment of paravalvular prosthetic regurgitation, but it is associated with high operative risk and variable results (2,3). Recently, percutaneous treatment of paravalvular prosthetic regurgitation has emerged as a less invasive alternative, with feasibility demonstrated in early studies (4,5). However, comprehensive data on the long-term outcome of percutaneous repair are lacking, leading to uncertainty regarding its clinical efficacy.

Accordingly, we examined the long-term outcome of percutaneous repair of paravalvular prosthetic regurgitation in a large, consecutive cohort of patients.

Methods

Study population. The Mayo Clinic Institutional Review Board approved the present investigation.

We retrospectively identified all 136 patients who underwent percutaneous repair of paravalvular prosthetic regurgitation at the Mayo Clinic (Rochester, Minnesota) before January 20, 2011. Each patient had met the following criteria for percutaneous repair: 1) severe dyspnea or clinically significant hemolytic anemia; 2) moderately severe or severe paravalvular prosthetic regurgitation; 3) no active endocarditis; and 4) provision of informed consent. Clinically significant hemolytic anemia was defined as symptomatic anemia (hemoglobin <13 g/dl in women or <15 g/dl in men) requiring transfusion, with laboratory evidence of intravascular hemolysis. Informed consent entailed a detailed discussion and understanding of the risks associated with complex catheter techniques (e.g., transseptal access, apical puncture), the off-label use of device occluders, the unknown clinical efficacy of the procedure, and consideration of alternative therapies, including open surgical correction. There were no specific anatomic criteria for exclusion, although all patients had paravalvular regurgitation involving less than one-third of the sewing ring. Of these 136 patients, 10 declined use of their medical records for research. The remaining patients consented to participate in accordance with Minnesota law, forming the present cohort. This cohort includes patients examined in our initial experience with this therapy and in our previous imaging review (4,6,7).

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Percutaneous repair. Percutaneous repair of paravalvular prosthetic regurgitation was performed with techniques described previously (4,6,7). Single- or multiple-device occluders were placed under fluoroscopic and echocardiographic guidance with care to minimize risk of prosthetic impingement and device embolization. Patients were continued on previously prescribed antiplatelet and anticoagulant therapy without additional medical prescription. Aortic and mitral paravalvular regurgitation, before and immediately after the procedure, was graded semiquantitatively using Doppler echocardiography and color-flow imaging (grade I, mild; grade II, moderate; grade III, moderate to severe; and grade IV, severe) by echocardiographers experienced in the intraoperative assessment of mitral valve repair and regurgitation (8). In equivocal cases, angiography was used with grading according to Sellers criteria (9).

Clinical follow-up. Patients were contacted by mailed questionnaire and telephone survey to determine occurrence of adverse clinical events, symptoms, and vital status. Sudden cardiac death was defined as instantaneous and unexpected death with or without documented ventricular fibrillation within 1 hour after a witnessed collapse, or nocturnal death in patients who previously were in stable clinical condition, or appropriate discharge of an implanted defibrillator (4). Occurrence of stroke was defined according to standard criteria (10).

Data analysis. Survival estimates with 95% confidence intervals (CIs) were calculated for study endpoints using the Kaplan-Meier method. To examine the impact of residual regurgitation on outcome, patients were grouped according to no, mild, and moderate or severe residual paravalvular prosthetic regurgitation for comparisons. Cox regression analyses with stepwise techniques were used to identify variables independently associated with the endpoints that were incorporated into the final models. Variables included in the model were age; male sex; presenting symptoms (heart failure [HF] or hemolytic anemia); treated prosthesis location (aortic or mitral); prosthesis type (mechanical or biologic); history of coronary artery disease, peripheral vascular disease, hypertension, atrial fibrillation, chronic obstructive pulmonary disease, prior stroke, creatinine clearance <60 ml/min, and coronary artery bypass graft; left ventricular ejection fraction, right ventricular systolic pressure, and medication use (beta-receptors, angiotensin-converting enzyme inhibitor, or angiotensin receptor blocker). For symmetrically distributed data, analysis of variance was used for comparison; the Kruskal-Wallis test was used in the event of skewed data. Contingency tables were analyzed for association with a chi-square or Fisher exact tests. Statistical significance was inferred at $p < 0.05$.

Results

Patients. Mean age was 67 ± 12 years, and 53.2% were men (Table 1). HF was the most common indication for the procedure, occurring in 117 patients (92.9%). Transfusion-dependent, hemolytic anemia was present in 37 patients (36%). Treated defects were most commonly paramitral and involved mechanical prostheses. Significant morbidity was frequent. Using the Society of Thoracic Surgeons' risk calculator, the estimated operative mortality for open repair in the cohort was 6.7 ± 5.4% (11).

Abbreviations and Acronyms

CI = confidence interval

HF = heart failure

Percutaneous repair. Percutaneous repair was attempted in a total of 154 paravalvular defects (Table 2), resulting in no, mild, and moderate or severe residual regurgitation in 47 patients (37%), 49 patients (39%), and 30 patients (24%), respectively. Three patients with moderate residual regurgitation underwent a second percutaneous attempt in follow-up, with reduction of regurgitation in only 1 of these patients. In 11 patients (8.7%), the procedure was unsuccessful due to either inability to cross the defect with wire or delivery catheter, prosthetic leaflet impingement from the occluder, or persistent severe regurgitation despite device placement.

Survival. Median follow-up for the study patients was 11.0 months, with a range of 1 to 85 months (mean 17 ± 17 months; 99% complete). No acute procedural deaths occurred, but 3 deaths occurred within 30 days. Two other patients (1.6%) suffered disabling strokes on days 4 and 9 after their procedure. One stroke was hemorrhagic, occurring while the patient was receiving heparin bridging. The second stroke was an embolic event.

Twenty-nine deaths occurred during follow-up (Table 3). The most common cause of death was HF (37% of deaths), whereas noncardiac causes accounted for 9 deaths (30% of deaths). Three deaths resulted from perioperative complications in patients who had subsequent cardiac surgery for failed percutaneous repair. For the entire cohort, the estimate for 3-year survival free of all-cause mortality was 64.3% (95% CI: 52.0% to 76.6%) (Fig. 1). Overall survival did not significantly differ for patients with no (69.9% [95% CI: 51.0% to 88.8%]), mild (62.4% [95% CI: 41.6% to 83.2%]), or moderate or severe (58.1% [95% CI: 32.0% to 84.3%]) residual regurgitation, before and after multivariate adjustment.

Symptoms and clinical events. Among the 89 surviving patients who presented with HF as the indication for the procedure, 64 patients had no or only mild exertional dyspnea. Symptom improvement was confined to those patients who had no or only mild residual regurgitation (Fig. 2).

In the overall population, 2 patients had acute device embolization; both occluders immediately were retrieved successfully percutaneously. In follow-up, there were no incidences of late embolization, infection, or other device complications. Hemolytic anemia persisted in 14 of 29 survivors. There was no relation between the degree of residual regurgitation and incidence of persistent hemolytic anemia. Compared with other patients, those with hemolytic anemia had poorer survival and need for cardiac surgery before and after multivariate adjustment (Fig. 3).

Table 1 Baseline Characteristics

Characteristic	All Patients (N = 126)	Residual Regurgitation			p Value
		None (n = 47)	Mild (n = 49)	Moderate or Severe (n = 30)	
Age (yrs)	67 ± 13	70 ± 13	65 ± 13	68 ± 10	*
Male	67 (53.2)	23 (48.9)	30 (61.2)	14 (46.7)	*
Presenting symptoms					
Heart failure	117 (92.9)	45 (95.7)	44 (89.8)	28 (93.3)	0.52
Hemolytic anemia	37 (29.4)	15 (31.9)	12 (24.4)	10 (33.3)	0.16
Right heart failure	15 (11.9)	11 (23.4)	2 (4.1)	2 (6.7)	0.01
Treated prosthesis type					
Aortic	27 (21.4)	6 (12.8)	15 (31.6)	6 (20.0)	0.10
Mitral	99 (78.5)	41 (87.2)	34 (69.4)	24 (80.0)	0.10
Bioprostheses	49 (38.9)	19 (40.4)	21 (42.8)	9 (30.0)	0.42
Mechanical prostheses	77 (61.1)	28 (59.6)	21 (42.8)	21 (70.0)	0.42
Time of implant to percutaneous repair (mos)	67 ± 75	64 ± 73	50 ± 61	99 ± 91	0.01†
Medical history					
Coronary artery disease	40 (31.7)	17 (36.2)	20 (40.8)	3 (10.0)	0.01
Peripheral vascular disease	10 (7.9)	6 (12.8)	2 (4.1)	2 (6.7)	0.28
Hypertension	63 (50.0)	24 (51.1)	25 (51.0)	14 (46.7)	0.92
Atrial fibrillation	69 (54.7)	27 (57.4)	26 (53.1)	16 (53.3)	0.90
Chronic obstructive pulmonary disease	17 (13.4)	7 (14.9)	7 (14.3)	3 (10.0)	0.81
Previous stroke	28 (22.2)	15 (31.9)	8 (16.3)	5 (20.0)	0.13
Creatinine clearance <60 ml/min	71 (56.3)	32 (68.1)	25 (51.0)	14 (46.7)	0.11
Congenital heart disease	2 (1.6)	1 (2.1)	1 (2.0)	0 (0)	0.49
Radiation heart disease	4 (3.2)	0 (0)	3 (6.1)	1 (3.3)	0.23
Prior procedures					
≥2 sternotomies	70 (55.6)	27 (57.4)	25 (51.0)	18 (60.0)	0.88
Other left-sided valve replacement‡	38 (30.1)	14 (29.7)	14 (28.6)	10 (33.3)	0.90
2 left-sided mechanical prostheses	26 (20.6)	12 (25.5)	9 (18.4)	5 (20.0)	0.57
Previous surgical leak repair	24 (19.0)	10 (21.3)	7 (14.3)	7 (23.3)	0.54
Coronary artery bypass graft	40 (31.7)	18 (38.3)	20 (40.8)	3 (10.0)	0.01
Permanent pacemaker	17 (13.5)	8 (17.0)	5 (10.2)	4 (13.3)	0.62
Implanted defibrillator	5 (4.0)	0 (0)	4 (8.2)	1 (3.3)	0.12
Left ventricular ejection fraction (%)	56 ± 13	55 ± 13	55 ± 15	58 ± 12	*
Left ventricular end-diastolic diameter (mm)	52 ± 9	50 ± 11	54 ± 9	53 ± 7	*
Left ventricular end-systolic diameter (mm)	36 ± 9	35 ± 8	38 ± 11	35 ± 8	*
Right ventricular systolic pressure (mm Hg)§	55 ± 18	55 ± 21	52 ± 16	59 ± 18	*
Medications					
Beta-receptor antagonists	89 (70.6)	34 (72.3)	34 (69.4)	21 (70.0)	0.95
ACE inhibitor or ARB	58 (46.0)	21 (44.7)	21 (42.9)	16 (53.3)	0.88
Diuretic	91 (72.2)	33 (70.2)	36 (73.4)	22 (73.3)	0.93
Digoxin	36 (28.6)	13 (27.7)	9 (18.4)	14 (46.7)	0.03
Warfarin	77 (61.1)	29 (61.7)	27 (55.1)	20 (66.7)	0.54
STS estimated operative mortality	6.7 ± 5.4	7.6 ± 5.2	6.1 ± 6.4	6.2 ± 4.1	*

Values are mean ± SD or n (%). *p values for all group comparisons for continuous variables were >0.05. †p value for comparison of moderate or severe versus mild. ‡Valve replacement apart from the prosthesis that was treated percutaneously. §Echocardiographic estimation.

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; STS = Society of Thoracic Surgeons.

Two patients underwent cardiac surgery after failed percutaneous repair during the same hospitalization. In addition, 18 patients subsequently underwent cardiac surgery for either failed percutaneous repair or significant residual regurgitation in follow-up. Overall, 3-year estimate for survival free of any death or need for cardiac surgery was 53.5% (95% CI: 41.4% to 65.6%). The degree of residual regurgitation significantly affected the need for cardiac surgery. For patients with no, mild, and moderate or severe residual regurgitation, 3-year estimate of survival free of death or need for cardiac surgery was 63.7% (95% CI: 44.5% to 82.8%), 59.0% (95% CI: 38.2 to 79.9%), and 30.9% (95% CI: 9.1 to 52.6%) (p = 0.01), respectively (Fig. 4). These differences in survival remained significant after multivariate adjustment.

Discussion

The principal findings of the present investigation are: 1) percutaneous repair of paravalvular prosthetic regurgitation

Table 2 Procedural Characteristics

Characteristic	All Patients (N = 126)	Residual Regurgitation			p Value
		None (n = 47)	Mild (n = 49)	Moderate or Severe (n = 30)	
General anesthesia	104 (82.5)	42 (89.3)	38 (77.6)	24 (80.0)	0.29
Echocardiography					
Intracardiac	15 (11.9)	2 (4.3)	9 (18.4)	4 (13.3)	0.10
Transthoracic	18 (14.2)	6 (12.7)	7 (14.3)	5 (16.7)	0.89
Transesophageal	103 (81.7)	41 (87.2)	38 (77.6)	24 (80.0)	0.45
Perivalvular defects					
Number attempted	154	55	59	40	
Periaortic	30	7	15	8	
Perimitral left ventricle to left atrium	122	47	43	32	
Perimitral left ventricle to right atrium	2	1	1	0	
Total number of devices implanted	156	63	58	34	
Patients with multiple defects closed	20	6	8	6	
Technique used					
Periaortic retrograde	30 (23.8)	7 (14.9)	15 (30.6)	8 (26.7)	0.18
Perimitral					
Antegrade transeptal	98 (77.7)	40 (85.1)	34 (69.4)	24 (80.0)	0.17
Right internal jugular vein to left ventricle	2 (1.6)	1 (2.1)	1 (2.0)	0 (0)	0.45
Apical puncture	13 (10.3)	8 (17.0)	2 (4.1)	3 (10.0)	0.11
Transaortic exteriorization	36 (28.5)	15 (31.9)	10 (20.4)	11 (36.7)	0.24
Retrograde aortic approach	2 (1.6)	1 (2.1)	1 (2.0)	0 (0)	0.45
Simultaneous or anchor wire	12 (9.5)	5 (10.6)	4 (8.2)	3 (10.0)	0.89
Amplatzer occluder device type					0.10
Atrial septal occluder	12 (9.5)	5 (10.6)	4 (8.2)	3 (10.0)	
Vascular Plug II	77 (61.1)	31 (65.9)	34 (69.4)	12 (40.0)	
Patent ductal occluder	20 (15.8)	5 (10.6)	7 (14.3)	8 (26.7)	
Ventricular septal occluder	10 (7.9)	5 (10.6)	2 (4.1)	3 (100)	
Procedure time (min)	147 ± 52	150 ± 48	135 ± 56	162 ± 50*	0.05†
Fluoroscopy time (min)	56 ± 34	50 ± 29	51 ± 31	74 ± 39†	0.01,† 0.003*
Contrast used (ml)	32 ± 49	17 ± 29	44 ± 57	36 ± 53†	0.004*
Length of stay after procedure (days)	4.9 ± 6.6	3.7 ± 4.0	4.3 ± 7.1	8.3 ± 8.3*	0.02,† 0.003*

Values are n (%) or mean ± SD. Two patients received 2 different types of devices. *P value for comparison versus none. †P value for comparison versus mild. All other p values for comparison of continuous variables between groups were >0.05.

can lead to durable improvement in symptoms of HF in selected patients; 2) severity of residual regurgitation after percutaneous repair directly affects the long-term durability of symptom relief; and 3) significant mortality persists in patients with symptomatic paravalvular prosthetic regurgitation after percutaneous repair. Our findings, which were observed in a high-risk patient cohort, demonstrate clinical efficacy that may reduce the need for re-operation in these patients, in whom morbidity and the risk of open surgery frequently is increased. Nonetheless, continued refinements

Table 3 Clinical Events

Event	All Patients (N = 126)	Residual Regurgitation			p Value
		None (n = 47)	Mild (n = 49)	Moderate or Severe (n = 30)	
Death	29 (23.0)	9 (19.1)	12 (24.5)	8 (26.7)	0.64
Heart failure–related	11 (8.7)	2 (4.3)	6 (12.2)	3 (10.0)	0.35 0.45
Sudden cardiac death	1 (0.7)	0 (0)	1 (2.0)	0 (0)	0.45 0.93
Noncardiac	9 (7.1)	3 (6.4)	3 (6.1)	3 (10.0)	0.93
Unknown	7 (5.6)	3 (6.4)	2 (4.1)	2 (6.7)	0.85
Severe symptoms*	14 (14.5)	3 (7.9)	5 (13.8)	6 (27.3)	<0.0001
Persistent hemolytic anemia*	17 (17.7)	6 (15.8)	7 (19.4)	4 (18.2)	0.21
Subsequent cardiac surgery	20 (15.8)	3 (6.4)	4 (8.2)	9 (30.0)	0.0020
Stroke	2 (1.6)	0 (0)	1 (2.0)	1 (3.3)	0.48

Values are n (%). *Percentage calculated for survivors only.

to improve procedural success are needed to enhance the durability of its clinical efficacy.

Although percutaneous repair of paravalvular prosthetic regurgitation was first reported nearly 2 decades ago, this therapy only definitively emerged with recent innovations in delivery catheter and device occluder design. Feasibility studies, albeit mainly small case series, have demonstrated acute procedure success occurring in >80% of treated patients. The present investigation extends previous acute studies by examining the durable efficacy of percutaneous repair of paravalvular prosthetic regurgitation. The 3-year estimate of survival of all-cause mortality was 64.5%. Limited life expectancy after repair of paravalvular prosthetic regurgitation also has been observed in surgical series, with 1 study reporting a 10-year survival of only 30%, likely reflecting the substantial morbidity of these patients (3). In our series, although cardiac etiologies were the most common cause of death (9.5% of total patients) and there was a significant number with unknown cause (5.6%), noncardiac causes also were frequent (7.1%), indicative of significant comorbidity. These morbidities included high incidences of multiple prior sternotomies (56%), renal failure (56%), pulmonary hypertension (33%), low ejection fraction (26%), and previous stroke (22%).

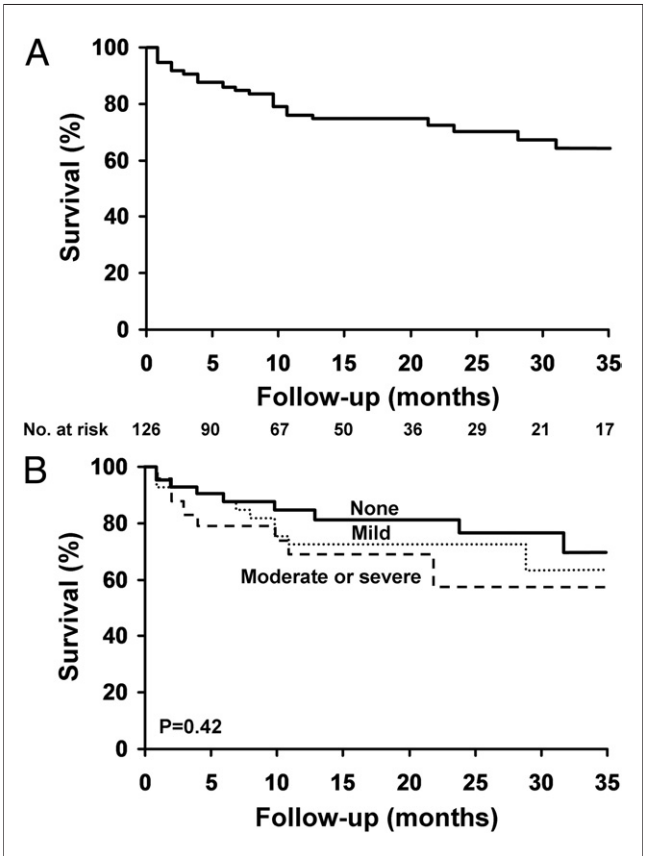

Figure 1 Survival After Percutaneous Repair of Paravalvular Prosthetic Regurgitation

Survival free of all-cause mortality is shown for **(A)** the entire patient cohort and **(B)** according to degree of residual paravalvular prosthetic regurgitation.

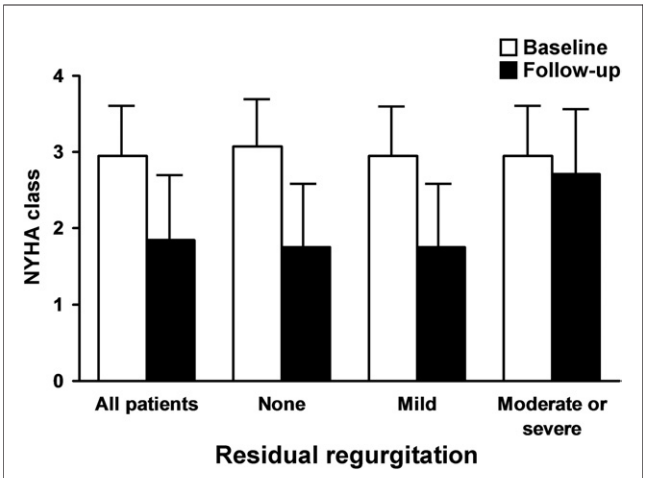

Figure 2 Symptom Improvement With Percutaneous of Paravalvular Prosthetic Regurgitation

New York Heart Association (NYHA) functional class **(open bars)** at baseline and **(solid bars)** at follow-up in the overall population and according to degree of residual paravalvular prosthetic regurgitation. *p < 0.05 versus baseline.

Among survivors who had presented with HF as the primary indication for the procedure, 72% had clinical improvement with mild or no symptoms in follow-up. This improvement occurred with a relatively low early mortality (30-day incidence, 2.4%), and was more common in patients who had no or only mild residual regurgitation. These data suggest that percutaneous therapy, when successful, may be a viable alternative to open surgery, particularly in patients in whom morbidity significantly increases the risk for re-operation.

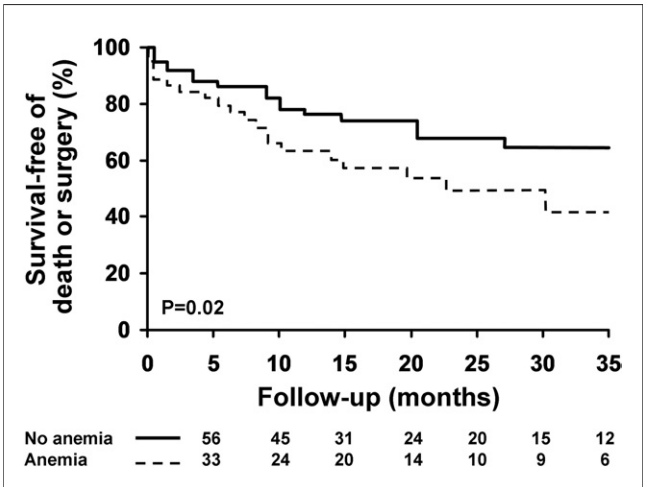

Figure 3 Outcome According to Presence or Absence of Hemolytic Anemia

Survival free of the combined endpoint of death or need for cardiac surgery is shown according to the presence or absence of hemolytic anemia as an indication for percutaneous repair of paravalvular prosthetic regurgitation.

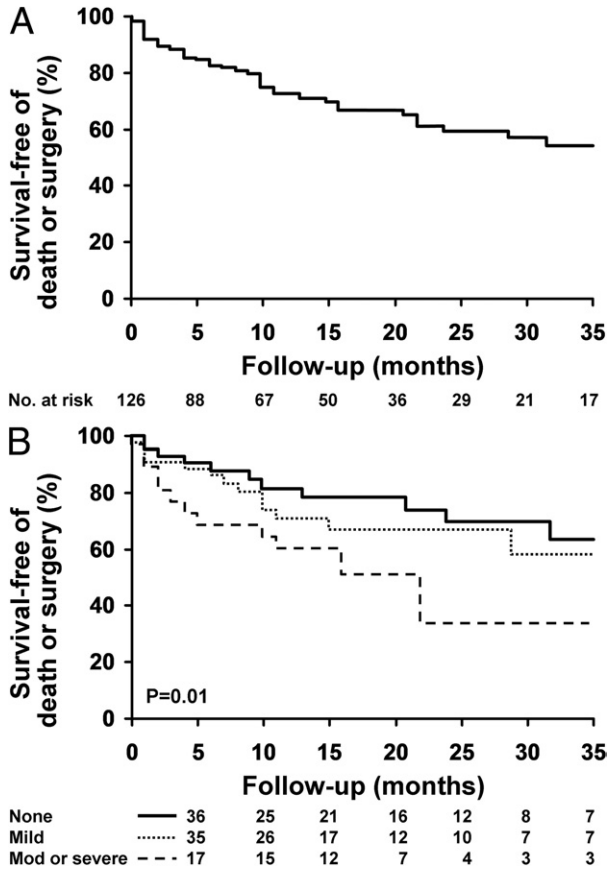

Figure 4 Survival Free of Death or Need for Cardiac Surgery

Survival free of the combined endpoint of death or need for cardiac surgery is shown for **(A)** the entire patient cohort and **(B)** according to degree of residual paravalvular prosthetic regurgitation.

Percutaneous repair of paravalvular prosthetic regurgitation is a challenging procedure in which complex catheter techniques with a steep learning curve are used. Competency in the performance of these techniques, in conjunction with care given in a multidisciplinary setting, is a key component to acute procedural success. Importantly, the present investigation observed a direct relation between residual paravalvular prosthetic regurgitation and survival free of adverse events. These data are analogous to previous studies of native valvular disease, in which a moderate degree of regurgitation even in an asymptomatic patient has longitudinal implications (12).

The implications of residual regurgitation after percutaneous repair are significant, as current technology is not purposefully designed for this procedure, and there is significant potential for continued regurgitation despite successful placement of an occluder. In the present study, grading of residual regurgitation encompassed all visible flow through the paravalvular defect. However, significant residual regurgitation, when present, usually occurred juxtaposed rather than through the device. Later in our experience, we incorporated newer percutaneous techniques, such as simultaneous placement of multiple, smaller devices for oblong defects. This approach, which was selectively used in 12 patients, helped more fully reduce residual regurgitation and may lead to improvement in long-term clinical efficacy when more broadly applied in future studies. Further study on the most appropriate antithrombotic therapy in the use of these devices for this indication also is required, particularly because we observed 2 major periprocedural stroke events. In our practice, dual antiplatelet therapy is empirically prescribed for up to 6 months after device closure of atrial septal defects or patent foramen ovale, but such therapy currently is not routinely used in patients undergoing paravalvular leak repair.

Paravalvular prosthetic regurgitation is an established etiology of hemolytic anemia, with early reports of this association dating back to the 1960s (13). The present investigation included a significant subset of patients with transfusion-dependent, hemolytic anemia (29.4%). During follow-up, hemolytic anemia remained in 14 of 29 survivors. The reasons for lack of better efficacy with percutaneous closure in these patients are not clear. The incidence of persistent hemolytic anemia was related to severity of residual regurgitation, but this finding could be attributable to the relatively small patient samples. Theoretically, either flow turbulence from an intravascular device or flow acceleration from reduction in regurgitant orifice size could exacerbate hemolytic anemia. However, we observed exacerbation of hemolytic anemia in only 1 patient. Further study to define the role of percutaneous repair in the treatment of patients for this indication is needed.

Study limitations. The retrospective nature of this study has known limitations, including potential for referral basis. Notably, serial echocardiography was not performed, and data on residual regurgitation at final follow-up were not available due to the referral nature of our clinical practice. Of note, the present investigation consists of a consecutive cohort of patients after exclusion of patients who did not provide informed consent for use of their medical record for research purposes. Patient follow-up was high (99%) and included detailed prospective examination of all adverse clinical events, need for surgery, current symptoms, and vital status, including cause of death when possible.

Conclusions

The present investigation demonstrated that percutaneous repair is a viable option with the potential for durable clinical efficacy. Percutaneous repair can be undertaken as part of therapeutic strategy for the treatment of severely symptomatic paravalvular prosthetic regurgitation. Nonetheless, mortality remains significant after the procedure, and the long-term efficacy is dependent on residual paravalvular regurgitation. Further studies to refine patient selection and improve the early technical success of the procedure are needed.

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