Published in final edited form as:

Catheter Cardiovasc Interv. 2018 April 1; 91(5): 958–965. doi:10.1002/ccd.27318.

Paravalvular leak closure under intracardiac echocardiographic guidance

Neil Ruparelia, DPhil MRCP^{1,†}, Jacob Cao, BSc¹, James D. Newton, MD FRCP¹, Neil Wilson, MD^{1,2}, Matthew J. Daniels, PhD MRCP¹, and Oliver J. Ormerod, DM FRCP¹

¹Department of Cardiology, Oxford Heart Centre, John Radcliffe Hospital, Headley Way, Oxford OX3 9DU, United Kingdom

²Department of Paediatrics-Cardiology, Children's Hospital Colorado, Aurora, Colorado 80045

Abstract

Objectives—The objective of this study was to determine the safety and efficacy of intracardiac echocardiography (ICE) to guide percutaneous paravalvular leak (PVL) closure.

Background—PVL following surgical valve replacement occurs in 2%–15% of patients. Percutaneous treatment is an accepted management strategy in patients deemed to be too high risk for redo surgery. This is most commonly performed with transesophageal (TOE) guidance requiring general anesthesia that both potentially further increase the risk of intervention. ICE can be used to guide intervention, facilitating procedures to be performed under local anesthesia without esophageal intubation potentially making procedures shorter and safer and further enabling the treatment of patients that may have been turned down for intervention.

Methods—All patients that underwent ICE-guided percutaneous transcatheter PVL closure between 2006 and 2016 at the John Radcliffe Hospital, Oxford, United Kingdom were retrospectively analyzed.

Results—Twenty-one procedures were performed in 18 patients during the study period. Fourteen patients (77.8%) underwent successful ICE guided PVL closure. There were no ICE-related complications. Eleven patients (78.6%) reported symptomatic improvement of at least one New York Heart Association (NYHA) Class and the remaining 3 patients had no change. No patient demonstrated objective evidence of persistent hemolysis following successful closure. There was one death within 30 days of the procedure and 1 year survival was 71.4%.

Conclusions—Percutaneous paravalvular leak closure guided by ICE without the requirement of general anesthesia is feasible, safe, and associated with acceptable procedural success rates.

iDORCID

Neil Ruparelia DPhil MRCP <http://orcid.org/0000-0003-3968-2750>

Correspondence: Dr Oliver Ormerod, John Radcliffe Hospital, Headley Way, Oxford OX3 9DU, United Kingdom. oliver.ormerod@ouh.nhs.uk.

Disclosure Statement

Nothing to report.

Keywords

aortic valve disease; intracardiac echocardiography; mitral valve disease; paravalvular leak; structural heart disease intervention

1 Introduction

Paravalvular leak (PVL) occurs in 2%–15% of patients following surgical valve replacement [1] with PVL following mitral valve surgery three times more common than aortic valve surgery [2]. Frequently, PVL is mild and noted incidentally at routine follow-up with no clinical sequelae [3,4]. However, some patients progress and develop congestive heart failure, symptomatic hemolysis, or a combination of both. The presence of moderate to severe PVL is an independent risk factor for mortality [5].

Redo surgery remains the treatment of choice [6,7]; however, this is complicated by technical challenges, variable outcomes, and high preoperative risk [8,9]. More recently, percutaneous closure has become an established and accepted alternative therapeutic strategy for the management of this patient group and is associated with advantages including shorter procedure times, avoidance of repeat sternotomy, and faster recovery [10–14].

Percutaneous PVL closure is typically performed with transesophageal (TOE) guidance under general anesthesia. However, in this high-risk patient group, both general anesthesia and TOE may be associated with significant additional risk (e.g., due to the presence of significant lung disease) or contraindicated (e.g., presence of esophageal varices) independent of the PVL closure procedure itself. Intracardiac echocardiography (ICE) provides high-resolution real-time imaging without the requirement for general anesthesia or esophageal intubation and for septal defect closure has been associated with shorter procedure and fluoroscopic times [15]. Its use in a frailer PVL closure cohort, therefore, is particularly attractive. Data to support its use for this indication are limited to single case reports [16]. Accordingly, we examined the acute and longer term outcomes of a large patient series that underwent ICE-guided PVL closure at our institution.

2 Materials and Methods

2.1 Study population

All patients that underwent ICE-guided percutaneous transcatheter PVL closure between 2006 and 2016 at the John Radcliffe Hospital, Oxford, United Kingdom were retrospectively analyzed. All patients were confirmed to have moderate or severe PVL on the basis of echocardiography in combination with attributable congestive cardiac failure and/or significant hemolysis on the basis of clinical examination and laboratory investigation. Hemolytic anemia was defined as a hemoglobin <10 g/dL with evidence of hemolysis (abnormalities on blood smear, raised lactate dehydrogenase, high reticulocyte count, low haptoglobin) requiring blood transfusions with no other cause of blood loss. Aortic leak locations were described in relation to the location of anatomical coronary cusps. Mitral leaks were described by the use of the “clock-face” system in the “surgical view” as

previously described [10,17]. Patients did not routinely undergo preprocedural computed tomography and/or TOE. All patients were discussed by the “Heart Team” prior to proceeding to percutaneous intervention. ICE guided intervention was decided upon either when TOE was contraindicated, when general anesthesia was deemed to be of high-risk or when unavailable at short notice due to logistic reasons. Written informed consent was obtained from all patients following explanation of all treatment options and procedure-related risks, according to the Declaration of Helsinki. All clinical data during follow-up were collected from hospital visits or telephone consultation.

2.2 Procedure

ICE guidance was typically performed from an RA or RV view. Following insertion of a 9 French (Fr) femoral venous sheath under local anesthesia, ICE images were obtained using an ACUSON AcuNav ultrasound catheter (Siemens Medical Solutions, USA, Inc., Mountain View, CA). ICE guidance was used to visualize the PVL, guide transseptal puncture (if required), aid in device selection and sizing, determine residual PVL prior to definitive device deployment and detect periprocedural complications.

Techniques employed to close PVL are in accordance with those previously published [10,11]. For periaortic leaks (Figure 1), a retrograde approach was generally performed via the femoral artery. The defect was crossed under ICE and fluoroscopic guidance with steerable diagnostic coronary catheters (e.g., multipurpose, Amplatz left 1 (AL1)) and 0.035' guidewire. For perimitral leaks (Figure 2), a transseptal puncture was performed via the femoral vein under ICE and fluoroscopic guidance for more lateral leaks (6–10 o'clock on clock face) where an antegrade approach was felt preferable. With the aid of a steerable sheath in the left atrium, the defect was crossed with a 0.0350 wire. For leaks that were located on the septal side (2–4 o'clock on clock face), a retrograde approach was usually employed; however, each case was evaluated individually and the final route and technique employed was at the operator's discretion. In both cases, following crossing of the defect, a larger delivery sheath was advanced and over a stiff wire (e.g., Amplatzer Super Stiff wire) through which the device was advanced and deployed. The choice of device was based on the anatomic size and location of the leak and functional assessment of residual leak with ICE in situ and angiography prior to definitive deployment. PVL was graded semiquantitatively (grade 0: none; grade 1: mild; grade 2: moderate; grade 3: moderate-severe, severe) accepting the limitations of current technology [18]. If the initial device was not fully occlusive, the decision was made to exchange the device for a larger one or to implant additional small devices. In each case, prosthetic valve function was evaluated prior to deployment of the device.

2.3 Clinical follow-up

All patients were evaluated postprocedure clinically and with transthoracic echocardiography (TTE) prior to discharge and all complications were recorded. All patients were reviewed regularly by clinic visits. Specifically, information with regards to New York Heart Association (NYHA) class, residual leak, device embolization, presence of hemolytic anemia, requirement for blood transfusion, occurrence of stroke or myocardial infarction,

and bacterial endocarditis was noted. For patients that died during the follow-up period, the cause of death was ascertained by review of the clinical record.

2.4 Statistics

Continuous variables are expressed as mean $\pm$ standard deviation (SD). Normality of each continuous variable was tested with the Kolmogorov–Smirnov test. Categorical variables are presented as numerical values and percentages. Analyses were performed with SPSS version 21.0 (SPSS Inc., Chicago, IL) and GraphPad Prism version 5.0 (Graph-Pad, San Diego, CA).

3 Results

3.1 Patient population

Of a total of 94 PVL procedures performed between 2006 and 2016 at the John Radcliffe Hospital, Oxford, United Kingdom, a total of 21 procedures were performed in 18 patients under ICE guidance. The patient demographics (61.1% male, mean age: 73.4 ± 7.6 years) are summarized in Table 1.

All patients presented with signs and symptoms consistent with congestive cardiac failure and in addition 4 patients (22.2%) demonstrated objective evidence of active hemolysis. There were no signs of active infection in any patient prior to closure. As expected, the estimated operative mortality was high (logistic EuroSCORE: 23.6 ± 12.3 , Society of Thoracic Surgeons (STS); mortality estimate: 4 ± 2.2).

3.2 Procedural success

All procedures were performed under local anesthesia with ICE guidance and are summarized in Table 2. At total of 21 ICE-guided PVL closures were attempted in 18 patients during the study period with leaks in biological prostheses (33.3%) and mechanical prostheses (66.6%). Eleven patients (61.1%) were treated for para-aortic PVL and 7 patients (38.9%) were treated for paramitral PVL.

First-time technical success (defined by a reduction of PVL to <moderate) was achieved in 13 (72.2%) patients. The five patients that were unsuccessfully treated with ICE-guided closure occurred early in our experience. Two patients returned electively and were successfully treated with TOE guided percutaneous closure without further complication. One patient suffered a device embolization following deployment of a 14×5 mm Amplatzer vascular plug III to treat a para-aortic leak in to the left ventricle. We were unable to retrieve this percutaneously, and the patient proceeded to successful emergency cardiac surgery and made an uncomplicated recovery. We were unable to cross a para-aortic defect in one patient in spite of excellent visualization with ICE, the patient was managed medically with redo surgery deemed too high-risk. In one patient, we initially attempted an antegrade approach for a lateral paramitral leak, but in spite of excellent visualization and multiple attempts at positioning a device, we were unable to obtain an acceptable position without valve interference. The initial procedure was therefore abandoned but was successfully treated under ICE guidance via a retrograde approach and the implantation of a 5×4 mm duct occluder.

There were two periprocedural vascular complications that were self-resolving and required no further intervention. There were no periprocedural instances of acute myocardial infarction, stroke, or death and no ICE-related complications. Procedure times were 86 ± 33 min for para-aortic leak closure and 120 ± 94 min for paramitral leak closure.

3.3 Follow up

Of the 14 patients (77.8%) that ultimately underwent successful ICE-guided PVL closure, median follow-up was 1,025 days (interquartile range: 129–1640 days). At 30-day follow-up, one patient died following paramitral PVL closure. The procedure was acutely successful with reduction of the regurgitation to mild; however, the patient developed cardiogenic shock that did not resolve in spite of maximal circulatory support and the patient died during the index hospital admission with no evidence of interference of prosthetic valve function on the basis of echocardiography. Postmortem demonstrated the device in situ with no evidence of other myocardial, structural damage, or device embolization as a cause for the clinical presentation. There were no instances of stroke, myocardial infarction, or further vascular complication. Eleven patients (78.6%) reported symptomatic improvement and the remaining 2 patients no change. No patient demonstrated objective evidence of persistent hemolysis.

During longer term follow-up, two patients were noted to have further progression in PVL following closure associated with a deterioration in symptoms attributable to heart failure. One patient was successfully treated with redo ICE-guided PVL closure, while we were unable to successfully treat the recurrent PVL percutaneously in the second patient who was treated medically due to the risk of surgical repair being too high. One patient presented at 6 month follow-up with increasing breathlessness, echocardiography demonstrated a recurrence of the PVL and late embolization of the device into the iliac artery that was successfully retrieved. A repeat percutaneous closure attempt under general anesthesia and TOE guidance was unsuccessful and this patient was also medically treated. Five patients (35.7%) died during the follow-up period, and survival at 1 year was 71.4%.

4 Discussion

The principal findings of this study are as follows: (1) ICE-guided PVL closure is feasible with an acceptable procedural success rate associated with an improvement in symptoms. (2) ICE-guided PVL closure is safe with no ICE-related complications reported. (3) Failure with this approach does not preclude attempted closure with another approach. (4) There is a learning curve associated with the use of ICE, with improved success rates and shorter procedure times with greater experience.

PVL occurs in a reported 2%–15% of patients following surgical valve replacement [1]. Percutaneous closure is now an accepted alternative treatment option to redo surgery for symptomatic patients [10–14] that often present with multiple co-morbidities. This is most commonly performed with TOE guidance that requires GA that itself is associated with increased procedural risk.

ICE performed via a dedicated catheter has been demonstrated to be useful in both the diagnosis of cardiac pathology [19,20] and also in the guidance of a number of cardiac interventions including transseptal puncture [21], patent foramen ovale closure [22], atrial septal defect closure [22], ventricular septal defect closure [23], electrophysiology ablation [24], and left atrial appendage occlusion [25]. There have previously been single case reports demonstrating the potential of ICE in PVL closure [16], we here report a large single-center case series. The first-time procedural success rate in our case series was 72.2% with an overall success rate of 77.8% that is similar to previously reported larger case series that used TOE and GA to guide percutaneous closure [10,11]. Furthermore, there were no complications associated with the use of ICE confirming safety in addition to efficacy of this approach.

There did appear to be a “learning curve” with regards to ICE use for this indication, with a greater failure rate early on in our reported case series. With greater operator experience, we achieved improved rates of procedural success in combination with shorter procedure times. In the setting of a failed procedure, the use of ICE in the index procedure did not preclude either a further attempt with the same approach or a reattempt with the aid of GA and TOE guidance.

ICE is versatile and can provide adequate image quality but is limited by reduced depth penetration that can limit visualization of certain cardiac structures. With regards to aortic valve imaging, placement of the ICE catheter in the right atrium provided adequate visualization in the majority of cases, with placement in the right ventricle helpful in a minority of cases (Figure 3). Mitral valve imaging is more challenging with ICE particularly for lateral leaks, and whilst again catheter placement in the right atrium is often adequate, placement in the right ventricle or even the left atrium can enable better visualization of the anatomy (Figure 3) [20]. Using these approaches, we were able to use ICE to guide both para-aortic and paramitral PVL closure when both antegrade and retrograde techniques were utilized (Figures 1 and 2). However, in spite of these man oeuvres, there was one patient who was unable to adequately visual the PVL that was a lateral paramitral defect (patient 3). The patient, however, did return for successful closure under GA and TOE guidance. Finally, the cost of the current single-use catheter is a limitation; however, this is partially offset by reduction in the need of additional staff (e.g., anesthetist) and shorter procedure times.

ICE technology has been limited to two-dimensional and color Doppler assessment of regurgitant jets alone and by restrictions as to where the catheter can be safely positioned. However, recent advances have enabled real-time three-dimensional/volume imaging [26], may facilitate more frequent use with better visualization and interrogation of the anatomy of interest, and likely associated increases in procedural success rates into the future [27].

We here demonstrate the safety and efficacy of ICE-guided percutaneous closure and reported the largest case series to date. In the future, with greater operator experience, procedure success rates may further improve in addition to better case selection for this approach and most importantly cases where this approach may not be associated with procedural success (e.g., lateral paramitral leaks).

4.1 Study limitations

This was a retrospective study and the decision to utilize ICE to guide PVL closure was decided by the team on a case-by-case basis and so the impact of selection bias with regards to procedural success rates cannot be excluded. The patient numbers are relatively small and therefore did not allow for statistical analysis to determine predictors of positive procedural and clinical outcomes. We were unable to determine the effect of acute procedural success upon long-term outcomes.

5 Conclusion

Percutaneous PVL closure guided by ICE without the requirement of general anesthesia is feasible, safe, and associated with acceptable procedural success rates.

References

- [1]. Ionescu A, Fraser AG, Butchart EG. Prevalence and clinical significance of incidental paraprosthetic valvar regurgitation: A prospective study using transoesophageal echocardiography. *Heart*. 2003; 89:1316–1321. [PubMed: 14594888]
- [2]. Garcia E, Sandoval J, Unzue L, Hernandez-Antolin R, Almeria C, Macaya C. Paravalvular leaks: Mechanisms, diagnosis and management. *EuroIntervention*. 2012; 8:Q41–Q52. [PubMed: 22995111]
- [3]. O'Rourke DJ, Palac RT, Malenka DJ, Marrin CA, Arbuckle BE, Plehn JF. Outcome of mild periprosthetic regurgitation detected by intraoperative transesophageal echocardiography. *J Am Coll Cardiol*. 2001; 38:163–166. [PubMed: 11451267]
- [4]. Rallidis LS, Moyssakis IE, Ikonomidis I, Nihoyannopoulos P. Natural history of early aortic paraprosthetic regurgitation: A five-year follow-up. *Am Heart J*. 1999; 138:351–357. [PubMed: 10426851]
- [5]. Eleid MF, Cabalka AK, Malouf JF, Sanon S, Hagler DJ, Rihal CS. Techniques and outcomes for the treatment of paravalvular leak. *Circ Cardiovasc Intervent*. 2015; 8:e001945.
- [6]. Genoni M, Franzen D, Vogt P, et al. Paravalvular leakage after mitral valve replacement: Improved long-term survival with aggressive surgery? *Eur J Cardio-Thorac Surg*. 2000; 17:14–19.
- [7]. Pinheiro CP, Rezek D, Costa EP, et al. Paravalvular regurgitation: Clinical outcomes in surgical and percutaneous treatments. *Arq Bras Cardiol*. 2016; 107:55–62. [PubMed: 27305109]
- [8]. Taramasso M, Maisano F, Denti P, et al. Surgical treatment of paravalvular leak: Long-term results in a single-center experience (up to 14 years). *J Thorac Cardiovasc Surg*. 2015; 149:1270. [PubMed: 25648478]
- [9]. Akins CW, Bitondo JM, Hilgenberg AD, Vlahakes GJ, Madsen JC, MacGillivray TE. Early and late results of the surgical correction of cardiac prosthetic paravalvular leaks. *J Heart Valve Dis*. 2005; 14:792–799. [PubMed: 16359061]
- [10]. Ruiz CE, Jelnin V, Kronzon I, et al. Clinical outcomes in patients undergoing percutaneous closure of periprosthetic paravalvular leaks. *J Am Coll Cardiol*. 2011; 58:2210–2217. [PubMed: 22078427]
- [11]. Sorajja P, Cabalka AK, Hagler DJ, Rihal CS. Percutaneous repair of paravalvular prosthetic regurgitation: Acute and 30-day outcomes in 115 patients. *Circ Cardiovasc Intervent*. 2011; 4:314–321.
- [12]. Garcia E, Arzamendi D, Jimenez-Quevedo P, et al. Outcomes and predictors of success and complications for paravalvular leak closure. An analysis of the Spanish real-world paravalvular LEaks closure registry (HOLE registry). *EuroIntervention*. 2016
- [13]. Nietlispach F, Maisano F, Sorajja P, Leon MB, Rihal C, Feldman T. Percutaneous paravalvular leak closure: Chasing the chameleon. *Eur Heart J*. 2016; 37:3495–3502. [PubMed: 27161614]

- [14]. Angulo-Llanos R, Sarnago-Cebada F, Rivera AR, et al. Two-year follow up after surgical versus percutaneous paravalvular leak closure: A non-randomized analysis. *Cathet Cardiovasc Intervent*. 2016; 88:626–634.
- [15]. Bocciaandro F, Baptista E, Muench A, Carter C, Smalling RW. Comparison of intracardiac echocardiography versus transesophageal echocardiography guidance for percutaneous transcatheter closure of atrial septal defect. *Am J Cardiol*. 2004; 93:437–440. [PubMed: 14969617]
- [16]. Sharma M, Tseng E, Schiller N, Moore P, Shunk KA. Closure of aortic paravalvular leak under intravascular ultrasound and intracardiac echocardiography guidance. *J Invasive Cardiol*. 2011; 23:E250–E254. [PubMed: 21183776]
- [17]. De Cicco G, Russo C, Moreo A, et al. Mitral valve periprosthetic leakage: Anatomical observations in 135 patients from a multicentre study. *Eur J Cardio-Thorac Surg*. 2006; 30:887–891.
- [18]. Zoghbi WA, Enriquez SM, Foster E, et al. Recommendations for evaluation of the severity of native valvular regurgitation with two-dimensional and Doppler echocardiography. *J Am Soc Echocardiogr*. 2003; 16:777–802. [PubMed: 12835667]
- [19]. Neelankavil J, Chua J, Howard-Quijano K, Mahajan A. Intracardiac echocardiography. *J Cardiothorac Vasc Anesth*. 2015; 29:502–505. [PubMed: 25649699]
- [20]. Asrress KN, Mitchell AR. Intracardiac echocardiography. *Heart*. 2009; 95:327–331. [PubMed: 19176565]
- [21]. Shalaganov TN, Paprika D, Borbas S, Temesvari A, Szili TT. Preventing complicated transseptal puncture with intracardiac echocardiography: Case report. *Cardiovasc Ultrasound*. 2005; 3:5. [PubMed: 15737242]
- [22]. Luxenberg DM, Silvestry FE, Herrmann HC, Cao QL, Rohatgi S, Hijazi ZM. Use of a new 8 French intracardiac echocardiographic catheter to guide device closure of atrial septal defects and patent foramen ovale in small children and adults: Initial clinical experience. *The J Invasive Cardiol*. 2005; 17:540–545. [PubMed: 16204749]
- [23]. Cao QL, Zabal C, Koenig P, Sandhu S, Hijazi ZM. Initial clinical experience with intracardiac echocardiography in guiding transcatheter closure of perimembranous ventricular septal defects: Feasibility and comparison with transesophageal echocardiography. *Cathet Cardiovasc Intervent*. 2005; 66:258–267.
- [24]. Hijazi ZM, Shivkumar K, Sahn DJ. Intracardiac echocardiography during interventional and electrophysiological cardiac catheterization. *Circulation*. 2009; 119:587–596. [PubMed: 19188519]
- [25]. Matsuo Y, Neuzil P, Petru J, et al. Left atrial appendage closure under intracardiac echocardiographic guidance: Feasibility and comparison with transesophageal echocardiography. *J Am Heart Assoc*. 2016; 5
- [26]. Brysiewicz N, Mitiku T, Haleem K, et al. 3D real-time intracardiac echocardiographic visualization of atrial structures relevant to atrial fibrillation ablation. *JACC Cardiovasc Imag*. 2014; 7:97–100.
- [27]. Patzelt J, Schreieck J, Camus E, Gawaz M, Seizer P, Langer HF. Percutaneous mitral valve edge-to-edge repair using volume intracardiac echocardiography - first in human experience. *Cardiovasc Imag Case Rep*. 2017; 1:41–43.

Figure 1.

Percutaneous closure of a para-aortic leak guided by intracardiac echocardiography. Baseline aortography (A) demonstrating severe para-aortic regurgitation and appearance on ICE (white arrow, B). With the ICE catheter positioned in right atrium (yellow arrow, C) and fluoroscopic (C) and ICE guidance (D), initial 14 × 5 mm Amplatzer vascular plug (AVP) III deployed. In view of residual leak, second 8 × 4 mm AVP III deployed guided by fluoroscopy (E) and ICE (F). Final aortography (G) demonstrated excellent final result with

mild residual aortic regurgitation and final appearance on ICE (H) [Color figure can be viewed at wileyonlinelibrary.com]

Figure 2.

Percutaneous closure of a para-mitral leak guided by intracardiac echocardiography (ICE). Baseline ICE appearance of mitral valve prosthesis (white arrow, A) and leak (B) with ICE catheter positioned in left atrium (yellow arrow, C). Initial placement of 8 mm ventricular septal defect occluder via anterograde approach resulted in obstruction of mitral valve leaflet (D) and so retrieved and procedure abandoned. Second attempt via retrograde approach (E) ICE catheter positioned in right ventricle (yellow arrow, E) and appearance of mitral valve appearance (white arrow, F). Amplatzer 5 × 4 mm duct occluder deployed (G) with no

compromise of valve function (H). Final fluoroscopic appearance (I) and on ICE (J) demonstrated minimal residual leak and compromise of prosthetic valve function [Color figure can be viewed at wileyonlinelibrary.com]

Figure 3.

Appearance of aortic and mitral valve with different ICE catheter positions. Appearance of aortic valve when ICE catheter is positioned in the standard right atrium position (A) and when placed in the right ventricle in the short-axis (B) and long-axis (C) views. Mitral valve appearance when ICE catheter is positioned in the standard right atrium position (D) and when placed in the right ventricle (E) and left atrium (F) [Color figure can be viewed at wileyonlinelibrary.com]

Table 1
Patient demographics (n = 18)

Characteristic	Value
Age	73.4 ± 7.6 years
Sex (male)	11 (61.1%)
Treated prosthesis type	
<i>Aortic</i>	11 (61.1%)
<i>Mitral</i>	7 (38.9%)
Presenting symptoms	
<i>Heart failure</i>	18 (100%)
<i>Hemolytic anemia</i>	9 (50%)
Coronary artery disease	8 (44.4%)
Renal failure (glomerular filtration rate <60 mL/min/1.73 m ²)	9 (50%)
Stroke	2 (11.1%)
Ejection fraction < 35%	0 (0%)
Atrial fibrillation	8 (44.4%)
Diabetes mellitus	2 (11.1%)
Peripheral vascular disease	2 (11.1%)
Previous procedures	
<i>Coronary artery bypass grafting</i>	5 (27.8%)
<i>Permanent pacemaker implantation</i>	4 (22.2%)
<i>2 previous sternotomies</i>	4 (22.2%)
Medications	
<i>Aspirin</i>	8 (44.4%)
<i>Warfarin</i>	12 (66.6%)
<i>Beta-blockers</i>	5 (27.8%)
<i>Digoxin</i>	4 (22.2%)
<i>Diuretics</i>	12 (66.6%)
<i>Angiotensin enzyme inhibitor</i>	8 (44.4%)
Logistic EuroSCORE	23.6% ± 12.3
Society of Thoracic Surgeons estimated mortality	4% ± 2.2

Table 2

Procedural details and outcomes

Patient	Valve	No. of leaks	Location of leak	Approach	Devices implanted	Acute success	Comments/complication	Residual leak	Procedure time (min)	Further intervention?
1	MM	1	10–2 ^a	Retrograde	8 mm VSD occluder (not deployed)	No	Unable to achieve stable device position	3	330	Successful GA TOE guided closure
2	AB	1	NCC	Retrograde	6 mm VSD occluder	Yes	None	1	85	No
3	MM	1	5–8 ^a	N/A	N/A	No	Unable to clearly visualize defect	3	100	Successful GA TOE guided closure
4	MB	1	2–4 ^a	Antegrade	6 mm VSD occluder	Yes	None	1	50	No
5	AM	1	LCC	Retrograde	14 × 5 mm AVP III (embolized)	No	Device embolization to left ventricle	3	50	Unable to retrieve device, emergency SAVR
6	MM	1	5–8 ^a	Antegrade	6 mm VSD occluder	Yes	Femoral hematoma	0	80	No
7	MM	1	2–4 ^a	Retrograde	14 × 5 mm AVP III	Yes	None	1	70	No
8	AM	1	NCC	Retrograde	N/A	No	Unable to cross defect	3	160	No medical treatment
9	AB	1	NCC	Retrograde	14 × 5 mm AVP III 12 × 5 mm AVP III	Yes	Femoral pseudoaneurysm	0	75	No
10	MM	1	5–8 ^a	Antegrade (ICE in LA)	8 mm VSD occlude (not deployed)	No	Not deployed due to valve interference	3	175	Repeat ICE-guided attempt (see below)
10 (repeat)	MM	1	5–8 ^a	Retrograde	5 × 4 mm duct occluder	Yes	None	1	100	No
11	AM	1	NCC	Retrograde	12 × 5 mm AVP III	Yes	None	2	120	No
12	AM	2	RCC LCC	Retrograde	14 × 5 mm AVP III 8 × 6 mm duct occluder	Yes	None	1	60	No
13	AB	1	RCC	Retrograde	14 × 5 mm AVP III	Yes	None	3	60	Deterioration in PVL during follow-up, further procedure (see below)
13 (repeat)	AB	1	RCC	Retrograde	14 × 5 mm AVP III (not deployed)	No	Not deployed due to valve interference	3	135	No medical treatment
14	AM	1	NCC	Retrograde	10 × 5 mm AVP III	Yes	None	2	75	No

Patient	Valve	No. of leaks	Location of leak	Approach	Devices implanted	Acute success	Comments/complication	Residual leak	Procedure time (min)	Further intervention?
15	MB		2-4 ^a	Retrograde	6 mm VSD occluder	Yes	None	2	50	No
16	AB	1	RCC	Retrograde	8 mm VSD occluder	Yes	None	1	65	No
17	AM	2	RCC LCC	Retrograde	14 × 5 mm AVP III 10 × 5 mm AVP III	Yes	None	1	100	No
18	AM	1	NCC	Retrograde	14 × 5 mm AVP III 8 × 4 mm AVP III	Yes	None	1	60	Deterioration in PVL during follow-up, further procedure (see below)
18 (repeat)	AM	1	NCC	Retrograde	12 × 5 mm AVP III	Yes	None	1	75	No

Abbreviations: AB, aortic bioprosthetic valve; AM, aortic mechanical prosthesis; AVP III, Amplatzer vascular plug III; AVP III, Amplatzer vascular plug III; GA, general anesthesia; LCC, left coronary cusp; MM, mitral mechanical prosthesis; MB, mitral bioprosthetic valve; N/A, not applicable; NCC, noncoronary cusp; RCC, right coronary cusp; SAVR, surgical aortic valve replacement; TOE, transesophageal echocardiography; VSD, ventricular septal defect.

^a As per “clock face” from surgical view of mitral valve [11,18].