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Transcatheter Umbrella Closure of Valvular and Paravalvular Leaks

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Objectives. **Our aim was to adapt the technique of transcatheter umbrella closure of intracardiac defects for closure of valvular and paravalvular defects.**

Background. **The double-umbrella device developed by Rashkind and Cuaso has been safely and effectively delivered across a host of intracardiac defects, but transcatheter closure of valvular and paravalvular leaks has not been reported.**

Methods. **Between February 1987 and September 1990, eight patients who were believed to be poor operative candidates were taken to the catheterization laboratory for transcatheter double-umbrella closure of a valvular or a paravalvular leak. Four patients had a paravalvular leak around a prosthetic aortic valve. The other four patients had a valvular leak: one patient with a regurgitant native aortic valve after a Stansel procedure and three patients with a regurgitant porcine valve in a left ventricular apex to descending aorta conduit.**

Results. **Placement of a double-umbrella device was attempted in seven of the eight patients and was successful in all seven. Device placement was not attempted in one patient because of the crescentic shape of his defect. Two patients required two devices for each closure; the other five required only one device each. Angiography, performed on six patients after device closure, demonstrated that three patients had a completely occluded defect, two had trivial residual flow and one patient had mild residual flow through the device. All significant complications occurred in one patient who had hemolysis and oliguria that resolved when the initial umbrella was replaced by a larger device. In addition, two devices migrated to the patient's pulmonary arteries but were retrieved in the catheterization laboratory without difficulty. No other early or late complications occurred in 21 to 50 months of follow-up. Of the four patients with a paravalvular leak, the one who did not receive a device died at operation, one patient died at operation for an associated defect (in the operating room the umbrella was found securely in place across the paraaortic defect) and two patients are clinically well at home after 21 and 32 months, respectively. Of the four patients with closure of a valvular leak, one patient remains well at home 50 months later, one patient died at operation for associated defects and two patients had additional successful surgical treatment and remain well 29 months after device placement.**

Conclusions. **Transcatheter umbrella closure appears to be a reasonable alternative for closure of a valvular or paravalvular leak in patients who are poor operative candidates.**

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The first double-umbrella device for intracardiac use, introduced in 1976, received little attention (1). However, since 1979, when Rashkind and Cuaso (2) developed the double-umbrella device for transcatheter closure of a patent ductus arteriosus, steady progress has been made in transcatheter umbrella closure of congenital and postoperative cardiac defects. This device has been safely and effectively placed in children with a host of defects including aortopulmonary collateral channels, aortopulmonary windows and venous connections (3,4). The recently developed clamshell double umbrella has allowed expansion of this list to include atrial and ventricular septal defects and patent foramens ovale in both children and adults (5–7). The goal of current studies is to identify which cardiac defects are amenable to closure with these devices and the safest and most efficient means of delivery of the device in each class of defects.

Transcatheter umbrella closure of paravalvular and valvular leaks has not previously been reported. This approach is appealing because patients with a paravalvular or valvular leak often have a complex surgical history and significantly compromised cardiac function that place them at increased risk for additional cardiac surgery. We adapted the technique of transcatheter umbrella delivery for closure of valvular and paravalvular leaks, and report the successes and failures of this technique in eight patients.

Methods

Patient selection. Patients were considered candidates for attempted transcatheter closure of a valvular or paravalvular

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Table 1. Clinical and Hemodynamic Findings and Outcome in the Eight Study Patients

Pt No	Age (yr)/ Gender	Cardiac History	Acute Problems	Pertinent Medical History	Hemodynamics at Cath	Device	Follow-Up
1	73/M	AVR ×3; pacemaker for CHB	Paraaortic leak (Ao–RV); NYHA class IV CHF	Mediastinitis ×1; large stroke ×1	Q_p/Q_s = 2:1; CI = 2.2; PCWp = 30	23-mm Rashkind	NYHA class I CHF 32 mo later
2	12/M	Surgical repair CCAVC ×1; MVR ×3; AVR ×1	Paraaortic leak (Ao–LV); Paramitral leak; NYHA class IV CHF	Mediastinitis ×1	PCWp = 15; CI = 3	12-mm Rashkind	Died at operation for paramitral leak; device found well seated in paraaortic leak
3	7/M	Konno repair with AVR ×1	Paraaortic leak (Ao–LV); significant V. ectopic activity requiring medication	None	LVEDP = 8; CI = 2.7	12-mm Rashkind	Well 21 months later; V. ectopic activity resolved
4	18/M	AVR ×2; surgical repair paraaortic leak ×1	Paraaortic leak (Ao–LV); hemolysis causing damage to transplanted kidney	Renal transplant	LVEDP = 21; CI = 3.1	None	Died at surgical repair
5	5/F	TGA; hypoplastic RV + Ao; Stansel repair ×1	Severe AR in a Fontan procedure candidate. NYHA class III	Phrenic nerve palsy; endocarditis ×1	LVEDP = 26; CI = 1.7	23/28-mm custom-made clamshell device	4 mo later LVEDP = 18; 6 mo later successful bilateral cavopulmonary anastomosis; NYHA class II
6	7/M	Congenital AS; hypoplastic Ao; LV–AoDT conduit ×1	Severe regurgitation of conduit valve	None	LVEDP = 14; CI = 3.3	23-mm Rashkind	Well 47 mo later
7	27/M	Congenital AS; surgical valvotomy ×2; AVR ×1; LV–AoDT conduit ×1	Severe regurgitation of conduit valve; NYHA class II CHF; recurrent V. Tach	None	LVEDP = 28; CI = 2.8	40-mm clamshell ×2	2 mo later successful Konno repair; well 29 mo later
8	13/M	Congenital AS; AVR ×1; LV–AoDT conduit ×1	Severe regurgitation of conduit valve; NYHA class IV CHF	None	LVEDP = 40; CI = 1.4	23 mm Rashkind + 40-mm clamshell	Died at attempted Konno repair 5 days later

Ao = aorta; AoDT = descending aorta; AR = aortic regurgitation; AS = aortic stenosis; AVR = aortic valve replacement; Cath = cardiac catheterization; CCAVC = common atrioventricular canal; CHB = complete heart block; CHF = congestive heart failure; CI = cardiac index (liters/min per m^2); F = female; LV = left ventricle; LVEDP = left ventricular end diastolic pressure (mm Hg); M = male; MVR = mitral valve replacement; NYHA = New York Heart Association; PCWp = pulmonary capillary wedge pressure (mm Hg); Pt = patient; Q_p/Q_s = pulmonary to systemic flow ratio; RV = right ventricle; Tach = tachycardia; TGA = transposition of the great arteries; V. = ventricular.

leak only if 1) closure was indicated for hemodynamic reasons, and 2) either the patient was a poor operative candidate or additional surgical treatment was planned and the defect could not easily be reached from the same operative approach. This determination was made by the patient's cardiologist in conjunction with the cardiac surgeon. Each patient had had two to six prior cardiac operations. All patients had at least one of the following medical conditions: complex congenital heart disease, history of bacterial mediastinitis, history of a large perioperative stroke, phrenic nerve palsy, recent renal transplant and recurrent ventricular tachycardia. No patient was refused therapy because of unfavorable clinical status.

Study group. Between February 1987 and September 1990, eight patients aged 5 to 73 years (median 13) were taken to the catheterization laboratory for closure of a valvular or a paravalvular leak. The history, hemodynamic findings and results of attempted device closure for all of these patients are listed in Table 1.

A paravalvular leak around a prosthetic aortic valve was present in four of the eight patients. The remaining four had a valvular leak. One of these four (Patient 5) had a regurgitant native aortic valve (this patient had single ventricle and complex congenital heart disease and had undergone surgical anastomosis of the end of the pulmonary artery to the side of the aorta; the other three patients had a regurgitant porcine valve in a left ventricular apex to descending aorta conduit. In the four patients with a paravalvular leak and in the one patient whose only hemodynamically significant lesion was a regurgitant left ventricle to descending aorta conduit (Patient 6), we hoped that transcatheter umbrella placement would eliminate the need for surgical intervention in the near future. In the three patients with complex lesions and a valvular leak (Patients 5, 7 and 8), we were performing a palliative procedure to reduce the risk of the cardiac operation that each needed in the near future. It was the opinion of our surgical colleagues that the transcatheter closure of the defect would markedly simplify the later

operation. A protocol for the use of a double-umbrella device to close nonpatent ductus arteriosus structures had previously been approved by the Committee on Clinical Investigation in our hospital. Informed consent regarding the experimental nature of this procedure was obtained in writing from the patient or the patient's parents.

Hemodynamic and angiographic evaluation. Vascular access was obtained percutaneously in each case through the femoral vein and femoral artery. Right and left heart catheterization was performed whenever possible. The defects were then evaluated angiographically to determine their size, shape and location. The paravalvular defects were profiled angiographically from several angles to accurately document their geometry and their proximity to the valve leaflets and coronary ostia.

Our protocol for closure of nonpatent ductus arteriosus structures, previously described (3), was then used. The procedure involves "test" occlusion of the defect with a balloon-tipped catheter to help us determine the size of the defect, its distensibility, its tendency to be displaced within the thorax by catheter manipulations and the likelihood that hemodynamic status will be favorably altered by closure of the defect. An end-hole balloon-tipped catheter is advanced across the defect over a wire. The balloon is inflated with dilute contrast medium and drawn slowly back through the defect while contrast medium is gently withdrawn from the balloon until the balloon fits snugly into the defect and occludes it (Fig. 1). This process is recorded on videotape or videodisc and allows us to perform measurements of a defect's dimensions. Complete hemodynamic data can also be obtained during balloon occlusion to help determine how closure of the defect will effect hemodynamic status.

Catheter closure technique. After we determined that closure of the defect was possible and potentially beneficial, we used the size of the defect to determine the size of the umbrella used for closure. For effective closure, the diameter of the umbrella should be at least 2.5 times the stretched diameter of the defect (3,6–8). In all cases delivery of the device was attempted through a long Mullins sheath. An 8F long sheath was used to deliver 12-mm patent ductus arteriosus occluders. An 11F long sheath was used to deliver the 17-mm, 23-mm, 40-mm and custom-made 23/28-mm devices. The device was loaded into the delivery system and placed across the defect in the manner previously described (3,6–9).

Other procedures. All patients received the usual dose of heparin (100 U/kg body weight) at the beginning of the procedure. Anticoagulation was not reversed after the procedure. Umbrella devices were not soaked in topical thrombin before placement unless they were to be placed distal to the carotid circulation (10). All patients received prophylactic antibiotic therapy just before device placement.

Evaluation after closure. Hemodynamic and angiographic assessment after defect closure was performed whenever the patient's clinical status permitted. After placement of the device, a chest X-ray film was obtained in all eight patients and two-dimensional echocardiography was performed in three.

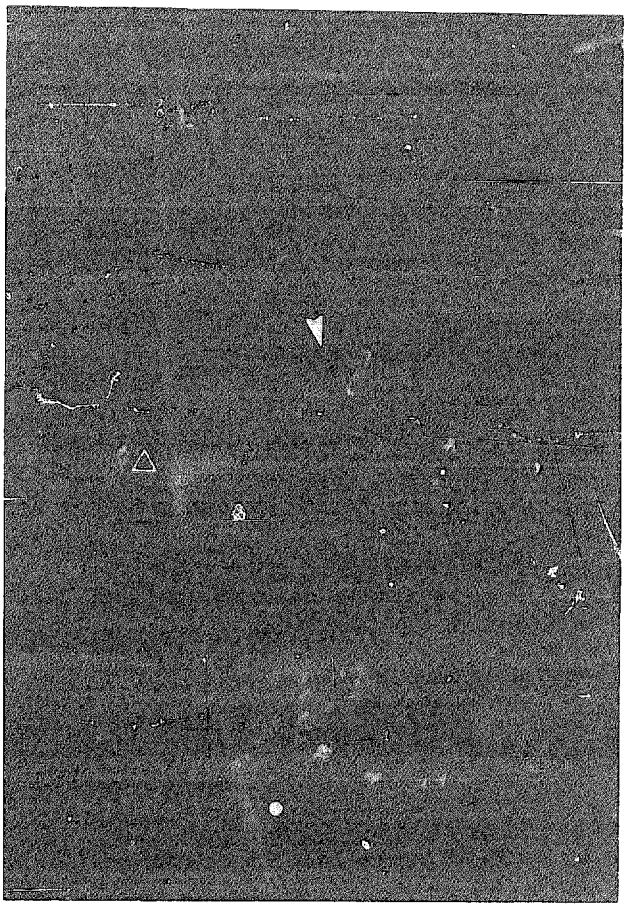

Figure 1. Balloon sizing of a paraaortic defect. Contrast medium is being withdrawn from the balloon (**open arrowhead**) as the balloon is gently pulled through the defect over a guide wire that is positioned in the ventricle (**circle**). Note the leaflets of the prosthetic aortic valve in the open position during systole (**closed arrowhead**).

Results

Hemodynamic and angiographic evaluation. Angiographically the paravalvular leaks in Patients 1, 2 and 3 measured 6, 3 and 3 mm in diameter, respectively, and in all views appeared to be symmetric. The paraaortic leak in Patient 4 was crescentic in shape—wide in one dimension and quite narrow in another. Because it was believed that this shape would not lend itself to closure with an umbrella device, transcatheter closure of this defect was not attempted (Fig. 2).

Angiography demonstrated free regurgitation of the native aortic valve in Patient 5 and of the porcine valve in the left ventricle to descending aorta conduit in Patients 6, 7 and 8. In each of these conduits angiography demonstrated a narrowing where a device could be securely placed.

Only Patient 1, with an aorta to right ventricle paraaortic fistula, had a measurable shunt; the pulmonary to systemic

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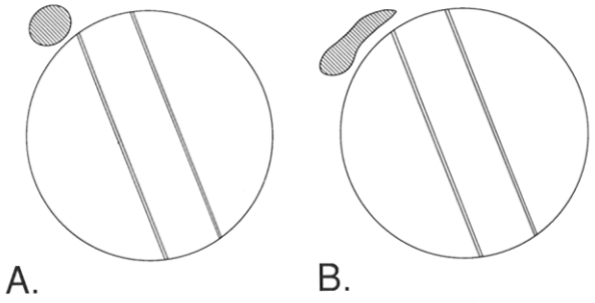

Figure 2. **A,** Diagram of a symmetrically shaped paravalvular defect **(hatched area)** that would be amenable to transcatheter device closure. **B,** Diagram of an asymmetrically shaped paravalvular defect **(hatched area)** that would not be amenable to transcatheter device closure.

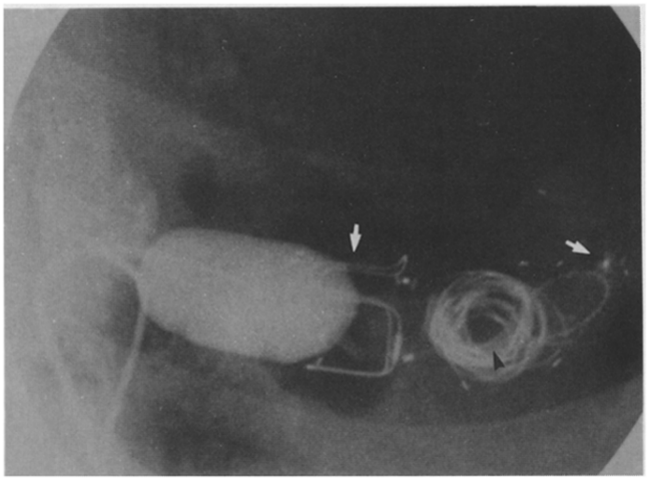

Figure 3. Balloon tamponade of a conduit after device placement to promote stasis and clotting. Note that two clamshell devices **(white arrows)** and multiple coils **(black arrowhead)** were required for closure of this conduit.

flow ratio was 2:1. In all but one patient the left ventricular end-diastolic pressure was elevated before device placement.

Test balloon occlusion confirmed the angiographic sizing of the paravalvular defects. Unlike ventricular septal defects and atrial septal defects (5–7), these lesions were noncompliant. Surrounded by the rigid sewing ring of the valve and firm annular tissue, they stretched very little with balloon sizing. For regurgitant valves in left ventricle to descending aorta conduits, the test balloon occlusion of the conduit was a crucial determinant of whether device closure of the regurgitant conduit would be tolerated. The two 12-mm conduits were easily occluded with the use of 5F and 7F end-hole balloon-tipped catheters. The 20-mm conduit required a larger balloon diameter for occlusion (Meditech occlusion balloon catheter 27/8/100). In each of these cases the conduit had been placed originally because of severe aortic valve and anulus stenosis. To evaluate whether conduit occlusion was hemodynamically tolerated, we measured the aortic valve gradient, left ventricular end-diastolic pressure and thermodilution cardiac output at rest and during balloon occlusion. After occlusion of the conduit, Patient 6 had a 16-mm gradient across his native aortic valve and Patients 7 and 8 had a 60-mm gradient. In each case, balloon occlusion brought about either a decrease in or no change in left ventricular end-diastolic pressure and an increase or no change in the cardiac index.

Catheter approach. As the location of the defect in these eight patients varied, so did the catheter approach.

Patient 1. The paraaortic fistula was between the aorta and the right ventricle. It was approached in a manner analogous to that of the double-catheter approach described previously for transcatheter closure of ventricular septal defects (7). The defect was crossed with an end-hole balloon-tipped catheter from the aorta. A long guide wire was advanced through this catheter into the right ventricle and out into the inferior vena cava. The venous end of the wire was then snared and externalized through the femoral venous sheath. The defect was then balloon sized and the device was delivered by the venous route.

Patients 2, 3 and 4. Each of these patients had a paravalvular leak around a prosthetic aortic valve connecting the aorta to the left ventricle. All three defects were approached in retrograde fashion and crossed from the aorta with a 0.038 torque control wire. This wire was exchanged for a 0.038 exchange wire with a hand-formed large curve. Balloon sizing and device delivery were performed over this wire.

Patient 5. The regurgitant native aortic valve in this patient was approached from the ascending aorta. A 7F end-hole balloon-tipped catheter was advanced easily across the valve when the balloon was inflated. An exchange wire was then advanced into the single ventricle through that catheter, and over this we attempted device delivery.

Patients 6, 7 and 8. Each of these patients had a left ventricle to descending aorta conduit with a regurgitant porcine valve. In each case the conduit was entered from the descending aorta with the use of an end-hole balloon-tipped catheter. After balloon occlusion this catheter was exchanged over a wire for a long sheath for device delivery.

Catheter closure technique. Of the eight patients taken to the catheterization laboratory for possible device closure of a valvular or paravalvular leak, seven underwent attempted device placement. One device was required for closure in five patients, and more than one device was required in the other two. Both of these latter patients had a left ventricle to descending aorta conduit. In each there was free flow through the conduit after a first and a second device were placed, and flow was not occluded until a series of coils had been packed between the two devices and the distal end of the conduit had been balloon tamponaded for 10 to 30 min to promote stasis and clotting (Fig. 3).

In all, nine double-umbrella devices were placed across

these seven defects. The size and type of device placed in each case are listed in Table 1. We did have a 23/28-mm clamshell device custom made for closure of the native aortic valve in Patient 5. We designed this device so that the 23-mm arms would sit on the aortic side of the valve and be less likely to interfere with the coronary artery ostia. Seven devices were delivered from the aorta by way of a long sheath; one was delivered from the right ventricle by way of a long sheath (Patient 1 with the aorta-right ventricle paraaortic fistula), and one (in Patient 5) was delivered from the aorta without the use of a long sheath.

This latter child, (Patient 5), (with a regurgitant native aortic valve) underwent a modification of our usual device delivery technique because the 11F-long sheath necessary for delivery of the custom-made 23/28-mm device would not pass across the narrowed iliac artery, even after balloon dilation of that artery. In this patient, the rigid metal pod of the delivery catheter was advanced without the aid of the Mullins long sheath. Without this long sheath to guide it around the aortic arch, the metal pod consistently passed up into the brachiocephalic vessels instead of traversing the arch and entering the ascending aorta. Therefore, a 7F balloon-tipped catheter was advanced through the opposite femoral artery up into the left subclavian artery. This balloon of this catheter was then inflated and the catheter pulled back toward the arch as the device delivery system was advanced toward the arch from below. The balloon deflected the delivery catheter down into the ascending aorta, where it was positioned across the aortic valve. The device was then released in the manner described by Rashkind and colleagues (2,4,8) for closure of a patent ductus arteriosus before introduction of the Mullins sheath.

Evaluation after device placement. We could not angiographically evaluate our success in Patient 1 because of his renal failure. Using oximetry, we demonstrated a reduction in the pulmonary to systemic flow ratio from 2:1 to 1.3:1. Angiography demonstrated that the defects causing the other two paravalvular leaks were completely occluded (Fig. 4) and that, of the four patients with attempted closure of a valvular leak, one had a completely occluded conduit, two had trivial residual flow and one had mild residual flow past the device in the native aortic valve.

Follow-up transthoracic echocardiography was performed in four of the seven patients who received an umbrella device. One of these four studies was technically limited because of poor echocardiographic windows. The other three studies confirmed the degree of residual leak that had been seen angiographically after device placement.

Complications. All significant complications occurred in Patient 1. When this 70 year old man first left the catheterization laboratory, he had a significant residual leak across a 17-mm Rashkind device that was in place across an aorta to right ventricle fistula. Over the next few hours, oliguria developed and hemolysis that was presumably due to the residual flow through or around the device. The device migrated to the pulmonary artery 12 h later as demonstrated on chest X-ray film, and the hemolysis immediately resolved. The patient was returned to the catheterization laboratory where a second, 23-mm, device was placed incorrectly, slightly below the level of the prosthetic aortic valve. This umbrella immediately embolized to the pulmonary artery. Finally, a third, 23-mm, device was successfully placed across the defect. The two errant devices were retrieved from the pulmonary artery with a basket-snare catheter and were removed from the femoral vein by cutdown procedure. This patient's renal function significantly improved over the next 7 days as did his hemodynamic status.

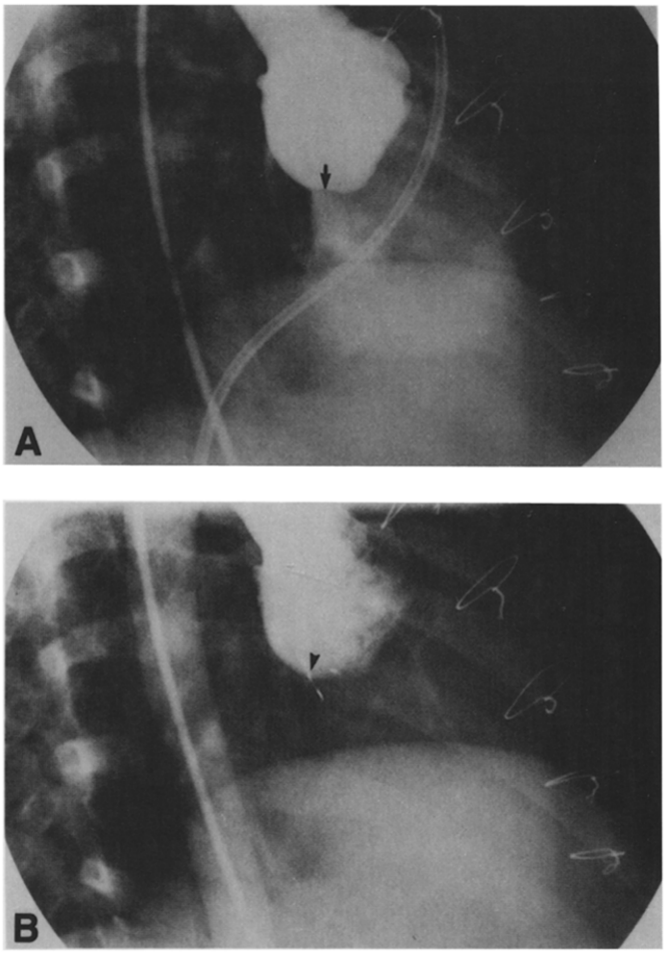

Figure 4. **A,** Aortic root injection demonstrating paravalvular leak. Note the jet of contrast medium (**arrow**) regurgitating into the left ventricle. **B,** Same patient after device placement (**arrowhead**) across the defect.

Transient pulse loss occurred in two patients. Both patients were successfully treated with systemic anticoagulant therapy for 36 h (11). There were no other early complications. Specifically, there were no known strokes or other embolic phenomena, arrhythmias or infections.

Follow-up. These eight patients were followed up for 21 to 50 months. Of the four patients whose paravalvular leak we evaluated (Patients 1 to 4), Patient 1 had clinical improvement from New York Heart Association congestive heart

failure class IV to class I and is well 32 months after device placement. Patient 2 was clinically unchanged after closure of a paraaortic leak and died after aortic valve replacement and attempted surgical repair of a paramitral leak. Had we known that the paramitral leak contributed substantially to the congestive heart failure and hemolysis, we would not have attempted closure of the paraaortic leak. In the operating room the umbrella device was found well seated across his defect. Patient 3 is asymptomatic 21 months after device placement. The ventricular ectopic activity that, before device placement, consisted of frequent couplets and triplets despite antiarrhythmic therapy, resolved within 6 months, and he currently requires no antiarrhythmic medication. Patient 4, who did not undergo device closure because of the crescentic shape of the defect, died at attempted surgical repair.

Of the four patients whose valvular leak we closed (Patients 5 to 8), Patient 5 had a decrease in ventricular end-diastolic pressure from 24 mm Hg before device placement to 18 mm Hg 4 months later. Device closure of the native aortic valve apparently relieved some of the volume load on this patient's single ventricle and the improved ventricular function allowed her to undergo a successful bilateral cavopulmonary anastomosis 6 months after placement of the device. At that operation the device was found centrally located in the valve. The medial arms on the left ventricular side were embedded deep into the muscle of the septum, preventing this side of the device from sitting snugly under the valve and causing the small residual leak that had been seen angiographically. The device was removed and the aortic valve was closed surgically. She is well 29 months after initial device placement. Patient 6 was well before device placement and remains well 4 years later. The condition of Patients 7 and 8 was unchanged after conduit occlusion. In these two patients our goal was not clinical improvement; each required extensive surgical reconstruction of a left ventricular outflow tract and we and the patients' surgeons felt certain that prior occlusion of the left ventricle to descending aorta conduit would markedly simplify this procedure. Patient 7 did undergo a successful Konno operation (enlargement of the aortic root and aortic valve replacement) 2 months later and is now well at home 29 months after device placement. Patient 8 died at attempted Konno procedure 2 days after device placement. There have been no known late complications such as stroke, infection, arrhythmia or prosthetic valve dysfunction.

Discussion

We have described a method of transcatheter umbrella closure of a variety of paravalvular and valvular leaks. Although these procedures were successful in seven cases, and produced lasting clinical improvement in five, several points should be made regarding our results.

Complications. Of the seven patients who received a device, two (Patients 4 and 8) died, both during surgical repair of an associated defect and without apparent relation to umbrella closure. The paraaortic leak was effectively closed by the 12-mm device in Patient 4, but he died after attempted surgical repair of a hemodynamically significant paramitral leak. At operation, the paraaortic leak appeared to be closed by a well seated device, and it does not appear that closure of this leak contributed to the patient's death.

Patient 8 presented to the hospital after an interval of several years in India when he could not be followed up. He had severe congestive heart failure with a left ventricular end-diastolic pressure of 20 mm Hg, and he was brought to the catheterization laboratory in extremis. Although test balloon occlusion of the conduit caused a slight increase in his cardiac index, there was no change in left ventricular end-diastolic pressure and there was a 60-mm gradient across the native aortic valve. It is likely that closure of the leaking conduit traded a volume load for a pressure load on the left ventricle but did not produce enough hemodynamic improvement to alter an inexorable clinical decline. He was taken for surgical reconstruction of his left ventricular outflow tract 2 days later and died in the operating room.

Hemolysis was a complication of device placement in one patient (Patient 1); it resolved once the device had migrated and did not recur when a larger device was put in its place. This patient's defect was a paraaortic fistula between the aorta and the right ventricle. It seems that hemolysis occurred because there was significant residual flow through or around this device and a large pressure gradient across it. Thus, the regurgitating blood was probably at high velocity causing hemolysis. We recommend close monitoring of all patients for signs of hemolysis whenever a defect with a high pressure gradient across it is incompletely closed by a device and there is significant residual flow through the device.

Device migration occurred twice in one patient with a paraaortic leak and not in any other patient. It seems that a high pressure gradient across a defect can also increase the risk of migration of a device placed across it. A device placed in a defect with a high pressure gradient across it should be somewhat larger than what one would normally choose for that sized defect.

Semilunar valve closure. The clinical need for device closure of a native semilunar valve should not arise very frequently. We cannot conclude from our experience with this one patient (Patient 5) whether the device as currently designed will be effective in this location. We can only report that in this one case where device placement contributed significantly to the patient's eventual successful surgical outcome, the device did not fit snugly under the valve and allowed a residual mild leak.

Endocarditis. The long-term risk of bacterial endocarditis after double-umbrella placement is not known.

Echocardiographic evaluation. Because of the shadowing produced by prosthetic valves, transthoracic echocardiography was not helpful in defining the anatomy of these leaks.

Most of these devices were placed before the advent of transesophageal echocardiography in this institution. Currently we recommend that the precatheterization evaluation include a transesophageal echocardiographic evaluation of the defect to determine the size and shape of the defect and its proximity to the coronary ostia and prosthetic valve leaflets. Furthermore, we expect that transesophageal echocardiography during the procedure would assist device placement and provide assessment of closure.

Summary. We evaluated eight patients with an extraordinarily complicated surgical and medical history for possible transcatheter umbrella closure of a valvular or paravalvular leak. We chose to attempt device placement in seven, and were able to partially or completely close all seven defects. Of these patients, five remain well at 6 to 50 months' follow-up and 2 of these were able to undergo successful surgery. It seems certain that in each of these cases the operation was simplified by prior device placement. Transcatheter umbrella closure is a reasonable alternative for closure of selected valvular and paravalvular leaks in patients who are poor operative candidates. It should be considered in the overall treatment plan for such patients.

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