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Long-Term Outcomes of Percutaneous Paravalvular Regurgitation Closure After Transcatheter Aortic Valve Replacement

A Multicenter Experience

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ABSTRACT

OBJECTIVES This study sought to evaluate acute and long-term outcomes of percutaneous paravalvular regurgitation (PVR) closure after transcatheter aortic valve replacement (TAVR).

BACKGROUND Severe symptomatic PVR is a predictor of all-cause mortality after TAVR. The current use of devices for transcatheter closure of PVR has been adapted from other indications without known long-term outcomes.

METHODS The study population consisted of a series of cases pooled together from an international multicenter experience. Patients underwent transcatheter implantation of a closure device for the treatment of clinically relevant PVR after TAVR with balloon-expandable or self-expandable prostheses. Procedural success was defined by successful deployment of a device with immediate reduction of PVR to a final grade ≤2 as assessed by echocardiography.

RESULTS Twenty-seven procedures were performed in 24 patients with clinically relevant PVR after the index TAVR procedure (54.2% Edwards Sapien [Edwards Lifesciences, Irvine, California], 45.8% CoreValve [Medtronic, Minneapolis, Minnesota]). The study population included 75% men with a mean age of 80.6 ± 7.1 years and mean Society of Thoracic Surgeon score of 6.6%. The most frequently used device was Amplatzer Vascular Plug (St. Jude Medical, St. Paul, Minnesota) in 80% of the cases. Overall, 88.9% (24 of 27) of the procedures were technically successful and the results assessed by echocardiography were durable. However, cumulative survival rates at 1, 6, and 12 months were 83.3%, 66.7%, and 61.5%. Most of the deaths (8 of 11) were due to noncardiac causes.

CONCLUSIONS Transcatheter closure of PVR after TAVR can be performed with a high procedural success rate; however, the long-term mortality remains high mainly due to noncardiac causes. (J Am Coll Cardiol Intv 2015;8:681-8)

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ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation

AVR = aortic valve replacement

PVR = paravalvular regurgitation

TAVR = transcatheter aortic valve replacement

Transcatheter aortic valve replacement (TAVR) is an effective treatment for patients with severe symptomatic aortic stenosis who are considered either ineligible or at high risk for surgical AVR (1,2). After conventional AVR, the occurrence of paravalvular regurgitation (PVR) is infrequent and often necessitates rapid action (3,4). Conversely, residual PVR is more common after TAVR and has been reported in up to 90% of the patients independent of either of the 2 available types of devices and approaches (5). In most cases, PVR is mild and clinically silent. However, when moderate or severe it has been associated with hemodynamic deterioration and worse early (6) and late (7) clinical outcome.

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When aortic regurgitation (AR) is exclusively or mainly paravalvular, the possible mechanisms are as follow: 1) malposition (too high or too low with respect to the aortic annulus); 2) annulus/prosthesis mismatch; 3) incomplete expansion of the prosthesis stent frame; and 4) presence of bulky calcified nodules preventing the good adherence of the bioprosthesis to the left ventricular outflow tract. Based on the pathophysiology, the management strategy includes post-dilation (8), valve-in-valve implantation (9), or repositioning with the snare technique (10). Sometimes, however, none of these techniques are effective, necessitating additional maneuvers.

Transcatheter closure of PVR has been previously described for post-surgical valves (11,12). More recently, percutaneous device closure of PVR following TAVR have been described in small series, with single center experience and have focused on a particular valve type (13–17). In addition, the devices used for transcatheter closure of PVR defects are adapted from other indications and long-term outcomes are unknown. The current study was aimed to represent the largest multicenter case series of patients who underwent transcatheter closure of PVR after Edwards prostheses (Edwards Sapien and Sapien XT, Edwards Lifesciences, Irvine, California) or Medtronic CoreValve (Minneapolis, Minnesota) with long-term follow-up.

METHODS

POPULATION AND PROCEDURE. We examined the clinical, procedural, and long-term follow-up data of all consecutive patients with clinically relevant PVR after TAVR who underwent percutaneous closure of a paravalvular defect at 4 high-volume catheterization laboratories in different countries: the United States, Italy, Germany, and Canada. There was no restriction for the type of TAVR previously implanted in the aortic position, namely the self-expanding Medtronic CoreValve or 1 of the balloon-expandable Edwards prostheses (Edwards Sapien and Sapien XT). Decision to perform the PVR closure was clinically driven in all cases. To date, there are no devices that have been developed and labeled for this purpose, hence selection of the device for PVR closure and other material for the procedure, vascular access, use of additional diagnostic tools, and periprocedural and post-procedural medications were at the operators' discretion.

DEFINITIONS AND OBJECTIVES. The surgical risk before TAVR was estimated with the STS-PROM (Society of Thoracic Surgery Predicted Risk of Mortality) (18) and the logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) (19). In addition, patients were classified as inoperable or at high risk for surgery based on the judgment by the heart team. Symptomatic status before and after PVR closure was classified based on the New York Heart Association functional class. Prosthetic PVR was classified by echocardiography using recommended semiquantitative criteria (20,21): 0 = absent, no regurgitant color flow; 1 = trace, pinpoint jet; 2 = mild-to-moderate, circumferential extension <10%; 3 = moderate-to-severe, circumferential extension 10% to 29%; and 4 = severe, circumferential extension ≥30% and/or holodiastolic flow reversal in the descending aorta. Because PVR may be caused by different and often multiple mechanisms (5,13,22), in this study, physicians were asked to retrospectively classify the main mechanism into 4 categories based on all available imaging documentation: high implant (part of the inflow aspect of the prosthesis lies above the annular ring, allowing a regurgitation from the aortic sinus below the tissue skirt into the left ventricle); low implant (implantation of the prosthesis or part of the sealing pericardial skirt of the prosthesis below the virtual annular ring, leaving an open communication between the aorta and the left ventricle); undersized valve (mismatch between the annulus size and the prosthesis); and incomplete adherence to the annulus (correct device sizing but presence of bulky native valve calcifications causing incomplete apposition of the frame). Procedural success was defined by successful deployment of a closure device with immediate reduction in the degree of PVR with a final grade ≤2 as assessed by echocardiography. The occurrence of adverse events was evaluated using recommended criteria (20). Myocardial infarction was attributed by a combination of clinical criteria and cardiac biomarkers

(universal definition of myocardial infarction > 72 h after the index procedure; within 72 h from the procedure threshold values were >15× the upper reference limit for troponin or 5× for creatine kinase-myocardial band). Cerebrovascular accidents included transient ischemic attack and stroke. Serious bleeding was defined as the need of transfusion or intervention. Acute kidney injury was classified as stage 1 (increase in serum creatinine to 150% to 199% compared with baseline or increase of >0.3 mg/dl), stage 2 (increase in serum creatinine to 200% to 299%), or stage 3 (increase in serum creatinine to ≥300% or serum creatinine of >4.0 mg/dl with an acute increase of at least 0.5 mg/dl). Clinicians were asked to report any serious vascular complication, including any aortic damage or access-related vascular injury leading to a serious bleeding or requiring intervention. Participating investigators were asked to provide the longest available follow-up and the most updated echocardiography data. All patients provided written informed consent before the procedure and also gave written informed consent for the processing of their anonymous data.

STATISTICAL ANALYSIS. Continuous variables were expressed as mean ± SD. Categorical variables were presented as frequencies and percentages. Survival during follow-up was estimated with the Kaplan-Maier curve. All analyses were performed with the SPSS software (version 17.0, SPSS Inc., Chicago, Illinois).

RESULTS

Overall, 27 procedures were performed in 24 patients (1 patient underwent 3 and another patient had 2 procedures). None of the patients had central AR grade ≥2. The procedures were performed 316 ± 515 days (range 3 to 1,409) after TAVR. Baseline patients' characteristics are listed in Table 1. The study population included 75% men and 25% women with a mean age of 80.6 ± 7.1 years and mean Society of Thoracic Surgeon Score of 5.4 ± 3.9%. Seven patients (29.2%) had porcelain aorta. In total, 13 patients (54.2%) had an Edwards Sapien valve, and 11 (45.8%) a Medtronic CoreValve. The vast majority of the patients were in New York Heart Association functional class III/IV (91.7%). Valve post-dilation after TAVR was attempted in 18 patients (75.0%), either at the time of index procedure (15 of 18) or just before the PVR closure procedure (3 of 18), and 1 patient had undergone valve-in-valve procedure (4.2%) at the time of the index procedure. Figure 1 describes the main estimated cause of PVR. Table 2 summarizes the procedural details. The procedures were performed under general anesthesia in 13 of 27 patients (48.2%), deep sedation in 7 (25.9%), and local anesthesia in 7 (25.9%). Transesophageal echocardiography was used in 20 procedures (74.1%) and intracardiac echocardiography in 1. Overall, 22 procedures (81.5%) were performed with retrograde approach from the aorta and 5 (18.5%) via antegrade transseptal approach. Different catheters (4- to 6-F) were used to cross the leak, and various devices (6 to 15 mm) were deployed (Table 2). Considering the single procedures, transcatheter PVR closure was successful in 24 of 27 cases (88.9%); final success (including multiple procedures in 2 patients) was

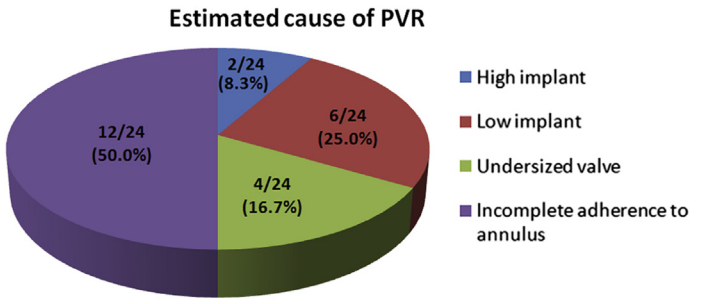
TABLE 1 Baseline Characteristics (N = 24)

Demographics	
Age, yrs	80.6 ± 7.1
Male	18 (75.0)
Clinical history	
Diabetes	10 (41.7)
Hypertension	22 (91.7)
Previous myocardial infarction	8 (33.3)
Previous coronary artery bypass graft	4 (16.7)
Previous cardiac surgery	4 (16.7)
Previous cerebrovascular accident	5 (20.8)
Chronic obstructive pulmonary disease	5 (20.8)
Surgical risk	
STS score, %	6.6 ± 3.9
Logistic EuroSCORE, %	23.5 ± 20.1
Porcelain aorta	7 (29.2)
Inoperable	21 (87.5)
High-risk	3 (12.5)
TAVR device	
Medtronic CoreValve	11 (45.8)
Edwards Sapien	13 (54.2)
Access route for TAVR	
Transfemoral	18 (75.0)
Transapical	5 (20.8)
Subclavian	1 (4.2)
Clinical presentation	
NYHA II	2 (8.3)
NYHA III	16 (66.7)
NYHA IV	6 (25.0)
Echocardiography	
AR grade after TAVR	
Grade 2	1 (4.2)
Grade 3	10 (41.7)
Grade 4	13 (54.2)
LVEF before PVR closure	54 ± 13
Post-dilation after TAVR	18 (75.0)
Valve-in-valve after TAVR	1 (4.2)

Values are mean ± SD or n (%).

AR = aortic regurgitation; EuroSCORE= European System for Cardiac Operative Risk Evaluation; LVEF = left ventricle ejection fraction; NYHA = New York Heart Association; PVR = paravalvular regurgitation; STS = Society of Thoracic Surgery; TAVR = transcatheter aortic valve replacement.

FIGURE 1 Causes of PVR



Main mechanism of paravalvular regurgitation (PVR) estimated on the basis of available imaging.

achieved in 22 of 24 patients (91.7%). In 1 procedure, the attempt to cross the leak with the wire was unsuccessful; in another case, the transcatheter valve was displaced supra-annularly during the attempt to cross the leak. The embolized valve was immediately repositioned using an inflated balloon in the descending aorta and a second larger valve was then successfully implanted in the correct position. A third patient had a residual PVR grade 3 (baseline grade 4). Devices used were as follow: Amplatzer Vascular Plug 2, 3, or 4 (St. Jude Medical, St. Paul, Minnesota) in 20 procedures (80%); Ventricular Septal Defect occluder (St. Jude Medical) in 4 (16%); and the Azur HydroCoil (Terumo Corporation, Tokyo, Japan) was attempted in 1 where it was not successful. In 6 cases (22.2%), 2 devices were necessary to obtain a good procedural result. Average procedural duration was 86 ± 62 min, with a total amount of contrast dye of 89 ± 74 cc (range 0 to 300 cc; 4 cases were accomplished without contrast and 11 with <50 cc). There were 8 serious periprocedural complications (29.7%): 1 minor stroke without residual deficit (24 h after the procedure, in a patient with recurrent cerebrovascular accidents and severe not treatable bilateral carotid stenosis); 1 serious bleeding

TABLE 2 Procedural Characteristics of Transcatheter Closure of PVR

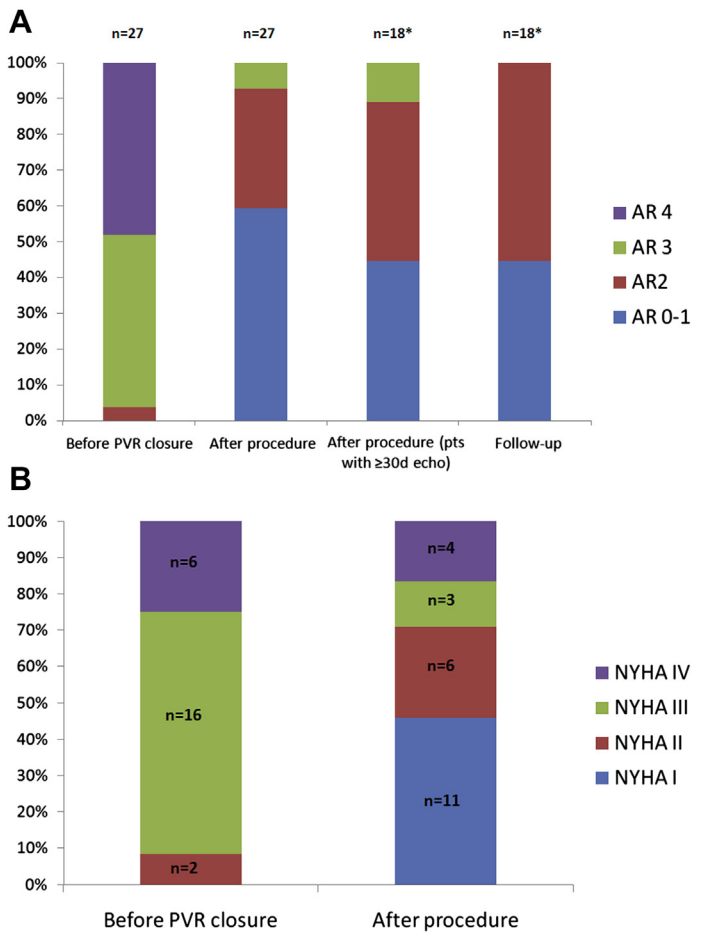
ID #	Annulus Size (TTE) (mm)	TAVR Type	Valve Size (mm)/Route	Location of PVR	Mechanism of PVR	Balloon Post-Dilation	Days After TAVR	Closure Device	Guiding Catheter	Device Size(s) (mm)
1	23	CoreValve	26/TF	Anterior	Low implant	Yes	803	AVP 2	AL1 6-F	8
2	20	CoreValve	29/SCL	Anterior	Low implant	No	685	AVP 4	AL1 6-F	6/8
3	26	CoreValve	29/TF	Anterior/posterior	IAA	Yes	740	AVP 4	MP 5-F	8
4	22	Sapien	23/TF	Posterior	IAA	Yes	742	AVP 4	MP 6-F	8
5	26	CoreValve	29/TF	Anterior	Low implant	No	715	AVP 2	MP 6-F	8
6	24	Sapien	26/TA	Anterior	Undersized	Yes	37	AVP 2	MP 6-F	6/8
7	22	Sapien	23/TA	Anterior	Undersized	Yes	1,409	AVP 2	MP 5-F	8/10
8	21	Sapien	26/TA	Anterior/posterior	Low implant	No	30	AVP 2	AL2 6-F	6
9*	23	Sapien	26/TA	Anterior/posterior	Low implant	Yes	55	AVP 2	AL2 6-F	12
10*	23	Sapien	26/TA	Posterior	—	—	86	Azur Terumo Coil	AL2 6-F	15
11*	23	Sapien	26/TA	Posterior	—	—	177	VSD	AL1 6-F	8
12	21	Sapien	23/TA	Anterior/posterior	IAA	Yes	3	VSD	AL2 6-F	10
13	21	Sapien	26/TF	Anterior/posterior	IAA	Yes	43	AVP 2	AL2 4-F	12
14	23	Sapien	26/TF	Concentric and central	IAA	Yes	253	VSD	AL1 6-F	10
15*	21	Sapien	26/TF	Posterior/anterior	High implant	Yes	142	AVP 2	AL2 6-F	12
16*	21	Sapien	26/TA	Posterior	—	—	177	N/A	N/A	N/A
17	23	Sapien	26/TF	Posterior	High implant	No	17	VSD	AL3 6-F	8
18	24	Sapien	26/TF	Anterior/posterior	IAA	Yes	607	AVP 2	AL2 6-F	6
19	22	CoreValve	29/TF	Posterior/	Low implant	No	869	AVP 4	AL1 5-F	5
20	18.5	CoreValve	26/TF	Anterior	IAA	Yes	98	AVP 3	AL1 5-F	3
21	24	CoreValve	29/TF	Anterior/posterior	IAA	Yes	10	AVP 4	AL1 5-F, JR4 5-F	4/5
22	19.5	CoreValve	27/TF	Anterior/posterior	IAA	Yes	27	AVP 3	JR4 5-F	5
23	29.5	CoreValve	31/TF	Anterior	IAA	Yes	21	AVP 2, AVP 3	MP 5-F/ AL1 5-F	4/5
24	26	Sapien	26/TF	Posterior	IAA	No	758	AVP 3	JR4 5-F	5
25	29	CoreValve	29/TF	Posterior	IAA	Yes	36	AVP 4	MP 6-F	12
26	20	Sapien XT	20/TF	Posterior	Undersized	Yes	54	N/A	N/A	N/A
27	24	Sapien XT	26/TF	Posterior	Undersized	Yes	74	AVP 2	Destiny Terumo 7-F	8/10

*Multiple procedures in the same patient.

AL = Amplatz left; AVP = Amplatzer Vascular Plug; F = French; IAA = incomplete adherence to the annulus; JR = Judkins right; MP = multipurpose; N/A = not available (unsuccessful procedure); SCL = subclavian; TA = transapical; TF = transfemoral; TTE = transthoracic echocardiography; VSD = Ventricular Septal Defect Occluder; — = same patient as above; other abbreviations as in Table 1.

(3.7%) (pulmonary hemorrhage); 3 cases of acute kidney injury stage 3 (11.1%); 2 cases of ventilator-associated pneumonia; and 1 valve embolization. No serious vascular complications were observed. The acute and mid-term procedural results evaluated with echocardiography are shown in Figure 2A. Before the procedure, 13 patients had grade 4 AR, 13 had grade 3, and 1 patient had grade 2 AR. After the procedure there were no patients with AR grade 4, 2 (7.4%) with AR grade 3, 9 (33.3%) with grade 2, and 16 with grades 0 and 1 (59.3%). Remarkably, the 2 patients with AR grade 3 after the procedure showed an AR grade 2 during follow-up. Functional status changes between PVR closure and the time of the last follow-up are described in Figure 2B. During an average follow-up of 12.3 ± 11.4 months (range 0 to 31 months), 11 patients expired: 3 were deaths of cardiovascular origin (2 worsening heart failure, 1 endocarditis); and 8 were from noncardiovascular causes. Among deaths of noncardiovascular origin, 3 were procedure-related (1 acute renal failure, 2 ventilator-associated pneumonia and respiratory failure) and 5 were not procedure-related (1 late acute renal failure, 1 cancer, 1 clostridium difficile infection, 2 progressive senescence). Of importance, post-procedure AR grade was ≤2 in all patients who died, including those who died because of worsening heart failure. Cumulative survival at 1, 6, and 12 months was 83.3%, 66.7%, and 61.5% (Figure 3), respectively. At 2-year follow-up, cumulative survival was 55.4%.

FIGURE 2 Changes in AR and Functional Status After the Procedure



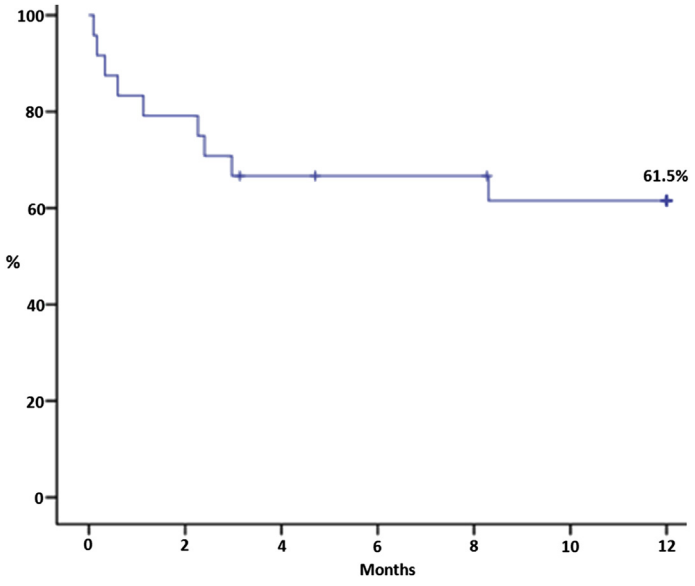
(A) Aortic regurgitation (AR) assessed with echocardiography before paravalvular regurgitation (PVR) closure, after the procedure, and during follow-up. For a reliable comparison of post-procedural and follow-up results, only paired data for patients with at least 1 evaluation >30 days **(*)** were included (18 patients, average timing of echocardiography 8.8 ± 7.7 months, range 1 to 27 months. Exclusions: 3 deaths in <30 days, 1 patient with valve-in-valve procedure, 2 patients without echocardiography at >30 days). **(B)** New York Heart Association (NYHA) functional class before and after PVR closure procedure in the 24 patients. For patients with multiple procedures, functional status was assessed after the last procedure.

DISCUSSION

We describe the long-term outcome of percutaneous closure of clinically relevant paravalvular aortic regurgitation after TAVR. The principal findings of our study can be summarized as follows: 1) percutaneous closure of PVR after TAVR is a complex, not standardized procedure, which carries sizable risks; 2) the procedure can be accomplished with high success rates and is associated with an improved functional status in many patients, but the overall clinical efficacy remains to be demonstrated. There was a high rate of serious periprocedural complications and high mortality during follow-up; and 3) the reduction of AR seems stable or even reduced during follow-up.

Several cases of successful use of various occluder devices have been described for transcatheter closure of PVR post-TAVR. In previous reports, we described both antegrade and retrograde transcatheter PVR closure with different devices and using different guiding catheters (13–15). We highlighted a number of potential drawbacks, including the difficulty crossing the PVR space with the wire, the failure to advance the guiding catheters through the struts of the valve on the aortic side, the need to shift approaches, and the risk of device embolization (14). The present study confirms that percutaneous closure of PVR is a complex and customized procedure. Different patient management strategies were used in this series including type of anesthesia, guiding catheters to cross the leak, and closure devices. The preferred devices were the Amplatzer Vascular Plugs, which are a family of braided-nitinol self-expanding devices

FIGURE 3 12-Month Survival After the Procedure



Kaplan-Meier cumulative survival after paravalvular regurgitation closure.

designed for transcatheter vessel embolization. Of interest, in 7 of 27 cases (26%), the procedure was performed under local anesthesia without echocardiography guidance. Multiple closure devices were used less frequently in comparison to post-surgical PVR closure series (23). This may be due to the smaller extent of leakage in transcatheter prostheses or to the more limited space available in between the prosthetic valve frame and native structures.

The rate of periprocedural complications was significant (29.7%), and acute kidney injury was the most frequent complication. This observation discourages the use of contrast dye during the procedure in this fragile cohort of patients. Indeed, in 4 cases, no contrast was used, suggesting the feasibility of this strategy. In 1 case, there was displacement of the previously implanted transcatheter valve, which was successfully managed by repositioning the valve in the descending aorta and implanting a second larger valve in the annulus. It is important to note the challenge of passing a delivery sheath through highly irregular spaces that may lead to valve dislodgement. The ability to use smaller diagnostic catheters to deliver occluder devices across PVR may certainly reduce this risk. The low profile Amplatzer Vascular Plug 4 is compatible with 0.038-inch diagnostic catheters and recently Feldman et al. (17) described 6 cases of successful transcatheter PVR closure after using Edwards Sapien prosthesis with 4- to 5-F catheters. There were 2 cases that suffered from ventilator-associated pneumonia that led to respiratory failure and death. Hence, avoiding general anesthesia and use of a retrograde approach should be strongly considered especially in severely compromised patients.

In terms of efficacy, PVR grade was significantly reduced in most of the patients (**Figure 2**), and these results seemed durable. The mortality rate at follow-up was high, but in most of the cases, deaths were due to noncardiac causes and related to the severe comorbidities. The high rate of mortality, however, may still raise concerns. We did not have a reliable control population, so it is difficult to estimate the true impact of our procedures on the final outcome. Previous studies reported 1-year mortality rates between 30% and 70% in patients with moderate-to-severe AR after TAVR (24–29). Considering available data and the fact that 87.5% of our patients were deemed inoperable, in many instances because of comorbidity other than that captured by surgical scores, the fatality rate of our series seems more justifiable.

Significant PVR may be detected and treated both during the TAVR procedure or later on, as was done in the cases reported herein. Different treatment strategies may be preferred based on the timing of detection and the cause of PVR. In our series, the most common (50%) cause of PVR after TAVR was incomplete adherence of the inflow aspect of the prosthesis to the aortic annulus. Severe native valve calcifications may cause incomplete/asymmetrical expansion of the frame, and bulky calcifications may interfere with the adherence of the prosthesis to the annulus. In such cases, post-dilation appears to be very effective in reducing the degree of AR (8). Excessive post-dilation should however, be avoided to prevent leaflets damage and consequent severe central regurgitation. Another risk of post-dilation is annular rupture that, although infrequent, may be fatal. When post-dilation is not effective and there is a residual focal PVR, the use of a closure device may be considered.

The second most frequent (25%) mechanism of PVR in our study was low implantation of the prosthesis or part of the prosthesis. In such cases, a part of the sealing pericardial skirt of the prosthesis is located below the virtual annular ring of the annulus, leaving an open communication between the aorta and the left ventricle (13). In these cases, post-dilation is generally not useful. Minimal repositioning by pulling the valve with the snare technique is possible but is often ineffective and potentially dangerous (10). A possible solution is the

implantation of a second valve within the first one: the valve-in-valve technique (9). This procedure is very effective, has a favorable procedural outcome, and should probably be preferred when severe AR is manifest at the end of TAVR procedure. Our study suggests that transcatheter PVR closure may be considered as an alternative to a second TAVR procedure when valve-in-valve is not performed during the first procedure, as long as there is a focal area where a device can be of use. High implantation of the prosthetic valve was a less frequent event in our series, maybe because it is less amenable to transcatheter treatment described herein. Post-dilation maybe helpful in these cases; however, valve-in-valve is the best treatment, especially for high implants with risk of embolization. The second prosthesis should preferably be a balloon-expandable valve, because it is required to be implanted in a lower position, whereas with the self-expandable prosthesis, the outflow tract may remain underexpanded into the first prosthesis.

Another relevant mechanism of PVR after TAVR is annulus/prosthesis mismatch, that is, implantation of an undersized prosthesis in relation to the aortic annulus (30). Preventing incongruence between the aortic annulus and the device is of paramount importance; hence, multimodality assessment of the aortic annulus size is recommended before TAVR. Previous studies provided the evidence for a more reliable measurement of aortic annulus and less PVR by using 3-dimensional cross-section computed tomography-scan assessment (31). Post-dilation may be attempted in these cases, and only if there is a focal residual PVR should a closure device could be considered.

STUDY LIMITATIONS. This is a small, retrospective study and the use of closure devices for treatment of PVR was off-label, driven by the clinical necessity. The lack of a comparison group makes it difficult to estimate the benefit of the procedure beyond the impact on AR severity and reported changes in functional status. Larger experience will be needed to confirm safety and efficacy of this procedure. New sizing strategies, which include multimodality imaging of the aortic annulus and computed tomography measurement of annular diameters, perimeter, and area will likely help decrease the incidence of severe PVR. Next-generation valves have been designed to address the limitations of the first-generation devices, including features to reduce PVR such as sealing skirts or cuffs and the ability to reposition. This may change the incidence, the need, and the technique to close PVR (32,33).

CONCLUSIONS

The present study illustrates the potential role of transcatheter PVR closure after TAVR with placement of occluder devices and reports the long-term outcome of this procedure. Although the procedural success rate was high, procedural complications were common. Long-term outcome was strongly influenced by noncardiac mortality, making the interpretation of clinical efficacy more difficult. Overall, our data suggest that percutaneous PVR closure can be adopted in selected patients and performed by expert operators with acceptable long-term outcomes.

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PERSPECTIVES

PVR is common after TAVR and is associated with a worse clinical outcome. Management of clinically relevant PVR is challenging: although anecdotal cases of percutaneous treatment with closure devices adapted from other indications have been reported, the procedure is not standardized and information about mid-term outcomes is lacking.

This multicenter study reports a series of cases of percutaneous PVR closure after TAVR, providing procedural details, echocardiographic results, and mid-term clinical outcome. This therapeutic option may be useful in selected patients, but further investigation and development of dedicated devices would be desirable.

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