Percutaneous Closure of Perivalvular Leaks with Amplatzer® Occluders: Feasibility, Safety, and Short-Term Results

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Background and aim of the study: **Perivalvular leak (PVL) may have significant hemodynamic and/or hematological consequences, and re-do surgery is associated with considerable mortality and morbidity. Herein are reviewed the short-term results of percutaneous closure of PVLs using the Amplatzer® occluder.**

Methods: **Eleven patients (five males, six females; mean age 59.7 ± 7.3 years; range: 46-67 years) were referred for percutaneous closure of PVL using the Amplatzer occluder. Patients presented with congestive heart failure (n = 2), hemolysis (n = 1), or both (n = 8). The average number of previous heart operations was 2.4 ± 1.3 per patient; seven patients had undergone two or more operations. The procedure was performed under general anesthesia, with fluoroscopic and transesophageal echocardiographic guidance. Antegrade and retrograde approaches were used for the mitral and aortic leaks, respectively.**

Results: **The PVLs were in the mitral position (n = 8), aortic position (n = 1), or both (n = 2). Device deployment was achieved in 11 (91.7%) of 12 attempted valves (10 patients, 90.9%). Failure to cross the leak with the wire occurred in one patient, and interruption of mitral leaflet movement occurred in two patients. Leakage was decreased in six patients (60%), but residual leak was observed at 10 of the 11 sites. Hemolysis was reduced in four patients, increased in four, and remained unchanged in two. An improved NYHA functional class of one grade was noted in five patients. One patient required a second operative session to seal a residual leak.**

Conclusion: **Percutaneous closure of PVL using the Amplatzer occluder is feasible, but technically demanding. Although symptoms were improved, there was an inconsistent effect on hemolysis. At present, the Amplatzer occluder should be reserved for poor surgical candidates.**

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Perivalvular leak (PVL) is a common occurrence after valve surgery, with intraoperative jets being detected typically in 17.6% of cases after aortic valve replacement (AVR), and in 22.6% after mitral valve replacement (MVR) (1). These leaks usually remain unchanged or have disappeared by the time of follow up examination. In one transesophageal echocardiography (TEE) study conducted within an intensive care unit, at 2 h after the completion of surgery, periprosthetic jets were detected in 6% of patients after AVR, and in 32% after MVR (2). Although these jets are usually small, and do not have clinically important sequelae, PVL may be the cause of serious complications in the form of severe hemolytic anemia necessitating frequent blood transfusions. Moreover, if the leak is large then congestive heart failure (CHF) may ensue.

The incidence of significant PVL has been shown to vary according to patient selection in several series. For example, it may be associated with the suturing technique, to a diseased annulus as a result of infective endocarditis, to heavy calcification, or to previous surgery. Nowadays, an immediate postoperative leak is seldom encountered due to the widespread use of intraoperative TEE. Consequently, re-do surgery for PVL is rarely required, and has been indicated in less than 5% of patients with prosthetic valves (3-5). Mortality in valve reoperation is in the order of 10% (6-11). Residual leak is not infrequent (12).

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Recently, it was proposed to conduct the percutaneous closure of PVLs by using an occluder device. This technique was first reported in 1992 by Hourihan et al., who successfully closed two peri-aortic leaks using Rashkind devices. An additional procedure was abandoned due to the crescent shape of the leak (13). The details of several single case reports and one complete series were published during the early 2000s, usually with clinical improvement (14-21). Herein is summarized the authors' experience with percutaneous closure of PVL, using Amplatzer® ventricular septal defect (VSD), patent ductus arteriosus (PDA) or atrial septal defect (ASD) occluders.

Clinical material and methods

Patients

Between June 2003 and December 2006, 11 patients (five males, six females; mean age 59.7 ± 7.3 years; range: 46 to 67 years) were offered percutaneous closure of a PVL. In order to be included in the study, patients were required to have suffered from at least moderate PVL, complicated by significant CHF (NYHA functional class ≥3), severe hemolysis requiring frequent blood transfusions, or both. Percutaneous PVL closure was considered after local cardiac surgeons deemed reoperation either unadvisable or prohibitively dangerous.

Patients with severe rocking of the valve, with more than two leakage sites, or with evidence of active infective endocarditis, were excluded from study.

All patients provided their informed consent before participating in the study.

Baseline echocardiography

Each patient underwent complete transthoracic echocardiography (TTE) and TEE, performed by experienced cardiologists. Echocardiography was conducted using a Sonos 5500 instrument (Hewlett Packard, Andover, MA, USA) fitted with a 3.7/5 or 4/7 MHz multiplane transducer (Phillips, Andover, MA, USA). The results of all studies were recorded on super-VHS tape. The echocardiographic findings were reviewed by at least four cardiologists (two echocardiographers, two invasive cardiologists), who agreed on the interpretation and eligibility for percutaneous closure of the PVLs.

Each leak was assessed for its vena contracta. Mitral leaks were considered moderate if the vena contracta was 3-7 mm, and severe if >7 mm. For aortic valves, the cut-off point between moderate and severe regurgitation was set at 6 mm. Additional supportive parameters to determine the severity of regurgitation were in accordance with the American Society of Echocardiography recommendations (22). For convenience, the degree of regurgitation was categorized as 1, 2 or 3 for mild, moderate or severe regurgitation, respectively. Intermediate degrees were termed 1.5 and 2.5 for mild-to-moderate and moderate-to-severe, respectively.

Intra-procedural echocardiography

TEE was performed continuously throughout the operative procedure to assess leakage location and

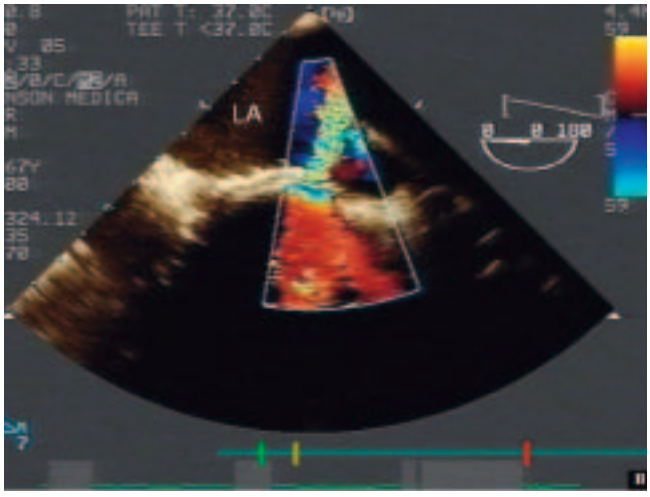

Figure 1: Mitral perivalvular leak, as demonstrated with transesophageal echocardiography.

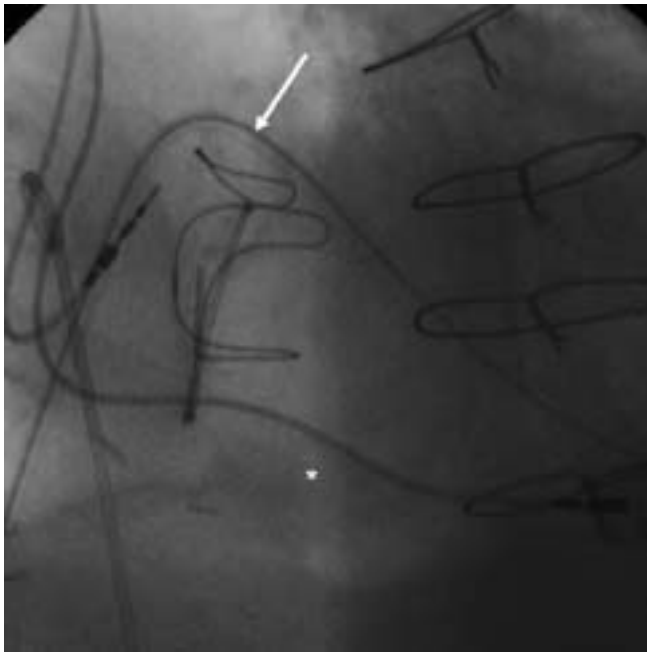

Figure 2: Fluoroscopy showing the sheath crossing the same leak, in a patient with mitral xenograft. The asterisk indicates a pacemaker wire.

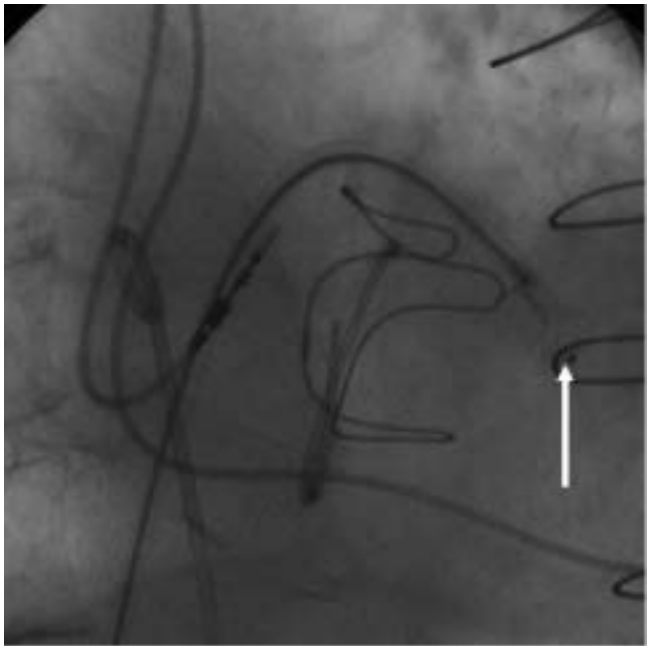

Figure 3: The distal edge of a patent ductus arteriosus occluder, which is open (arrow).

size, to direct the trans-septal puncture, for navigation of the wires and catheters, closure of the leak, deployment of the device, and for the assessment of any residual leak.

PVL closure

The majority of procedures were performed at the Rabin Medical Center, Petah Tiqva, Israel, and three at The CardioVascular Center, Frankfurt, Germany. All procedures were performed with the patient under general anesthesia. At least two interventional cardiologists and one echocardiologist participated in each case.

Closure of the peri-mitral defects was always attempted first, in antegrade fashion, via a trans-septal approach and using combined fluoroscopic and TEE guidance. The trans-septal puncture was performed using a Brockenbrough needle, with the Mullins introducer sheath/dilator set serving as a conduit. A diagnostic catheter (preferably right Judkins or Multipurpose) was inserted through the Mullins sheath and advanced towards the leak. Thereafter, a hydrophilic 0.035'' (0.9 mm) Terumo wire was advanced through the sheath and used to cross the leak. The catheter was advanced through the leak, and the wire was then exchanged for a stiff Amplatzer wire. The sheath was advanced over the wire, with the dilator being re-mounted if necessary. When the sheath had crossed the leak, the device was advanced and deployed. In the first five cases, contrast medium was injected to delineate the size and shape of the defect. In

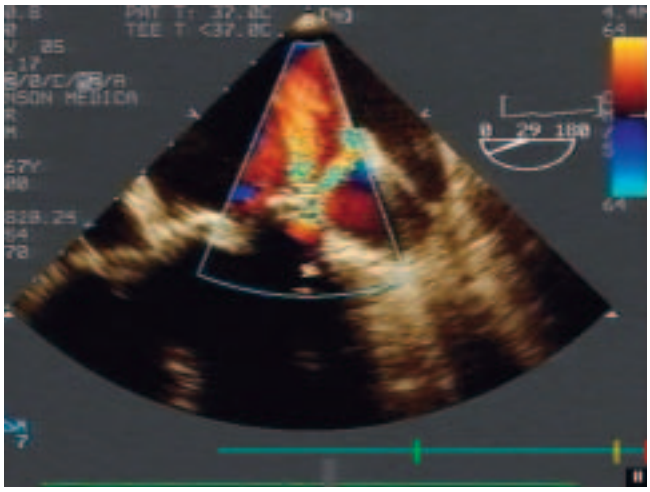

Figure 4: Transesophageal echocardiography after device implantation, showing a lesser degree of regurgitation.

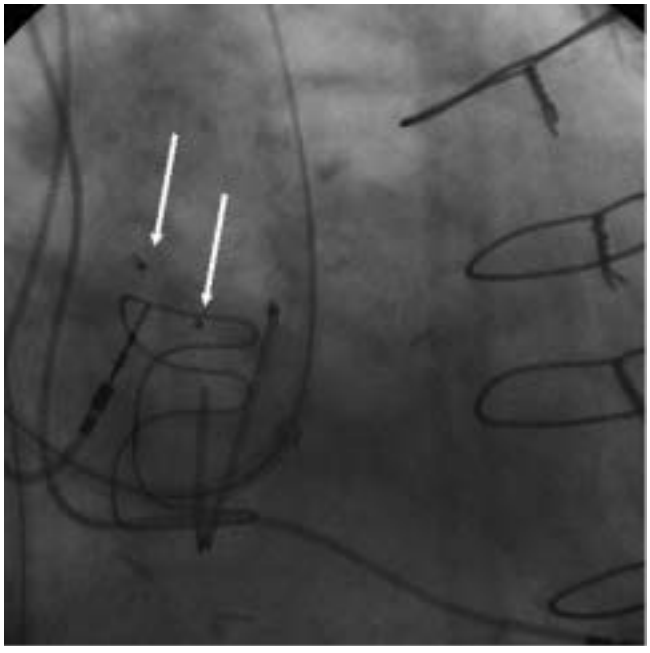

Figure 5: Fluoroscopic view of the open patent ductus arteriosus occluder (arrows).

three of the final four cases, the use of contrast medium was avoided in order to minimize contrast utilization. The device size in these three patients was chosen based exclusively on TEE sizing of the defect.

The peri-aortic leaks were approached in retrograde fashion through the femoral artery. The defect was advanced by a coronary diagnostic catheter and crossed with a Terumo wire. A pigtail catheter was followed, after which contrast medium was injected to delineate the size and shape of the defect. Thereafter, the pigtail catheter was exchanged for a designated delivery sheath and an Amplatzer device deployed

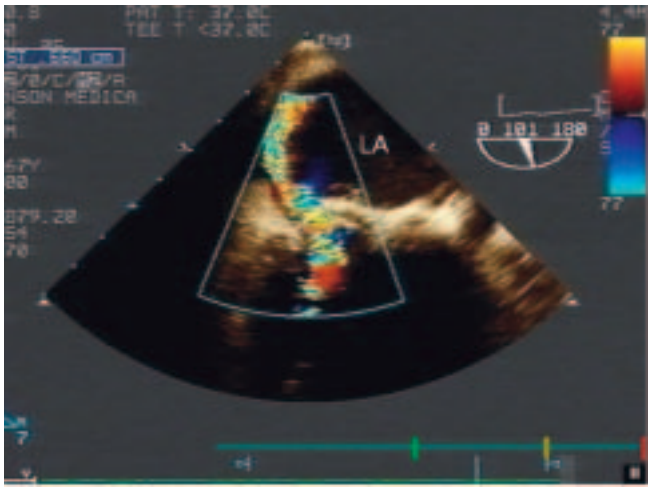

Figure 6: Transesophageal echocardiography showing a second large perivalvular leak in the same patient, located posteriorly.

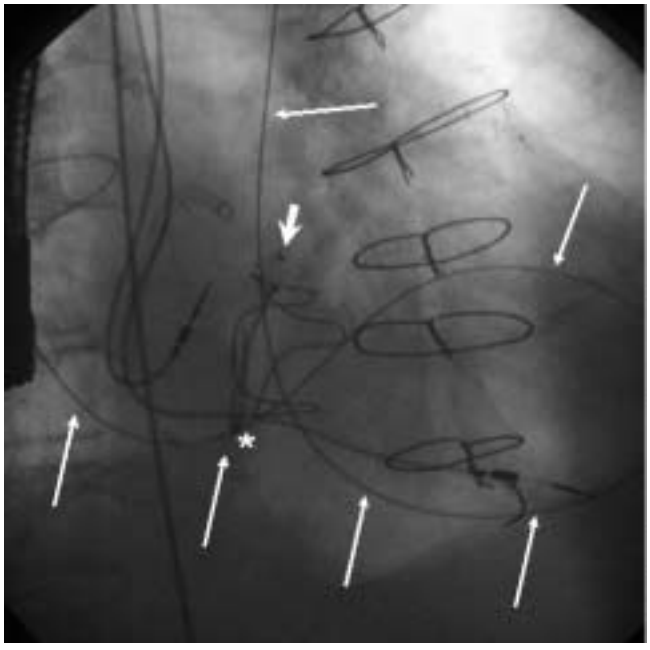

Figure 7: Fluoroscopy showing crossing of the second leak in retrograde fashion. The thin arrows indicate a wire coming from the aorta, entering the left ventricle and crossing the perivalvular region (*) to enter the left atrium, to which it was snared. The thick arrow indicates the second patent ductus arteriosus occluder device sealing the second leak.

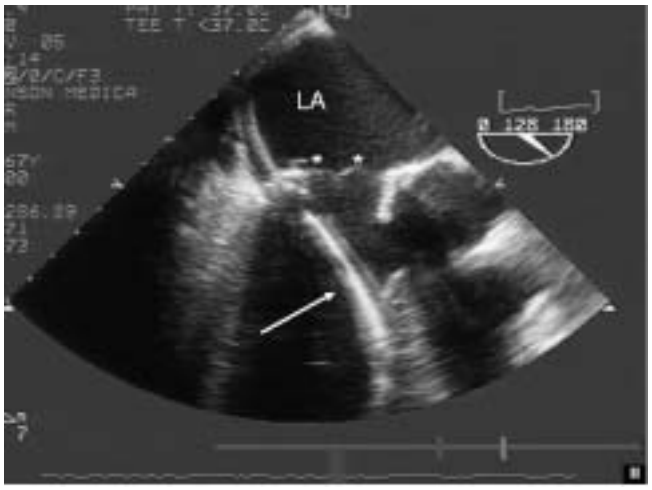

Figure 8: Transesophageal echocardiography showing the wire crossing the leak in the retrograde direction.

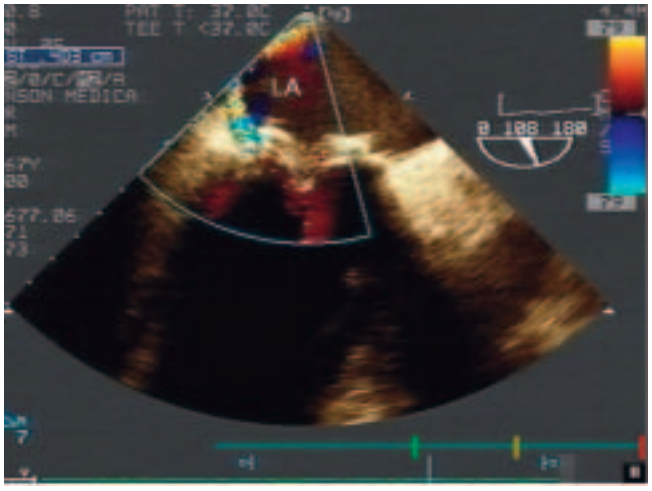

Figure 9: Transesophageal echocardiography after the second device implantation, showing a lesser degree of regurgitation in the posterior leak.

across the leak site. The device size was chosen to be at least 2 mm (i.e., one size) larger than the minimal diameter of the hole. In general, narrow, elongated holes were more likely to be approached using a PDA occluder, whereas wide and short tunnels were closed with VSD occluders.

Representative fluoroscopic and TEE images of one patient (ZY) with two peri-mitral leaks, treated by both an antegrade and retrograde approach, are shown in Figures 1 to 10.

The Parsonnet score was used to predict operative mortality (23); this was preferred to the EuroSCORE due to its ability to differentiate a first from a second reoperation.

Hemolysis

Mechanical hemolytic anemia was defined as anemia accompanied by all of the following: typical blood smears, high lactate dehydrogenase (LDH) levels (more than twice the upper limit of normal (ULN) of 480 IU/dl), indirect hyperbilirubinemia, and low haptoglobin levels. Severe hemolysis was defined by at

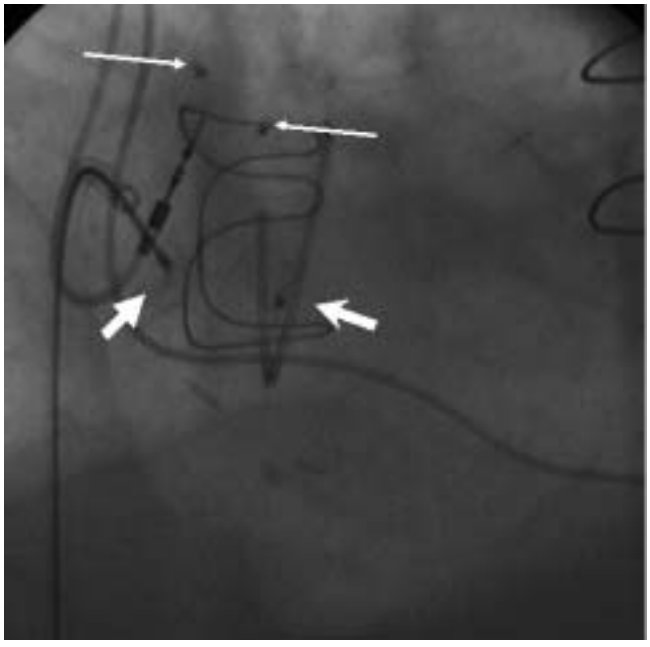

Figure 10: Fluoroscopy showing both devices in situ. Thin arrows indicate the anterior leak; thick arrows indicate the posterior leak.

least one of the following: frequent blood transfusions, LDH levels >5×ULN, or external administration of erythropoietin to overcome hemolysis. Mild hemolysis was defined by low haptoglobin levels, LDH levels up to 2×ULN, and normal hemoglobin. Moderate hemolysis was defined as intermediate between mild and severe hemolysis. The response to leakage closure at follow up was also based on these parameters. Patients were monitored for at least 48 h after the procedure, and thereafter followed up at one, three, six, 12, 18, and 24 months.

Statistical analysis

Paired continuous data were compared using a paired Student's *t*-test.

Results

Demographic profile and baseline clinical characteristics

The baseline characteristics of patients are summarized in Table I. The predicted reoperative mortality was 17.8 ± 5% (range: 13 to 30%), according to the Parsonnet score. The main indication for PVL closure was CHF; this was diagnosed in 10 patients (90.9%), five of whom suffered from severe hemolysis and two moderate hemolysis. Hemolysis was the only indication for the procedure in one patient. The average number of previous heart operations was 2.4 ± 1.3, and seven patients had undergone two or more (up to five) previous operations. The PVL was located around the mitral valve in eight cases, around the aortic valve in one case, and around both valves in two cases; hence, a total of 13 PVL sites was identified. A mitral xenograft was placed in one patient, but all other valves were mechanical (nine bileaflet, three single leaflet). Two patients had a remote history of prosthetic valve endocarditis, but none had any evidence of current endocarditis.

Immediate results

Closure of the mitral PVLs was attempted via an antegrade, trans-septal approach in all patients. In one

Table I: Patient characteristics.

Patient i.d.	Gender	Age (years)	No. of previous operations	Interval since last surgery (months)	Leaking valve*	NYHA class	History of IE	Degree of hemolysis	Predicted operative mortality (%)+
BJ	F	46	3	8	M	4	Yes	Severe	19
YP	M	55	5	8	A+M	3	No	Moderate	17
ZE	M	62	1	25	A	3	No	Moderate	18
HH	F	69	1	252	M	2	No	Severe	13
HS	F	50	3	144	A+M	3	No	Severe	19
BH	M	65	2	24	M	3	No	Severe	15
CS	F	67	1	18	M	2	No	Mild	17
ZY	M	67	2	5	M	4	Yes	Mild	30
ML	F	57	3	15	M	3	No	Severe	19
CI	M	59	1	144	M	2	No	Severe	10
LV	F	60	3	72	M	3	No	Severe	19

*A: Aortic; M: Mitral.
+Parsonnet score.
IE: Infective endocarditis.

Table II: Technical details.

Patient i.d.	Leaking valve	Device used*	Fluoroscopy time (min)	Contrast material used (ml)
BJ	M	ASD (8), PDA 8/6	40	NA
YP	A+M	Mitral: VSD (6) Aortic: mVSD (8, 8)	NA	150
ZE	A	mVSD (6)	97	80
HH	M	Failed attempt	84	NA
HS	A+M	pVSD (10)	53	NA
BH	M	mVSD (6, 4)	45	NA
CS	M	PDA (10/8)	14	182
ZY	M	PDA (12/10, 8/6)	106	0
ML	M	PDA (8/6)	97	93
CI	M	PDA (10/8)	47	0
LV	M	PDA (8/6)	20	0

*Values in parentheses indicate device size(s) (in mm).
A: Aortic; ASD: Atrial septal defect; M: Mitral; mVSD: Muscular VSD; NA: Data not available; pVSD: Peri-membranous VSD.

patient the wire could not be navigated across the leak, and the procedure was abandoned. In another patient with dual PVL, the anterolateral leak was successfully crossed in antegrade approach, but the posteromedial leak could not be crossed in this way. Thus, a wire was advanced retrogradely to the left ventricle through the aortic valve, and advanced through the leak to the left atrium, where it was snared (see Figs. 7 and 8).

The two aortic PVLs were approached in retrograde fashion. Overall, three patients received two devices for the same valve during the same session. One patient received a total of three devices (two aortic, one mitral). Procedural details for all patients are listed in Table II.

In five patients contrast medium was injected into the donor chamber in order to assess the leakage site and shape. In five additional patients, this evaluation was based exclusively on echocardiographic findings. Contrast was not used during the procedure in three cases.

In one patient there was a transient interruption of mitral leaflet movement which necessitated retrieval of the device and three additional attempts with various other devices; ultimately, a membranous VSD occluder was successfully deployed. The leak showed no signs of aggravation between attempts. In another patient, post-procedural fluoroscopy and echocardiography revealed a partial interruption of the occluder motion. However, the patient was stable, the transmitral gradients were comparable with pre-procedural values, and attempts to retrieve the device or to repeat the procedure seemed unjustified.

A total of 16 devices was used, including seven muscular VSD occluders (range: 4 to 8 mm), seven PDA occluders (8/6 to 12/10 mm), one peri-membranous VSD occluder (10 mm), and one ASD occluder (8 mm).

The mean fluoroscopy time (available for only 10 patients) was 60 ± 33 min (range: 14 to 106 min). The immediate results and short-term follow up data are summarized in Table III. Leakage was seen to decrease in six of 10 patients (60%), while residual leak remained at 10 of the 11 sites (90.9%). The severity of hemolysis was decreased in four patients (but later reappeared in one case), increased in four, and unchanged in two. There were no significant differences between the mean pre-procedural and post-procedural levels of hemoglobin (10.5 ± 1.7 and 9.7 ± 1.7 g/dl, p = 0.18), LDH (2,529 ± 1,769 and 2,311 ± 810 IU/ml, p = 0.7) and bilirubin (2.3 ± 1.2 and 2.2 ± 1.1 mg/dl, p = 0.91). An improvement in NYHA class of one grade was noted in five patients. One patient required a second session in order for a residual leak to be sealed.

Follow up

Ultimately, two patients required reoperation. In both cases the Amplatzer device was located in situ and easily removed. One reoperation was successful and uneventful, but the other resulted in intraoperative death due to profuse bleeding and biventricular failure. This patient was the first of the present series, and suffered from severe PVL at numerous sites; the mitral annulus was also severely diseased due to previous endocarditis.

Among the eight patients in whom a device was deployed and who did not require reoperation, one patient experienced an out-of-hospital sudden death; he was successfully resuscitated but suffered severe

Table III: Pre- and post-procedural outcome (in 10 patients with devices deployed in 11 sites).

Patient i.d.	Regurgitation grade*		Hb		LDH		Bilirubin		Post-op transfusion/ EPO	NYHA class		Status at follow up+
	Pre-	Post-	Pre-	Post-	Pre-	Post-	Pre-	Post-		Pre-	Post-	
BJ	3	3	11	7.7	771	3,510	0.8	3	Yes	4	4	Died at re-do (2)
YP	2†, 2‡	0†, 1‡	12.7	12.4	1,999	1,930	2.7	2.5	Yes	3	2	Alive (36)
ZE	3	2	11.4	9.8	1,817	2,069	2	2.1	No	3	2	Sudden death (8)
HS	2.5	1.5	10	9	4,130	2,414	2	2	Yes	3	3	Alive (23)
BH	2.5	2.5	8.7	8.2	5,634	2,561	4.9	3.9	Yes	3	2	Alive (re-do, 4)
CS	2.5	1.5	13.5	13.6	872	1,305	NA	1.3	No	2	1.5	Alive (18)
ZY	3	2	10.5	7.8	621	2,125	0.8	0.9	Yes	4	4	Died, CHF (11)
ML	2.5	1.5	9	12	4,379	2,063	3	1	No	3	2	Alive (10)
CI	2	2	9.6	8.9	1,735	3,198	2	2.2	Yes	2	2	Alive (6)
LV	2	2.5	8.8	9.4	2,972	1,946	2.1	1.7	No	3	2	Alive (6)

*See text for definition.
+Values in parentheses indicate follow up period (months).
†Mitral leak.
‡Aortic leak.
EPO: Erythropoietin; Hb: Hemoglobin; LDH: Lactate dehydrogenase; NA: Data not available.

anoxic brain damage and died within a few weeks. Another patient died at 11 months after the procedure, due to progressive heart failure. The other six patients were followed up for between six and 36 months, during which time the degree of residual PVL remained unchanged. At follow up, four patients had improved symptoms of heart failure, whilst two remained unchanged. Hemolysis had improved in four patients (one of whom experienced an initial worsening before improvement), but had worsened in one patient. Hemolysis remained a significant problem in three patients, including one patient who was left with an untouched peri-aortic leak (only the mitral defect was approached). Currently, all of these patients are receiving erythropoietin.

Table IV: Percutaneous closure of PVL: Case series.

Reference	Year	Patient age (years)	Gender	No. of previous operations	CHF	Hemolysis	Valve	Device	Post-procedural		Fluoroscopy time (min)	Follow up (months)
									Leak	Hemolysis		
13	1992	12	M	5	+	Significant	AVR	Rashkind	None	Severe	NR	Died in re-do MVR + AVR
		7	M	1	-	NR	AVR	Rashkind	None	NR	NR	21
14	2000	6	M	3	+	Significant	MVR (BL)	6 Gianturco coils	Trivial	Markedly reduced	121+98	17
15	2001	55	M	2	-	Severe	MVR (BL)	2 dumb-bell coils	NR	Markedly reduced	NR	9
16	2001	85	F	1	+	NR	MVR (xenograft)	Gianturco-Grifka coil	None	NR	NR	24
17	2003	37	M	2	+	Severe	MVR (CB)	Amplatzer	Severe	Severe	NR	6
18	2004	0.25	M	3	+	Significant	MVR (BL)	Amplatzer (PDA)	Small	Reduced	54	NA
19	2004	75	M	2	+	None	MVR	Amplatzer ASD occluder + Flipper™ coil	None	None	NR	6
20	2005	87	F	1	+	None	AVR (xenograft)	Amplatzer (PDA)	Small	None	NR	12

AVR: Aortic valve replacement; BL: Bileaflet; CB: Caged ball; MVR: Mitral valve replacement; NR: Not reported.

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Discussion

The results of the present study indicate that the percutaneous closure of PVLs using Amplatzer VSD, PDA or ASD occluders is feasible, and can be applied in carefully selected patients. However, the device rarely seals the leak completely, and there is an unpredictable effect on the severity of hemolysis. As yet, the long-term clinical outcome of this procedure is unknown, but it may be offered to those patients considered to be at very high risk for reoperation, and especially when the major symptom is related to heart failure. The offer to use this procedure in order to ameliorate hemolysis should be made with caution, at least initially, given the possible aggravation of hemolysis. It is possible that, pending additional supportive safety and efficacy data, the procedure might also be contemplated for patients at a lower risk of reoperation.

The main advantage of the Amplatzer device are that it can be retrieved completely and uneventfully into the sheath when the outcome is unsatisfactory in terms of residual leak, interruption with the occluder mechanism, or unstable positioning. Indeed, in one patient four devices were switched because of interruption of the occluder mechanism, with only the final deployment being successful.

As the shape of a PVL may be a major determinant of the procedure's success, the most accurate means of assessing shape is to inject contrast medium into the donor chamber (into the left ventricle or aorta for mitral and aortic leaks, respectively). The subsequent use of color-Doppler on TEE can serve to delineate the origin of the regurgitant flow as it leaves the level of the annulus into the recipient chamber, but not its shape throughout the course. The clinical relevance of this is somewhat dubious, however, as oversized devices (2 mm larger than the smallest orifice) were used in the present patients. If the tunnel is closed at one site, it is reasonable that the passage of blood will not occur, even if the other end is not completely covered. The use of TEE to measure the leak can obviate or minimize the use of contrast medium, especially in patients with compromised renal function, as was shown in two of the present cases. It is possible that the future application of intracardiac echocardiography will enable both accurate intraprocedural monitoring and an avoidance of general anesthesia.

Another unresolved question was whether the residual leak, after being sealed with the Amplatzer device, would reshape over time, and how this would affect hemolysis - if at all. Although endothelialization may obliterate the leak completely, until this occurs the shearing forces through a smaller leak, with its irregular border, may - at least temporarily - increase hemolysis (as occurred in three patients). Moreover, an oversized device can, in theory, impose radial forces that may weaken the adjacent tissues and enlarge the proportion of the ring which is subject to dehiscence. Thus, a longer period of follow up is most likely required to explore the fate of residual defects.

It is also likely that the cross-sectional profile of a leak is crescentic, since it locates in the interface between two circular structures. In future, a dedicated device of such shape might be more suitable for the closure of leaks than the current devices, which have a rounded neck. In addition, it may be advisable to reduce the radial forces of the neck of the device, in order to minimize the chances of extending the leak.

At present, very few data exist on the percutaneous closure of PVLs (13-21); details of nine case reports are summarized in Table IV. Of these nine patients, six underwent peri-mitral closure, three peri-aortic closure, and six had undergone at least two previous cardiac operations. The Rashkind double umbrella, Gianturco coil and dumb-bell coils were used in the earlier studies (13-15), and later the Amplatzer device (17-20). Among these patients, the leak was successfully closed in eight cases, with one patient requiring reoperation six months later due to severe mitral regurgitation and hemolysis (17). In another patient, symptoms of hemolysis and heart failure did not subside, presumably due to a severe leak surrounding an additional valve. This patient was referred for re-do surgery (AVR + MVR) but died intraoperatively (13).

Follow up data were available for six patients for between six and 24 months, and no additional complications were reported. With regards to hemolysis, data were available for six patients, with hemolysis being abolished in four cases but remaining severe in two (one with residual leak in the same valve, and one with residual leak at another valve). Whilst these favorable results may reflect a selection bias towards publishing only positive results, Pate et al. (21) recently reported a series of 10 patients in whom they had attempted percutaneous closure of PVL, using either ASD or PDA Amplatzer occluders or coils. The initial success in crossing the leak and deploying a device was 70%, and residual leakage occurred in three of seven patients, necessitating a repeat procedure. In one of these repeated procedures the device became dislodged and emergency surgery was required.

In conclusion, the percutaneous closure of PVLs with the Amplatzer VSD or PDA occluder is feasible, but the method is both technically demanding and time consuming. Moreover, its overall effect is modest since, despite improving symptoms it has an inconsistent effect on hemolysis. At present, the Amplatzer should be reserved for poor surgical candidates.

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