



Transcatheter Device Closure of Complex Paravalvular Leak after Bioprosthetic and Mechanical Pulmonary Valve replacement in Two Adult Patients

Zahra Khajali¹,^{ID} Ata Firouzi¹, Maryam Keshavarz Hedayati^{2,*},^{ID} Fateme Jorfi³, Mohamad Sadra Nazari²

¹Rajaei Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, IR Iran

²Buali Sina Medical and Research Center, Qazvin University of Medical Sciences, Qazvin, IR Iran

³Imam Khomeini Medical and Research Center, Jundishapur University of Medical Sciences, Ahwaz, IR Iran

ARTICLE INFO

Article Type:
Case Report

Article History:
Received: 27 Feb 2020
Revised: 30 Apr 2020
Accepted: 27 May 2020

Keywords:
Septal Occluder Device
Congenital Heart Disease

ABSTRACT

Introduction: Paravalvular leak after prosthetic valve operation affects up to 27% of all prosthetic heart valves implanted by conventional surgery, which can be the cause of serious complications like hemolysis and congestive heart failure. Surgical re-intervention is the conventional treatment of choice for severe cases, but it is associated with significant morbidity and mortality and is not always successful because of underlying tissue fragility. Over the last decade, transcatheter treatment of paravalvular leaks has emerged as an attractive alternative to surgery for high-risk patients and is now favored as the initial approach in some experienced centers. Significant paravalvular leaks are not common following a pulmonary valve replacement and may be more complex anatomically than left-sided paravalvular leak due to the variability in implant location and technique in the trabeculated and often dilated and fibrotic right ventricular outflow tract.

Case Presentation: This study aimed to report two patients with successful transcatheter closure of a complex paravalvular leak utilizing Ventricular Septal Defect (VSD) and Patent Ductus Arteriosus (PDA) occluder devices following mechanical and bioprosthetic Pulmonary Valve Replacement (PVR). The cases included a 34-year-old and a 26-year-old man who were known cases of tetralogy of Fallot with a history of total correction operation (TFTC).

Conclusions: The results showed that paravalvular leak could be a hemodynamically serious complication of surgical PVR and that transcatheter device closure was an acceptable way for the relief of these defects. However, the best approach for the closure of pulmonary paravalvular leak depends on specific anatomic structures and the origin or course of the coronary arteries that must be evaluated before device implantation.

1. Introduction

Paravalvular leak after prosthetic valve operation affects up to 27% of all prosthetic heart valves implanted by conventional surgery (1). It is usually a consequence of suture dehiscence between the sewing ring and the native tissue and can be the cause of serious complications like hemolysis and congestive heart failure (2). Surgical re-intervention is the conventional treatment of choice for severe cases, but it is associated with significant morbidity and mortality and is not always successful because of underlying tissue fragility. Over the last decade, transcatheter treatment of

paravalvular leaks has emerged as an attractive alternative to surgery for high-risk patients and is now favored as the initial approach in some experienced centers. Transcatheter repair has been reported to be technically feasible in 60-90% of cases according to different published articles. In addition, technical success has been associated with clinical improvement in 50 - 90% of cases (1).

Biological and mechanical prosthetic valves are used for pulmonary valve replacement in patients with repaired congenital heart abnormalities and chronic pulmonary insufficiency (3). Significant paravalvular leaks are not common following pulmonary valve replacement and may be more complex anatomically compared to left-sided paravalvular leak due to the variability in implant

*Corresponding author: Maryam Keshavarz Hedayati, Buali Sina Hospital, Buali Avenue, Qazvin, Iran, Cellphone: +98-9126819348, Email: m_k_hedayati@hotmail.com.

location and technique in the trabeculated and often dilated and fibrotic Right Ventricular Outflow Tract (RVOT) (2). Successful percutaneous closures of prosthetic mitral and aortic paravalvular leaks using occluder devices have been reported (4). There are also some reports regarding pulmonary bioprosthetic paravalvular leakage closure after Pulmonary Valve Replacement (PVR) in adults and children (5).

Herein, we reported two patients with transcatheter closure of a complex paravalvular leak utilizing Ventricular Septal Defect (VSD) and Patent Ductus Arteriosus (PDA) occluder devices following mechanical and bioprosthetic PVR. The cases were a 34-year-old and a 26-year-old man who were known cases of Tetralogy of Fallot (TOF) with a history of total correction operation (TFTC).

2. Case Presentation

One of the patients was a 34-year-old man who was a known case of TOF with the history of TFTC 22 years ago and mechanical PVR with a 27-mm SJ and permanent pacemaker implantation six years ago. The other patient was a 27-year-old man who was a known case of TOF with the history of TFTC 26 years ago, bioprosthetic PVR with a 27-mm PORCINE EPIC bioprosthetic valve 10 years ago, and permanent pacemaker implantation 26 years ago. The patients and their families were not ready for a third operation and they rejected surgical corrections despite strong recommendation. Hence, they were advised for catheterization and closure of the pulmonary valve leakage due to dyspnea, exercise symptoms, and severe pulmonary prosthetic valve leakage. The exact reason for the paravalvular leakage was unknown, but it was not endocarditis.

The first patient's echocardiogram at that time demonstrated normal left ventricle size and preserved systolic function (ejection fraction = 50%), severe right ventricle enlargement, moderate to severe right ventricular systolic dysfunction, normal left atrium and right atrium size, normal mechanical prosthetic pulmonary valve function with severe paravalvular leak from the anterolateral side of the sewing ring (as a defect) and acceptable gradient (peak gradient = 18 mmHg, mean gradient = 12 mmHg, no gradient in the right and left pulmonary arteries), left-sided aortic arch, no residual ventricular septal defect, no atrial septal defect, and mild to moderate tricuspid valve regurgitation (Figure 1).

Cardiac Magnetic Resonance Imaging (MRI) was also done, which showed normal left ventricle size without left ventricular hypertrophy and with preserved systolic function (ejection fraction = 54%), moderately enlarged right ventricle size, and moderately reduced systolic function. In addition, prosthetic pulmonic valve was found to be replaced below the true pulmonic annulus with an aneurysmally dilated segment post prosthetic valve (diameter = 48 mm) that might be the residual of the prior aneurysmally RVOT segment. The results also revealed severe prosthetic valve regurgitation (paravalve and transvalve regurgitation), no peripheral pulmonary stenosis, no obvious residual VSD, and RVOT fibrosis.

The second patient's echocardiogram at that time

demonstrated mild left ventricular enlargement with moderate systolic dysfunction (ejection fraction = 35 - 40%), severe right ventricle enlargement with moderate to severe systolic dysfunction, aneurysmal dilation of RVOT, interrupted Inferior Vena Cava (IVC), mild to moderate tricuspid valve regurgitation, no residual VSD, no aortic insufficiency, bioprosthetic pulmonary valve with no pulmonary valve stenosis and with a hole in the medial side of the prosthetic valve, and moderate transvalvular and severe paravalvular leakage into the trabeculated posteroseptal aspect of the RVOT.

Hematological evaluation for both patients did not reveal any evidence of hemolysis. For both patients, hemodynamic and angiographic data were studied before the intervention.

In the first patient, the guidewire was advanced through the catheter from the IVC pathway and then across the paravalvular leak. For the first time, a sizing balloon was performed for the evaluation of the defect size. The venous sheath and catheter were then removed and an introducer sheath was advanced over the guidewire to the level of the leak and the guidewire was removed. Then, a VSD occluder (8 mm) was mounted on a delivery cable, advanced through the introducer sheath across the paravalvular leak, and deployed without difficulty (Figure 2).

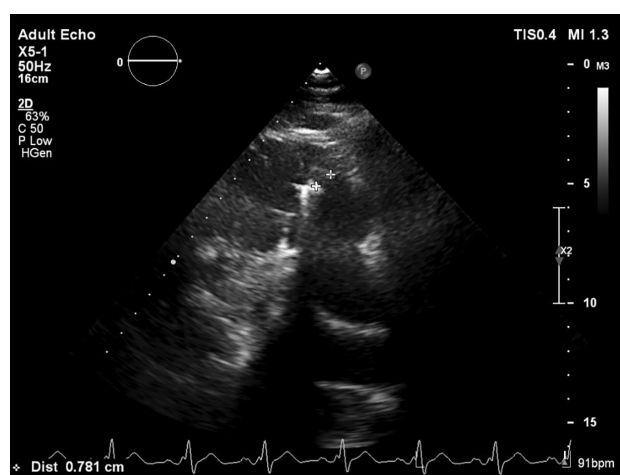


Figure 1. Defect in the Paravalvular Leak Site before the Procedure in the First Patient

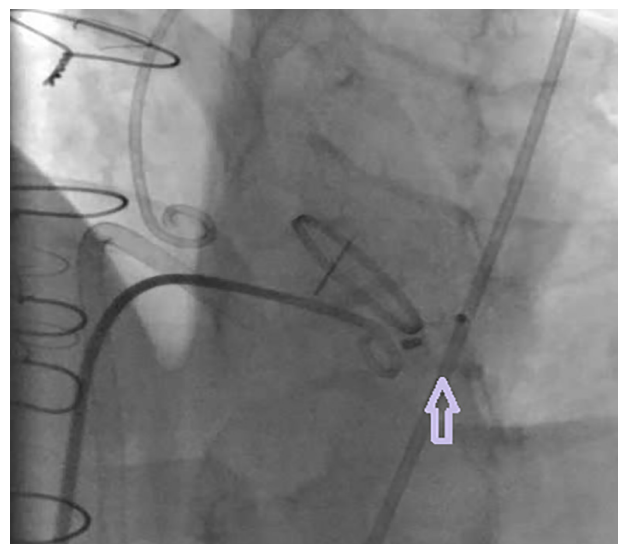


Figure 2. The Paravalvar Leak Device Occluder in the First Patient

Afterwards, the pulmonary artery angiography demonstrated mild to moderate residual pulmonary paravalvular leak.

In the second patient, the guidewire was advanced through the catheter from the azygos pathway to superior vena cava and then across the paravalvular leak. The venous sheath and catheter were then removed and an introducer sheath was advanced over the guidewire to the level of the leak and the guidewire was removed. Then, a PDA occluder 14/18 (occlutech) was mounted on a delivery cable, advanced through the introducer sheath across the paravalvular leak, and deployed without difficulty. Afterwards, pulmonary artery angiography demonstrated mild to moderate residual pulmonary paravalvular leak.

3. Discussion

Pulmonary regurgitation is common in patients with a prosthetic pulmonary valve. There are more complications and greater variability in the surgical approach to PVR compared to aortic valve or mitral valve replacement. The valve can be placed almost anywhere along the RVOT, depending on a variety of factors, including the trabeculated muscular infundibular level and the main pulmonary artery, both of which can be severely dilated with different orientations (2). Considering the complex anatomical feature of the RVOT and the variability of the PVR implant site and orientation, transcatheter closure of pulmonary paravalvular leaks is likely to differ from closure of other paravalvular leaks. The proximity of the defect to the coronary arteries, which may be abnormal in congenital heart diseases can also be an important matter and must be evaluated via angiography before device implantation. In the present study, the procedure was very hard due to the presence of permanent pacemaker leads in the right atrium and the right ventricle.

Transcatheter devices used for paravalvular leak closure have not been designed for occlusion of these defects and are not for pulmonary leaks. With the complexity and variability of the pulmonary paravalvular leak and features of RVOT anatomy, it is difficult to choose the best device. Percutaneous closure of paravalvular leaks is a way of avoiding reoperation after surgical valve replacement. However, it may be accompanied with high risks, including impairment of the prosthetic valve leaflet motion, device dislodgement and immobilization, and hemolysis. In the present study, despite the researchers' limited experience with using a VSD or PDA occluder device to close a prosthetic pulmonary paravalvular leak, relief of the paravalvular leak was achieved without any complications. As a matter of fact, this technique may be an effective alternative to reoperation in this population.

The patients recovered from the procedure without any complications. The results of the lab tests also did not show any hemolysis. Besides, echocardiography was done one day after the procedure and showed the paravalvular

occluder devices in proper position with no clots on them, no compressive effects on the adjacent sites, and mild to moderate jets of paravalvular leaks. They tolerated the procedure well and there was no evidence of valve leaflet obstruction, device migration, or hemolysis. After one month, they had no symptoms like those before the procedure and their symptoms had decreased compared to the past.

This case report indicated that paravalvular leak could be a hemodynamically serious complication of surgical PVR and that transcatheter device closure was an acceptable way for the relief of these defects. However, the best approach for the closure of pulmonary paravalvular leak depends on the specific anatomic structures and the origin or course of the coronary arteries, which must be evaluated before device implantation.

3.1. Ethical Approval

This study included the reports of two patients hospitalized at a center in the past and no clinical trials were performed.

3.2. Informed Consent

The presented cases saw and agreed with the submitted paper.

Acknowledgements

There is no acknowledgment.

Authors' Contribution

Study concept and design: Z.K. and M.K.H. Critical revision of the manuscript for important intellectual content: M.K.H. and M.N. The original idea and the protocol: Z.K. and A.F. Abstracting and writing the manuscript: M.K.H. and M.N. Guarantor: M.N. and F.J. Development of the protocol and preparing the manuscript: M.N. and F.J.

Funding/Support

No funding was received from any company or institution.

Financial Disclosure

The authors have no financial interests related to the material in the manuscript.

References

1. Noble S, Basmadjian A, Ibrahim R. Transcatheter prosthetic paravalvular leak closure. *Cardiovasc Med* 2012; 15 (9): 245-52. 2017.
2. Seery TJ, Slack MC. Percutaneous closure of a prosthetic pulmonary paravalvular leak. *Congenital Heart Disease*. 2014;9(1):E19-E22.
3. Smolka G, Pysz P, Ochala A. Percutaneous closure of paravalvular leak and ventricular septum defect. *Catheterization and Cardiovascular Interventions*. 2011;78(2):326-30.
4. Trehan V, Subhendu M, Chaturvedi V, Pandit B, Goyal M. Paravalvular leak closure with two large size devices. *Indian Heart Journal*. 2014;66(1):91-4.
5. Chikkabyrappa S, Mosca RS, McElhinney DB. Retrograde transcatheter device closure of a complex paravalvular leak after bioprosthetic pulmonary valve replacement in a pediatric patient. *Catheterization and Cardiovascular Interventions*. 2016;87(7):1294-7.