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Original article

Immediate and Mid-term Clinical Course After Percutaneous Closure of Paravalvular Leakage

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ABSTRACT

Introduction and objectives: Percutaneous closure of paravalvular leakage is an alternative to surgery in high-risk patients, but its use has been limited by a lack of specific devices. More appropriate devices—like the Amplatzer Vascular Plug III—have recently been developed, but information about their efficacy and safety is still scarce. The objective of the present study was to assess the mid-term results of paravalvular leakage closure with this device.
Methods: We analyzed the clinical and echocardiographic course both in-hospital and mid-term (13 [9] months) in a series of 20 consecutive patients (age, 68 years; logistic EuroSCORE, 29) with paravalvular leakage and attempted percutaneous closure.
Results: Closure was attempted for 23 leaks (17 mitral and 6 aortic) during 22 procedures in 20 patients. Implantation was successful in 87% of the leaks and the procedure was successful in 83%—with success being defined as a reduction in regurgitation of $\geq$ 1 degree. Survival at 1 year was 64.7% and survival free of the composite event of death/surgery was 58.8%. The degree of residual regurgitation was not associated with mortality but was associated with functional status. Survivors showed significant improvement in functional class.
Conclusions: Percutaneous closure of leakage with the Amplatzer Vascular Plug III is safe and efficient in the mid-term. However, mortality among high-risk patients is high independently of the degree of residual regurgitation, indicating that these procedures are performed when heart disease has reached an advanced stage.

Evolución inmediata y a medio plazo de las dehiscencias paravalvulares cerradas percutáneamente

Palabras clave:
Supervivencia
Prótesis valvular
Dehiscencia paravalvular
Cateterismo cardiaco
Dispositivo

RESUMEN

Introducción y objetivos: El cierre percutáneo de dehiscencias paravalvulares es una alternativa a la cirugía en pacientes de alto riesgo, pero la falta de dispositivos específicos ha limitado su uso. Recientemente se han desarrollado dispositivos más adecuados, como el Amplatzer Vascular Plug III, pero actualmente hay poca información de su eficacia y su seguridad. El objetivo es estudiar el resultado a medio plazo del cierre de dehiscencias paravalvulares con este dispositivo.
Métodos: Se analizó la evolución clínica y ecocardiográfica tanto hospitalaria como a medio plazo (13 $\pm$ 9 meses) de una serie de 20 pacientes consecutivos (edad, 68 años; EuroSCORE logístico, 29) con dehiscencias paravalvulares e intento de cierre percutáneo.
Resultados: Se intentó el cierre de 23 dehiscencias (17 mitrales y 6 aórticas) durante 22 procedimientos en 20 pacientes. Se logró el éxito del implante en el 87% de las dehiscencias y el éxito del procedimiento con una reducción de $\geq$ 1 grado de la insuficiencia en el 83%. La supervivencia al año fue del 64,7% y la supervivencia libre de muerte/cirugía, del 58,8%. El grado de insuficiencia valvular residual no se relacionó con la mortalidad, pero sí con el grado funcional. Entre los supervivientes se observó una mejora significativa en la clase funcional.

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Conclusiones: El cierre percutáneo de dehiscencias con el Amplatzer Vascular Plug III es seguro y eficaz a medio plazo, aunque la mortalidad de los pacientes de alto riesgo es alta independientemente del grado de insuficiencia residual, lo que indica que se realiza en un estadio avanzado de la cardiopatía.

Abbreviations

AVP: Amplatzer Vascular Plug
NYHA: New York Heart Association
PVL: paravalvular leakage

INTRODUCTION

Paravalvular leakage (PVL) is a frequent complication after the implantation of a prosthetic valve. This complication is due to failure of the surgical suture, favored by the presence of calcium, infection, tissue friability, or the noncircular shape of the annulus.[1,2] In most cases, PVL is small, being found by chance during postsurgical echocardiography. Only 1% to 5% of PVL causes symptoms of either congestive heart failure (in patients with large PVL), or hemolytic anemia (in smaller, tortuous, and multiple PVL).[2]

Medical treatment can improve symptoms but cannot correct the structural defect and consequently the treatment of choice has traditionally been surgical reoperation to close the defect and/or replace the prosthesis.[1] However, given the underlying predisposing factors, reoperation is associated with higher morbidity and mortality than initial interventions and is also associated with a higher rate of residual or recurrent PVL.[3]

Recently, percutaneous closure has been proposed as an alternative to surgery in high-risk patients, especially due to the development of devices with designs better–suited to PVL closure, like the Amplatzer Vascular Plug (AVP) III (AGA, St. Jude Medical; Minneapolis, Minnesota, United States). However, the few reports published on this device are limited to the immediate results of isolated cases and small series and no studies have assessed the long-term results. The objective of the present study was to analyze the immediate and mid-term clinical and echocardiographic course of a series of consecutive patients treated with the AVP III device as first choice.

METHODS

Study Population

From September 2010 to September 2012, percutaneous closure was scheduled in 22 patients in a single center. All were symptomatic and attended special sessions with participation by clinical cardiologists, interventional cardiologists, and surgeons. Two patients were excluded from percutaneous closure: 1 had an

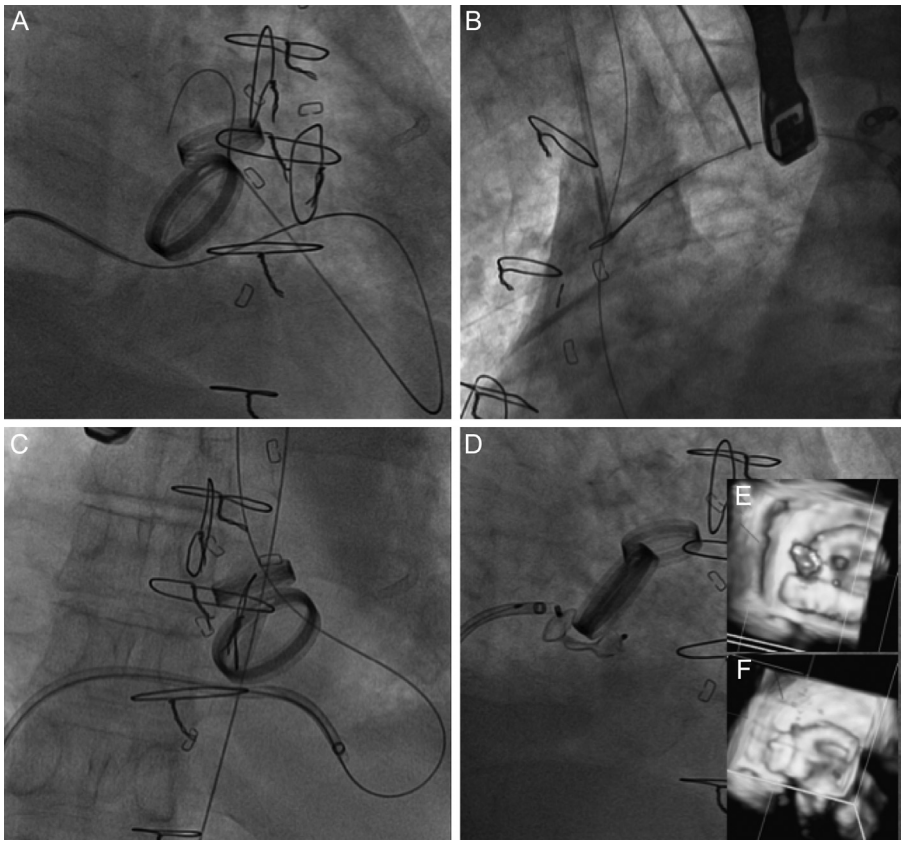

Figure 1. Closure of posterior paravalvular leakage on a mechanical mitral valve in the presence of bileaflet mechanical aortic prosthesis. A: the hydrophilic guidewire is advanced by anterograde access through the mitral paravalvular leak and into the aortic prosthesis. B: the guidewire is entrapped in the ascending aorta with a snare and externalized through a femoral artery to create an arteriovenous loop. C: this gives us sufficient push for the release sheath to pass. D: an Amplatzer Vascular Plug III 14/5 device is implanted. E: baseline 3-dimensional transesophageal echocardiography image. F: result postimplantation.