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Indications: The Edwards crimper is indicated for use in preparing the Edwards SAPIEN XT transcatheter heart valve for implantation.

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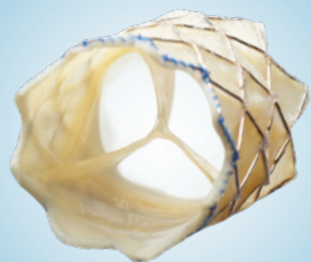
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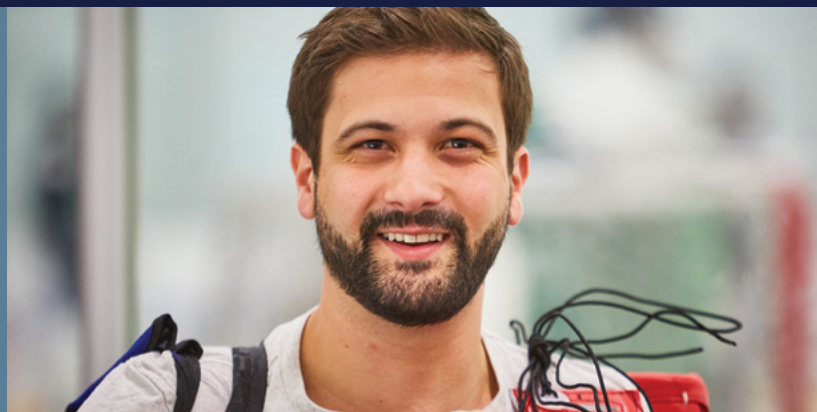
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Warnings/Precautions/Side Effects:
- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**

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- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.

- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.

- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.

- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.

- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site.

Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

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- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications:
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- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
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Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site.

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The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

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The Melody Transcatheter Pulmonary Valve and Ensemble II Transcatheter Delivery System has received CE Mark approval and is available for distribution in Europe.

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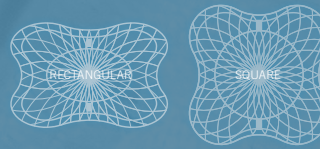
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Left Atrial Appendage Closure with Double Watchman Devices: A Case Report

Faisal Alsmadi, MBBS, FRCPC, FACP, FACC, FSCAI, MHRS,
Muhammad Azam Shah, MBBS, FCPS (Cardiology)*, Mohammad Bara Qattea, MD

Department of Cardiology, King Salman Heart Center, King Fahad Medical City, Riyadh, Saudi Arabia

Abstract

The risk of cardioembolic stroke is high in patients with atrial fibrillation. Antiplatelet agents, vitamin K antagonists, and new oral anticoagulants (NOACs) are effectively used to reduce the risk of thromboembolism in high-risk patients. However, increased risks of life-threatening bleeding and narrow therapeutic indexes result in inadequate utilization of these therapies. There is growing practice and evidences in favor of closing the left atrial appendage (LAA) percutaneously by using different devices in patients with either contraindicated or difficult anticoagulation. We report a rare case of a 75-year-old man with atrial fibrillation, high thromboembolic risk (CHADSVASc score of 4), and high bleeding risk score (HASBLED score of 4). He underwent LAA closure using 2 LAA percutaneous closure devices (Watchman) due to bilobed LAA. Considering the great variability in shape and size of the LAA, a single device may not always cover the whole ostium, which leads to residual leaks that can cause a nidus for thrombus formation. Although it technically sounds feasible, a few challenges are associated with double-device implantation. Sealing of the bilobed LAA is technically possible, especially with favorable anatomy, which includes totally separated bodies of both lobes with adequate body sizes.

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Key Words

Atrial fibrillation • Left atrial appendage closure • WATCHMAN device • Anticoagulation

Introduction

Prevention of cardioembolic stroke is one of the key goals in the treatment of patients with atrial fibrillation (AF). The risk of embolic stroke with nonvalvular AF is 5.6 times higher [1]. Anticoagulants such as vitamin K antagonists (VKA) and new oral anticoagulants (NOACs) are used effectively to reduce the risk of thromboembolism [2]. However, increased risks of mortality, bleeding, and narrow therapeutic indexes result in inadequate utilization of these therapies. There is growing practice and evidence in favor of closing the left atrial (LA) appendage (LAA) percutaneously by using different devices in patients with either contraindicated or difficult anticoagulation. Considering the great variability in the shape of the LAA, sometimes, a single device may not cover the whole ostium, which leads to residual leaks that can cause a nidus for thrombus formation. A previous report on double-device LAA closure using an Amplatzer cardiac plug (ACP) showed favorable results at follow-up [3]. We report a rare case of a 75-year-old man with AF and high thromboembolic risk who underwent LAA closure using double Watchman devices.

Case Summary

A 75-year-old man who had diabetes, hypertension, hypothyroidism, a post-coronary artery bypass grafting 32 years before, chronic kidney disease (glo-

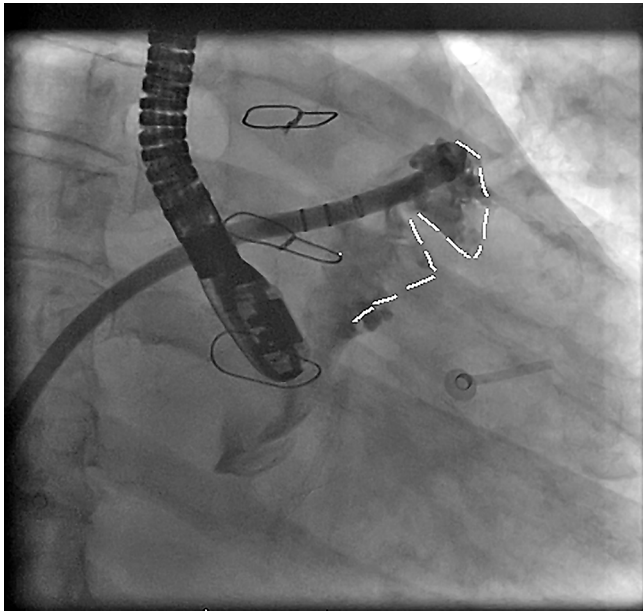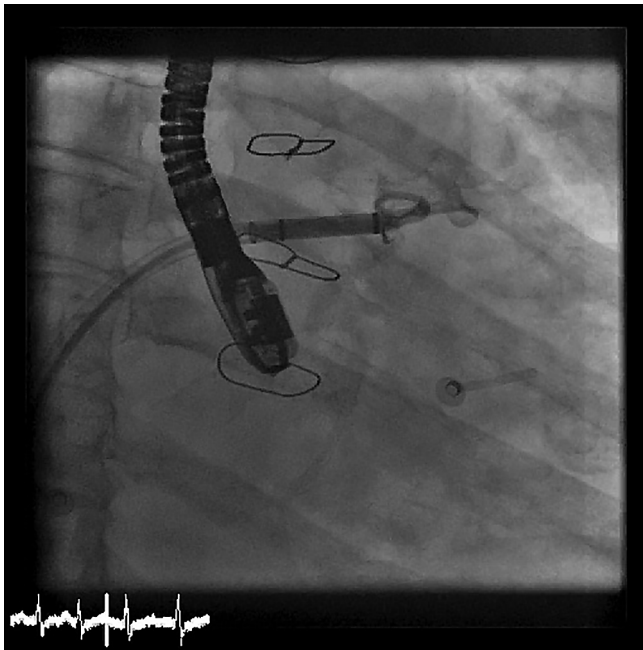* Corresponding Author:
Muhammad Azam Shah, MBBS, FCPS (Cardiology)
Department of Cardiology
King Salman Heart Center
Dabab Street, Sulaimaniya, PO Box 59046, Riyadh 11525, Riyadh, Saudi Arabia
Tel. +00566539417315; E-Mail: azamshah165@hotmail.com

Figure 1. On contrast injection (RAO 20º, CAU 18º) showing bilobed LAA morphology with very wide ostium.

Video 1. On contrast injection (RAO 20º, CAU 18º) showing bilobed LAA morphology with very wide ostium. View supplemental video at https://doi.org/10.12945/j.jshd.2019.010.18.sup.01.

merular filtration rate = 48 mL/min) with an ejection fraction of approximately 40% underwent a permanent AF (CHADSVASc and HASBLED scores of 4). He underwent anticoagulation using rivaroxaban 15 mg.

He was undergoing follow-up as an outpatient because of chronic anemia and heart failure symptoms, and was admitted at our hospital with lower gastrointestinal (GI) bleeding and decompensated heart failure. The patient was hemodynamically stable and had bilateral crepitation at the bases of the lungs along with mild pedal edema on physical examination. His hemoglobin level was 8.4 g/dL and serum creatinine was 193 µmol/L. Colonoscopy revealed two colonic polyps. Considering difficult anticoagulation due to the persistent anemia and lower GI bleeding, he was referred for LAA device closure.

Echocardiography documented a severely dilated LA (indexed LA volume, 63 mL/m^2). Pre-procedural transesophageal echocardiography revealed a LAA ostial diameter of 20 mm with a depth of 27 mm. The procedure was performed under general anesthesia. A right femoral venous access was used after the transseptal LA puncture pressure was measured. A double curved Watchman access sheath was positioned in the LAA over a pigtail catheter. On contrast injection (RAO 20, CAU 18), a bilobed LAA morphology with very wide ostium was observed (Figure 1, Video 1). After multiple measurements, implantation of two devices was planned as a single device was thought to be inadequate to cover the whole ostium. By using a 14-F Watchman delivery system, a 33-mm Watchman device (Atritech Inc., Boston Scientific, Plymouth, MA) was selected and implanted successfully in the anterior lobe. The device was released after confirming the stability by using a tug test. Both angiography and echocardiography revealed a significantly sized lobe posteriorly (Figures 2 and 3, Videos 2 and 3), which was sealed using a 21-mm Watchman device (Kissing Watchman) by using the same delivery system (Videos 4 and 5). Residual peri-device leaks were excluded, and the stability of both devices was assessed (Figures 4 and 5). The patient was extubated and transferred to the critical care unit for recovery. He was discharged afterward with clopidogrel 75 mg daily and an adjusted dose of warfarin. He underwent follow-up transesophageal echocardiography (TEE) after 6 weeks of the procedure, which showed well-seated watchman devices with trivial peri-device leakage (Video 6). No other complications were observed. The patient was advised to discontinue anticoagulation.
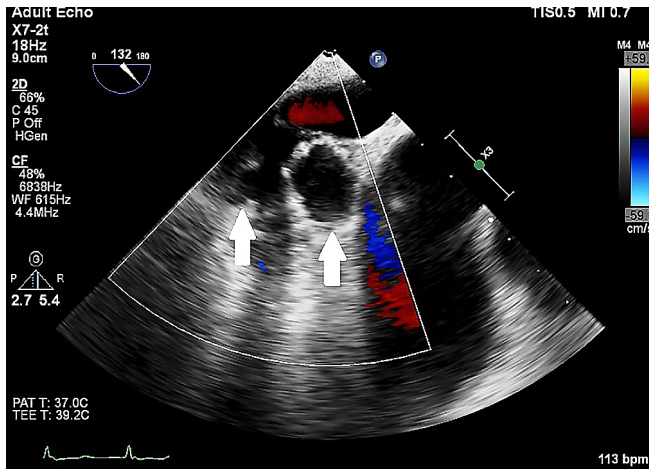
Figure 2. TEE image at 132 degrees with color showing implanted WATCHMAN device in anterior lobe with significant gap and flow posteriorly.

Figure 3. Contrast injection after implantation of WATCHMAN device anteriorly showed posterior lobe with good size ostium.

Video 2. Contrast injection after implantation of WATCHMAN device anteriorly showed posterior lobe with good size ostium. View supplemental video at https://doi.org/10.12945/j.jshd.2019.010.18.sup.02.
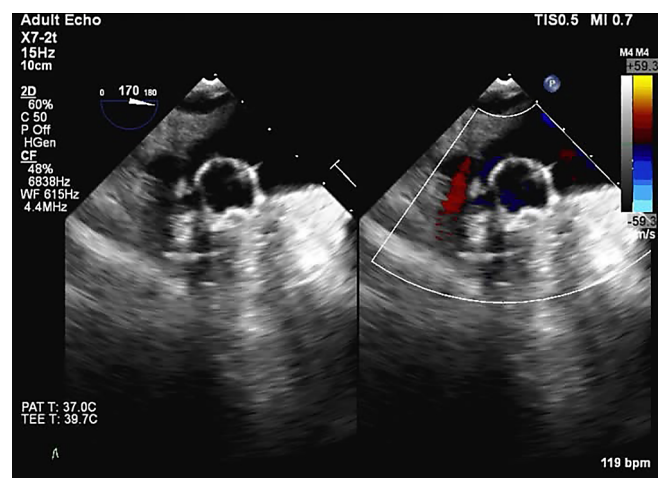
Video 3. TEE image at 170 degrees with color showing implanted WATCHMAN device in anterior lobe with significant gap and flow posteriorly. View supplemental video at https://doi.org/10.12945/j.jshd.2019.010.18.sup.03.

Discussion

AF is one of the most common cardiac arrhythmias (1–2% in Western countries) [4]. More than 15% of cerebral ischemia cases are related to AF [5]. Almost 90% of atrial thrombi are formed in the LAA in patients with nonvalvular AF [6]. Systemic anticoagulation is the therapy of choice to reduce the risk of thromboembolism in AF, but studies have shown that only few patients receive such therapies despite being indicated for multiple reasons, including complications and noncompliance [7]. Considering these limitations, percutaneous closure of the LAA is becoming increasingly popular in selected patients.
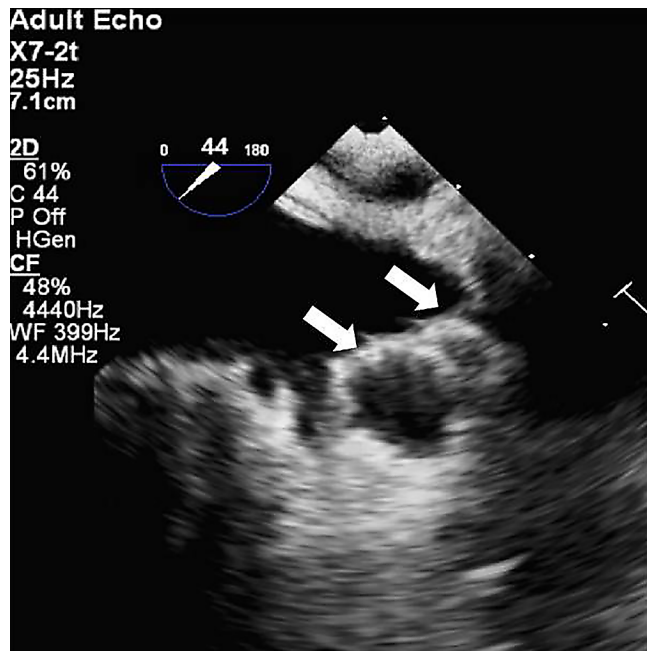
Figure 4. TEE 2D image at 44 degrees showing two WATCHMAN devices implanted side by side.
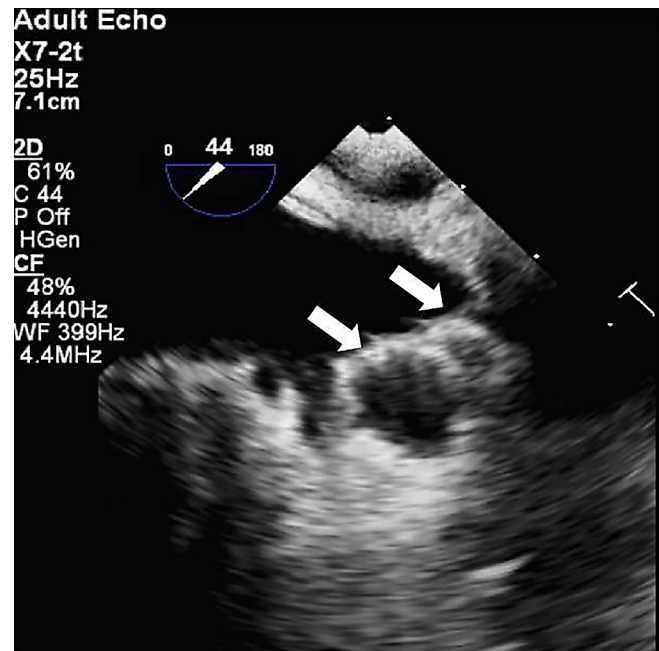
Figure 5. Cine image showing two WATCHMAN devices (Kissing WATCHMAN).
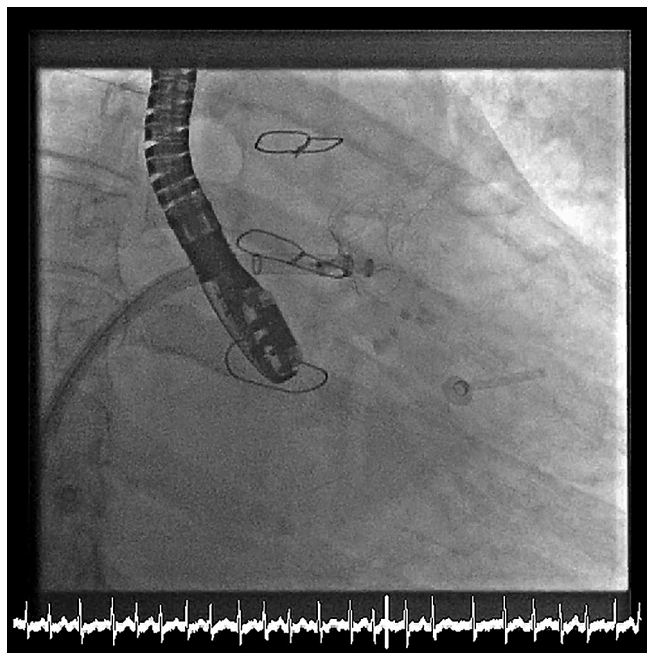
Video 4. Cine clip showing release of second WATCHMAN device. View supplemental video at https://doi.org/10.12945/j.jshd.2019.010.18.sup.04.
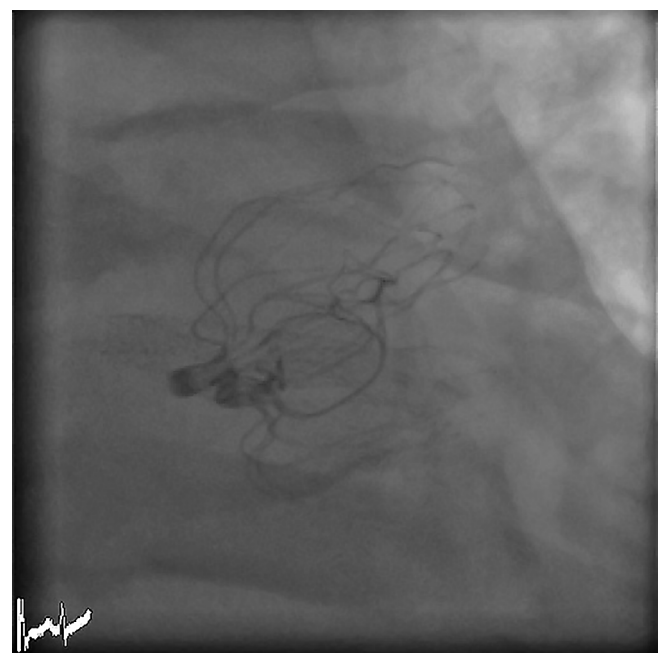
Video 5. Cine clip showing two WATCHMAN devices (Kissing WATCHMAN). View supplemental video at https://doi.org/10.12945/j.jshd.2019.010.18.sup.05.

Since the introduction of LAA closure devices about 15 years before, multiple types and shapes of devices have been introduced and tested, but the ACP and Watchman system are the most widely used. Multiple studies, including PROTECT-AF [8], CAP Registry [9], PREVAIL [10], and ASAP studies [11], have proved the efficacy and safety of the Watchman device in different sets of patients.
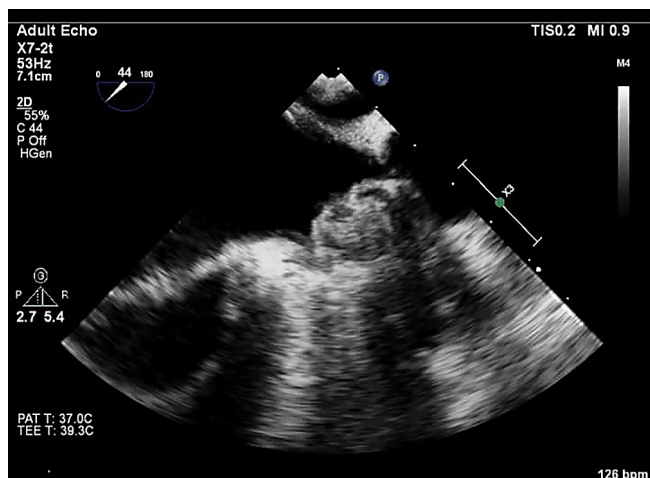
Video 6. TEE image showing well seated two WATCHMAN devices at 44 degrees. View supplemental video at https://doi.org/10.12945/j.jshd.2019.010.18.sup.06.

An autopsy study of the normal heart documented that 80% of the LAA have more than one lobe, with slightly more than half having 2 lobes [12]. Considering the great variability of the LAA anatomy in relation to size, shape, volume, number of lobes, and shape of the orifice, no single device is ideal to fit all [13]. The shape of the LAA ostium is elliptical in approximately 69% of cases, with a maximum depth ranging up to 51 mm, while the rounded shape is present in only 5–6% of cases. The diameters of the ostium show minimal changes during the cardiac cycle (1–2 mm) and no change during AF [14]. Consequently, implanting a round device into an oval-shaped ostium may lead to incomplete occlusion and peri-device leakage. This problem is reported in 32% of the cases after Watchman implantation [15]. Incomplete occlusion of the LAA is thought to result in a higher event rate, but 2 analyses that used the PLAATO and Watchman systems, respectively, showed no increased event rate of thromboembolism [16]. Occasionally, if gaps are significant, then it is possible to occlude them by using different devices fully [17]. This eccentricity in the shape of the orifice also poses hurdles in estimating the exact size of the ostium by using two-dimensional (2-D) TEE and frequently results in an underestimation of the exact diameter, which leads to implantation of an undersized device.

In addition to the eccentric shape of the ostium, another problem related to the single-device clo-sure technique is the maximum body size of the LAA. Even the new-generation ACP and Watchman devices can fit into a maximum body diameter of 30 mm [18]. Exclusion of the LAA might require 2 devices in such cases. Enio et al. reported a case series where 5 of their patients underwent double-device implantation using devices other than Watchman, with good anatomical results at follow-up [3]. Implanting 2 Watchman devices in a single patient to close bilobulated LAA was previously reported once. The report concluded that occlusion of 2 separate lobes with a common ostium is practically possible, as the main bodies of each lobe are separated by a thick ridge of pectinate muscle [19].

Although it technically sounds feasible, few challenges are associated with double-device implantation. First, the polyethylene terephthalate membranes and nitinol cage covering the Watchman device can be damaged while releasing the second device, which itself can serve as a nidus for thrombus formation due to residual leakage and difficult endothelialization. Second, putting 2 round-shaped devices over an elliptical ostium can lead to multiple residual flows between the LA and LAA. Third, no long-term data are available to support double-device implantation in the LAA; therefore, delayed mechanical complications are unknown.

This case shows that sealing of a bilobed LAA is technically feasible especially with a favorable anatomy, which includes totally separated bodies of both lobes with adequate body sizes. Although this procedure can potentially result in damaging the delicate membranous part of the Watchman device, for the time being, no data are available to evaluate the long-term effects of this interaction. We also suggest that 2-D TEE alone can underestimate the size and anatomy of the LAA. Preprocedural assessment using three-dimensional TEE and intraprocedural angiography is crucial for better occlusion of the LAA.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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Percutaneous Angioplasty of Coronary Obstruction in an Infant on Extracorporeal Membrane Oxygenation

Heather A. Sowinski, DO[1,2], Bennett P. Samuel, MHA, BSN, RN[1], Vishal R. Kaley, MBBS, MD[1],
E. Oliver Aregullin, MD, FAAP[1,2], Giedrius Baliulis, MD[1,2], Neal D. Hillman, MD[1,2],
Marcus P. Haw, MBBS, FRCS, FECTS[1,2], Joseph Vettukattil, MBBS, MD, DNB, CCST, FRCPCH, FRSM, FRCP[1,2*]

[1] Congenital Heart Center, Spectrum Health Helen DeVos Children's Hospital, Grand Rapids, Michigan, USA

[2] College of Human Medicine, Michigan State University, Grand Rapids, Michigan, USA

Abstract

The arterial switch operation (ASO) is the standard surgical technique for transposition of the great arteries. Although there have been significant improvements in long-term outcomes in patients undergoing the ASO when compared to the atrial switch procedure (Mustard or Senning), early and mid-term morbidity and mortality due to coronary complications have been identified. We describe percutaneous coronary artery angioplasty in a 9-week-old infant on extracorporeal membrane oxygenation status post ASO with optimal outcomes.

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Key Words
Arterial switch operation • Coronary artery • Percutaneous coronary angioplasty.

Introduction

Coronary artery complications may contribute to significant morbidity and mortality after the arterial switch operation (ASO). If coronary artery complications are present, revision of coronary buttons or surgical revascularization is usually performed to preserve myocardial function and avoid ischemic events. We report successful percutaneous coronary artery angioplasty with optimal long-term outcomes in an infant after ASO.

Case Presentation

A 9-week-old male infant post-surgical repair of double outlet right ventricle (DORV) and transposition of the great arteries (TGA) presented to our emergency department (ED) with cyanosis, and respiratory distress following a brief episode of poor feeding and emesis. Born at 39-weeks gestation by caesarean section at 3.12 kg, he had prenatal diagnosis of TGA. A postnatal echocardiogram confirmed the diagnosis of DORV with TGA, inverted coronary pattern, large perimembraneous ventricular septal defect (VSD) with inlet extension, subpulmonary stenosis due to muscle bundles, and patent ductus arteriosus. He was discharged to home with stable oxygen saturations and plan for close monitoring, but readmitted at age of 3 weeks requiring balloon atrial septostomy due to significant cyanosis. Surgical repair was performed at age 5 weeks and included ASO, closure of VSD and relief of subpulmonary stenosis by resecting the right ventricular outflow tract muscle bands. His post-operative course was complicated by abdominal ascites requiring peritoneal drainage placement. He was discharged to home on post-operative day 10
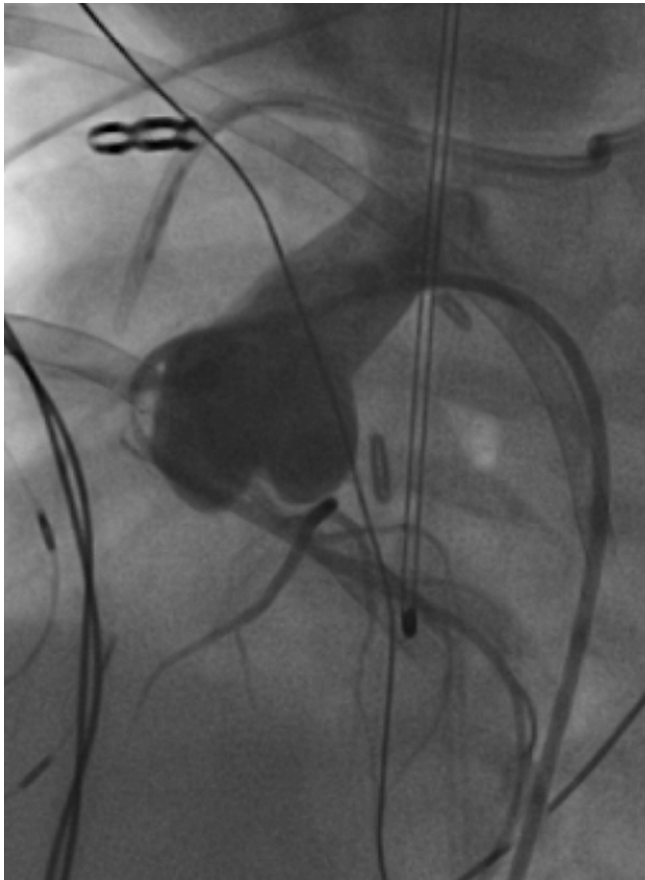
Figure 1. Initial lateral angiogram, with cranial and LAO angulation of the LMCA obtained with a non-tapered angled coronary guide catheter. The initial segment of the LMCA has a diminished filling and caliber. The proximal part of the LAD and the circumflex arteries are also seen. There is back filling of the ascending aorta and right coronary artery.

without any complications noted at his follow-up visit at age 8 weeks. The following week, he presented in respiratory distress.

Upon evaluation in the ED, the patient had supraventricular tachycardia with heart rate in the 160s that reverted to normal sinus rhythm following initiation of antiarrhythmic medications (esmolol and digoxin). Electrocardiogram (ECG) showed T-wave inversion in lead aVL and minor ST segment elevation in leads 2, 3 and aVF. Transthoracic echocardiogram demonstrated severely impaired biventricular systolic function. Subsequently, he developed 2:1 atrioventricular block requiring intubation, temporary pacing and adjustment of antiarrhythmic medications. His cardiac enzymes were elevated with Troponin T at

2.23 ng/mL. A computed tomography (CT) angiogram was performed due to the unknown etiology of the poor biventricular systolic function and showed marked narrowing of the left main coronary artery (LMCA), which in this case was on the right side of the aorta, and occlusion of the left anterior descending artery (LAD).

Considering the history and CT angiogram findings, the patient was taken to the operating room for possible coronary revascularization. Temporary epicardial pacing was initiated due to 3:1 and 4:1 heart block, which led to immediate loss of cardiac output requiring placement on cardiac extra corporeal membrane oxygenation (ECMO). Significant inflammation and adhesions were observed around the LMCA. The remains of topical hemostatic agent was found surrounding the LMCA as it curved around posterior to the pulmonary artery. The LMCA was significantly different in appearance from the proximal artery, however, there was no kinking or twisting. The button was inspected and found to be in perfect position. The dense fibrotic and coagulated material around the LMCA was dissected and released, but myocardial function did not instantly improve so the patient remained on ECMO without significant change in left ventricular function.

Without any improvement of myocardial function, cardiac catheterization was performed to reassess the results of the surgical intervention and coronary blood flow on this 4.5 kg infant. The femoral artery was cannulated with a 4 Fr sheath. A 4 Fr non-tapered angled coronary guide catheter was used to perform selective coronary angiograms, which delineated the presence of persistent narrowing in the proximal LMCA segment (Figure 1). A 0.014 balance middle weight guidewire was then passed into the LMCA and carefully positioned in the LAD. A 1.5 mm x 12 mm Apex™ PTCA dilatation catheter (Boston Scientific Corporation, Marlborough, MA) was passed over the coronary wire. Multiple inflations were performed to obliterate the waist. The wire and the balloon were removed after selective angiography of the LMCA, which showed significant improvement in flow (Figure 2).

Four days after the procedure, the patient was able to be weaned off ECMO support. Within 9 days, the ventricular systolic function returned to normal with
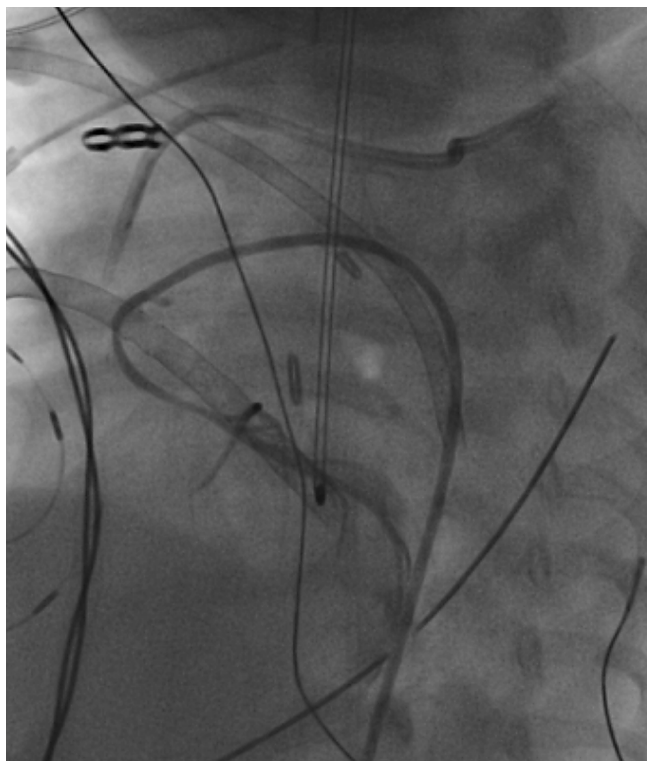
Figure 2. Lateral angiogram following percutaneous coronary angioplasty with cranial and LAO angulation of the LMCA obtained with a non-tapered angled coronary guide catheter. The initial segment of the LMCA has improved filling and caliber. The proximal part of the LAD and the circumflex arteries are also seen.

ejection fraction of 73%. The patient was discharge home 1 month after the procedure. At a follow-up visit, five months after the percutaneous coronary artery angioplasty, echocardiogram showed optimal flow through the coronary arteries, normal left ventricular systolic function with ejection fraction of 59%.

Discussion

The ASO has become the standard method for surgical correction of TGA since its introduction by Jatene and colleagues in 1975 [1]. Although there has

been a significant decrease in morbidity and mortality rates when compared to the atrial switch procedure operation and long-term outcomes, the risk of acute and subacute coronary artery complications is well recognized after ASO [2]. Surgical revascularization of the coronary artery is usually recommended to preserve myocardial function and avoid ischemic events if coronary artery complications are observed [3]. However, consideration must be given to alternative explanations for myocardial dysfunction especially after a period of weeks of normal recovery. The use of glutaraldehyde fixed hemostats should be avoided as evidenced by the inflammation of the coronary arteries in our patient. The case suggests that percutaneous coronary artery angioplasty may be an alternative to highly surgically demanding coronary artery revascularization in a small infant. Our experience shows that coronary artery balloon dilation can be performed safely and effectively in infants with inflammatory stenosis of the coronary arteries even on ECMO. Stent angioplasty was not possible in this infant due to the extremely small size of the coronaries. The potential for coronary in-stent restenosis and need for further repeated interventions with growth was also a concern. The prompt suspicion of coronary artery complications after ASO and timely intervention can rescue the left ventricular function and result in a complete recovery with optimal long-term outcomes. Percutaneous angioplasty must be considered in infants with post-operative coronary stenosis.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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Transcatheter Revision of Fontan Circulation by Connecting the Classical Glenn Circulation with the Inferior Vena Cava and Pulmonary Artery Circulation

Vishal R. Kaley, MBBS, MD[1], E. Oliver Aregullin, MD, FAAP[1,2], Stephen C. Cook, MD, FACC[1,2], Samuel J. Lacina, MD[1,2], Bennett P. Samuel, MHA, BSN, RN[1], Joseph Vettukattil, MBBS, MD, DNB, CCST, FRCPCH, FRSM, FRCP[1,2]*

[1] Congenital Heart Center, Spectrum Health Helen DeVos Children's Hospital, Grand Rapids, Michigan, USA

[2] Pediatrics and Human Development, College of Human Medicine, Michigan State University, Grand Rapids, Michigan, USA

Abstract

Patients with single-ventricle physiology require staged palliation. Additional interventions may be required due to Fontan failure, formation of collaterals or pulmonary arteriovenous malformations (PAVMs). Transcatheter interventions are preferable in this setting to avoid the risks of redo-sternotomy, and cardiopulmonary bypass. We present our experience with transcatheter revision of Fontan circulation in a cyanotic adult congenital heart patient with hypoplastic left heart syndrome (HLHS). Transcatheter Fontan completion may be a feasible option in patients with favorable anatomy and hemodynamics with optimal outcomes.

Key Words

Adult congenital heart disease • Hypoplastic left heart syndrome • Pulmonary arteriovenous malformations • Transcatheter intervention

Introduction

Surgical interventions in patients with single-ventricle physiology are challenging due to the need for staged palliation involving Norwood procedure followed by Glenn and Fontan surgery [1, 2]. Despite advancements in surgical technique, these patients are known to develop complications such as formation of collaterals or pulmonary arteriovenous malformations (PAVMs), Fontan failure, and Fontan associated liver disease (FALD) [3-5]. Multiple transcatheter and surgical interventions may be required for treatment of these complications. Transcatheter interventions are preferable in Fontan patients to decrease the need for re-do sternotomy and cardiopulmonary bypass (CPB). We present our experience with transcatheter Fontan completion in a cyanotic adult congenital heart patient with hypoplastic left heart syndrome (HLHS).

Case Presentation

A 31-year-old woman with HLHS presented with cyanosis and decreasing exercise capacity to an adult congenital heart clinic at a tertiary medical center in the Midwest. She was referred to the congenital heart interventional team to evaluate underlying anatomy, hemodynamics, and source of cyanosis.

After HLHS was diagnosed in the early neonatal period, she underwent stage-1 palliation. At 6 months of age, she was found to have a widely patent

* Corresponding Author:
Joseph Vettukattil, MBBS, MD, DNB, CCST, FRCPCH, FRSM, FRCP
Congenital Cardiology
Spectrum Health Helen DeVos Children's Hospital
100 Michigan NE (MC48), Grand Rapids, Michigan 49503, USA
Tel. +1 616 267 0988; Fax +1 616 267 1408;
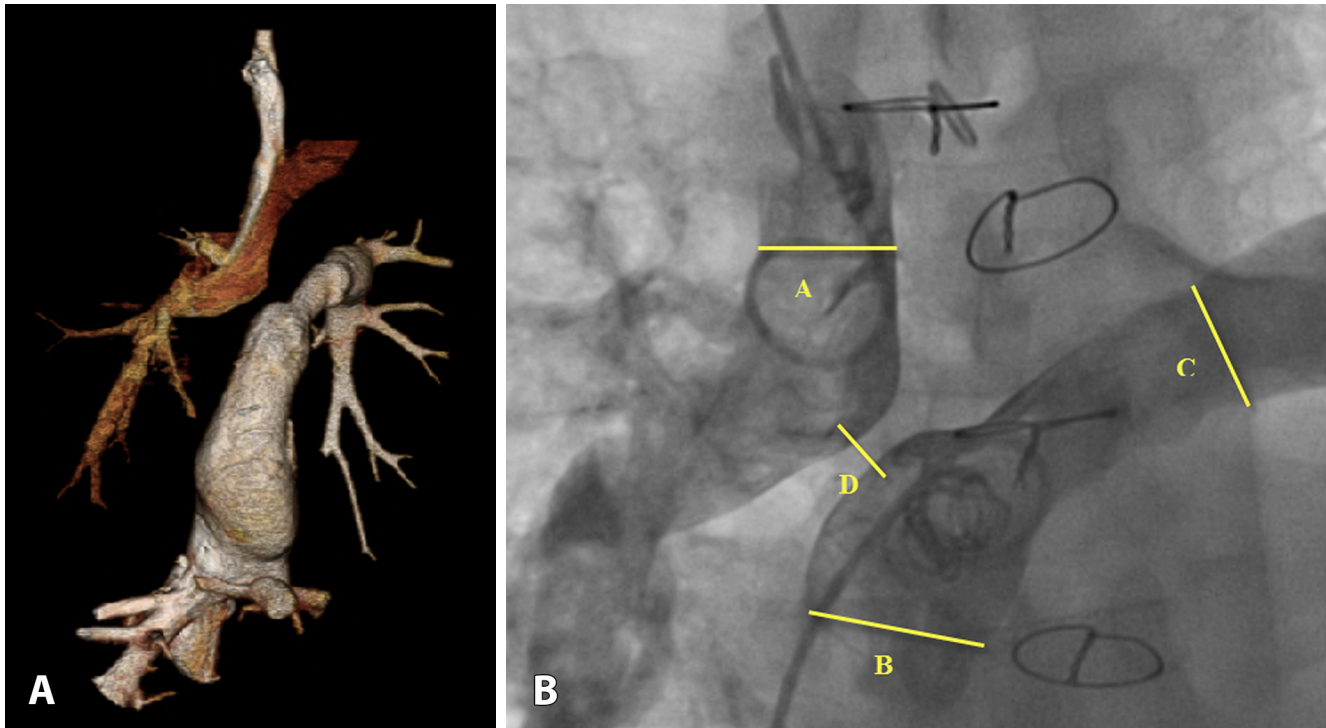E-Mail: joseph.vettukattil@helendevoschildrens.org

Figure 1. *Panel A.* Pre-procedure computed tomography scan and *Panel B.* Pre-procedure angiogram showing the Glenn anastomosis with superior vena cava connected to the right pulmonary artery (A=14 mm); Fontan conduit (inferior vena cava, B=18 mm; left pulmonary artery C=13 mm). The distance between the disconnected Glenn and Fontan anastomoses is D=5 mm.

Gortex aorto-pulmonary shunt with narrowing of the Norwood anastomosis. She then underwent surgical revision of the Norwood anastomosis. A classic-Glenn shunt procedure was also performed connecting the superior vena cava to the right pulmonary artery. At 16 months of age, she underwent Fontan procedure with diversion of the inferior vena cava and hepatic veins to the left pulmonary artery via intra-cardiac baffle. Despite subsequent cardiac catheterizations to occlude multiple veno-venous collaterals, she remained cyanotic.

Prior to cardiac catheterization, a cardiac computed tomography (CT) scan was performed to evaluate underlying anatomy. This demonstrated the anatomy of both the classic Glenn and Fontan anastomoses (Figure 1A). Small PAVMs were noted in the right lower lung lobe along with left-sided veno-venous collaterals. Based on cardiac CT findings, the potential risks associated with re-do sternotomy, and CPB, a multi-disciplinary team recommended transcatheter approach for Fontan completion.

Cardiac catheterization revealed mean Glenn and Fontan pressures of 11 and 15 mmHg, respectively. The patient was also noted to have developed hepatic cirrhosis. However, hemodynamic and angiographic assessment reinforced feasibility for transcatheter Fontan completion (Figure 1B). An 8.5 F SL2-transseptal sheath with a 21-gauge transseptal Brockenbrough needle was advanced from the right internal jugular vein into the roof of the Fontan baffle (Figure 2A). Once the needle was placed into the Fontan baffle, a 0.014 inch Mailman wire was advanced and then snared from the femoral vein to create a veno-venous loop. Using a V-18 control wire as a buddy wire, a 0.035 Amplatzer super-stiff wire was placed between the Glenn and Fontan anastomoses. Subsequently, a 28 mm Cheatham-Platinum (CP) covered stent pre-mounted on a 20 mm balloon-in-balloon catheter was deployed in between the two circuits (Figure 2B). Post-procedure angiogram demonstrated widely patent Glenn and Fontan anastomoses connected by the covered CP stent with unobstructed flow and favorable hemodynamics (Video 1; Figure 3A). The
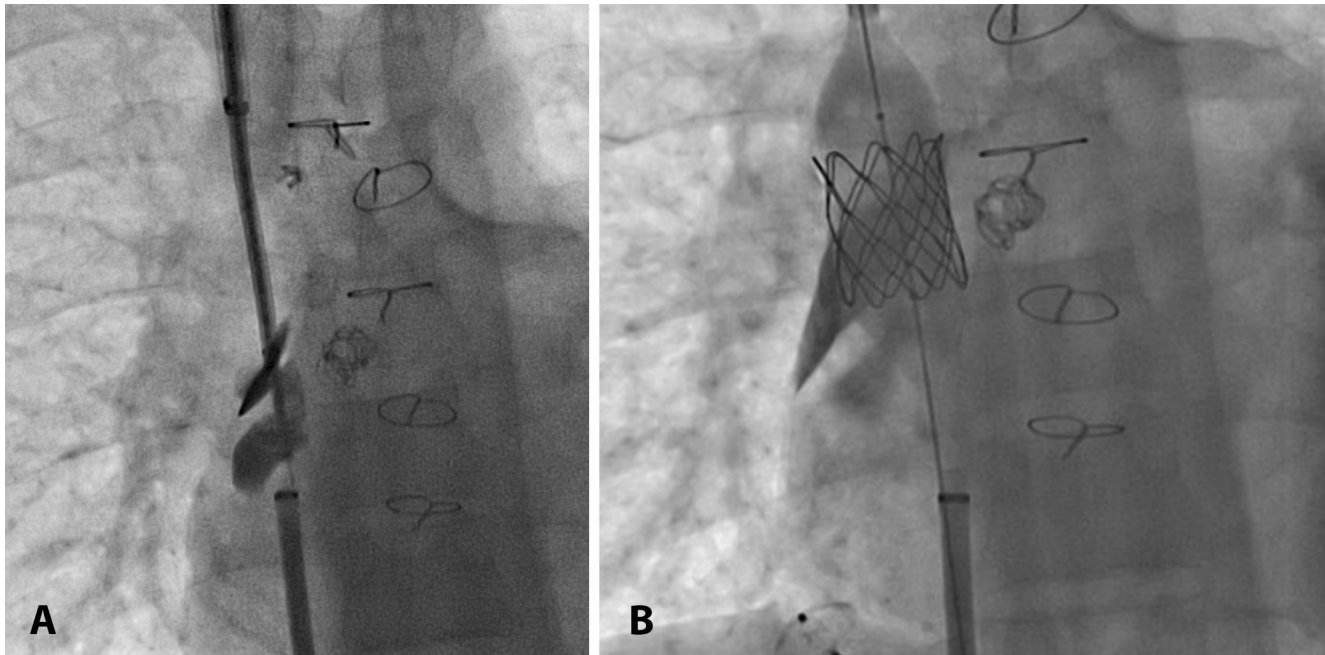
Figure 2. *Panel A.* Angiogram showing Brockenbrough needle being advanced from the right internal jugular vein into the roof of the Fontan baffle, and *Panel B.* 28 mm covered Cheatham Platinum stent placed between the Glenn and Fontan anastomoses.

Fontan pressure decreased to a mean of 13 mmHg, while the Glenn pressure was noted to be similar to the pre-procedure mean of 11-12 mmHg. The patient was discharged to home the next day. A cardiac CT obtained at 6-week follow-up showed patent Glenn and Fontan anastomoses connected by the covered CP stent (Figure 3B).

Discussion

The prognosis of patients with single ventricle physiology palliated using the Norwood, Glenn and Fontan procedures is influenced by multiple factors such as the anatomical relationship, flow patterns, and the pressures in the Glenn and Fontan circulations. These patients are at potential risk for the development of complications including PAVMs, Fontan failure, ventricular systolic or diastolic dysfunction, protein losing enteropathy, lymphatic abnormalities, plastic bronchitis, FALD, and reduced glomerular filtration rate [3, 4]. It is speculated that the risk for developing PAVMs increases when hepatic blood flow carrying hepatic factor; a protective factor to prevent formation of PAVMs, to the lungs is interrupted [5-7]. The risk for developing veno-venous collaterals, Fon-

Video 1. Post-procedure angiogram demonstrates widely patent Glenn and Fontan anastomoses connected by the covered CP stent with unobstructed flow and favorable hemodynamics. View supplemental video at https://doi.org/10.12945/j.jshd.2019.017.18.sup.01.
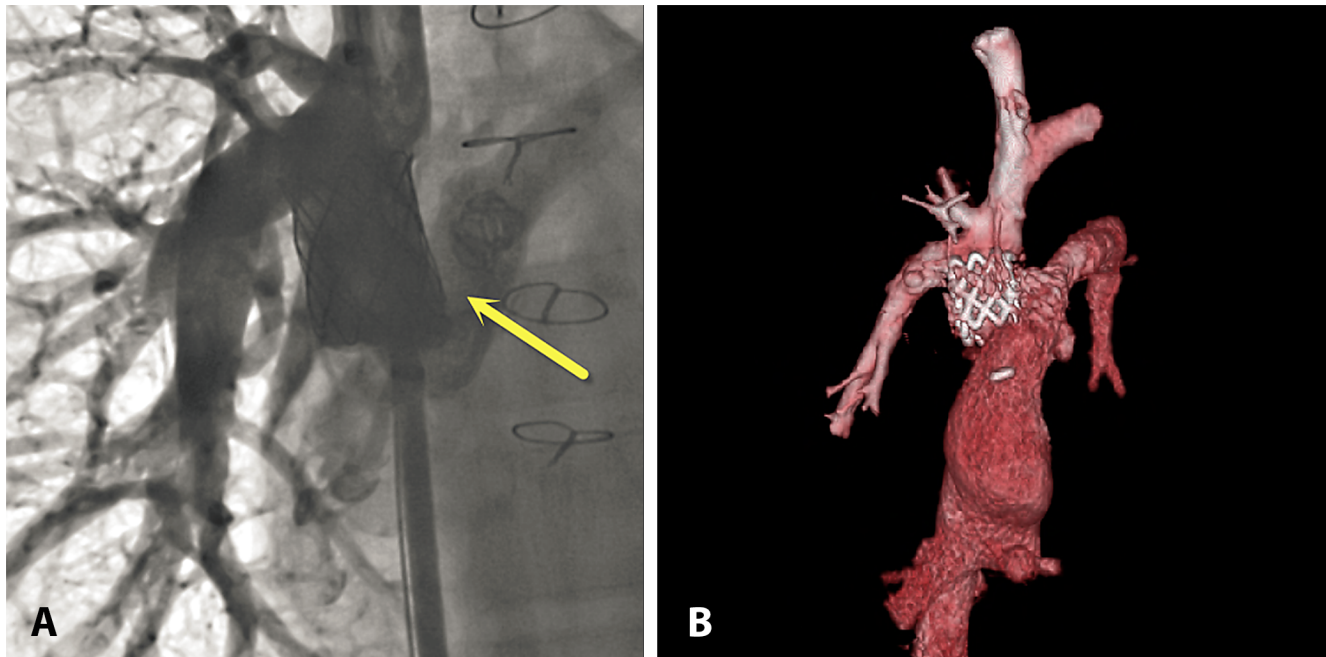
Figure 3. *Panel A*. Post-procedure angiogram, and *Panel B*. Follow-up computed tomography scan confirm widely patent Glenn and Fontan anastomoses connected by the 28 mm CP stent.

tan failure, and FALD is increased in patients with elevated Fontan pressures, which are known to increase further with activity [8]. As a result these patients may require multiple surgical or transcatheter interventions to address these late-onset complications. Surgical interventions are not without risk for these patients given the inherent need for re-do sternotomy, and CPB. As such, transcatheter interventions provide a safer alternative for these patients.

The proof of concept for transcatheter Fontan completion was first demonstrated using specially developed occluding stents in an ovine model [9]. Safety and feasibility in human subjects was then demonstrated in 16 patients with single ventricle physiology with successful transcatheter Fontan completion in 2007 [10]. The technique of transcatheter Fontan completion has been described in which patients underwent a planned modified cavopulmonary anastomosis followed by transcatheter Fontan completion [11]. The technique has not been widely accepted. Patients with traditional Glenn and unidirectional Fontan palliation with PAVMs have benefitted after reconnection of the pulmonary arteries. The feasibility of transcatheter reconnection of the pulmonary arteries in cyanotic patients with PAVMs

has been previously described. In this case series of 6 patients with unidirectional Fontan and PAVMs, oxygen saturations were noted to have improved following transcatheter reconnection of the pulmonary arteries. The transcatheter approach was noted to be less invasive with decreased morbidity compared to surgical pulmonary artery reconnection or brachial arteriovenous fistula placement [12].

The unique condition of developing PAVMs in the right lung and veno-venous collaterals in left lung in our patient may be explained by the absence of hepatic flow into the right lung and exposure of the left lung to higher Fontan pressures [6]. The liver cirrhosis may also be attributed to high pressures in the Fontan circuit. Anticipating the potential benefits of connecting both the Glenn and Fontan anastomoses to achieve even distribution of blood into the lungs, transcatheter approach for Fontan completion was selected as an alternative approach to surgical intervention.

Transcatheter Fontan completion was performed without preconditioning in this patient due to functional decline associated with chronic cyanosis, to avoid re-do sternotomy and CPB and multi-organ complications associated with Fontan failure and

chronic cyanosis. The procedure was successful with immediate fall in the Fontan pressures and optimal flow and equal distribution of blood to the lungs.

As such, transcatheter Fontan completion may be a feasible option in selected adult congenital patients with optimal outcomes even without surgical preconditioning. However, further studies in a larger cohort of are required to evaluate long-term outcomes.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

> **Comment on this Article or Ask a Question**

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Percutaneous Implantation of Venus P-Valve and Melody Valve in a Patient with Dysfunctional Native and Artificial Right Ventricular Outflow Tracts

Basil (Vasileios) D. Thanopoulos, MD, PhD[1*], Petros Dardas, MD[1], Alexandros Kallifatidis, MD[1], Shakeel A. Quireshi, MBChB, FRCP[2]

[1] Interventional Cardiology, St.Luke's Hospital, Thessaloniki, Greece

[2] Department of Paediatric Cardiology, Evelina Children's Hospital, London, United Kingdom

Abstract

Percutaneous pulmonary valve implantation is been increasingly performed for restoring pulmonary competence in appropriately selected patients. However, The currently available valves are not capable of being safely implanted in the majority of patient with outflow tract dysfunction as they cannot accommodate the larger outflow tract diameters seen in most patients. The Venus P-valve is a new percutaneous pulmonary valve designed specifically for implantation in large (up to 32 mm diameters) native right ventricular outflow tracts. In this report we describe the combined use of a Venus P-valve and Melody transcatheter pulmonary valves in a patient with a dysfunctional native and artificial right ventricular outflow tracts.

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Key Words

Percutaneous pulmonary valve implantation • Congenital heart disease • Tetralogy of Fallot

Introduction

Percutaneous pulmonary valve implantation using the Melody® (Medtronic, Minneapolis, MN, USA) (CE Marked 2006) and the Edwards Sapien XT (Edwards Lifesciences, Irvine, CA, USA, CE Marked 2017) valves is currently a widely accepted alternative to surgery for the management of selected patients with dysfunctional right ventricular outflow tract conduits or homografts [1]. However, only < 20% of patients following tetralogy Fallot repair are candidates for these two valves as they cannot be used in large patched right ventricular outflow tracts (RVOTs) [1]. The Venus P-valve (Venus Medtech, Shanghai, China) is a new self-expanding tri-leaflet porcine pericardial tissue percutaneous pulmonary valve designed specifically for implantation in large (up to 32 mm diameters) native RVOT [2-4]. Early clinical experience with implantations in humans has shown its safety and satisfactory early results. [2-4] In this short communication, we report the first-in-man use of Venus P-valve and Melody® transcatheter valves on separate occasions in a patient with dysfunctional native and artificial RVOT.

Case presentation

A 21 years male with tetralogy of Fallot underwent surgical correction at the age of 24 months. Due to the presence of an anomalous course of anterior descending artery across the RVOT an initial attempt was made to relieve the sub-pulmonary obstruction
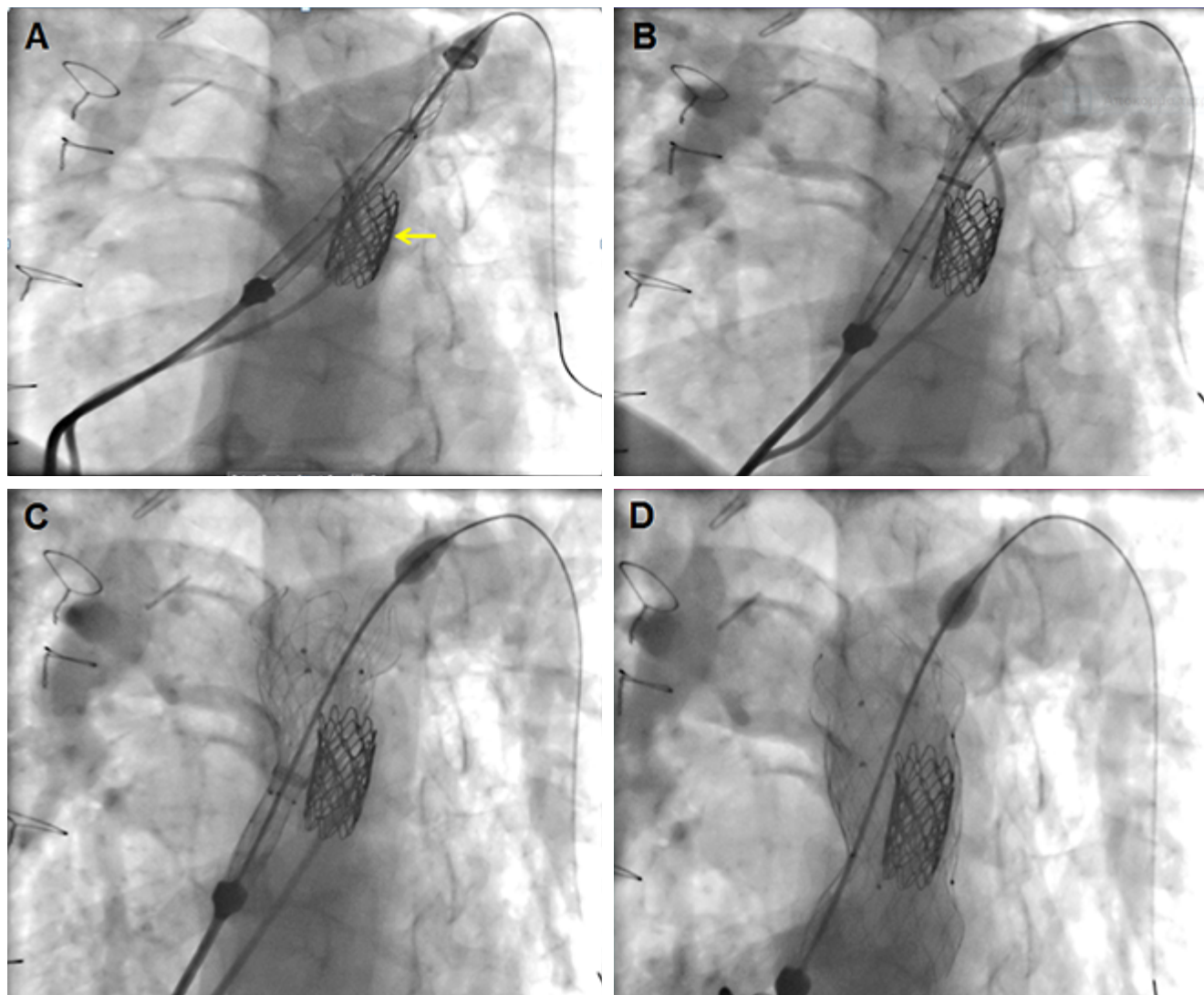
* Corresponding Author:
Basil (Vasileios) D. Thanopoulos, MD, PhD
Interventional Cardiology
St. Luke's Hospital
Panorama 552 36, Thessaloniki, Greece
Tel. +30 210 617 9839; Fax: +30 210 617 9839; E-Mail: vthanop@otenet.gr

Figure 1. *Panels A, B, C, D.* Pulmonary angiograms in LAO 40° and cranial 15° projections demonstrating the deployment steps of the Venus P-valve. *(Panel A)*. Venus P-valve delivery system positioned across the right ventricular outflow tract (RVOT) with its tip in the proximal LPA. Deployment of the of the distal *(Panel B)* and central *(Panel C)* part of the valve. *(Panel D)*. The valve is completed deployed with its proximal and distal flares expanded giving stability of the valve across the RVOT.

by partial resection of infundibular muscle and placement of a transannular patch. Nevertheless, the patient could not be weaned off bypass and therefore, a 14 mm Gore-Tex tube was placed between right ventricle (RV) and main pulmonary artery (MPA). The patient came off bypass and was discharged from the hospital in good clinical condition. During his follow-up the patient was doing quite well but over the years he developed progressively worsening exercise intolerance due to free pulmonary regurgitation through the Gore-Tex conduit that was confirmed by echocardiographic and cardiovascular magnetic Imaging (CMR) evaluation. The CMR estimated RVED-Vi and RVEF were 170 ml/m^2 and 45%, respectively. Cardiac catheterization performed in 2008 showed a subpulmonary pressure gradient of 45 mm Hg and mild pulmonary regurgitation across his native RVOT. In addition, a drop (from 125 mm Hg to 90 mm Hg) of the aortic arterial pressure was observed during test balloon occlusion of the Gore-Tex tube indicating that the blood flow through native RVOT was not sufficient enough to maintain by itself a normal cardiac

output. This could be attributed to the fact that the existed from the time of surgery residual infundibular stenosis had not yet completely regressed to permit the maintenance of a sufficient pulmonary blood flow exclusively though the native RNOT. After discussion with our surgeons and the family, in 2008, an 18 mm Melody® valve was placed successfully in the Gore-Tex tube. After the valve implantation the patient improved and he was doing quite well but 6 years later he developed again progressively aggravated exercise intolerance (NYHA class II –III symptoms) due to chronic pulmonary regurgitation this time through its operated native RVOT. In December 2017 echocardiographic and CMR evaluation revealed significant pulmonary regurgitation through the surgically placed transannular patch resulting in progressive dilatation of the RVOT and the pulmonary arteries. Doppler echocardiographic study showed a normal functioning Melody valve with no residual gradient and regurgitation. The CMR estimated RVEDVi and RVEF were 165 ml/m^2 and 48%, respectively. After the CMR study, the patient underwent cardiac catheterization with complete hemodynamic and angiographic studies. There was a 30 mm Hg pressure gradient across the RVOT. The maximum systolic diameters of the proximal RVOT (just below the valve level), estimated valve annulus, proximal and distal MPA measured using biplane angiography, were 31 mm, 26 mm, 32mm and 34. 5 mm, respectively. The length from the RVOT from the estimated valve annulus position to the PA bifurcation was 35 mm. Balloon sizing of the pulmonary arteries was performed with maximal inflation of an ASD 34 mm Amplatzer sizing balloon simultaneously with an ascending aortogram that excluded coronary artery proximity and obstruction. Balloon sized RVOT/MPA diameters were only 1 mm larger than the angiographic ones. After obtaining procedural permission on compassionate basis from the Greek Federal Drug Administration and a written consent from the parents and the patient, it was decided to proceed to percutaneous pulmonary valve implantation with Venus P-valve.

To ensure stability and good opposition to the wall of the MPA, the Venus P-valve was selected to be 4 mm larger than the measured balloon waist at the pulmonary valve annulus level and equal to the maximal angiographic systolic diameter of the MPA.
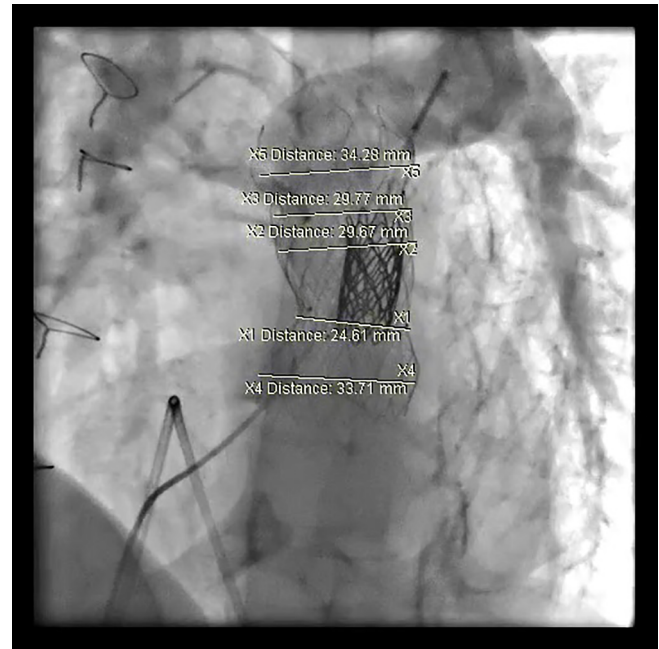
Video 1. Injection of contrast medium through a pig-tail 5F catheter into the proximal LPA showing competent Venus P-valve and Melody valves with no pulmonary regurgitation. View supplemental video at https://doi.org/10.12945/j.jshd.2019.024.18.sup.01.

The valve implantation was performed under general anesthesia using the previously described technique. [2-4] Based on the angiographic measurements and the anatomic characteristics of the RVOT, a 36 mm diameter and 35 mm length flared Venus P-valve was successfully implanted from the RVOT to MPA bifurcation through a 24 F delivery system. (Figure 1 A,B,C,D). The procedure was guided using frequent check angiograms through a Berman angiographic catheter placed in the MPA/RV from a second femoral venous approach. Post procedural pulmonary angiography and hemodynamic measurements showed a well positioned and opposed to the wall of MPA competent valve and no pressure gradient across the RVOT (Video 1). The procedure and radiation times were 312 minutes and 48 minutes, respectively.

The patient was discharged the next day of the procedure on oral aspirin 3-5 mg/Kg/day for life. Before discharge an electrocardiogram (ECG) recording, a biplane chest X-ray, and a transthoracic echocardiography (TTE) were performed. Fluoroscopic examination 3 and six months after the procedure showed a good valve position with no fractures (Figure 3). At
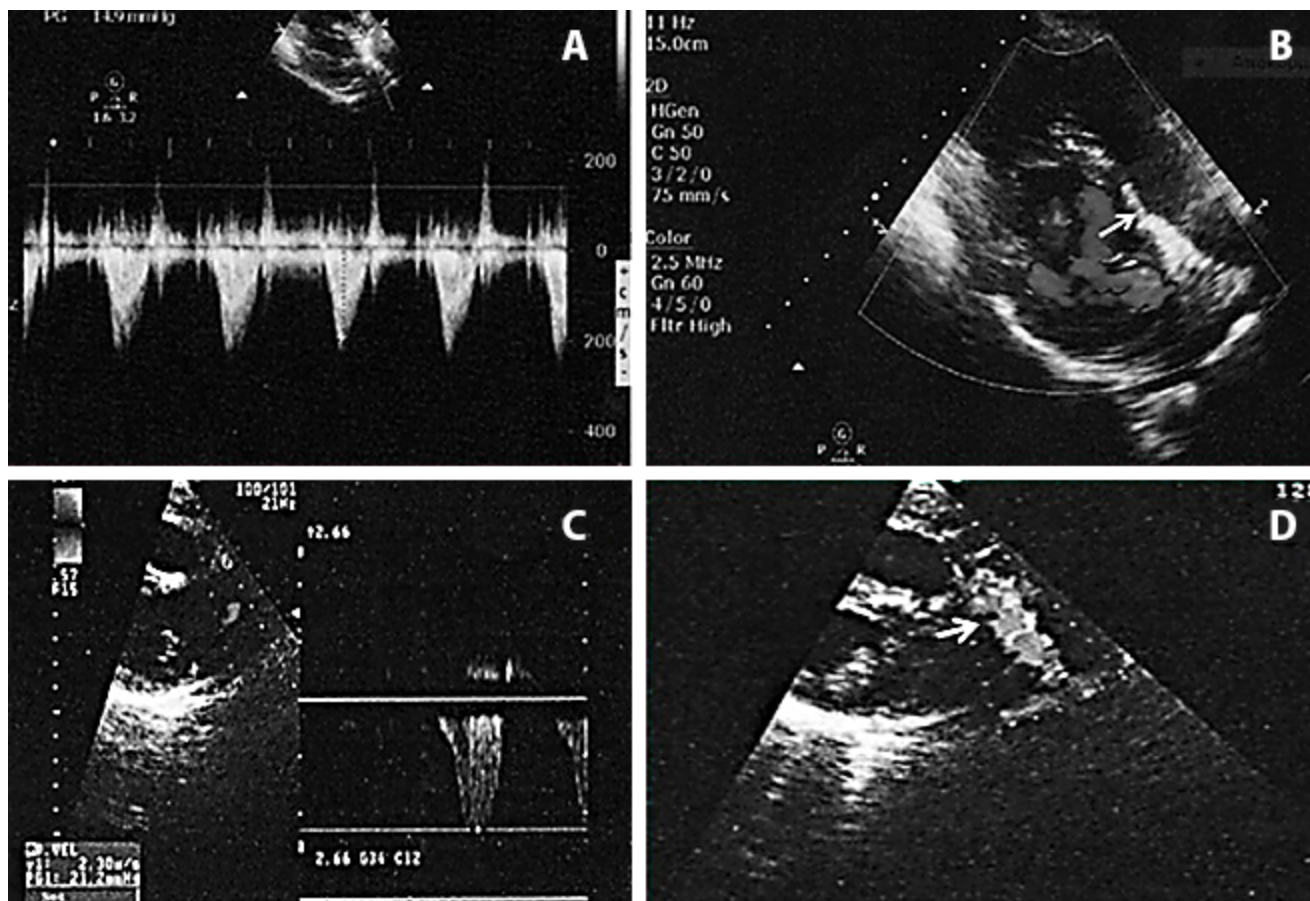
Figure 2. *Panels A, B, C, D.* Doppler and 2D echocardiogram , respectively, obtained from right parasternal view (RVOT) at 1-year follow-up demonstrating competent Venus *(Panels A, B)* P-valve and Melody® *(Panels C, D)* valves with a 15 and 21 mm Hg peak pulmonary pressure gradient.

6 month and 1-year follow-up Doppler echocardiography showed a competent Venus P-valve with a peak pressure gradient of 15 mm Hg across the RVOT (Figure 2 A, B). Continued improvement of the RV indices was documented in CMR at 6 month (RVEDVi -150 ml/m^2, RVEF – 50%) and 12 month (RVEDVi -120 ml/m^2, RVEF – 55%) follow-up. In addition, the patient reported significant progressive improvement in his clinical condition being in NYHA functional class I at 1 year follow-up. A TTE, an electrocardiogram and a chest-X ray were scheduled to be performed at 1, 6, and 12 months after the procedure, and then serially once a year. It should be noted, that the patient and his parents were informed that following the implantation of Venous-P valve the Melody® valve is no longer needed and the obstruction of the Gore-text conduit using an occluding device should be contemplated.

Discussion

At the current time, the implantation of the two available CE approved pulmonary valves is mainly recommended in patients with dysfunctional RVOT conduits and patched RVOT with diameters up to 22 mm and to 26 mm for Melody and Edwards Sapien valves, respectively. Recently, the Edwards Sapien S3 valve has been implanted in native RVOTs with a maximal diameter of 29 mm with quite satisfactory short term results. However, these valves were not especially designed for use in patients with larger diameter native RVOTs with transannular patches. In addition, pre-stenting and stage implantation is required for their off-label use in native RVOT that increases the complexity of the procedure and the patient risk.[1]

The Venus P-valve is a recently introduced pulmonary valve designed for implantation in a wider range

of post–operative patients with tetralogy of Fallot, who had transannular patch augmentation of RVOT. Recently, Cao et al [2], Promphan et al [3], and Garay et al [4] reported on their preliminary experience in humans using the Venus P–valve under Institutional approved protocols (the valve is not CE marked or FDA approved) with satisfactory early results. In this report a Melody and Venus P-valves were implanted sequentially in the rare case of a patient with post-operative TOF for the treatment of progressive dysfunction of an artificial and native RVOT, respectively. The procedures were successful with no complications and the patient was discharged the next day in excellent clinical condition. Fluoroscopy performed six months after the procedure, showed well-positioned valves with no fractures. Echocardiographic evaluation at the 1-year follow-up demonstrated a competent Venus P-valve with a small residual gradient across the RVOT. CMR follow-up showed significant improvement in RV volume and function parameters. Up to now approximately 110 Venous-P valves have been implanted worldwide with excellent short term results [5]. It should be noted that the Venous P- valve is being evaluated in CE trial for the assessment of its efficacy and safety.

Conclusions

Double PPVI can be used safely and effectively as an alternative to surgery for the treatment of selected post-operative patients with TOF and combined dysfunction of the native and surgically placed RVOT conduit. The Venus P-valve adds to our armamentar-
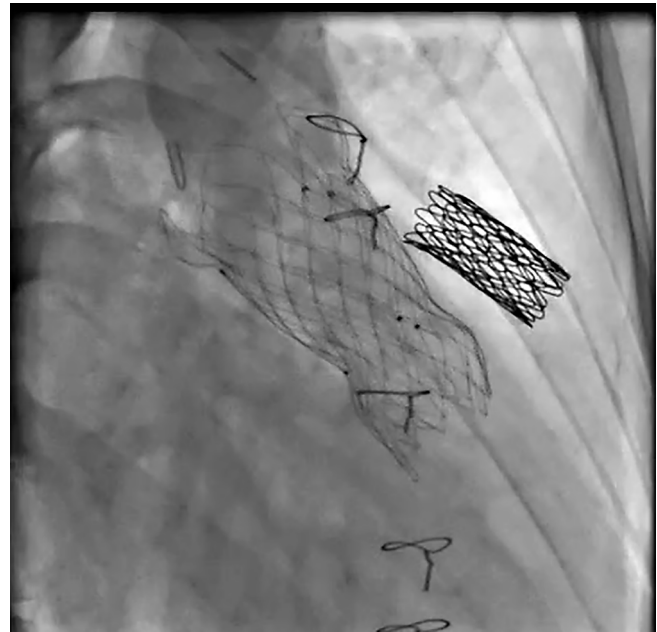

Figure 3. Fluoroscopic image six months after the Venus P-valve and Melody® valve implantation demonstrating absence of stent fractures.

ium for the treatment of patients with larger outflow tracts following surgical repair.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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Transcatheter Intervention for Paravalvular Leak in Mitroflow Bioprosthetic Pulmonary Valve

Vishal R. Kaley, MBBS, MD[1], E. Oliver Aregullin, MD, FAAP[1,2], Bennett P. Samuel, MHA, BSN, RN[1], Joseph Vettukattil, MBBS, MD, DNB, CCST, FRCPCH[1,2]*

[1] Congenital Heart Center, Spectrum Health Helen DeVos Children's Hospital, Grand Rapids, Michigan, USA

[2] Pediatrics and Human Development, College of Human Medicine, Michigan State University, Grand Rapids, Michigan, USA

Abstract

Paravalvular leak (PVL) is a complication caused by development of gaps due to dehiscence between the annulus and implanted valve. Clinically significant PVL in bioprosthetic pulmonary valves are extremely rare. Currently, surgical intervention is the first line of treatment. However, surgery is associated with greater risk for morbidity and mortality when compared to primary repair or valve replacement. We present a 22-year-old male who underwent successful transcatheter intervention for pulmonary PVL with hemodynamic and symptomatic improvement.

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Key Words
Paravalvular leak • Percutaneous • Pulmonary valve replacement • Regurgitation • Tetralogy of Fallot.

Introduction

Paravalvular leak (PVL) is a known complication due to suture dehiscence between the sewing ring and native tissue causing regurgitation around the replaced valve [1]. Large leaks may result in complications such as hemolysis, arrhythmias, and congestive heart failure [2]. The incidence of PVL following aortic and mitral valve replacement is 1-5%, and 2-12% respectively [1]. Clinically significant PVL following bioprosthetic pulmonary valve replacement is extremely rare.

The standard treatment for pulmonary PVL is surgery with valve replacement and repair due to the variability in implant location in the trabeculated and often dilated right ventricular (RV) outflow tract [3]. However, surgery is associated with greater risk for morbidity and mortality when compared to primary repair or valve replacement [4]. Transcatheter intervention for aortic and mitral valve PVL is effective with low rates of procedural complications [5], and may also be useful in the setting of pulmonary PVL.

Case Presentation

A 22-year-old male with tetralogy of Fallot and bilateral peripheral pulmonary artery (PA) stenosis presented with multiple episodes of syncope, chronic dyspnea on exertion and worsening lower extremity edema. He had a transannular patch repair early in life. Due to severe pulmonary regurgitation, his pulmonary valve was replaced with a 27 mm Mosaic tissue valve (Medtronic, Minneapolis, MN, USA) at 8-years of age. He was noted to have free pulmonary regurgitation, and depressed systolic function at 15-years of age. Subsequently, he underwent pulmonary valve replacement with a 25 mm Mitroflow bioprosthetic valve (Sorin, Saluggia, Italy) and intraoperative stenting of the branch PAs. His post-operative period was complicated requiring extracorporeal membrane
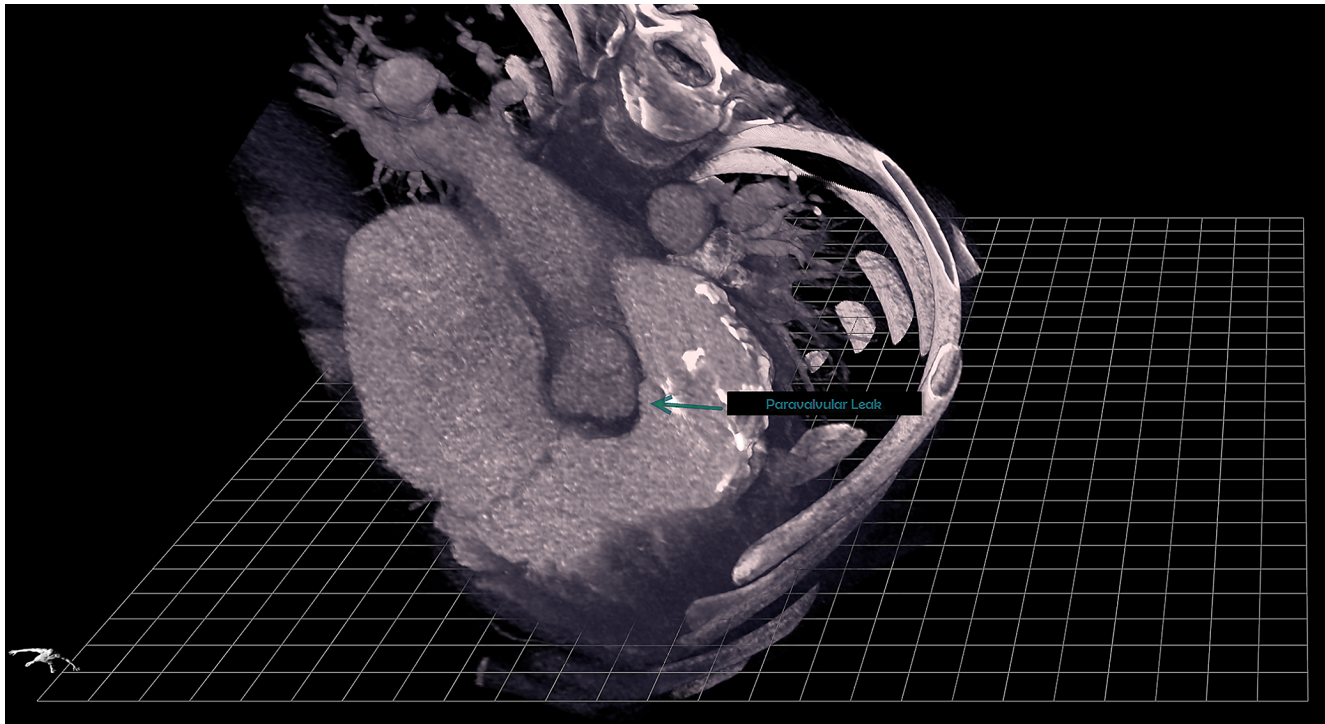
* Corresponding Author:
Joseph Vettukattil, MBBS, MD, DNB, CCST, FRCPCH
Congenital Heart Center
Spectrum Health Helen DeVos Children's Hospital
100 Michigan NE (MC248), Grand Rapids, MI , USA
Tel. +1 616 267 0988; Fax: +1 616 267 1408;
E-Mail: joseph.vettukattil@helendevoschildrens.org

Figure 1. Computed tomography viewed on True3D Viewer (Echopixel, Inc., Mountain View, CA) showing paravalvular tunnel in the posteromedial side of the pulmonary valve.

oxygenation support and prolonged tracheostomy leading to severe post-traumatic stress syndrome.

On recent evaluation, computed tomography scan showed grossly calcified valve leaflets with a PVL tunnel measuring 8x6 mm and approximately 9 mm in length in the posteromedial side of the pulmonary valve adjacent to the right aortic sinus. Moderate RV hypertrophy and mildly dilated RV volume (132 mL/m^2) was noted (Figure 1). He developed symptomatic ventricular tachycardia. Considering his complex history and associated risks with redo sternotomy, a multi-disciplinary team recommended transcatheter PVL closure.

A complete right and left heart catheterization was performed. Moderate stenosis was noted across the Mitroflow valve at the pulmonary position with gradient of 25-30 mmHg. The RV pressure was supra-systemic measured at 86/11mmHg as compared to the right femoral artery pressure of 74/47 mmHg. Elevated PA pressure of 56/6(28) mmHg with mean pulmonary capillary wedge pressure of 12 mmHg

was noted. The pulmonary vascular resistance was 5.2 Wu/m^2 with Qp:Qs of 1:1. PA angiography demonstrated moderate pulmonary insufficiency and PVL. The pulmonary PVL site was localized by balloon occlusion of the valve and simultaneous contrast injection into the PA (Figure 2A). Subsequently, a 0.035 inch glidewire was positioned across the PVL. The defect was sized using an Armada balloon (Abbott, Abbott Park, IL, USA; 8x4 mm; Figure 2B). After careful hemodynamic and angiographic evaluation, a 12mm Amplatzer vascular plug II (AVP II; Abbott, Abbott Park, IL, USA) was deployed in the tunnel-like leak without any complications or significant residual leak (Figure 2C). The diastolic PA pressure improved from 6 to 20 mmHg after PVL closure. The patient recovered well and was discharged to home the following day. The 6-week post-procedure transthoracic echocardiogram showed peak velocity of 3.2 m/sec with peak gradient of 42 mmHg and mean gradient of 24 mmHg through the pulmonary valve with moderate pulmonary regurgitation.
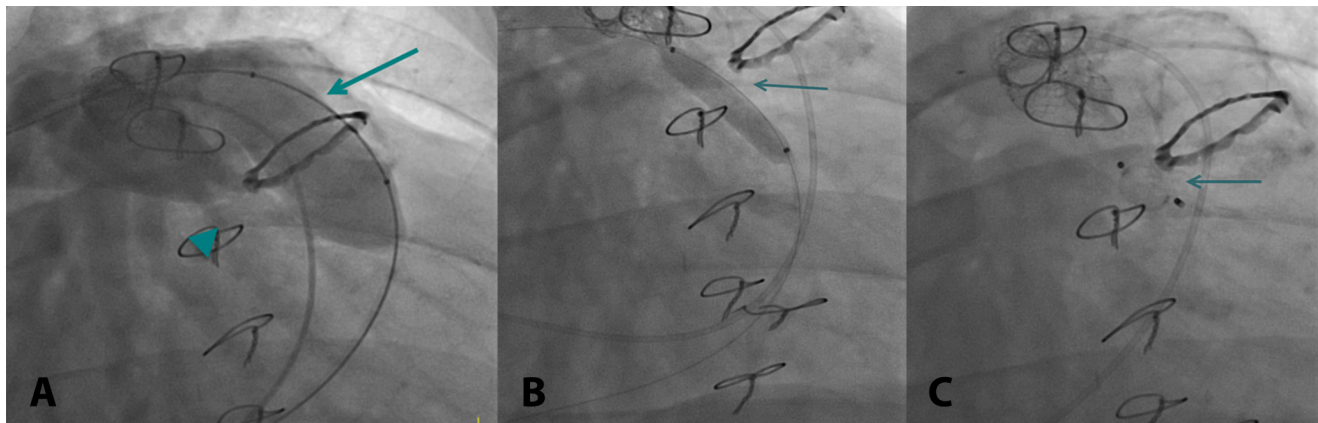
Figure 2. *Panel A.* Arteriogram showing the PVL (arrow head) after balloon occlusion (arrow) of the pulmonary bioprosthetic valve; *Panel B.* PVL size confirmed using Armada balloon (8x4mm) passed across the leak; *Panel C.* 12mm AVP II successfully deployed in the tunnel-like leak.

Discussion

The standard treatment for pulmonary PVL is surgical intervention with valve replacement and repair [3]. However, surgery is associated with a higher risk for morbidity and mortality than primary repair or valve replacement. In a study of 122 patients with PVL (mitral=67.2%, and aortic=32.8%), the 12-year survival following surgery was about 30%–40% with high rates of recurrence [4]. Transcatheter intervention in the setting of bioprosthetic mitral and aortic valve PVL has been shown to have better long-term outcomes than surgery [5]. The AVP II is the most common device used for mitral and aortic valve PVL due to the shape of its discs resulting in good epithelization and providing an optimal seal. Other off-label devices that may be used for PVL closure by physician discretion and expertise are ventricular septal defect, atrial septal defect, and patent ductus arteriosus occluders, AVP I, and AVP III [1]. However, no dedicated catheters or devices are currently approved for PVL closure by the U.S. Food and Drug Administration.

Although transcatheter closure of pulmonary PVL are previously reported using the AVP II and ventricular septal defect occluders [2, 3], it is associated with risks including impingement of valve leaflets, device embolization, hemolysis, pericardial effusion, and arrhythmias [1]. Successful transcatheter pulmonary PVL closure is dependent on appropriate case selection and operator expertise. The alternative to device occlusion is to use a covered stent in anatomically appropriate conduit with placement of transcatheter valve in the stent.

Pulmonary PVL following bioprosthetic valve implantation is rare, but can be a hemodynamically significant complication. Transcatheter intervention is a feasible treatment option with lower complication rates than surgery and must be considered in the setting of pulmonary PVL.

Conflict of Interest

The authors have no conflict of interest relevant to this publication.

> **Comment on this Article or Ask a Question**

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