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ORIGINAL ARTICLE

Trans-catheter paravalvular leak closure: a single-centre experience

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Abstract

Introduction A significant paravalvular leak (PVL) is estimated in at least 1–3% of patients undergoing surgical aortic and/or mitral valve replacement. Surgical repair of a PVL is associated with a 30-day mortality of approximately 10%. Percutaneous closure of PVL has emerged as an alternative to surgical repair.

Aim We sought to examine the clinical outcomes of patients treated with percutaneous closure of PVL at an Irish tertiary referral centre.

Methods A prospective registry was used to record patient and procedural characteristics at the time of the PVL procedure. Medical records were retrospectively reviewed to assess clinical outcomes during the index hospitalisation and at follow-up.

Results A total of 26 PVL procedures were performed in 21 patients (mean age 68 ± 13 years, 76% male). Heart failure (HF), haemolysis (HL) or a combination of both was the presenting symptoms in 62%, 24% and 14% of patients, respectively. In the entire cohort, clinical success was achieved in 18 patients (86%). Clinical success was achieved more frequently when HF was the clinical indication compared to HL (100% versus 66%). Among patients presenting with isolated HF ($n = 13$), the mean NYHA class at baseline and follow-up was 2.5± 0.7 and 1.4± 0.7, respectively. Thirty-day mortality was 0%. There was one (3.8%) major adverse procedural complication (stroke). A total of six deaths (28%) occurred during follow-up (22 ± 13.4 months).

Conclusions Patients with PVL represent a high-risk patient cohort. Percutaneous PVL offers a safe alternative to surgical PVL repair and appears particularly effective in those patients who present primarily with HF.

Keywords Paravalvular leak · Percutaneous intervention · Surgical valve replacement

Background

Paravalvular leak (PVL) can be a serious and challenging complication after surgical valve replacement and repair, or percutaneous valve implantation. The reported incidence of PVL is 7–17% post-mitral valve (MV) replacements, 5–10% post-aortic valve (AV) replacements and up to 25% post-trans-catheter aortic valve implantation (TAVI) [1–3]. Although most PVLs are small and asymptomatic, larger PVLs causing clinically significant heart failure and/or haemolysis can manifest in 1–3% of patients [4, 5]. Left untreated, larger PVLs have been associated with adverse cardiac outcomes [6, 7]. In TAVI recipients, a residual moderate to severe PVL has been shown to be associated with an increased risk of late mortality [3].

Traditionally, PVL closure was achieved with repeat sternotomy and valve replacement or repair.

Surgical re-intervention has been associated with significant morbidity and mortality and a high risk of PVL recurrence [8–11]. Percutaneous closure of PVLs has emerged as a less invasive strategy to traditional surgery, with lower complications rates and acceptable rates of clinical success [12, 13].

We sought to assess the clinical outcomes in a consecutive series of patients treated for PVL using percutaneous techniques since the inception of a percutaneous programme for PVL repair at an Irish tertiary referral hospital.

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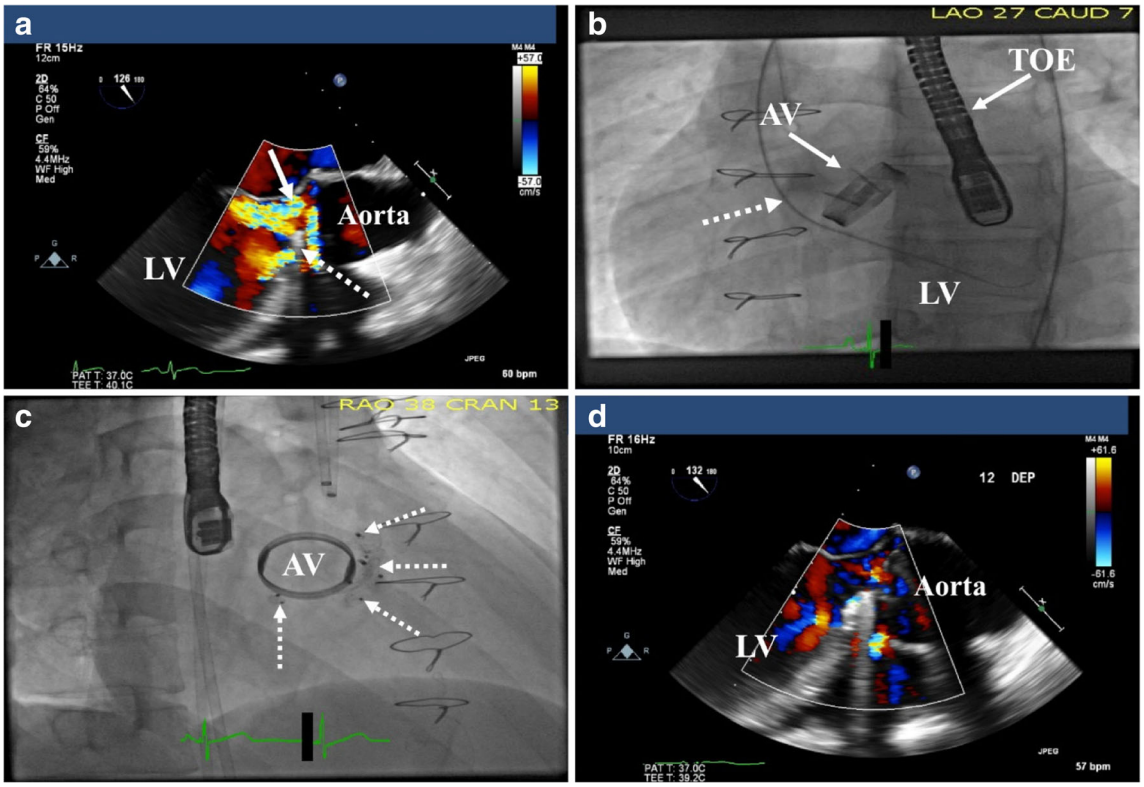

Fig. 1 Percutaneous aortic valve paravalvular leak closure. **a** Baseline trans-oesophageal (TOE) (parasternal view) of the aortic valve (dashed arrow) with colour Doppler showing multiple paravalvular leaks (arrows) causing severe aortic regurgitation. Left ventricle (LV). **b** Fluoroscopic image of the aortic valve (AV) during PVL procedure showing catheter crossing the paravalvular defect (interrupted arrow) into the left ventricle (LV). Trans-oesophageal echo probe (TOE). **c** Fluoroscopic image at the completion of the PVL procedure showing four PVL plugs (interrupted arrows) deployed around the aortic valve (AV). **d** Final TOE image (parasternal view) with colour Doppler at completion of PVL procedure showing residual trace PVL

Methods

Ethical approval for this study was obtained from the Research Ethics Committee, Mater Misericordiae University Hospital (Ref: 1/378/1881 TMR).

This was a retrospective observational study of all patients treated with percutaneous techniques for PVL at the Mater Misericordiae University and Mater Private Hospitals since the inception of a percutaneous PVL repair programme in 2012. The decision to employ a percutaneous approach was based on the outcome of the Heart Team meeting. Clinical and procedural data were prospectively entered into a database at the time of the procedure. Clinical outcomes were assessed based on a retrospective review of the medical record. Echocardiographic data was evaluated based on a review of echocardiographic studies and reports performed before, during and after the PVL procedure.

Definitions

Definitions for this study are in keeping with prior similar studies and a recent consensus statement defining outcomes following PVL repair [12, 14, 15]. Heart failure was defined as symptoms consistent with the New York Heart Association (NYHA) functional class ≥ II. Anaemia (Hb < 10 mg/dL) was considered to be haemolytic if other causes of anaemia were excluded and the serum level of lactate dehydrogenase was elevated (>600 units/L). The degree of PVL was defined as mild, moderate or severe. Technical success was defined as successful deployment of an occlusive device across the paravalvular leak without any interference with the valve prosthesis, or acute conversion to surgery. Procedural success was defined as technical success plus a significant reduction in regurgitation (i.e. ≥ 1grade). Clinical success was defined as a sustained improvement in NYHA by one or more functional class and/or an improvement in mechanical haemolysis allowing the patient to become transfusion free and improve symptomatically.

Procedure

All procedures were performed under general anaesthesia. Fluoroscopic and trans-oesophageal echocardiography (TOE) guidance was employed in all procedures. Supplementary transthoracic echocardiography (TTE) was used frequently, particularly for aortic PVL cases. All

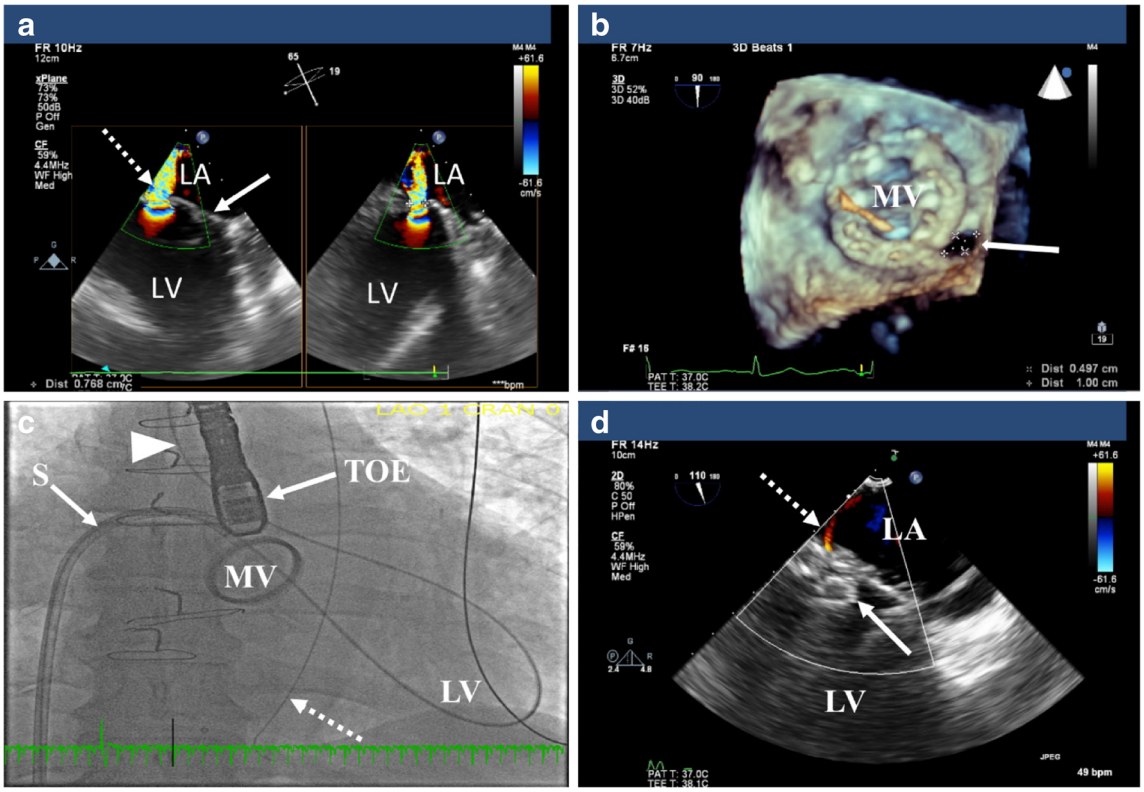

Fig. 2 Percutaneous mitral valve paravalvular leak closure. **a** Baseline trans-oesophageal (TOE) image of the mitral valve with colour Doppler showing severe paravalvular regurgitation (dashed arrow) adjacent to mechanical mitral valve (arrow). Left atrium (LA), left ventricle (LV). **b** Three-dimensional TOE image of the mitral valve (MV) as viewed from the left atrium showing a single large paravalvular leak (arrow) measuring 0.5 × 1 cm in diameter. **c** Fluoroscopic image during PVL procedure showing creation of an arteriovenous (AV) loop to facilitate delivery of paravalvular plug. The wire passed through the trans-septal sheath from the femoral vein and across the PVL into the left ventricle and subsequently across the aortic valve into the descending thoracic aorta. This wire was then externalised through the femoral artery completing the AV loop. Trans-septal sheath (S), left ventricle (LV), ascending aorta (arrow head), descending aorta (interrupted arrow). Trans-oesophageal echo probe (TOE). **d** TOE of the aortic valve with colour Doppler at completion of PVL procedure showing PVL device in position (arrow) and a trace of residual PVL (dashed arrow)

procedures were performed using anticoagulation with unfractionated heparin to achieve a target activated clotting time of > 250 s.

Aortic PVL A retrograde femoral artery approach was used in all aortic PVL cases. A hydrophilic coated Terumo™ guidewire (Terumo Cardiovascular, Tokyo) supported by a diagnostic catheter was passed retrogradely from the aorta through the target PVL into the left ventricle allowing delivery of a sheath through which an occluder device was delivered and deployed across the PVL (Figs. 1a–d).

Mitral PVL The majority of mitral PVL cases were performed using femoral venous access and trans-septal puncture allowing access to the left atrium. The mitral PVL was then crossed using an antegrade approach using a hydrophilic wire that was directed toward the PVL using a range of steerable Agilis™ sheaths (St. Jude Medical, Minnesota) and diagnostic catheter types under TOE guidance**.** This allowed delivery of a sheath into the left ventricle through which an occluder device was delivered and deployed across the PVL (Fig. 2a–d). In half of cases, the hydrophilic wire was advanced from the left ventricle into the aorta and subsequently snared from the femoral arterial access, creating an arteriovenous loop to facilitate sheath delivery and device deployment (Fig. 2c). With the assistance of a cardiothoracic surgeon, a single mitral case was treated using trans-apical access in the left ventricle with the PVL being crossed in a retrograde fashion from the left ventricle into the left atrium.

Statistical analysis

Normally distributed data are presented as mean ± standard deviation (SD) and non-Gaussian data are presented as median ± interquartile range (IQR). Categorical data are presented as frequencies and percentages. Changes in PVL grade and NYHA class (ordinal data) between baseline and following attempted PVL closure were analysed using the Wilcoxon rank test. Survival estimates with 95% confidence intervals (CIs) were calculated using the Kaplan-Meier method.

Table 1 Patient demographic and clinical variables

	Total ($n = 21$), *N* (%)	AV* ($n = 12$), *N* (%)	MV* ($n = 9$), *N* (%)
Male	17 (80.1)	11 (91.2)	6 (66.7)
Age (mean ± SD) (years)	68 ± 13	64 ± 15	68 ± 10
Presentation			
Elective	18 (86)	9 (75)	9 (75)
Urgent	3 (14)	3 (25)	–
NYHA functional class** ($n = 18, 12, 6$)			
Class II	8 (44.4)	7 (58.3)	1 (16.7)
Class III	9 (50)	4 (33.3)	5 (83.3)
Class IV	1 (5.5)	1 (8.3)	–
Diabetes mellitus	5 (23.8)	1 (8.3)	4 (44.4)
Creatinine (> 200 μmol/L)	4 (19)	2 (16.7)	2 (22.2)
Anaemia (< 10 g/dl)	11 (52.3)	6 (50)	5 (55.5)
Left ventricular ejection fraction			
≥ 40%	15 (71.4)	7 (58.3)	8 (88.9)
30–39%	4 (19)	3 (25)	1 (16.7)
< 30%	2 (9.5)	2 (16.7)	–
Number of previous valve surgeries			
1	16 (76.2)	9 (75)	7 (77.8)
2	3 (14.3)	2 (16.7)	1 (11.1)
≥ 3	2 (9.5)	1 (8.3)	1 (11.1)
Duration since last valve operation			
Median [IQR] (years)	2.4 [0.9–5.1]	2.2 [0.9–4.5]	2.4 [0.9–5.8]
Principle indication for closure			
Heart failure	13 (61.9)	10 (83.3)	3 (33.3)
Both haemolysis and heart failure	5 (23.8)	2 (16.7)	3 (33.3)
Haemolysis	3 (14)	–	3 (33.3)
Valve type			
Bioprosthesis	7 (33.3)	5 (41.7)	2 (22.2)
Mechanical prosthesis	11 (52.4)	5 (41.7)	6 (66.7)
TAVI	2 (9.5)	2 (16.7)	–
Annuloplasty ring	1 (4.7)	–	1 (16.7)

*One patient with staged closure of mitral and aortic PVLs, included in MV group only

**NYHA (New York Heart Association) class in patients with symptomatic heart failure (± haemolysis)

AV aortic valve, *MV* mitral valve, *N* number, *SD* standard deviation, *IQR* interquartile, first-third quartile, *TAVI* trans-catheter aortic valve implantation

Statistical analysis was performed using the IBM SPSS 20 statistical software.

Results

A total of 21 patients were included in the study. Of this group, 20 patients were treated for PVL involving a single valve (either aortic or mitral) and one patient was treated for PVL of both the mitral and aortic valves. Therefore, a total of 22 PVLs were treated. A total of four patients required a repeat procedure following an initial failed attempt and the patient with PVL involving two valves underwent staged procedures, resulting in a total of 26 procedures for the cohort.

Patient factors

Baseline patient demographics are shown in Table 1. The mean age was 68 ± 13 years and 80% of patients were male. Most procedures were elective (86%). Heart failure without haemolysis was the most common indication for attempted PVL closure (62%). There was a fairly even representation of the mitral and aortic valves as the target for PVL closure. Mechanical valves were more commonly treated compared to tissue valves (52.4% versus 33.3%). An Edwards Sapien XT

Table 2 Procedural variables ($n = 26$)

	AV PVL ($n = 14$), N (%)	MV PVL ($n = 12$), N (%)
Sheath size (French) [median [IQR]]	7 [6–10]	10 [8–12]
Number of defects targeted for closure ($n = 44$)		
1	6 (42.8%)	8 (66.6%)
2	6 (42.8%)	1 (8.3%)
3	1 (7.1%)	1 (8.3%)
≥ 4	1 (7.1%)	2 (16.7%)
Deployment success		
Yes	13 (92.8%)	10 (83.3%)
No (unable to cross defect with wire)	–	1 (8.3%)
No (unable to cross defect with sheath)	–	1 (8.3%)
Other*	1 (7.1%)	–
Number of devices implanted ($n = 47$)		
0	–	2 (16.7%)
1	4 (28.6%)	6 (50%)
2	7 (50%)	2 (16.7%)
3	2 (14.3%)	1 (8.3%)
4	1 (7.1%)	1 (8.3%)
Type of device implanted		
AVP II	7	7
AVP III	12	12
AVP IV	1	4
Occulotech PLD	–	1
Procedure time (minutes), median [IQR]	140 [90–210]	150 [140–200]
Screening Time (minutes), median [IQR]	45 [18–62]	53 [36–73]
Total x-ray dose (cGy cm^2), median [IQR]	32,000 [9800–75,700]	31,500 [12,100–70,000]

AV aortic valve, *MV* mitral valve, *PVL* paravalvular leak, *N* number, *TAVI* trans-catheter aortic valve implantation, *IQR* interquartile range (first to third quartile), *AVP* Amplatzer™ vascular plug (SJM, Plymouth, MN), *PLD* paravalvular leak device (Occlotech™, Jena, Germany). *Additional leak identified; procedure abandoned due prolonged radiation exposure

TAVI valve (Edwards LifeSciences, Irving, CA) was the target in two patients (9.5%).

Procedural variables

Procedural variables are shown in Table 2. Closure devices were successfully deployed in all patients undergoing aortic PVL closure except for one patient who required a second procedure to successfully treat the PVL. In the mitral cohort, PVL closure devices were not deployed in two of the nine patients during an initial attempt at PVL closure. In one of the patients, successful deployment was subsequently achieved using trans-apical access, and the second patient was successfully treated using a trans-septal approach using a large Occlulotech™ paravalvular leak device (PLD) that was not available during the initial procedure. Therefore, ultimately, PVL closure devices were deployed in all patients.

Table 3 Procedure complications

Minor	Major
Device embolisation requiring retrieval ($n = 2$)	Stroke* ($n = 1$)
Pseudoaneursym of CFA ($n = 1$)	
Acute limb ischaemia ($n = 1$)	
VT requiring cardioversion ($n = 1$)	

VT ventricular tachycardia, *CFA* common femora artery. *Stroke type—internuclear ophthalmoplegia

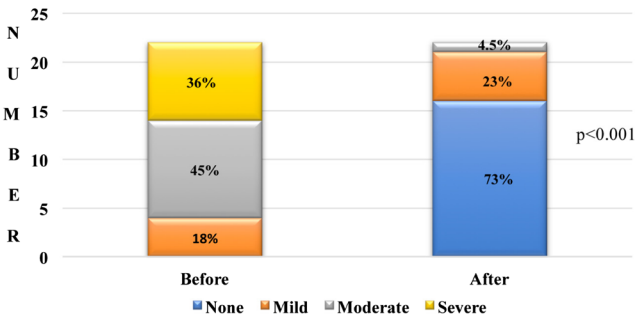

Fig. 3 Leak severity before and after attempted percutaneous PVL closure in 22 treated valves

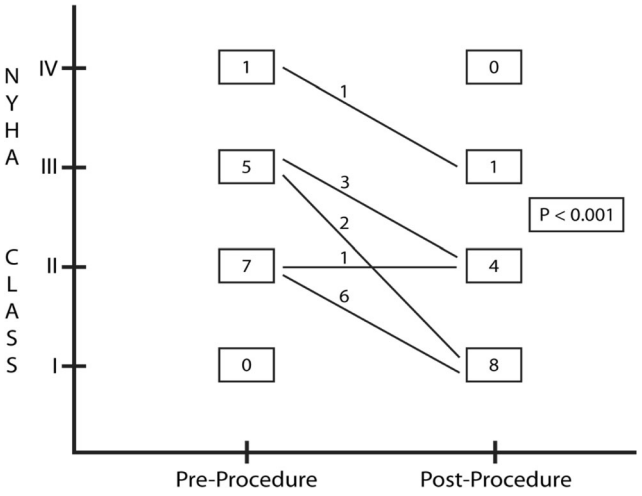

Fig. 4 NYHA class before and after attempted percutaneous PVL closure in 13 patients with isolated symptomatic heart failure

The mean number of PVL defects treated per procedure was 1.8 ± 1.3 and the mean number of plugs used per procedure was 1.7 ± 1.0 (range 0–4). With a single exception, vascular plugs from the Amplatzer™ vascular plug family (AVP II, III and IV) (St Jude Medical, Plymouth, MN) were the devices used, with the AVP III being the most popular. There was no significant difference in procedural times, x-ray screening time and radiation dose between patients undergoing aortic or mitral PVL closure.

Procedural complications

Procedure complications are shown in Table 3. There were no procedure-related deaths. A total of one major and five minor procedure-related complications occurred.

One patient suffered an ischaemic stroke within 24 h of the procedure which manifested clinically as an internuclear ophthalmoplegia. Symptoms from this event resolved after 2 weeks. A single patient developed ventricular tachycardia during a mitral PVL repair due to irritation of the left ventricle from the interventional wire that required cardioversion. There was no adverse consequence of this event. There were two arterial access complications. A right common femoral artery dissection caused by a suture-mediated closure device occurred in one patient that resulted in acute limb ischaemia at the completion of the PVL closure procedure. This was successfully treated with endovascular intervention. A second patient developed a small pseudoaneurysm of the left common femoral artery which resolved with conservative management. Device embolisation occurred in two patients during the procedure. In one case, the device embolised to the left ventricle and in the other patient, the device embolised to the right common iliac artery. Both were successfully retrieved using endovascular techniques with no adverse consequence.

Echocardiographic outcomes (22 treated valves)

Pre-procedure echocardiography demonstrated severe, moderate and mild regurgitation in 8 (36%), 10 (45%) and 4 (18%) cases, respectively. At most recent follow-up with echocardiography, 16 (73%) patients had trivial or no visible regurgitation of the treated valve, while 5 patients (23%) had mild regurgitation and a single patient (4.5%) had moderate regurgitation. Leak severity for the whole cohort significantly improved after attempted percutaneous PVL occlusion ($p < 0.001$) (Fig. 3).

Clinical outcomes

Clinical success (i.e. improvement in NYHA class ≥ 1 and/or effective treatment of haemolysis) was ultimately (i.e. following repeat procedures when required) achieved in 18

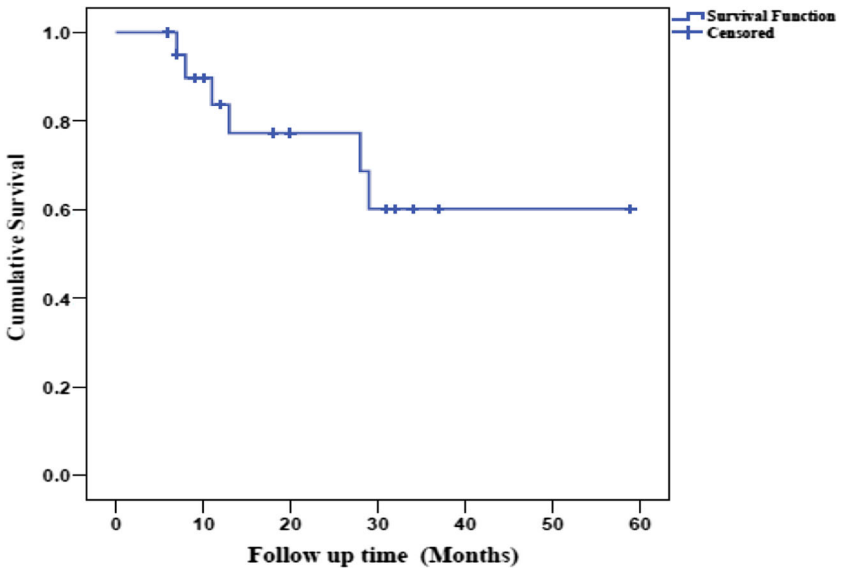

Fig. 5 The Kaplan-Meier estimate of survival free from death

of the 21 (86%) patient cohort. Among the patients with isolated aortic PVL and isolated mitral PVL and the single patient with combined aortic and mitral PVL, clinical success was achieved in 10 (91%), 7 (78%) and 1(100%) patients, respectively.

Clinical success varied based on the clinical indication for PVL closure. For patients with isolated heart failure, clinical success was achieved in all 13 (100%) patients. The mean NHYA class values at baseline were 2.5 ± 0.7 and 1.4 ± 0.7 at most recent follow-up ($p < 0.001$) (Fig. 4). In patients with isolated haemolysis, clinical success was achieved in two of three patients (66%); one patient ultimately required a surgical valve replacement. No patient developed new haemolysis requiring transfusion as a consequence of PVL closure. In the group with both heart failure and haemolysis, clinical success was achieved in three of five patients (60%), with failure being caused by persistent haemolysis in one patient and intractable heart failure in the other.

Survival

The mean follow-up for the cohort was 22 ± 13.4 months. There were no deaths within 30 days of the PVL procedure. There were six deaths (28.6%), occurring at a mean of 16 ± 10 months following the final PVL procedure. The mechanism of death was judged to be cardiac-related in five patients and non-cardiac (infectious) in the remaining patient. In one case, the death was felt to be directly related to failure to successfully treat the PVL. This patient had a failed attempt at mitral PVL closure for treatment of combined haemolysis and heart failure. The patient had three prior mitral valve replacements and was not felt to be candidate for re-do surgery and ultimately died from heart failure related to paravalvular mitral regurgitation. A Kaplan-Meier plot for survival free from all-cause mortality is shown in Fig. 5.

Discussion

This study reports the first published experience of percutaneous treatment of PVL at an Irish medical centre. In a modest-sized cohort of 21 patients, clinical success was ultimately achieved in 18 patients (86%), with no procedure-related mortality and a low rate of complications.

Safety of percutaneous PVL closure

The current series underscores the safety of percutaneous PVL closure. Most importantly, there were no deaths within 30 days of any attempted procedure in this cohort. This compares favorably with other larger series that have reported 30-day mortality rates of 1.7–4.5% with percutaneous PVL closure [11–13, 16]. Given that surgical series have reported 30-day mortality rates for surgical PVL closure of 6.9–10.7%, it is not surprising that percutaneous PVL closure is emerging as the primary strategy of choice for patients with PVL, with surgical PVL closure being reserved for those who fail or have unfavorable anatomy for percutaneous PVL closure [9, 11].

The minor complications encountered in the series related to two access site complications that were managed using endovascular and conservative strategies, respectively, and embolisation of two devices that were also retrieved percutaneously. A single patient required cardioversion for treatment of ventricular tachycardia induced by a wire in the left ventricle. The single stroke that occurred fortunately manifested as an internuclear ophthalmoplegia with a resolution of neurological symptoms after 2 weeks. Overall, therefore, there were no long-term adverse consequences of any of the minor or major complications in this series.

Impact of clinical indication on clinical outcomes

Clinical success was achieved in all 13 of the patients with heart failure as the clinical indication for PVL closure compared to 5 of the 8 (63%) patients with either isolated haemolysis or the combination of haemolysis and heart failure as the clinical indication. This finding is consistent with prior studies and underscores the technical challenge of treating PVL-related haemolysis where complete or near-complete seal of the PVL is often required to eliminate the jet causing mechanical haemolysis [17, 18]. In treating PVL-related heart failure, even modest reductions in the PVL are associated with improvements in NYHA class. Hence, the bar for achieving clinical success in this patient subgroup is easier to achieve. This consideration also explains the lower clinical success rate when treating mitral PVL compared to aortic PVL, since mitral PVL is much more likely to cause haemolysis.

Complexity of PVL closure—a case for specialist centres

Percutaneous PVL closure procedures are generally complex with an average procedure time of nearly 2.5 h in this cohort. While the majority of aortic cases are performed using a retrograde approach using arterial access, and mitral cases are performed using a trans-septal approach, a broad range of interventional skills are required to deal with the range of technical challenges that can arise in attempting percutaneous PVL closure. For example, a trans-apical approach was required in one of the current cohort to allow closure of multiple mitral PVLs that could not be accessed using the trans-septal approach. The creation of an arteriovenous loop was required in half of the mitral valve cohort in order to allow delivery of the sheath across the PVL through which the PVL plug is delivered. Percutaneous retrieval of two embolised devices and endovascular management of one significant vascular

access site complication also helped to mitigate the morbidity of the procedure for the cohort. In addition to the technical challenges outlined, all of the cases in the current cohort were supported by high-level TOE imaging guidance that included 3D TOE during mitral PVL closure procedures.

The technical and imaging demands of percutaneous PVL closure would strongly argue for centralisation of services in the Irish context. Previous studies have clearly shown a learning curve with percutaneous PVL closure [19]. Although it would be anticipated the adoption of percutaneous PVL closure will increase in time, it would be expected that procedural volumes for this procedure in Ireland will remain modest, and hence, concentration of experience to specialist referral centre(s) should help optimise patient outcomes.

Conclusions

This study documented the safety and efficacy of percutaneous PVL closure as a primary strategy for treatment of PVL at a specialist referral centre in Ireland. Clinical success rates for patients with heart failure as the presenting symptom were superior to those with haemolysis as a significant component of the clinical presentation.

Compliance with ethical standards

Ethical approval for this study was obtained from the Research Ethics Committee, Mater Misericordiae University Hospital (Ref: 1/378/1881 TMR).

Conflict of interest The authors declare that they have no conflict of interest.

References

1. Hammermeister K, Sethi GK, Henderson WG, Grover FL, Oprian C, Rahimtoola SH (2000 Oct) Outcomes 15 years after valve replacement with a mechanical versus a bioprosthetic valve: final report of the Veterans Affairs randomized trial. J Am Coll Cardiol 36(4):1152–1158
2. Ionescu A, Fraser AG, Butchart EG (2003) Prevalence and clinical significance of incidental paraprosthetic valvar regurgitation: a prospective study using transoesophageal echocardiography. Heart 89(11):1316–1321
3. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Kapadia S, Dewey T, Babaliaros V, Szeto WY, Williams MR, Kereiakes D, Zajarias A, Greason KL, Whisenant BK, Hodson RW, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG (2016) Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 374(17):1609–1620
4. Miller DL, Morris JJ, Schaff HV et al (1995) Reoperation for aortic valve periprosthetic leakage: identification of patients at risk and results of operation. J Heart Valve Dis 4(2):160–165
5. Jindani A, Neville EM, Venn G et al (1991) Paraprosthetic leak: a complication of cardiac valve replacement. J Cardiovasc Surg 32(4):503–508
6. Cho IJ, Hong GR, Lee S, Chang BC, Ha JW, Chung N (2014) Predictors of prognosis in patients with mild to moderate paravalvular leakage after mitral valve replacement. J Card Surg 29(2):149–154
7. Genoni M, Franzen D, Vogt P, Seifert B, Jenni R, Künzli A, Niederhäuser U, Turina M (2000) Paravalvular leakage after mitral valve replacement: improved long-term survival with aggressive surgery? Eur J Cardiothorac Surg 17(1):14–19
8. Rihal CS, Sorajja P, Booker JD, Hagler DJ, Cabalka AK (2012) Principles of percutaneous paravalvular leak closure. JACC Cardiovasc Interv. 5(2):121–130
9. Taramasso M, Maisano F, Denti P, Guidotti A, Sticchi A, Pozzoli A, Buzzatti N, de Bonis M, la Canna G, Alfieri O (2015) Surgical treatment of paravalvular leak: long-term results in a single-center experience (up to 14 years). J Thorac Cardiovasc Surg 149(5):1270–1275
10. Angulo-Llanos R, Sarnago-Cebada F, Rivera AR, Elízaga Corrales J, Cuerpo G, Solis J, Gutierrez-Ibañes E, Sanz-Ruiz R, Vázquez Álvarez ME, Fernandez-Avilés F (2016 Oct) Two-year follow-up after surgical versus percutaneous paravalvular leak closure: a non-randomized analysis. Catheter Cardiovasc Interv 88(4):626–634
11. Wells JAT, Condado JF, Kamioka N et al (2017 Mar 13) Outcomes after paravalvular leak closure: transcatheter versus surgical approaches. JACC Cardiovasc Interv. 10(5):500–507
12. Sorajja P, Cabalka AK, Hagler DJ, Rihal CS (2011 Aug) Percutaneous repair of paravalvular prosthetic regurgitation: acute and 30-day outcomes in 115 patients. Circ Cardiovasc Interv 4(4): 314–321
13. Calvert PA, Northridge DB, Malik IS, Shapiro L, Ludman P, Qureshi SA, Mullen M, Henderson R, Turner M, Been M, Walsh KP, Casserly I, Morrison L, Walker NL, Thomson J, Spence MS, Mahadevan VS, Hoye A, MacCarthy PA, Daniels MJ, Clift P, Davies WR, Adamson PD, Morgan G, Aggarwal SK, Ismail Y, Ormerod JOM, Khan HR, Chandran SS, de Giovanni J, Rana BS, Ormerod O, Hildick-Smith D (2016) Percutaneous device closure of paravalvular leak: combined experience from the United Kingdom and Ireland. Circulation 134(13):934–944
14. Taramasso M, Maisano F, Latib A, Denti P, Guidotti A, Sticchi A, Panoulas V, Giustino G, Pozzoli A, Buzzatti N, Cota L, de Bonis M, Montorfano M, Castiglioni A, Blasio A, la Canna G, Colombo A, Alfieri O (2014) Conventional surgery and transcatheter closure via surgical transapical approach for paravalvular leak repair in high-risk patients: results from a single-centre experience. Eur Heart J Cardiovasc Imaging 15(10):1161–1167
15. Ruiz CE, Hahn RT, Berrebi A, Borer JS, Cutlip DE, Fontana G, Gerosa G, Ibrahim R, Jelnin V, Jilaihawi H, Jolicoeur EM, Kliger C, Kronzon I, Leipsic J, Maisano F, Millan X, Nataf P, O'Gara PT, Pibarot P, Ramee SR, Rihal CS, Rodes-Cabau J, Sorajja P, Suri R, Swain JA, Turi ZG, Tuzcu EM, Weissman NJ, Zamorano JL, Serruys PW, Leon MB (2017) Clinical trial principles and endpoint definitions for paravalvular leaks in surgical prosthesis: an expert statement. J Am Coll Cardiol 69(16):2067–2087
16. Garcia E, Arzamendi D, Jimenez-Quevedo P et al (2017) Outcomes and predictors of success and complications for paravalvular leak closure: an analysis of the SpanisH real-wOrld paravalvular LEaks closure (HOLE) registry. EuroIntervention 12(16):1962–1968
17. Sorajja P, Cabalka AK, Hagler DJ, Rihal CS (2011 Nov 15) Long-term follow-up of percutaneous repair of paravalvular prosthetic regurgitation. J Am Coll Cardiol 58(21):2218–2224
18. Sorajja P, Bae R, Lesser JA et al (2015) Percutaneous repair of paravalvular prosthetic regurgitation: patient selection, techniques and outcomes. Heart 101(9):665–673
19. Sorajja P, Cabalka AK, Hagler DJ, Rihal CS (2014) The learning curve in percutaneous repair of paravalvular prosthetic regurgitation: an analysis of 200 cases. JACC Cardiovasc Interv 7(5):521–529