Percutaneous Treatment of Mitral Valve Periprosthetic Leakage. An Alternative to High-Risk Surgery?

Rafael García-Borbolla Fernández, Manuel Sancho Jaldón, Germán Calle Pérez, Antonio E. Gómez Menchero, Ricardo de Zayas Rueda, Roque Arana Granado, Ernesto Marante Fuertes, and Pedro Cabeza Laínez

Sección de Hemodinámica, Servicio de Cardiología, Hospital Universitario Puerta del Mar, Cádiz, Spain

Periprosthetic mitral valve regurgitation due to paravalvular leakage is one of the complications of valve replacement surgery. We report a series of 8 patients with severe symptomatic periprosthetic mitral regurgitation in whom surgery could not be performed because of the high risk. All patients were assigned to percutaneous closure of periprosthetic mitral valve leaks using an Amplatzer duct occluder. The procedure was successful in 5 patients. A significant reduction in periprosthetic regurgitation and a clinical improvement were observed in 4 of the patients. The procedure was unsuccessful in 3 patients: in 2 due to interference with the prosthesis discs; in the other, because it was not possible to pass through the leak. One of these 3 patients died a few hours after the procedure due to severe stroke. Percutaneous closure of paravalvular leakage in patients at a high surgical risk is technically feasible and has an acceptable clinical success rate.

Key words: Mitral regurgitation. Cardiac catheterization. Percutaneous closure. Amplatzer duct occluder.

Cierre percutáneo de las dehiscencias periprotésicas mitrales. ¿La alternativa a una cirugía de alto riesgo?

La insuficiencia mitral periprotésica secundaria a fugas perivalvulares es una complicación de la cirugía de reemplazo valvular. Presentamos una serie de 8 casos con insuficiencia mitral periprotésica severa y sintomática, rechazados para cirugía por alto riesgo y en los que se decidió el cierre percutáneo de la fuga periprotésica mitral. En todos se utilizó dispositivo Amplatzer de cierre ductal. El procedimiento fue exitoso en 5 de los pacientes. Se objetivó disminución significativa de la insuficiencia periprotésica y mejoría clínica en el seguimiento en 4 pacientes. Se fracasó en 3 (2 por interferencia con los discos de la prótesis y 1 por no poder atravesar la fuga), de los que 1 falleció a las pocas horas del procedimiento por ictus masivo. El cierre percutáneo de dehiscencias perivalvulares en pacientes con alto riesgo quirúrgico es un procedimiento técnicamente posible y con una tasa de éxito clínico aceptable.

Palabras clave: Insuficiencia mitral. Cateterismo cardiaco. Cierre percutáneo. Amplatzer ductal.

INTRODUCTION

The presence of paravalvular leaks following valve replacement surgery is not an uncommon complication (2%-17%), according to the series)^{1,2} that depends on the suture technique, and is more frequent when there is severe annular calcification or following endocarditis. In the majority of cases, these periprosthetic leaks are small and have no clinical consequences, but on some occasions, they produce severe hemolysis that requires repeated

Correspondence: Dr R. García-Borbolla Fernández. Brunete, 6, 1º. 11007 Cádiz. España. E-mail: rafaelgborbolla@hotmail.com

Received February 6, 2008. Accepted for publication May 27, 2008. transfusions or, if they are too large, heart failure refractory to medical treatment. In some of these patients, surgical treatment is associated with very high rates of morbidity and mortality, which increase depending on the number of previous surgical procedures.³⁻⁵ Percutaneous closure may be an alternative for the symptomatic improvement of these patients.

METHODS

Eight patients were included (75% men; mean age, 63.7 [23.7] years) between November 2002 and February 2007. Their baseline characteristics are shown in Table 1. They were all evaluated jointly with the cardiac surgery department and a further intervention was ruled out because of the high surgical risk. The indication for the procedure

Patient	Sex	Age, y	Previous Surgeries	Comorbidity	Indication	Device Size, mm	Prosthesis Implantation
1	Male	77	MVR, MMP, PM	Severe COPD, CRF	Heart failure	_	No
2	Male	46	MMP, MMP	-	Heart failure	8/6 (n=2); 6/4 (n=1)	Yes
3	Male	61	CS, mediastinitis, MMP	Recent AMI, PTE	Heart failure	6/4	Yes
4	Male	76	MMP, MMP, PM	Acute multiorgan failure	Heart failure	16/14	Yes
5	Female	41	MVR, BMP, MMP	_	Heart failure	_	No
6	Female	75	BMP + BAP + Morrow myectomy	CRF in hemodialysis	Heart failure + hemolysis	12/10	Yes
7	Male	72	MVR, MMP, MMP, sternal dehiscence, PM	Severe COPD, CRF, UGH, colonic diverticulosis	Heart failure + hemolysis	6/4	Yes
8	Male	62	MMP, MMP + MAP	-	Hemolytic anemia	_	No

AMI indicates acute myocardial infarction; BAP, biological aortic prosthesis; BMP, biological mitral prosthesis; COPD, chronic obstructive pulmonary disease; CRF, chronic renal failure; CS, coronary revascularization surgery; MAP, mechanical aortic prosthesis; MMP, mechanical mitral prosthesis; MVR, mitral valve repair; PM, permanent pacemaker; PTE, pulmonary thromboembolism; UGH, upper gastrointestinal hemorrhage.



Figure 1. A: retrograde approach to the leak; fluoroscopic image showing how the loop catheter snares the guide wire in left atrium to form an arteriovenous circuit. B: implantation of a third Amplatzer duct occluder in a patient with several periprosthetic leaks.

was heart failure refractory to medical management and/or hemolytic anemia that required repeated transfusions.

The procedure was carried out with general anesthesia, using transesophageal echocardiography (TEE), in addition to fluoroscopy, as an imaging technique. Prior to the procedure, TEE was performed in all patients in order to locate the leak and determine the degree of periprosthetic regurgitation.

Transseptal puncture was carried out in all 8 patients in the attempt to pass through the leak in antegrade direction. Multipurpose catheters were utilized, Judkins right and Judkins left mammary catheters, passing through the leak with a Terumo[®] hydrophilic guide wire (Terumo Medical Corp., Somerset, New Jersey, United States). This route was possible in 5 patients. In 2 patients, given that antegrade catheter placement was impossible, retrograde passage from left ventricle was achieved, passing the hydrophilic guide wire into left atrium, where it was snared with a loop catheter, establishing an arteriovenous circuit (Figure 1A). In 1 patient, catheter placement in the leak was not achieved.

In all the cases in which the leak was catheterized. a sheath was introduced antegradely and the Amplatzer occluder for ductus arteriosus (AGA Medical, Minnesota, United States) was placed (Figure 1B). The sizes ranged between 4/6 mm and 14/16 mm. The selection was made according to the criteria of the operator on the basis of the size of the base of the leak, as observed with TEE. In 4 cases, a single device was used and, in 1 patient, 3 were placed during a single procedure (Table 1). Mitral regurgitation was assessed using TEE immediately after device implantation (mild, moderate, or severe, depending on the area according to color Doppler and continuous wave spectral Doppler). All patients underwent clinical and echocardiographic follow-up.

RESULTS

A single procedure was performed in every case and was successful in 5 patients. The implantation was not possible in 2 of them because of interference with the discs of the prostheses. Of these, in 1, the interference persisted even when the smallest size



Figure 2. A: Transesophageal echocardiogram showing lateral periprosthetic mitral regurgitation under baseline conditions. B: Disappearance of mitral regurgitation following implantation of an Amplatzer duct occluder.

TABLE 2. Clinical and Echocardiographic Follow-up of the Patients in Whom Prosthesis Implantation Was Achieved

Sex	Age, y	Previous Functional Class, Degree of Mitral Regurgitation	Functional Class During Follow-up, Degree of Mitral Regurgitation	Follow-up
Male	46	III, severe	ll, mild	18 months
Male	61	IV, severe	ll, mild	12 months
Male	76	IV, severe	IV, mild	21 days (death)
Female	75	IV, severe	III, moderate	6 months
Male	72	IV, severe	II, moderate	36 months (death)

was employed and, in the other, who had a very wide leak, the attempt was made with a device immediately inferior in size, but it continued to block the prosthesis and did not appear to be stable; thus, a repeated attempt was ruled out. The third failure occurred in a patient with severe hemolysis, a small leak and a double metallic mitral and aortic prosthesis. Device placement for the mitral leak was not possible, despite the fact that the patient tolerated adequately the retrograde passage to left ventricle through a metallic aortic prosthesis.

Of the 5 patients in which the devices were implanted correctly, a decrease in mitral regurgitation was observed immediately by means of TEE in 4 of them (Figure 2), which was maintained in transthoracic echocardiographic (TTE) monitoring during follow-up. In 1 patient in whom no significant immediate changes were observed, improvement in mitral regurgitation from severe to moderate was confirmed by serial TTE during follow-up, with accompanying clinical improvement.

In the 2 patients (6 and 7) with anemia in whom the device was implanted correctly, the lactate dehydrogenase concentration improved, with no significant change in the hemoglobin levels. Both had chronic renal failure and one of them had recurrent gastrointestinal hemorrhages secondary to colonic diverticulosis, which required blood transfusions.

Of the 5 patients in which the initial results were successful, 1 died 22 days after the procedure. He

was a patient with multiple organ failure who, despite the significant improvement in the mitral regurgitation (from severe to mild), he died of septicemia of respiratory origin. Patient 7 died 3 years later of gastrointestinal complications, although improvement in the mitral regurgitation had been observed during follow-up. Three patients are alive after a mean follow-up of 15 (5) months, with improvement in the dyspnea functional class in all of them and a decrease in the degree of mitral regurgitation (Table 2).

Of the 3 patients in whom implantation of the device was not achieved, 1 died a few hours later of a severe stroke, despite adequate anticoagulation during the procedure (patient 1). The second patient was reevaluated and the decision was finally made to assume the risk of a new surgical intervention (patient 5). After 36 months of follow-up, he is in dyspnea function class I. The last patient, in whom the only indication was hemolytic anemia, improved progressively with the administration of erythropoietin (patient 8).

DISCUSSION

Although surgery continues to be the technique of choice for the repair of periprosthetic leaks, the rate of mortality increases with the number of previous interventions,² being 13%, 15%, and 37% after the first, second, and third intervention, respectively.

Thus the current classifications of surgical risk tend to underestimate the risk in these patients.³

Percutaneous closure of periprosthetic leaks was described for the first time by Hourihan et al⁶ in 1992. These authors successfully closed 2 paravalvular leaks around a prosthetic aortic valve using the Rashkind double umbrella device. Since then, isolated cases of closures of mitral valve leaks with coils⁷⁻⁹ and with the CardioSEAL Clamshell[®] (Nitinol Medical Technologies, Boston, Massachusetts, USA) have been reported and, in the most recent series, with Amplatzer occluders.⁹⁻¹⁴

The results of these series show that the implantation of the device is feasible in a high percentage of patients and that, although it rarely closes the defect completely, it produces a significant decrease in the degree of mitral regurgitation and improvement of the symptoms. This is probably due to the fact that, at least in the large defects, the feasibility of complete closure is limited because of their semilunar shape. Thus, specific designs for defects of this type would be convenient in order to increase the incidence of complete closure of the leaks. Among the devices currently available, the Amplatzer duct occluder is perhaps the most suitable one because of its form.^{15,16} with a large enough distal disc to support the left ventricular pressure and with a lower probability of interfering with the valve prosthesis.

In their series, Hein et al¹⁵ observed a worsening of the hemolysis in 45% of their patients, probably in relation to the incomplete closure of the leak. In our series, in the 2 patients in whom the indication was heart failure and hemolysis, a decrease in the latter was observed. With the current data,^{11,13,14} we consider it necessary to be cautious when the indication is hemolysis alone.

Although our series includes few patients to allow us to draw conclusions concerning its effectiveness, percutaneous closure is technically possible and can improve the degree of mitral regurgitation and the symptoms in those patients considered to be of high surgical risk.

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