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Preface

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Letter from the Editor-in-Chief

Ziyad M. Hijazi, MD

Rush University Medical Center, Chicago, Illinois, USA

Dear Colleagues,

In early 2012, Dr. Steve Korn and I discussed the possibility of establishing a journal dedicated for structural heart disease and when we started the discussions, we became convinced it is the right thing to do. I wanted a partner with great knowledge and expertise in the field. I immediately thought of few people and eventually, we agreed that Dr. John Carroll would be an ideal fit. Therefore, the three of us have agreed to launch the Journal of Structural heart Disease (JSHD). Before the agreement, we asked what and why is the need for another medical journal? There are several answers to the question of **Why**?

The Journal of Structural Heart Disease is focused on a specific area of cardiovascular medicine but it is much more. JSHD has been born and it will subsequently undergo a **metamorphosis** driven by evolving technologies as well as the development of a broad-based community of participants. Metamorphosis of a journal is akin to the biological process of physical transformation and growth as an animal grows and differentiates.

The primary goal of JSHD is to **build a community** of individuals with an interest in SHD. The journal is an open access, peer reviewed journal. It will appeal to a multidisciplinary group of specialists, including adult interventional cardiologists, pediatric/congenital interventional cardiologists, cardiac surgeons (congenital and non-congenital), imaging specialists, cardiovascular anesthesiologists, engineers, nurses and technologists working in structural and congenital heart disease. We hope to include patients and patient advocates as essential members of the community. Individuals who suffer from structural heart diseases and undergo treatments can bring a perspective that is impossible to replicate by well-meaning clinicians.

A **community craves interaction** among its members in order to move forward. Passive readership is good for some purposes but interactivity opens doors for learning on multiple levels. PICS-AICS, CSI in Frankfurt, and the Dallas-Leipzig meeting, to name a few, are examples of the value of interactions. The JSHD will try to promote this level of interactivity without the need to travel at a specific time and to a specific place.

Technology advances in terms of computer-based graphics, internet-based delivery, links to large databases, and applications that enhance communications will be part of the upcoming metamorphosis of JSHD. This will occur in stages as we learn more in terms of the technology requirements, costs, and feasibility for the members of the community to utilize these technologies.

Despite the fact that JSHD is the official journal of the PICS Foundation, it is not linked to a professional society or a particular country. That model has been important to the growth of our profession but in 2015 our community is multidisciplinary, international, and not country-based. The JSHD will attempt to take this international perspective to the next level.

I would like to acknowledge contributions of many in the planning of the JSHD, to the authors of the first series of articles, and to the reviewers. We also want to thank Sidra Medical & Research Center for the unlimited support to launch this journal. We request

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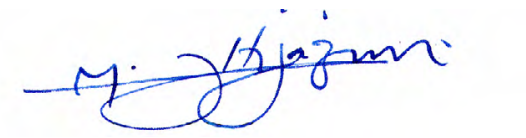
feedback from the readers and participants in order to promote the journal's quality and ability to achieve the goals we have briefly outlined.

Finally, I would like to extend my sincerest gratitude to John Carroll, MD who until just few days ago was my Co-Editor-in-Chief. John had many personal issues in the last year and upon his request and reluctantly I accepted that he steps down from the journal as a Co-Editor in Chief. John contributed so much to the planning phase of the journal and I'm personally grateful that he was involved.

Sincerely,



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Comment on this Article or Ask a Question

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Historical Perspective

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40 Years of Device Closure

Reflections from a Country Doctor

Terry Dean King, MD

Ochsner Pediatric Cardiology, West Monroe, Louisiana, USA

Key Words

ASD closure • Cardiac umbrella • Device closure • Septal closure

Introduction

2015 marks the 40th anniversary of ASD closure. As I reflect on that day, I remember how quiet the Ochsner Clinic had become. Very little was being said, I suppose in an attempt to limit the nervousness inherent in such an endeavor. We had successfully completed our canine research and were presented with an opportunity to use the device on a 17 year old female that was refusing surgery. I remember the rigors of the approval process, however today, I marvel at how easy it really was.

Imagine that day, beautiful weather on a crisp New Orleans spring day, normal by most accounts, but for some, the day would prove to be anything but normal. Imagine the entire hospital administration and the board of directors assembled in the board room receiving moment to moment updates about the procedure. Imagine the cath lab team and the surgical team assembling for this first implant. Imagine the courage of a 17 year old willing to have a procedure that had never been done on a human. Maybe she was protected by the naivety of her age or maybe she believed herself to be immortal (common in that age group). Lastly, imagine the relief, the tears of joy and the thrill of the moment when the umbrella locked in place.

We successfully placed the King-Mills umbrella in 5 patients. They are scattered across the country, from the east coast to the west coast and from the Mississippi Delta to the Rocky Mountains. Their current ages range from 57 to 84 years and all but one are "living large" with children and grandchildren. The 5th patient we implanted the device in, died at age 84, 9 years post implant of Hodgkin's lymphoma. All told, that is about 169 implant years.

The good news is, actually, the great news is, the devices achieved the intended goal and none of the patients had any untoward side effect. Age has a tendency to creep up on us all, and these patients have been no exception, however, I think it is safe to say the King Mills Cardiac Umbrella was a success.

I have been blessed to watch the advances in technology in device closure. Stainless steel and Dacron

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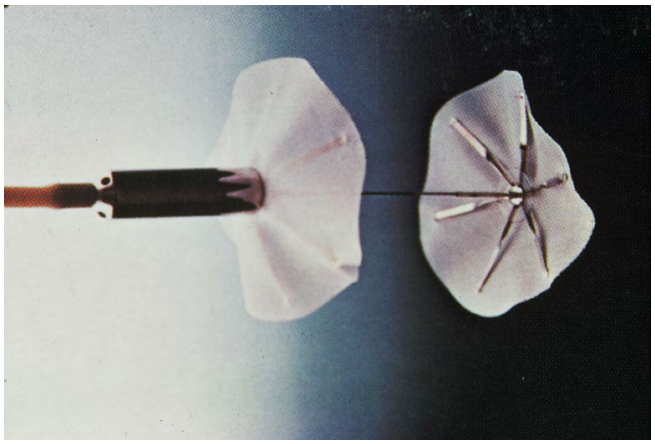

have been replaced with metals with memory. Large bore delivery systems have been replaced with much smaller systems. And while our procedure significantly decreased hospital stays for surgical closure, techniques today have allowed procedures to be done on an outpatient basis.

I contend that those 5 patients are the true heroes. They, like the thousands that have followed, put their faith and trust in us to first "do no harm" and in doing so, forged a path for others to come. I eagerly anticipate the day that the ultimate ASD closure device or procedure arrives. I agree with Dr. Bailey who said back in the early 1950's that a perfect closure won't leave a foreign object behind.

I am reminded of the Hippocratic Oath that states I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow. One measure of success is the caliber of people who choose to follow you. In this, I have achieved great success. I tip my hat to those who continue to advance this technology. For what I have found to be true in these 40 years, it is the relationships with my patients and my colleagues that have become my treasured memories.

Comment on this Article or Ask a Question

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Building a Structural Heart Disease Team

How to Integrate People

John M. Lasala, MD, PhD*, Alejandro Aquino, MD

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Abstract

Although the field of structural heart disease intervention is by no means a nascent one, it has undergone an unprecedented period of growth and organization over the past decade. The long-established stalwarts of aortic and mitral valvuloplasty have been joined by newer techniques including shunt (ASD/PFO) closure, transcatheter aortic valve replacement (TAVR), transcatheter pulmonary valve therapy, and mitral valve repair (MitraClip). As this field continues to unify, the expectation is that it will only grow. The prevalence of aortic and mitral valve disease is expected to increase as the population ages. This fact and the inevitable broadened commercial availability of these procedures will drive the number of structural procedures upwards. As an illustrative example, it is postulated that by 2015 the number of TAVR procedures will reach 25,000 per year.

Key Word

Heart Team

Growth of Structural Heart Disease

Although the field of structural heart disease intervention is by no means a nascent one, it has undergone an unprecedented period of growth and organization over the past decade. The long-established stalwarts of aortic and mitral valvuloplasty have been joined by newer techniques including shunt Atrial Septal Defect (ASD) and Patent Foramen Ovale (PFO) closure, transcatheter aortic valve replacement (TAVR), transcatheter pulmonary valve therapy, and mitral valve repair (MitraClip). As this field continues to unite, the expectation is that it will only grow. The prevalence of aortic and mitral valve disease is expected to increase as the population ages [1]. This fact and the inevitably broadened commercial availability of these procedures will drive the number of structural procedures upwards. As an illustrative example, it is postulated that by 2015 the number of TAVR procedures will reach 25,000 per year [2].

Building a Multidisciplinary Team Approach

The Importance of Multidisciplinary Team

As our field moves forward, it does so riding the edge of technological innovation but without prior organizational doctrine to guide the construction of a structural heart disease program. The concept of multidisciplinary care has long been utilized in other medical fields, the most conspicuous example being oncology. Trials evaluating forms of revascularization for coronary artery disease (SYNTAX and BARI) [3,4] introduced the concept of multidisciplinary care into cardiovascular medicine in the form of the "heart team." While there are indications from Neily et al. [5] that a cohesive team approach may improve mortality outcomes, the advantage of a multidisciplinary team (MDT) extends beyond procedural success. When dealing with the complexity of structural heart disease, the MDT is fundamental in the evaluation,

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decision-making, and post-procedural care. A cohesive team minimizes fragmentation in decision-making and improves coordination and delivery of care. It is crucial for patient safety, which is vital given that a substantial portion of this population may be frail and/or have multiple co-morbidities.

Structure and Challenges of a MDT

At the core of a multidisciplinary team lay a partnership between interventional cardiologists and cardiothoracic surgeons. However, as outlined by the 2012 ACC/STS consensus statement on TAVR, a complete heart team should also include others: a non-invasive cardiologist, imaging specialists (echocardiography, CT, MRI), cardiothoracic anesthesiologist, nurse practitioner, and cardiac rehabilitation specialists [6]. It must be noted that when dealing with congenital or acquired structural disease, for example, ASD/VSD, a strong relationship with pediatric interventional cardiologist is advantageous. The heart team must also extend beyond the individual physicians who form it and reflect a broader cooperation between cardiology and surgery divisions. Incorporating several members from each division strengthens the MDT by expanding the clinical input available for the decision-making process, as well as improving the flow and availability of care to the patients. Importantly, the opinion of a second surgeon regarding the operability of a candidate is often required for enrollment in several existing TAVR protocols.

Specifically for MitraClip, the heart team must include a cardiologist and cardiothoracic surgeon both experienced in mitral valve disease and treatment. The surgeon can lend expertise as to suitable mitral valve anatomy but also importantly assess patient frailty, an important criterion for patient selection. The use of 3D echocardiography in addition to standard 2D and Doppler imaging is vital in assessing mitral valve anatomy and pathology and thus suitability for MitraClip. This highlights the importance of having an experienced echocardiographer not only as a member of the MDT but also present during procedure to help guide deployment.

The primary challenge to a MDT is having effective communication and coordination between the different providers each with a busy clinical schedule. Fundamental to overcoming this hurdle and vital to the success of the MDT is a network of support staff including clinical and research coordinators. The clinical coordinator is a key member of the MDT who can serve as a pivot point through which the evaluation of a patient can be planned and executed. They can compile diagnostic results and facilitate the flow of information between the different members of the heart team. Because many patients are outside referrals, the coordinator can spearhead the gathering results from any previous diagnostic evaluation. Finally, as many devices and procedures are still in the investigational phase, the research coordinators are necessary to the enrollment of patients in ongoing studies or registries.

An MDT Model

While the ACC/STS consensus statement outlines the composition of a MDT, there exists no blueprint for organizing a team that will be cohesive and effective. Individual structural heart programs must adapt their model within the unique environments of their academic center. Below is a summary of our experience in applying the MDT approach to valvular heart disease (TAVR, MitraClip).

Outpatient Evaluation

Patients referred with complex valvular heart disease are seen in a weekly comprehensive valve clinic that brings together elements from cardiology and cardiothoracic surgery. Prior to being scheduled for consultation, the patient's available information is reviewed and any additional required diagnostic testing (e.g., transthoracic echocardiography, pulmonary function testing, CT) is scheduled for the day of their appointment day if possible. Additionally, the patient meets with any pertinent research coordinators and undergoes any needed ancillary studies (blood draw, frailty testing, etc.). This maximizes the amount of pertinent information available to the clinical team allowing a more precise evaluation and fruitful discussion with the patient. Once the patient has been seen, the history and physical as well as all available objective data (echocardiography, coronary angiogram, CT, etc.) are reviewed as a team. Therapeutic options are discussed and any additionally needed

Table 1. Adopted from Holmes et al. [6]

Components of TAVR Screening
Demographics • Age • Gender
Comorbidities (*many used for STS Score*) • CAD • PVD • CHF (NYHA Class) • COPD (FEV1) • Renal Function
Imaging to Confirm • Presence and severity of AS (echo) • CAD burden (angiography) • Presence of cerebral vascular disease (carotid doppler) • LV Function (echo) • Associated valvular lesion (echo)
Imaging for Procedural Planning • Annular size (2D and 3D echo, CT) • Aortoiliac anatomy

Table 2. TAVR Follow-Up

Post-Procedure Follow Up
Initial 2-Week Visit with CT Surgery • Chest X-ray • Laboratory studies (BMP, etc.) • ECG
1-Month Visit in Valve Clinic • ECG • Transthoracic echo
6-Month Visit • Laboratory studies only
1-Year Visit then Yearly Visits • Transthoracic echo

diagnostic testing is planned. The session culminates with a cardiologist and cardiothoracic surgeon meeting the patient and presenting all medical, interventional, and surgical options.

Inpatient Evaluation

A substantial number of patients evaluated by the valve team are transferred from referring institutions and have developed advanced valvular heart disease and secondary heart failure. It is even more challenging to apply the MDT approach to this subset of patients as there is no longer the advantage provided by the structured setting of the valve clinic. Communication between various members of the team is crucial. Again, a well-organized central core of support staff can facilitate this task and help meet the goal of patient evaluation by both a CT surgeon and cardiologist within 24 hours.

Weekly Meeting

Complementary to the valve clinic, weekly MDT meetings are held at our institution. This weekly valve meeting is the nucleus for the valve service and brings together the entire valve team as well as additional faculty including several cardiothoracic surgeons, interventional cardiology operators, and echocardiographers. Bringing such a comprehensive group of providers together offers many advantages. There is a broader contribution into the discussion regarding patient candidacy and ongoing management. This is a facilitated forum for clinical input including opinions from cardiothoracic surgeons regarding patient operability and frailty. Both inpatient and outpatient referrals who have completed the extensive screening for TAVR or MitraClip (Table 1) are presented. Importantly, this is also an opportunity to prioritize and schedule patients for procedure allowing timely delivery of care to those most in need of treatment.

Follow Up

Post procedure patients are seen initially at 2 weeks by cardiothoracic surgery at which time they undergo evaluation with chest X-ray, electrocardiogram, and laboratory studies (Table 2). Subsequently, patients are seen in valve clinic at 1 month, 6 months, 12 months, and then yearly thereafter. Echocardiographic studies are obtained prior to discharge, 1 month and then yearly. Again, having the MDT available at valve clinic provides the ability to address a wide range of post-procedural issues.

Conclusion

As the field of structural heart disease matures there will be many lessons learned regarding the construction and organization of a viable program. The concept of a multidisciplinary heart team is a solid foundation on which to build. The primary challenge is to bring together providers from different specialties in a cohesive and effective manner. In order to accomplish this there must be forums that allow joint patient assessment, this role can be filled by establishing a joint valve clinic and supplementing this with weekly meetings with other members of the heart team. Finally, the importance of strong support staff cannot be over-emphasized, as they can facilitate the flow of information between members of the heart team.

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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Real-Time 3D Transesophageal Echocardiographic Guidance of Prosthetic Valve Paravalvular Leak

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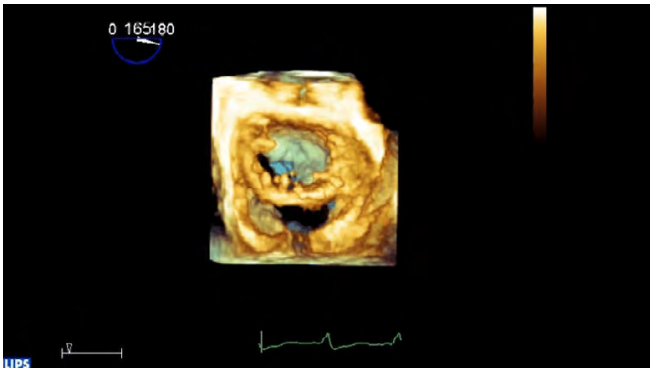
Abstract

Paravalvular leak (PVL), defined as retrograde blood flow adjacent to an annuloplasty ring (Figure 1 a, Video 1) or prosthetic valve (Figure 1 b, Video 2), is a rare but serious complication of heart valve surgery. Though most PVLs are asymptomatic, 1–5% of patients develop serious clinical consequences such as heart failure, endocarditis, or hemolysis [1,2]. Surgical repair may be necessary in severe cases, however for those who are at high surgical risk, a percutaneous approach can be performed to occlude these defects [1,3-9]. Real-time three-dimensional transesophogeal echocardiography (3DTEE) during percutaneous closure procedures is invaluable for intra-procedural guidance. In this article, we will review the literature and outline two cases where real-time 3DTEE guidance was critical for successful closure of symptomatic PVL.

Key Word

3D TEE Guidance



Video 1. Annuloplasty ring dehiscence.

Cases

Case 1

A 64-year-old female with history of congenital heart disease requiring ostium primum atrial septal defect (ASD) repair and multiple mitral valve replacements presented with worsening heart failure. Most recently, she underwent a third mechanical mitral valve replacement (in the setting of severe PVL), mechanical aortic valve replacement, tricuspid valve repair, and ventricular septal defect repair. Since her last surgery, she developed New York Heart

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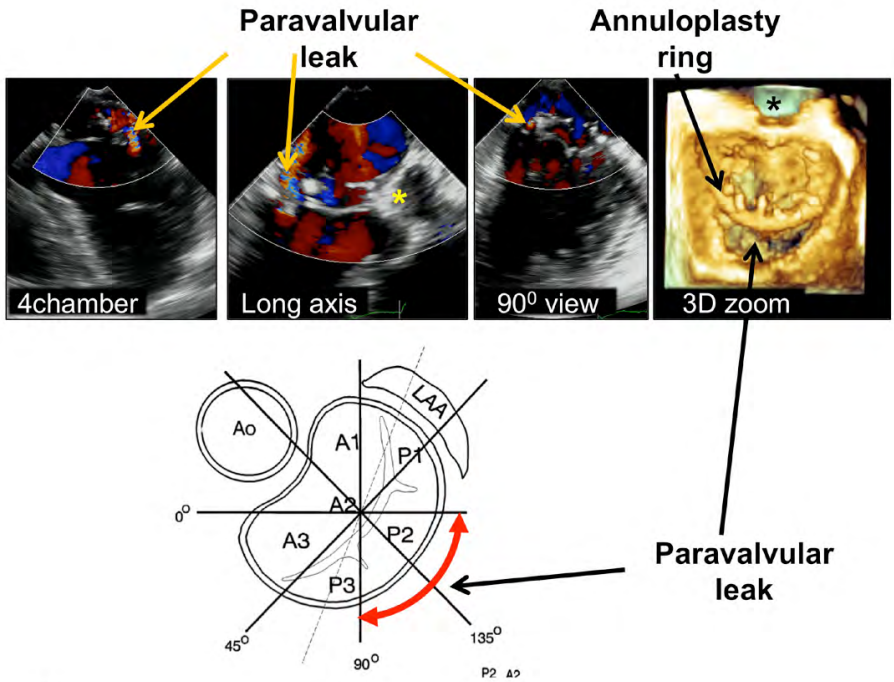


Figure 1a. Paravalvular leak adjacent to an annuloplasty ring. 2D TEE 4-chamber **(top row, far right)**, long axis **(top row, center right),** and 90-degree views **(top row, center left)** depict the case of a patient with extensive paravalvular leak spanning across three viewing planes along the posterior portion of the mitral annulus **(bottom figure)**. This is well seen on 3D image **(top row far right)**.

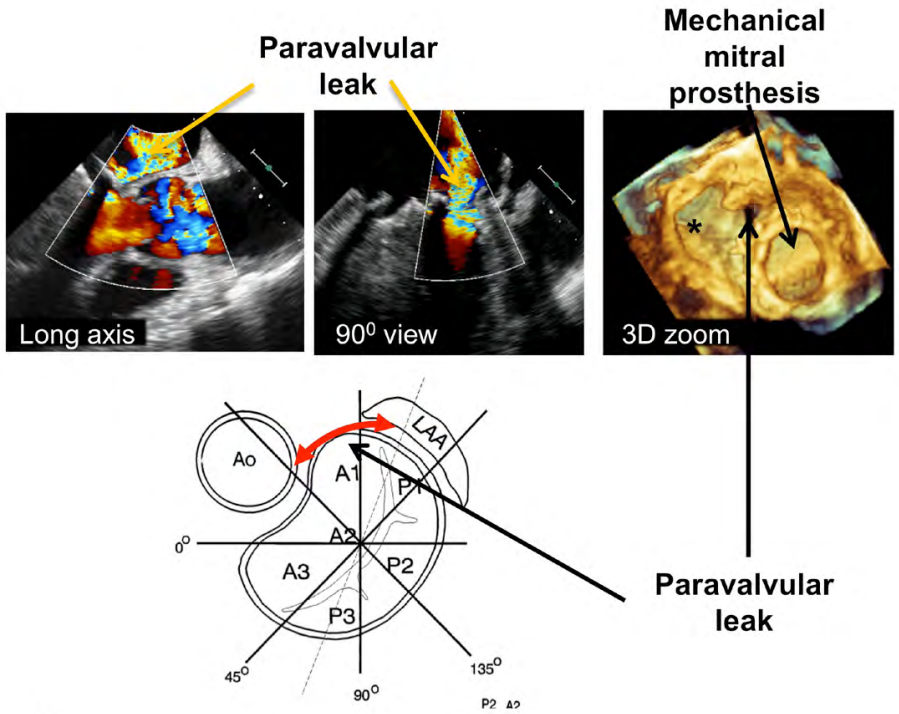


Figure 1b. Paravalvular leak adjacent to a prosthetic valve. 2D TEE long axis **(top row, far right)**, and 90 degree views **(top row, center)** depict the case of a patient with paravalvular leak spanning across two viewing planes along the anterior wall of the mitral annulus on the side of the aorta and the left atrial appendage **(bottom figure showing approximate location of the leak)**. This is well seen on 3D image **(top row far right)**. Asterisk shows the location of the left atrial appendage.

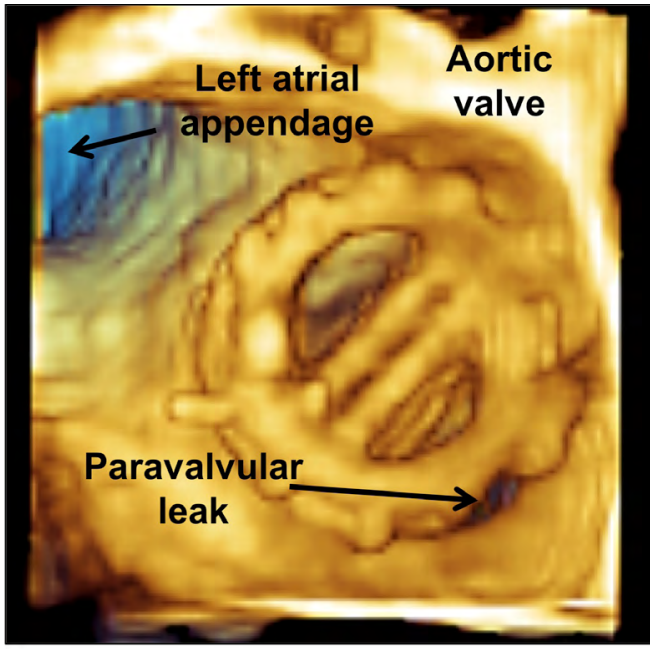
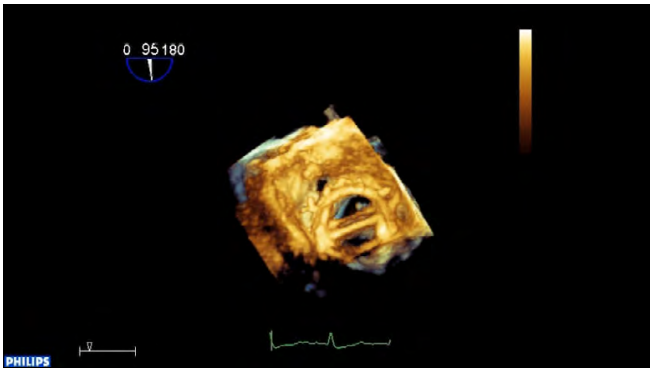
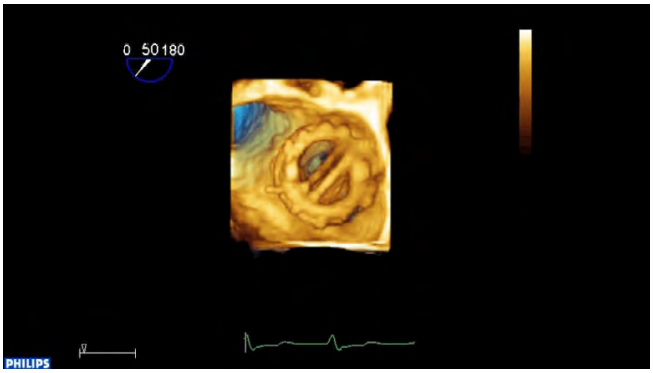


Figure 2. 3D zoom view of the mechanical mitral prosthesis with paravalvular leak as noted. Aortic valve is in the 12 o'clock position.



Video 2. Mechanical mitral prosthetic dehiscence.



Video 3. Case 1: Mechanical mitral prosthesis with paravalvular leak in the 4 o'clock position.

Association (NYHA) Class III heart failure symptoms and atrial fibrillation. Diagnostic evaluation including right heart catheterization and TEE revealed severe pulmonary hypertension (PA pressure 84/34 mmHg with a mean of 50 mm Hg) and an area of partial dehiscence of the prosthetic mitral valve with a large PVL. Due to her worsening heart failure and history of multiple sternotomies, surgical repair was deemed to be associated with prohibitive risk and a percutaneous approach was planned.

Due to location of the defect (Figure 2, Video 3) and the presence of a mechanical aortic valve, a trans-apical approach was chosen for percutaneous closure over a trans-septal or retrograde aortic approach. After apical access was obtained, the paravalvular defect was identified and crossed with a 0.035inch x 150 cm Terumo straight stiff glide wire (Terumo Medical, Somerset, New Jersey, USA) (Figure 3) with 3DTEE guidance. Initially, an 8-mm muscular ventricular septal defect occluder (St. Jude Medical, St. Paul, Minnesota, USA) was positioned and deployed into the large defect. On 3DTEE and fluoroscopy, there was evidence of entrapment of a mechanical mitral valve leaflet and the device was retrieved. Next, a 6mm muscular VSD occluder device (St. Jude Medical, St. Paul, Minnesota, USA) was placed into the defect without compromise of leaflet mobility on TEE (Figure 4, Video 4) and fluoroscopy. TEE confirmed closure of the large PVL. Using transthoracic echocardiographic guidance, the trans-apical puncture site was closed with a 6mm/4mm Amplatzer Duct Occluder (St. Jude Medical, St. Paul, Minnesota, USA). The patient tolerated the procedure well and was discharged home 3 days later.

Case 2

A 72-year-old male with history of rheumatic heart disease requiring mechanical mitral and aortic valve replacements was transferred for consideration of repeat mitral valve replacement. He was initially hospitalized with acute pulmonary edema and severe hemolytic anemia requiring blood transfusions. Upon transfer there was significant volume overload, and severe intravascular hemolysis as evidenced by low

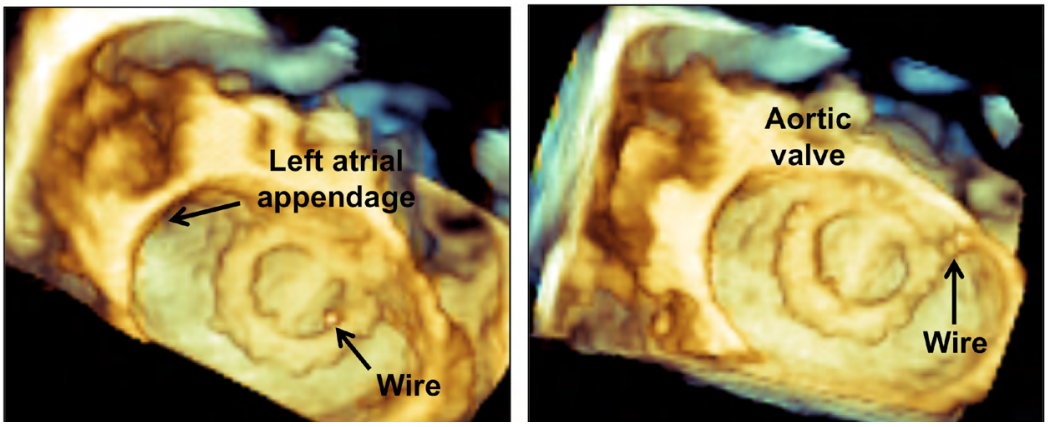


Figure 3. 3D full volume rendering of the mechanical mitral prosthesis with the guide wire in the wrong location **(left panel)** and guide wire in the right position **(right panel)**. Aortic valve is in the 12 o'clock position.

hemoglobin and haptoglobin, elevated lactate dehydrogenase, and an unconjugated hyperbilirubinemia. The etiology of the patient's heart failure and hemolytic anemia were determined to be secondary to severe PVL of the mechanical mitral valve on TEE. Due to severe deconditioning and comorbidities patient was deemed high surgical risk, and a percutaneous approach was preferred.

Given the anatomy and location of the PVL, a trans-apical approach was chosen to facilitate crossing and closure of the defect. With 3DTEE guidance, the PVL anatomy was identified showing two distinct PVLs with the larger dehiscence located along the inferolateral aspect of the valve annulus (Figure 5). With TEE guidance, the defect was crossed with a guidewire and a 6mm Amplatzer VSD occluder device was placed across the defect, however, TEE and fluoroscopic imaging showed evidence of entrapment of the posterior mechanical mitral valve leaflet (Video 5, Video 6, Video 7). The occluder device was removed and a 4mm Amplatzer VSD occluder device was positioned across the defect and deployed with resolution of PVL demonstrated by TEE. The trans-apical puncture site was closed with a 6mm/4mm Amplatzer Duct Occluder.

Discussion

Incidence

The incidence of PVL post heart valve surgery is 5 to 17% [10-12]. PVL occur more commonly in patients with prosthetic mitral compared to those with prosthetic aortic valves. The estimated incidence ranges between 7–32% in the mitral position and 2–10% in the aortic position, with the most clinically significant complications occurring in the mitral position [10,11,13]. The majority of PVLs are frequently single, but may be multiple in 27% of patients [14]. It is unclear whether PVLs occur more frequently in bioprosthetic valves vs. mechanical valves [10].

Etiology and Natural History

PVL occur as a consequence of an incomplete seal between the ring of the implanted valve and the surrounding cardiac tissue. Known risk factors for PVL occurrence include annular calcification, small prosthetic size, inadequate suturing technique, and infection [15]. PVLs that are identified soon after implantations are most often secondary to technical complications of the operation; in contrast, PVLs identified late after surgery are most frequently a consequence of infectious endocarditis or secondary to significant annular calcification [16].

PVL size correlates directly with onset of symptoms; with larger size leaks resulting in heart failure symptoms. Smaller PVL may create high velocity jets into the low pressure left atrium. These jets may collide with structures such as the limbus, which separates, the appendage from the left superior pulmonic vein, resulting in hemolysis. The number of PVLs does not appear to correlate with symptoms, but increasing numbers of leaks increase the risk of associated

hemolysis [14]. With follow-up, leaks may increase or decrease in size, or, less commonly, may spontaneously close [13,17,18]. Importantly, the presence of PVL results in turbulent blood flow thereby augmenting the risk for the development of infective endocarditis in the presence of bacteremia. If regurgitant flow is significant and not corrected, the natural history of PVLs may mimic that of native valve regurgitation. Uncorrected hemolysis eventually results in severe anemia.

Clinical Findings

Patients with symptomatic PVLs present with congestive heart failure in over 90% of cases. Most report NYHA Class III or greater symptoms [19,20]. Clinical presentation may occur immediately after surgery or significantly later [21]. Hemolytic anemia is present between 30–75% of cases referred for intervention [19,20].

The regurgitation associated with large PVLs is often associated with a murmur on cardiac auscultation. In para-mitral valve leaks, a blowing, holosystolic murmur is typically heard radiating to the axillae. However, paravalvular regurgitatant jets may be oriented differently than jets associated with intra-valvular regurgitation; if the jet is oriented posteriorly, radiation may be noted in the back. If the jet is oriented anteriorly, radiation to the base may be heard. The murmur appreciated in para-aortic valve leaks is typically a blowing, decrescendo, diastolic murmur that is heard best at the left sternal border with the patient sitting forward and in end-expiration.

The majority of patients presenting with symptomatic PVLs have elevations of N-terminal pro-brain natriuretic peptide. Brain natriuretic peptide is typically elevated in patients with congestive heart failure, but it has also been shown to correlate with the severity and symptoms of aortic and mitral regurgitation [22,23]. When hemolytic anemia is present, laboratory studies will show decreased hemoglobin, markedly elevated lactate dehydrogenase, markedly decreased haptoglobin, and increased indirect bilirubin.

Echocardiography

Transesophageal (TEE) and transthoracic (TTE) echocardiography should be used to assess prosthetic valve function and the spatial characteristics of PVLs. Color Doppler can help identify the location, direction, and severity of regurgitant blood flow. However, because the spatial resolution of traditional TEE and TTE is limited, the addition of 3D allows for improved spatial resolution and therefore provides more information regarding the size and shape of PVLs [24,25]. This information is especially helpful during percutaneous closure procedures. RT3D TEE allows for operators to visualize the length of the

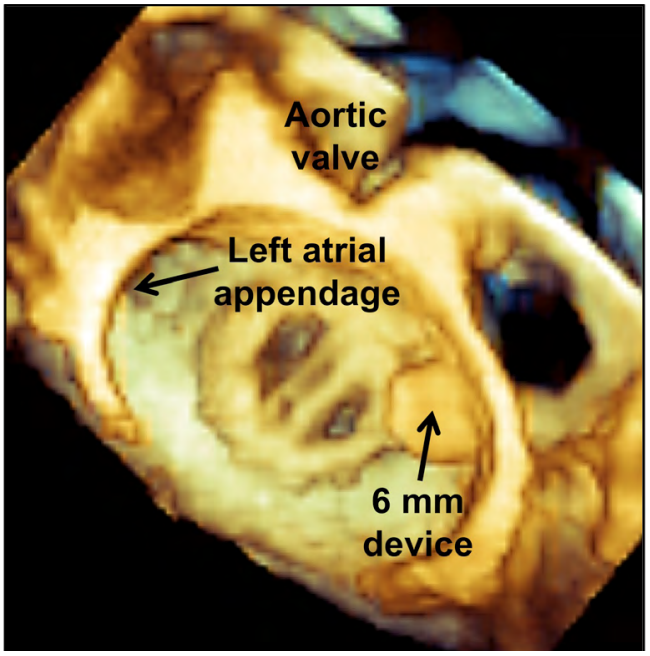
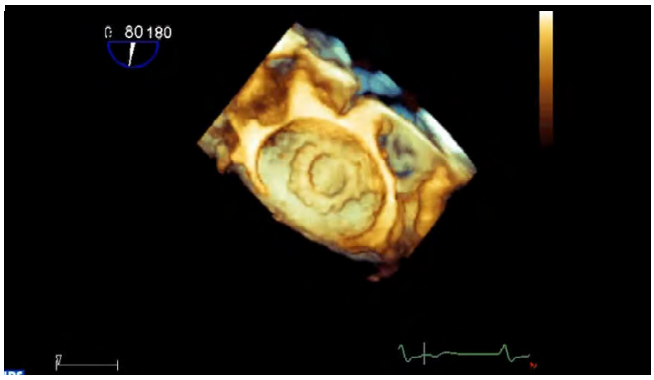


Figure 4. 3D full-volume rendering of the mechanical mitral prosthesis with 6-mm occluder device in position. Aortic valve is in the 12 o'clock position.



Video 4. Case 1: 3D acquisition of 6 mm occluder device expansion.

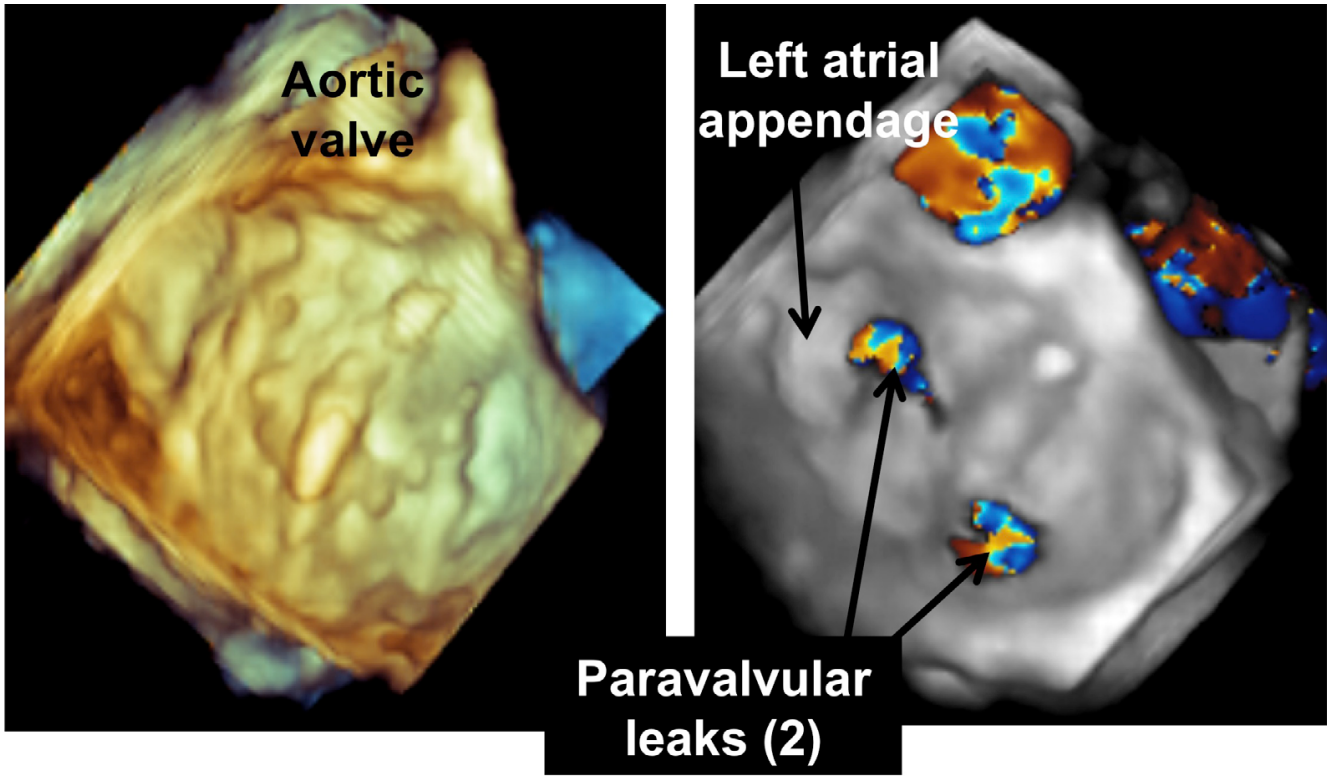


Figure 5. 3D zoomed rendering of the mechanical mitral prosthesis **(left panel)**. With this modality, it is difficult to appreciate the two disks associated with the valve prosthesis in this patient. The paravalvular leaks are not seen. The 3D color zoom acquisition of the mitral prosthesis allows better appreciation of the location and number of paravalvular leaks **(right panel)**. This patient has two paravalvular leaks. Aortic valve is in the 12 o'clock position.

catheter or guidewire, identify the size, shape, and number of PVL, and ensure that any deployed closure device does not impair movement of the mechanical valve leaflets.

The majority of PVL are crescentic, oval, or round in shape. Their track can be parallel, perpendicular, or serpiginous in relation to the direction of prosthetic blood flow. The most common location for mitral PVLs are along the posterior wall (5–6 o'clock from the surgeon's perspective) and along the aortic-mitral curtain (10–11 o'clock) [19,26]. The prevalence of PVLs in the posterior mitral annulus has been attributed to the following: (1) the posterior annulus provides a limited surgical field view for suturing (2) the proximity of the circumflex artery may lead to more superficial suturing, and (3) calcification and fibrosis are more prevalent in the posterior annulus [24].

The recommended methods used to assess the severity of para-mitral valve regurgitation are similar to those used to evaluate native mitral regurgitation. Color flow regurgitant jet area, jet density, and systolic pulmonary venous flow reversal are all recommended in the assessment of para-mitral valve regurgitation [27]. The proportion of the circumference of the sewing ring occupied by the regurgitatant jet provides an approximate guide to severity, with more than 20% indicating severe regurgitation and less than 10% consistent with mild regurgitation [27]. The proximal isovelocity surface area (PISA) measurement has not been validated in paravalvular regurgitation, but large PISA shell measurements of paravalvular regurgitant jets have been reported to be more consistent with severe regurgitation [28]. Jet eccentricity may limit traditional assessment with color Doppler.

Aortic PVLs are more commonly located in the vicinity of the non-coronary or right coronary cusps [29]. Para-aortic regurgitation is also assessed with accepted criteria that are used to assess native aor-

tic insufficiency. Typical criteria include pressure half-time, jet width, jet density, and diastolic flow reversal in the descending aorta [27].

There are several challenges associated with assessment of paravalvular regurgitation with echocardiography. Mechanical valves create significant image distortion due to acoustic shadowing, and showing may actually hide the presence of regurgitant jets. When multiple PVLs are present, echocardiographic assessment is difficult due to eccentric regurgitant jets and absence of validated echocardiographic parameters.

Other Imaging Techniques

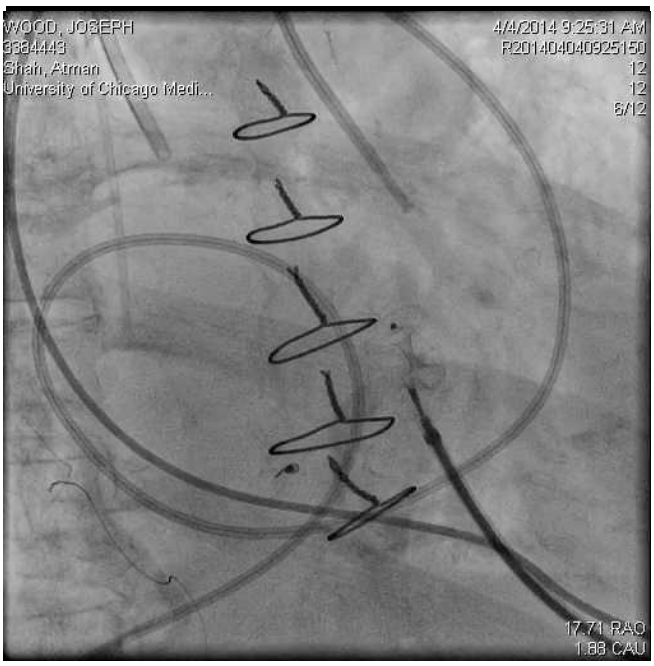
PVLs may also be evaluated with EKG-gated computed tomographic angiography (CTA). These images can be retrospectively reconstructed to form 4D-reconstructions, that allow for detailed visualization of PVLs. These images have been used to assist planning for percutaneous PVL closure procedures [19]. Like echocardiography, CTA is limited by artifact from high-density structures like the prosthetic valve and extensive calcification. In addition, CTA requires IV contrast and radiation exposure, therefore, the risk of IV contrast and radiation exposure must therefore be weighed against the potential benefit.

Angiography has historically been used to assess the location, size, and hemodynamic severity of PVLs. However, it is difficult to determine the 3D anatomic and spatial characteristics of the defect with angiography, alone. Invasive assessment of the PVL with test balloons to assess PVL size, distensibility, and hemodynamic implications of closure is no longer recommended due to the risk of balloon entrapment.

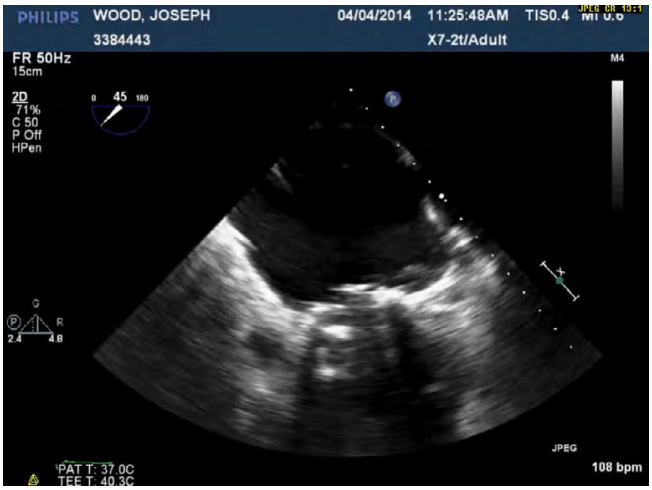
Treatment

Medical therapy in large PVLs is directed at symptom reduction by either treating the heart failure or treating the anemia caused by hemolysis. Despite these interventions, the majority of patients with severe PVL require definitive, structural correction via either open surgery or transcatheter-based intervention.

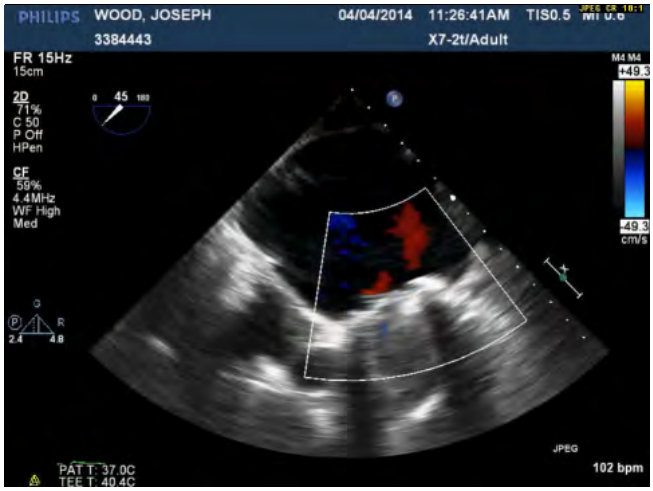
Until recently, surgical management of PVLs was the only available treatment for severe disease. Surgical correction improves overall survival and symptoms in patients with severe PVL, when compared to medical therapy, alone [12]. Surgery entails either repair of the PVL or re-do replacement of the prosthetic valve. Many approaches to surgical correction of mitral PVLs have been described, but most involve either direct suturing, patching, or incorporation of autologous tissue from neighboring structures [30-34]. The choice of repair versus replacement depends



Video 5. Case 2: Fluoroscopy showing evidence of entrapment of the posterior mechanical mitral valve leaflet.



Video 6. Case 2: 2D TEE showing evidence of entrapment of the posterior mechanical mitral valve leaflet.



Video 7. Case 2: 2D color Doppler TEE showing evidence of entrapment of the posterior mechanical mitral valve leaflet.

largely on the specific etiology of PVL, location, and size of the leak. Operative mortality for surgery to replace a dysfunctional mechanical or bioprosthetic valve is 5% to 14% [35,36]. Hospital mortality has been described as 13% for initial re-operation, with subsequent operations associated with significantly higher mortality [37].

Since first described in 1992, percutaneous transcatheter closure of PVLs has become an attractive alternative to surgical correction [3]. Advancement of real-time 3DTEE imaging has contributed to the success of catheter-based techniques. These procedures do not require cardio-pulmonary bypass, and therefore may carry a lower risk than traditional surgery. A variety of techniques have been described in the literature [1,3-9].

Percutaneous PVL repair may be performed from multiple access points; retrograde via the femoral or radial artery, antegrade via femoral vein (with trans-septal perforation to access the left heart), or directly via trans-apical puncture [38]. The specific access site and approach is determined in a case-by-case basis with consideration for the location of the defect, location of the prosthesis, other anatomical considerations, multiple patient-specific issues, and operator experience.

Closure of aortic PVL is typically performed via retrograde arterial approach. A guidewire is advanced through the leak, with real-time 3DTEE and fluoroscopy used to ensure that the wire is crossing the PVL. The size and shape of the defect, typically evaluated by echocardiography determines the size of the delivery catheter used. The occlusion device is then loaded onto the delivery catheter, advanced into position, and deployed. Before and after release of the occlusion device, the operator must confirm free motion of the prosthetic leaflets, stable anchoring of occlusion device, and reduction of the regurgitant jet [38].

Mitral PVL closure is technically more challenging than aortic PVL closure. It is typically performed using the femoral venous trans-septal approach. Trans-septal puncture typically requires simultaneous TEE or intracardiac ultrasound to minimize the risk of complication. The location of the PVL itself along the mitral annulus determines the optimal approach for the procedure. For example, if the PVL is close to the atrial septum, it may be difficult to engage the PVL via the femoral venous trans-septal approach. Furthermore, retrograde arterial approach may be needed to snare the wire placed via the trans-septal approach to provide a more stable rail for device deployment. However, left ventricular structures (such as trabeculae, papillary muscles, and chordae) may complicate retrograde engagement of mitral PVRs. In some instances, access via a trans-apical approach is required. This approach provides direct engagement of mitral PVL at any location around the mitral annulus. It is typically achieved with surgical access and direct visualization of the left ventricular apex, although fully percutaneous trans-apical access is possible, as shown in the above cases [39,40].

At this time, the majority of percutaneous PVR repairs are performed with Amplatzer devices (St. Jude Medical, St. Paul, Minnesota, USA), although vascular coils have also been used [1,20,25,41-43]. The devices used are either cylindrical or oval in shape. The success of percutaneous PVL repair hinges on proper selection of occlusion devices. Selection is predicated on the size and shape of the PVL. Because most PVL are oval in shape, oval occlusion devices may be preferred in most cases. Large PVL require large occlusion devices. Unfortunately, larger occlusion devices increase the risk for prosthetic leaflet impingement, because the discs of the device can overhang the sewing ring. Some authors have suggested that this risk may be alleviated by placing multiple smaller occlusive devices in the large defect [38].

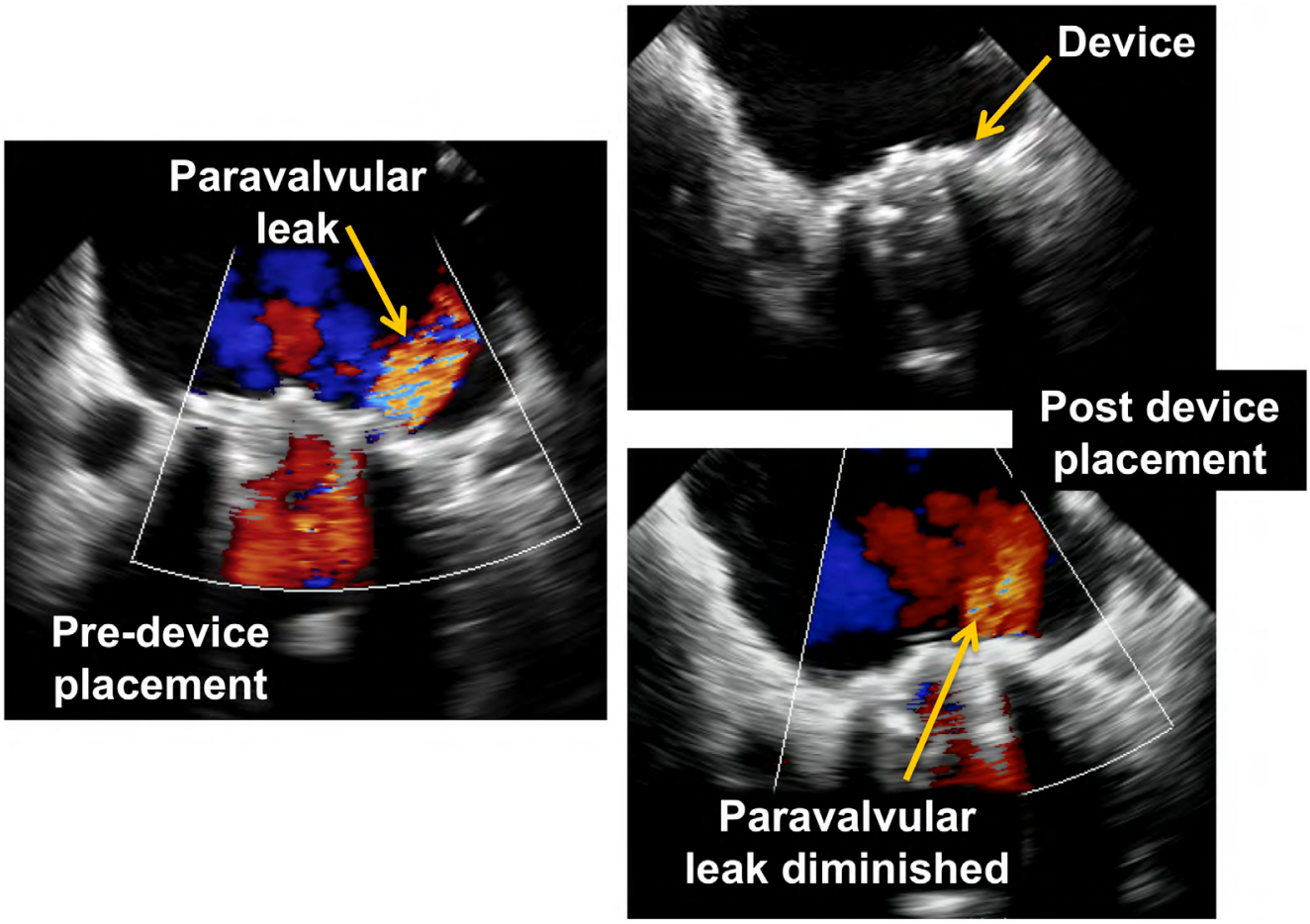


Figure 6. 2D TEE images of the paravalvular leak that was closed with device **(left panel)**. The top right image shows the device in situ and the bottom right image shows diminished significance of this paravalvular leak post device placement.

Percutaneous PVL closure has a technical success rates of 77 to 88% in high-volume centers, with some reporting success rates greater than 95% [20,25,40,42]. Clinically, significant success has been reported from 67 to 77% of cases. Peri-procedure complication rates have been reported around 10%, with a mortality of approximately 1%. Peri-procedural complications include cardiac tamponade, device embolization, damage to prosthetic valve, and stroke. Late embolization of occlusive devices has been reported, but is rare [44,45].

Conclusions

Symptomatic PVL is an uncommon, but serious complication of surgical valve replacement. Assessment of the severity of PVL requires thoughtful interpretation of clinical presentation and multiple imaging modalities. Once identified, successful closure of symptomatic PVL can be achieved with surgical re-operation or percutaneous closure from a variety of approaches. As highlighted in the two cases, real-time 3D TEE is invaluable in guiding the successful percutaneous closure of PVL.

Conflict of Interest

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

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Balloon Aortic Valvuloplasty

Patient Selection and Technical Considerations

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Abstract

BAV has had resurgence in association with the dissemination of TAVR. The lack of clear mortality benefit from BAV does not translate to lack of efficacy as a palliative therapy. BAV remains a useful bridge to surgical AVR or TAVR, and for symptom relief in patients who are not candidates for either AVR approach. It is also useful as a diagnostic test for patients with low gradient-low output AS, and for those with mixed pulmonary and aortic valvular disease. BAV is used commonly for TAVR pre dilatation, and this is sometimes helpful for annulus size assessment. Careful attention to balloon diameter selection and the details of technique are important for optimizing outcomes.

Key Words

Balloon • Aortic • Valvuloplasty • General

Introduction

It is widely recognized that balloon aortic valvuloplasty balloon aortic valvuloplasty (BAV) does not contribute to an improvement in survival among nonsurgical or very high-risk patients with aortic stenosis. Unfortunately, the value of BAV as a palliative therapy has been overlooked in the shadow of this lack of mortality benefit. Clinical improvement after BAV occurs in the vast majority of patients. While in many this clinical improvement is short-lived, a majority of patients feel improved symptoms for as long as 1 year [1]. The utility of this therapy as a palliative treatment is seen best among patients, who truly have no other option [2]. For example, the extreme risk patient, who is a candidate for neither surgical nor transcatheter AVR may undergo BAV periodically for relief of symptoms. In our practice, there are patients, who have had roughly once yearly BAV procedures over a period of 2 or 3 years. This was, of course, more common before the availability of TAVR.

Indications for Balloon Aortic Valvulolasty (BAV)

Contemporary indications for balloon aortic valvuloplasty (BAV) in adults are framed by the use of transcatheter aortic valve replacement (TAVR) as the mainstay of therapy for patients with aortic stenosis (AS) who are high risk for surgical valve replacement (SAVR) [3]. BAV has clinical utility in several circumstances in current practice. The 2014 AHA/ ACC guideline for the management of patients with valvular heart disease characterizes this in a single level IIb (level of evidence C) recommendation, stating, "Percutaneous aortic balloon dilation may be considered

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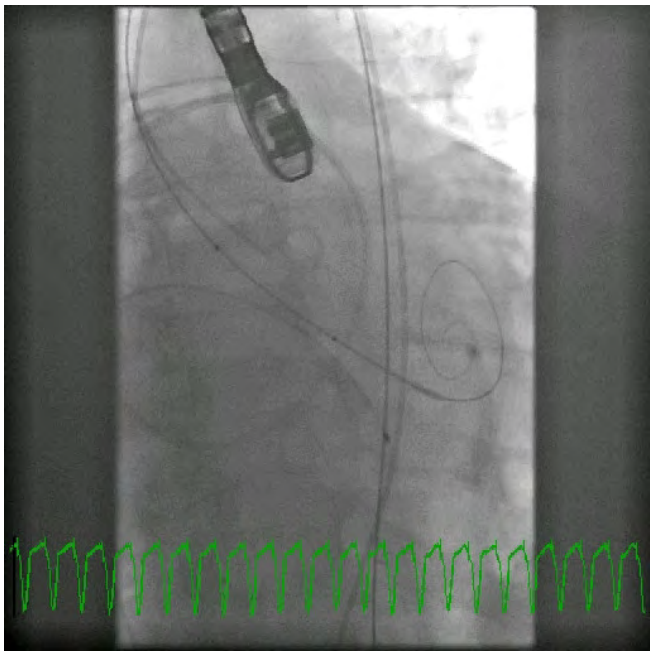

Figure 1. Hand injection of contrast during BAV with a 22mm balloon showed locking of the balloon and no contrast regurgitation around the balloon.

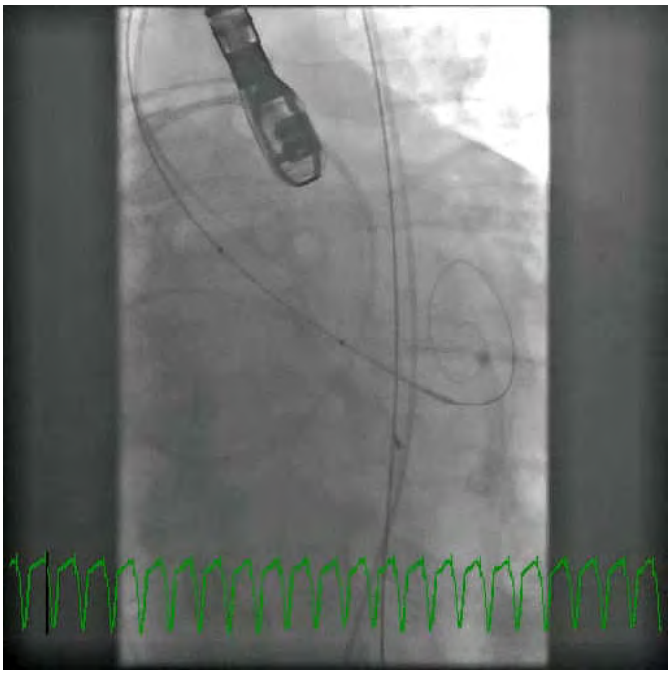

Figure 1 Video.

as a bridge to surgical AVR or TAVR in patients with severe symptomatic AS" [4,5]. This defines an important role for BAV among patients who are unstable or in refractory heart failure prior to valve replacement with either SAVR or TAVR [6]. These patients may present with refractory heart failure or shock, and BAV can make them more manageable for the short term.

BAV is also used in several other clinical situations (Table 1). Another important utility of BAV is as a diagnostic test. Patients with low gradient and low output aortic stenosis with low left ventricular ejection fraction represent a frequent diagnostic conundrum. Prior to aortic valve replacement, BAV in this population may unmask the myocardial reserver for a more invasive valve replacement therapy. The best example of this patient group is those with mixed chronic lung and valvular heart disease. The degree to which they may improve after valve therapy is often uncertain, and those who have a favorable response to BAV may be expected to similarly benefit from aortic valve replacement.

A more controversial use of BAV is prior to non-cardiac surgery. While many patients with severe aortic stenosis can undergo non-cardiac surgery when special care is taken to manage their hemodynamic situation, there are clearly patients, who have no reserve for whom management during non-cardiac surgery is challenging. The patient, who presents with an absolute aortic valve area less than 0.5 cm^2, or those with low cardiac output, very high pulmonary or pul-

Table 1. Indications for BAV

Bridge to SAVR
• Stabilize shock
• Treat severe CHF
• Bridge to TAVI
Symptom relief
• Stabilization while evaluation is undertaken
Diagnostic test: see how patient responds
• Low gradient/low output patient
• Mixed lung and valve disease
Therapy for "no-option" patient
• Anyone can undergo AVR
• Apical-descending aorta conduit is an option for some
Pre-op for non-cardiac surgery
Predilatation
• Sizing

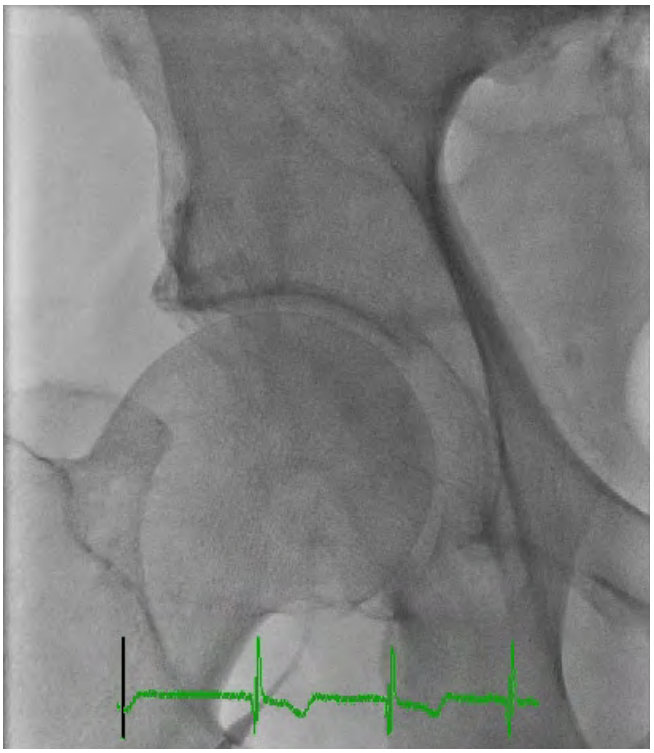

Figure 2. Micropuncture contrast injection after fluoro guided femoral access to ensure sheath insertion in a non-calcified segment of the common femoral artery.

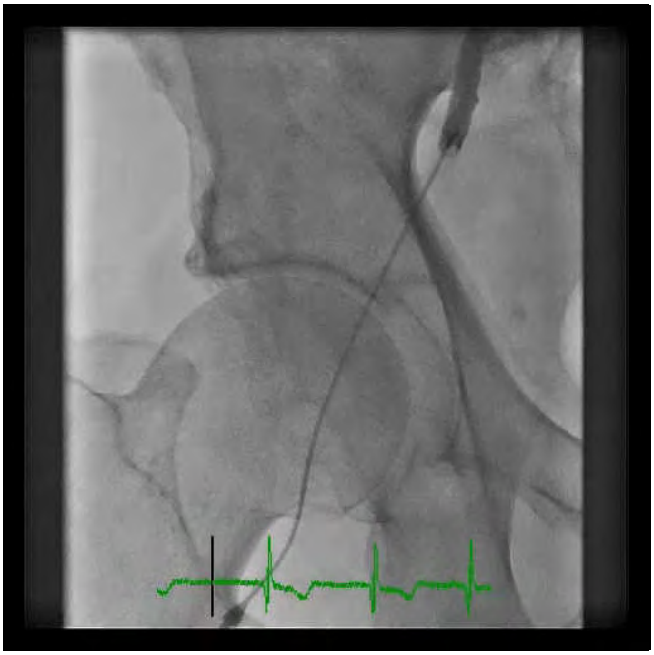

Figure 2 Video.

monary wedge pressures, or refractory symptomatic heart failure, may be stabilized enough by BAV to make non-cardiac surgery more tolerable for both the patient and the Anesthesia Team [7].

Recently, the major use of BAV has been for predilatation during TAVR procedures. While the need for predilatation can be argued for some patient groups and for many average TAVR procedures, another utility of BAV for TAVR is to help with valve annulus sizing or choice of prosthesis size [8]. When predilatation with a balloon matched to the expected annulus size yields a sealing of the annulus evidenced by contrast injection during the balloon inflation, greater confidence can be found for a TAVR valve with the frame corresponding to the balloon size. Conversely, when the balloon will not lock in the valve, and a contrast injection during balloon inflation results in clear contrast regurgitation into the left ventricle, the balloon presents an undersized diameter for a given valve annulus.

Special care must be taken to be sure that the fully inflated predilatation balloon size measurement is accurate. Many balloons are manufactured with some variability in the technical specification. In addition, hand inflation using a large syringe typically results in under-filling of the balloon, and it is likely in that setting that the balloon will not achieve its nominal diameter. Two methods to insure correct and full inflation include either use of a volume driven inflation with an inflation device, or the addition of a side syringe and a high pressure stopcock to the larger hand inflation syringe.

BAV can be used as an aid to sizing for TAVR [9]. It is not uncommon to have ambiguity for the selection of TAVR device size, even with CT annulus measurements. This problem results when patients are truly on the borderline between valve prosthesis sizes based simply on measurements, and is exacerbated by the challenges of heavily calcified leaflets or left ventricular outflow tract, and the underappreciated problem of suboptimal CT scan images for analysis. One method favored by some operators to help resolve

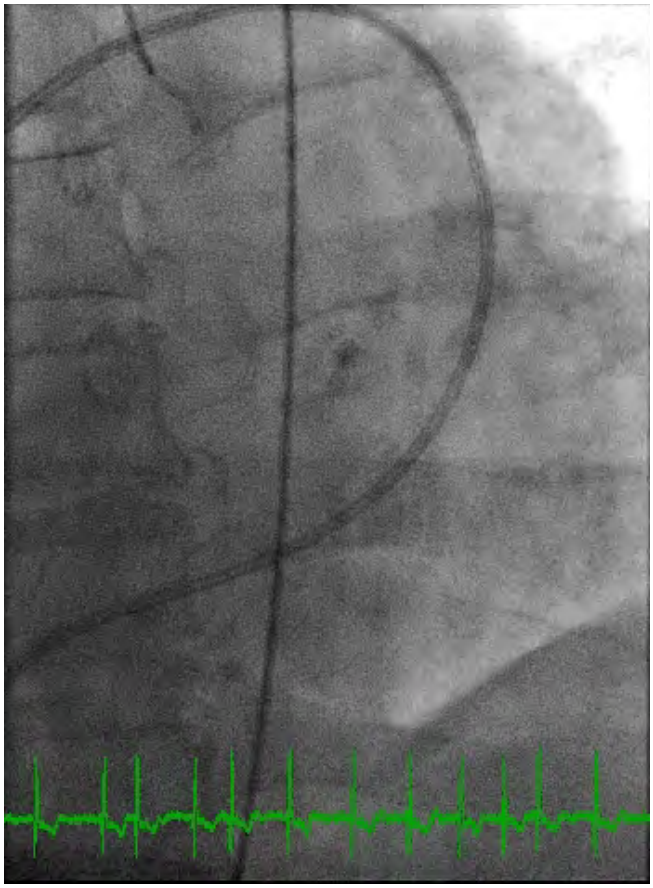

Figure 3. After arterial access is obtained, the valve is crossed using an AL1 diagnostic catheter and a straight tipped guide wire.

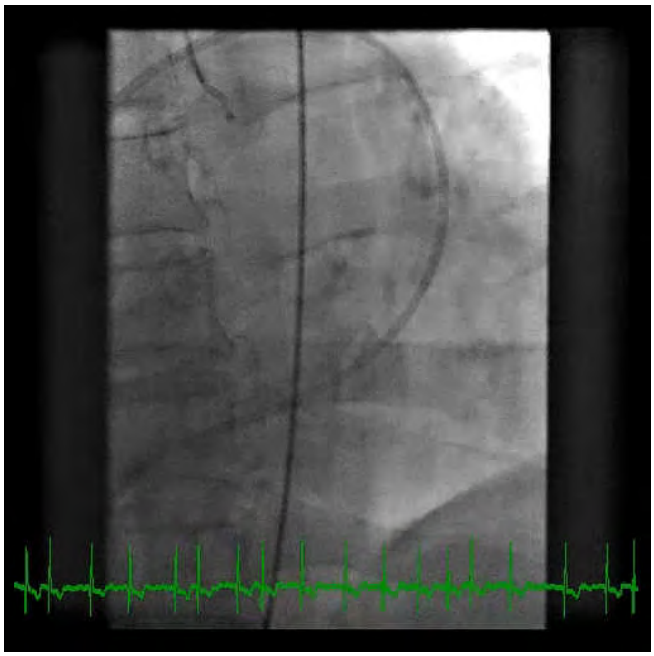

Figure 3 Video.

ambiguity when TAVR device sizing is problematic is to inject contrast in the aortic root during the BAV for TAVR predilatation. A balloon size is typically selected to approximate the short axis CT diameter of the valve. The short axis dimension of the annulus can also be ascertained from the typical transthoracic or transesophageal log axis echo.

The balloon is inflated and contrast is injected into the aortic root at the peak of balloon inflation (Figure 1). CT measurements prior to planned TAVR were borderline for a 23-mm vs. a 26-mm Edwards S3 implant. Hand injection of contrast during BAV with a 22-mm balloon showed locking of the balloon and no contrast regurgitation around the balloon. A 23-mm valve was implanted with a good result, including minimal paravalvular leak. The use of hand injections or various forms of power injections is completely non-standardized. A caveat is that the tip of the pigtail used for injection may be trapped between the balloon and the aortic wall, especially if the sinotubular junction is small in diameter, and a power injection may result in a dissection of the aortic root. During contrast injections it is often difficult to assess whether there is significant contrast regurgitation around the balloon. Generally little or no contrast regurgitation into the left ventricle especially when associated with a balloon that locks into the native aortic anulus during inflation suggests that a valve prosthesis frame of about that diameter will be successful.

BAV Techniques

Retrograde BAV

The technique retrograde BAV was described initially for pediatric patients in 1985 and first reported in adult patients with degenerative calcific aortic stenosis in 1986. The technique was largely unchanged for two decades. More recently, several advances have contributed to the predictability of the procedure and its practically [10]. Balloons for BAV

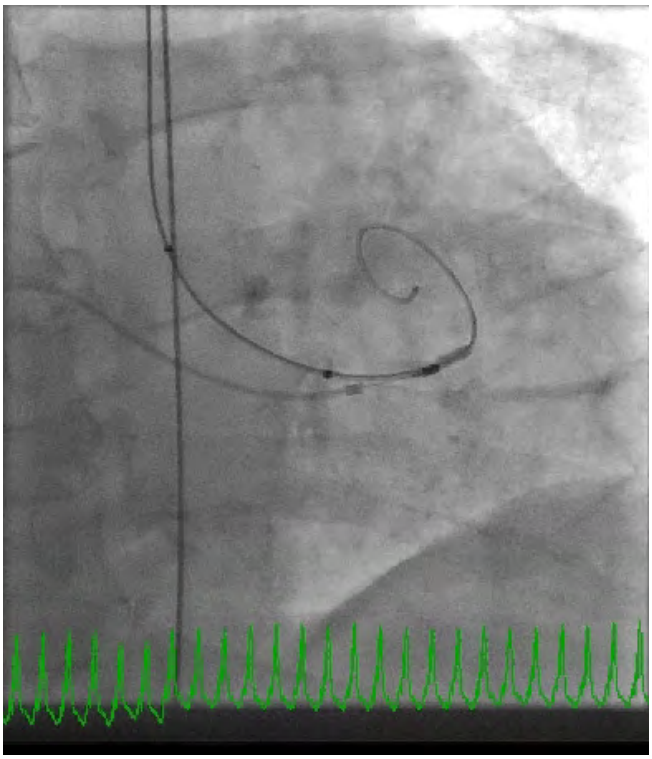

Figure 4. Rapid right ventricular pacing to cause hypotension, at a heart rate between 170 and 200 beats per minute, is initiated and when the blood pressure falls, the valvuloplasty balloon is inflated.

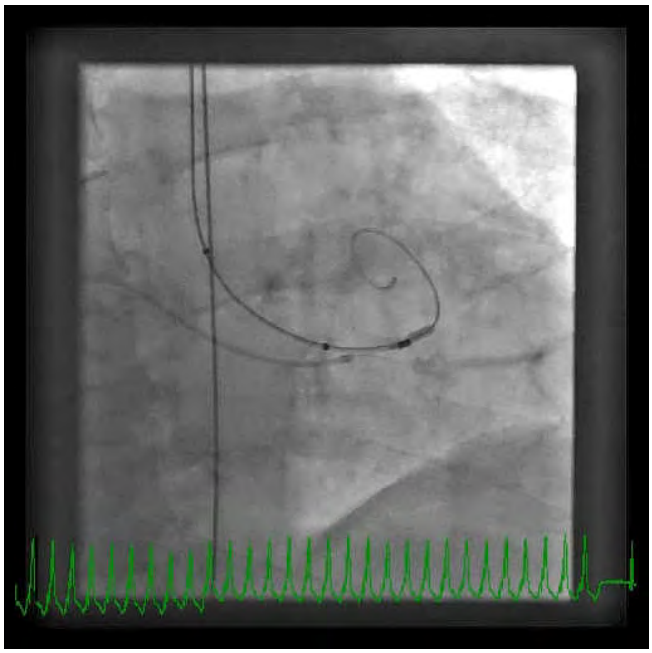

Figure 4 Video.

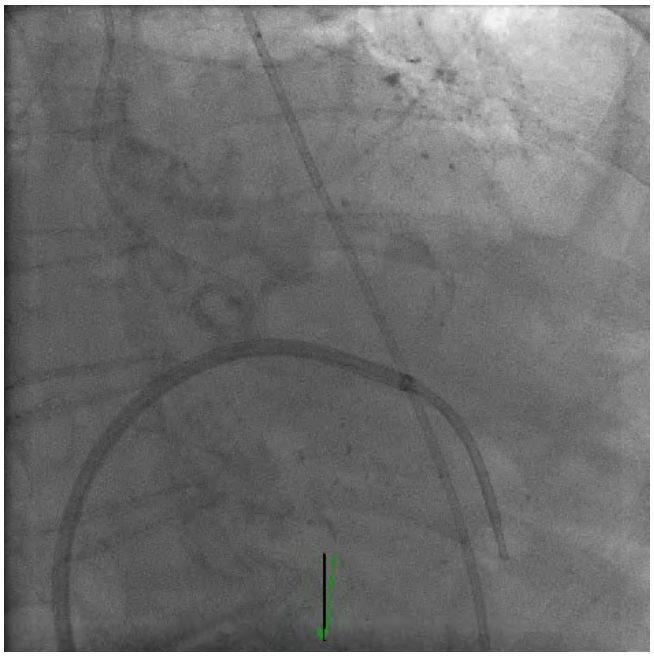

Figure 5. A 7-French single-lumen balloon catheter is inflated in the left atrium and with counterclockwise rotation of a standard Mullins sheath the balloon tip catheter is floated across the mitral valve.

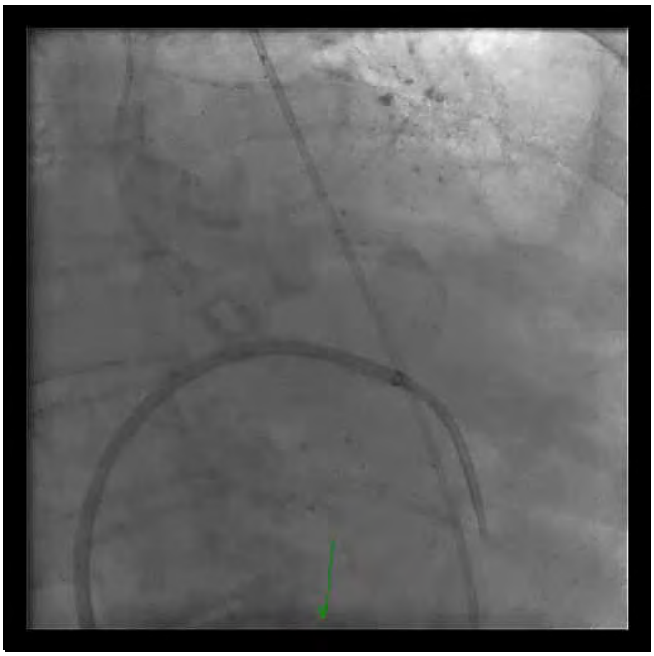

Figure 5 Video.

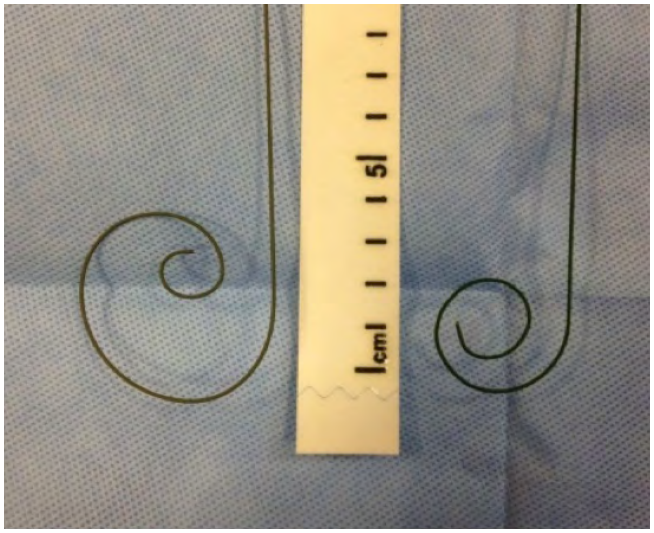

Figure 6. A standard 0.035" J-tip wire can be introduced into the single-lumen balloon catheter with a large curve added, so that the balloon catheter can be directed around the left ventricular apex.

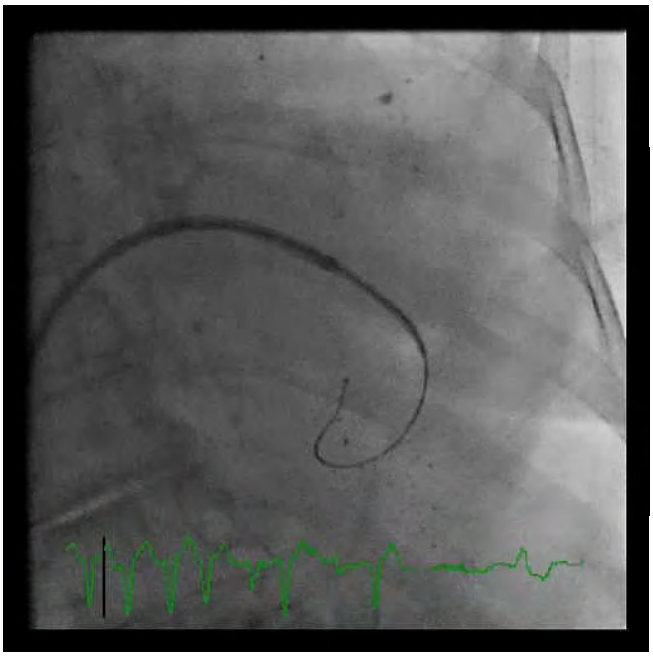

Figure 6 Video.

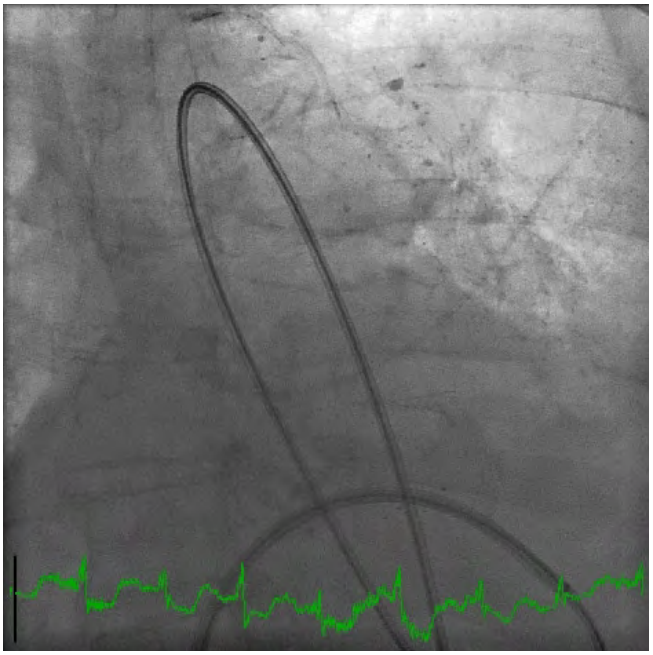

Figure 7. An exchange length 0.032 inch extra stiff wire is passed through the balloon catheter into the descending aorta above the aortic bifurcation.

Figure 7 Video.

have improved significantly. In addition to technology improvements, several key advances in the technique have made it more successful. Particularly, the advent of rapid right ventricular pacing during balloon inflations to minimize balloon movement or "watermelon seeding" has made the procedure much

more manageable. The basic technique involves obtaining femoral arterial access, performing suture preclosure, and placing an arterial sheath ranging in diameter from 10 up to 14 French, depending on the balloon type and size. Meticulous technique using fluoro- or ultrasound-guided femoral access to ensure sheath insertion in a non-calcified segment of the common femoral artery is critical (Figure 2). After access is obtained, the valve is crossed using standard techniques (Figure 3) and stiff exchange wire is placed as a rail for delivery of the balloon. The balloon is advanced retrograde over the guidewire into the left ventricle and positioned across the native aortic valve annulus. Rapid pacing at a heart rate, typically between 170 and 200 beats per minute is initiated and when the blood pressure falls, the balloon is inflated (Figure 4). After full inflation is achieved, the balloon is withdrawn and rapid pacing discontinued. If the balloon was ejected from the ventricle during the inflation, and blood pressure recovery has been adequate, a second inflation may be performed. At that point, the result is assessed and if appropriate to the situation, a larger balloon can be used when the result does not meet the planned expectations. The balloon and wire are withdrawn, and the existing suture is used to close the arterial sheath insertion site, usually with a wire left in place so that if the preclosure fail, an additional Perclose device can be used or a sheath inserted so that manual compression may be undertaken when the anticoagulation normalizes or is reversed. Careful attention to the hemodynamics before and after each inflation is crucial. While it is not necessary to re-measure the transaortic gradient after each inflation it is critical to carefully assess the changes in aortic diastolic pressure as an indicator of increase aortic insufficiency. If a second inflation is necessary, the possibility of more than mild aortic insufficiency should be excluded before proceeding for the second attempt.

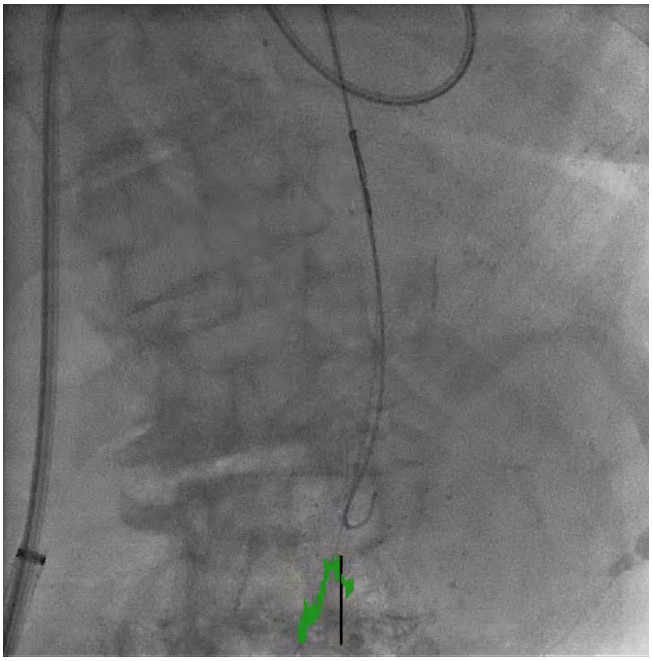

Figure 8. The left femoral artery access can be used to introduce a 10mm gooseneck snare to catch the distal end of the 0.032 inch wire.

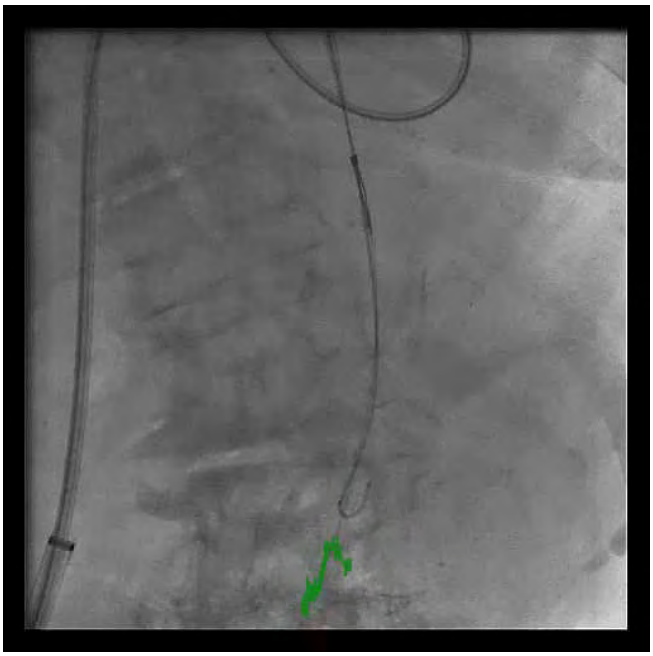

Figure 8 Video.

Antegrade BAV

A much less utilized approach is to deliver a balloon into the native aortic annulus using transvenous-trans-septal access [11]. From the trans-septal puncture into the left atrium, a single-lumen balloon catheter can be floated into the left ventricle and then into the aorta. This allows delivery of a stiff wire antegrade so that the balloon for BAV may be

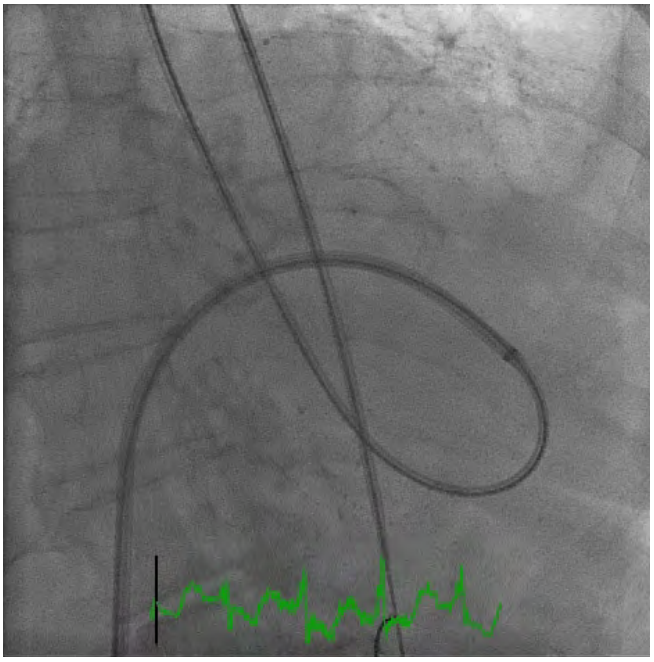

Figure 9. The snared support wire may be left parked in the descending aorta, as this will provide adequate support for antegrade balloon passage.

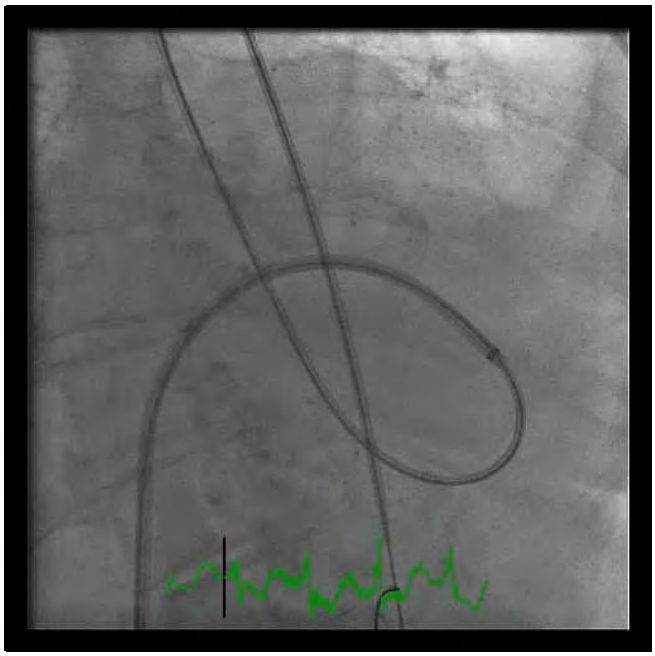

Figure 9 Video.

introduced on the venous side of the circulation and tracked through the left atrium and left ventricle to straddle the aortic valve. Antegrade BAV is technically more demanding than retrograde BAV. Many of the procedure steps are unfamiliar to many BAV and TAVR operators. One of the advantages of antegrade BAV is utilization of a vein rather than an artery for access. This is occasionally useful in patients with severe peripheral arterial disease. Another advantage is stability of the balloon during inflation in the aortic valve even without rapid pacing. Since there is an arterial-venous loop, the balloon can be controlled from both antegrade and retrograde directions and is highly stable. In addition, the use of venous access allows for the utilization of much larger diameter balloons. In our series, this resulted in larger acute valve areas BAV compared to a retrograde technique.

The next several paragraphs will detail the specific procedure steps of antegrade BAV. The initial set up for antegrade BAV includes 7 French left femoral arterial and 7 or 8 French left femoral venous access, and for the trans-septal puncture, 14 French right femoral venous access. The arterial access sheath size is required to place a 10mm gooseneck snare via the left femoral arterial sheath and still have enough room for arterial pressure measurement. The left femoral venous access is for initially pulmonary artery catheterization and cardiac output measurement, and subsequently for medication administration if needed. The 14 French right femoral venous access facilitates trans-septal puncture and allows for placement of a Inoue balloon catheter.

After access is obtained, trans-septal puncture is performed. A posterior mid fossa level puncture allows easiest access to the mitral orifice. A 7 French single-lumen balloon catheter is inflated in the left atrium and with counterclockwise rotation of a standard Mullins sheath the balloon tip catheter is floated across the mitral valve (Figure 5). At this point, the transaortic valve pressure gradient can be measured. A standard 0.035" J-tip wire can be introduced into the single-lumen balloon catheter with a large curve added, so that the balloon catheter can be directed around the left ventricular apex (Figure 6). At this point, it is sometimes necessary to switch to a floppy tip straight wire such as a Wholey wire to cross the aortic valve antegrade and with the single-lumen catheter balloon deflated, pass the balloon catheter

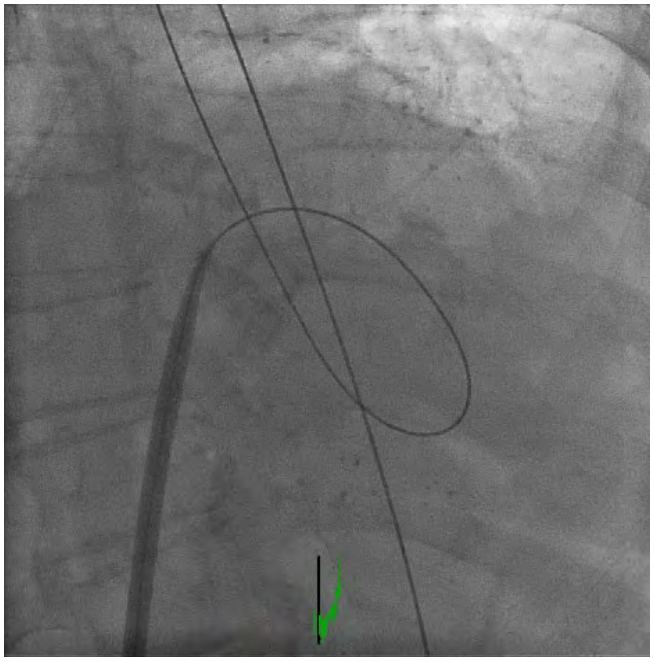

Figure 10. Dilation of the interatrial septum.

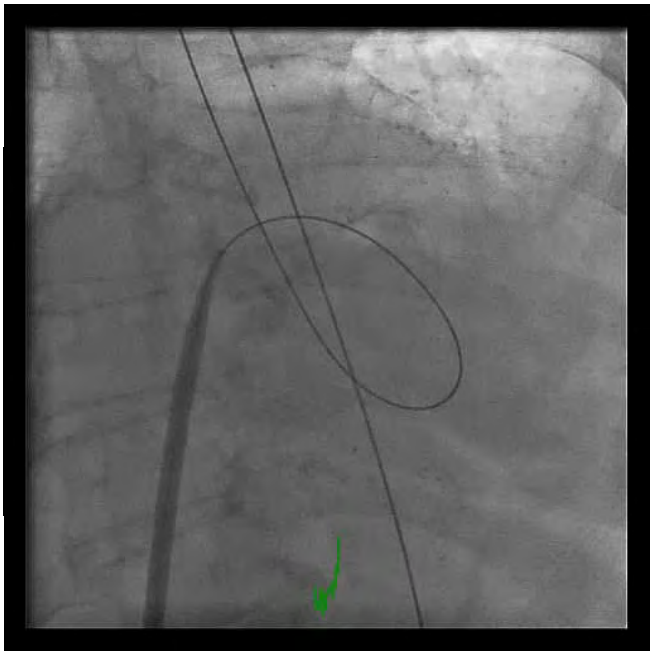

Figure 10 Video.

into the aortic root. The balloon catheter is then maneuvered with a wire into the descending aorta. At this point, an exchange length 0.032 inch extra stiff wire is passed through the balloon catheter into the descending aorta above the aortic bifurcation (Figure 7). The left femoral artery access can be used to introduce a 10-mm gooseneck snare to catch the distal end of the 0.032-inch wire (Figure 8). While it is possible to exteriorize the arteriovenous loop, there is no need for this and the snared support wire may be left parked in the descending aorta, as this will provide adequate support for antegrade balloon passage (Figure 9).

The Mullins sheath and single-lumen balloon catheter are then withdrawn through the 14 French right femoral venous sheath exchanged for Inoue balloon 14 French dilator. The septum is dilated (Figure 10). The Inoue balloon is prepped. The Inoue balloon is then introduced in it stretched configuration. In the United States, the smallest available balloon is the maximum recommended inflated diameter of 26 mm. For most women, a single balloon inflation of 24 or 25 mm can be performed. For most men, a single inflation of 25 or 26 mm, using the calibrated inflation syringe, is adequate.

The stretched balloon is introduced into the left atrium, and then unstretched. The balloon is tracked around the arteriovenous loop through the mitral valve and into the aortic valve. It sometimes requires pushing from the venous side and pulling on the arterial side to get the balloon into position in the native aortic valve. Without any need for rapid pacing, the balloon is inflated in its usual stepwise fashion (Figure 11). The distal part of the balloon was inflated on the arch side of the aortic valve and pulled back to engage the valve and then the balloon is fully inflated. A rapid inflate-deflate is important. It is also important, as soon as the balloon deflated, to back it out of the aortic valve into the left atrium, and to re-establish the arteriovenous loop so that there is no tension on the mitral valve leaflets.

In some cases, progressive hypotension begins as soon as the arteriovenous loop is introduced and the procedure must be aborted. In other cases, the onset of this mitral regurgitation related hypotension is gradual and if the procedure can be accomplished rapidly, the arteriovenous loop can be decompressed or removed before significant hypotension occurs.

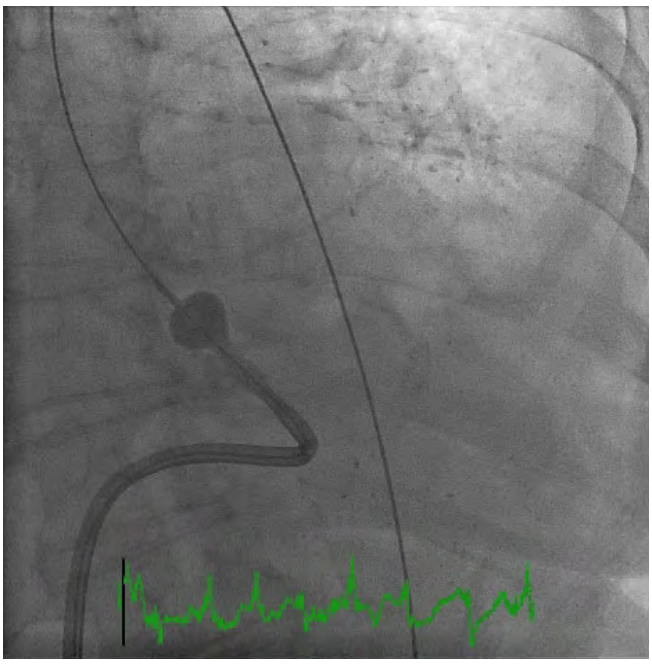

Figure 11. The balloon is inflated in stepwise fashion without any need for rapid pacing.

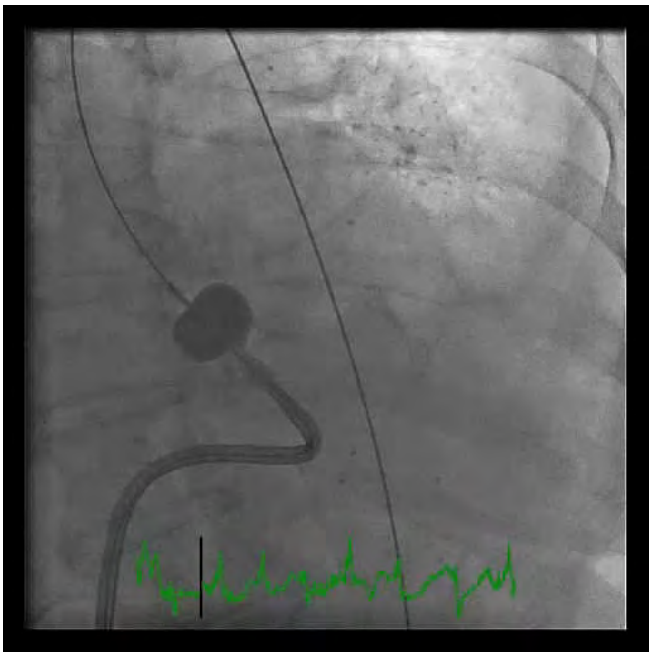

Figure 11 Video.

Unlike the case in retrograde BAV, the Inoue balloon completely occludes the aortic outflow and this is often poorly tolerated by the left ventricle. Episodes of slow pressure recovery with the antegrade technique are more common than with the retrograde technique. It is my practice to have both atropine and epinephrine or phenylephrine open and available for this possibility. Epinephrine or phenylephrine doses of 50 up to 250 µg are usually sufficient without causing rebound hypertension.

After the balloon catheter has been pulled back into the left atrium it can be stretched and removed over the wire. At this point, it is critical to place a diagnostic catheter from the venous side over the 0.032-inch wire and pass this catheter across the mitral and aortic valves and into the aorta. The gooseneck snare can be removed, and then the exchange wire pulled back into the diagnostic catheter. A pigtail is best used for this purpose, as the pigtail is pulled back it can be left in the left ventricle. This is easier if the Mullins sheath is introduced over the wire before the pigtail is placed. A post intervention gradient can be assessed to determine the results of the procedure. Covering the arteriovenous loop wire with a diagnostic catheter before removing the wire is critical, since the wire can "cheese cut" the mitral valve if it is pulled back without protecting the valve.

Future Perspectives in Aortic Valvuloplasty Technologies

Most of the current balloons in use for aortic valvuloplasty were not specifically designed for this purpose and thus have limitations. They have predominantly been peripheral angioplasty balloons which are cylindrical in shape, with a spectrum of balloon diameter lengths and compliance characteristics. Until recently, none of these have been FDA approved for the BAV indication. The re-emergence of "stand-alone" BAV, TAVR pre- and post-dilations have led to balloon innovations. One such balloon is the True Dilation Balloon Valvuloplasty Catheter (C. R. Bard, Inc., Tempe, Arizona, USA). This balloon is cylindrical in shape. The balloon matrix is embedded with high-strength fibers rendering the balloon noncompliant and thus achieving precise diameters when inflated. In addition, the shaft size is approximately 10 Fr to permit larger inflation lumens and thus faster inflation and deflation times. Rapid right ventricular pacing is still

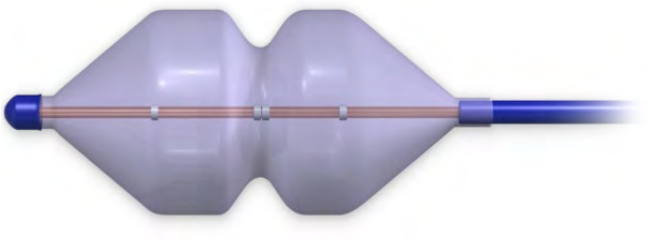

Figure 12. The Intervalve V8 balloon has a geometric "hourglass" configuration designed to take advantage of the complex aortic valve and adjacent anatomy.

recommended to minimize balloon slippage.

A second novel aortic valvuloplasty balloon, the V8 (Intervalve, Inc., Plymouth, Minnesota, USA) has a geometric (i.e., "hourglass") configuration designed to take advantage of the complex aortic valve and adjacent anatomy (Figure 12). Intended benefits include: 1) precise balloon position with stable fixation with or without rapid pacing, 2) greater resultant aortic valve areas due to hyperextension of the valve leaflets into the sinuses of Valsalva by the proximal bulb, and 3) enhanced safety with the retention of a narrower balloon waist, reducing the likelihood of annular rupture. In a propensity-matched study with 40 patients, the delta increase in AVA by echocardiography for the V8 balloon was 0.30 ± 0.23 cm^2 vs. 0.17 ± 0.21 cm^2 for standard cylindrical balloons (P = 0.063). There was no severe AI, new IVCD's, or need for PPM's. There were no major adverse events in the V8 group defined as procedure-related death, stroke or emergency surgery [12]. As per direct communication with Intervalve, in over 400 cases procedural mortality was less than 0.5%. The V8 has a 10Fr shaft and permits rapid inflation/deflation times. A subsequent iteration in development has a radio-opaque ring on the balloon waist to assist in establishing co-planarity with the target AV annulus for TAVR positioning.

A third novel valvuloplasty balloon, the Valvulosculpt Balloon (Angioscore, Fremont, California, USA) is cylindrical in shape and has a helical wire lattice on the exterior balloon surface to enhance fixation and potentially augment AVA by proposed leaflet scoring. This balloon is in early phase testing and not yet FDA approved. It has been related to the authors by direct communication with Angioscore that further testing with the intention of coming to market has been frozen.

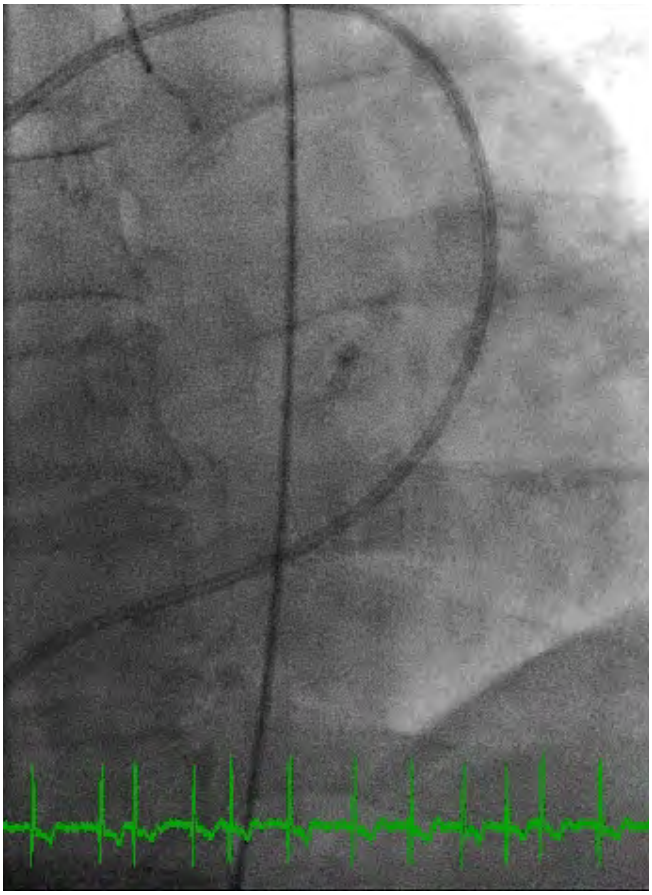

Figure 13. Pre-shaped, extra stiff, guide wires including the "Safari" wire (left-Boston Scientific, Plymouth, MN) and "Confida" (right-Medtronic, Minneapolis, MN) have recently been brought to market for TAVR as well as BAV.

Finally, catheter-based concepts for calcific valve leaflet remodeling have been proposed. Energy sources for consideration include high-frequency ultrasound, with application of the lithotripsy, and transmission of vibration through direct catheter-to-leaflet contact with a mechanical device.

Pre-shaped, extra stiff, guide wires including the "Safari" wire (Boston Scientific, Plymouth, Minnesota, USA) and "Confida" (Medtronic, Minneapolis, Minnesota, USA) have recently been brought to market for TAVR as well as BAV (Figure 13, Safari left & Confida right). These new wires offer better straightening of tortuous vascular anatomy and large distal curves with smooth transitions in the LV. These features enhance greater wire stability and support as well as a

diminished likelihood of LV perforation.

Complications

BAV may cause clinically important complications, mainly during the procedure that should be addressed immediately. The main complications include death (2.5%), stroke (2%), vascular complications (2.5%), severe aortic insufficiency (1.5%) and permanent pacemaker requirement (<1%) [13]. These risks should be carefully addressed to the patients prior to the procedures. Severe aortic insufficiency is more common with balloon oversizing. A strategy for the short term management of severe aortic insufficiency is tachycardia pacing [14]. In the worst cases a permanent pacemaker can be implanted and used to keep the heart rate between 90–110 bpm to minimize the diastolic time. It is noteworthy that high volume operators may have a lower incidence of these complications. Also, the studies are somewhat heterogeneous, and the risk of the patients may vary from one study to the other. For example, in one study the investigators included patients with cardiogenic shock who underwent BAV, and the in-hospital mortality was 56%, but the overall risk of patients without cardiogenic shock was still 2% [15]. This emphasizes the underlying risk inherent in the patients that undergo BAV, and the importance of careful patient selection for the procedure.

Conclusions

BAV has had resurgence in association with the dissemination of TAVR. The lack of clear mortality benefit from BAV does not translate to lack of efficacy as a palliative therapy. BAV remains useful a bridge to surgical AVR or TAVR, and for symptom relief in patients who not candidates for either AVR approach. It is also useful as a diagnostic test for patients with low gradient-low output AS, and for those with mixed pulmonary and aortic valvular disease. BAV is used commonly for TAVR predilatation, and this is sometimes helpful for annulus size assessment. Careful attention to balloon diameter selection and the details of technique are important for optimizing outcomes.

Conflict of Interest

Dr Feldman is a consultant to Abbott, BSC, and Edwards. Dr Pedersen has ownership interest in InterValve.

Comment on this Article or Ask a Question

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Of Becoming a Structural Heart Disease Expert: Another Giant Leap?

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Abstract

Over the last 10 years, Structural Heart Disease (SHD) has emerged as a distinct sub-specialty of interventional cardiology. However, to date there are no formal training guidelines or training programs. We believe as the population ages, over the next few years, this sub specialty will continue to mature and guidelines for training will become established.

Key Words

Structural heart disease • Coronary angioplasty • Training in SHD

In July of 1969, how many children watched Neil Armstrong and Buzz Aldrin land the Apollo 11 on the surface of the moon, and take the first steps on its surface? Many of us remember Armstrong and more or less Aldrin; however, does anyone remember who kept the spaceship in orbit? Well, the pilot's name was Michael Collins and he was an Italian born American [1].

At that time, everyone was dreaming of becoming an astronaut. These were supermen: tough, smart, brave and dedicated professionals who operated the most complex, most advanced technology and equipment to fly to space and land on the moon. They had the satisfaction and the glory of being pioneers and discoverers. They were our heroes. They had earned the admiration of everyone, doing what nobody could have done before them. Their "one small step for man"…became a "one giant leap for mankind"…

Does this remind you of what is happening today with Structural Heart Disease (SHD)? Cardiologists are very curious individuals, and I guess, this quality is inherent in our profession. When Andreas Grüentzig first opened the door to what is now called interventional cardiology by performing and describing percutaneous coronary angioplasty (PTCA), a large number of cardiology trainees wanted to become "interventionalists" [2]. Over the past 30 years, this sub-specialty has matured, and there are now concise training requirements [3]. Nonetheless within the nearly last 10 years, the evolution of coronary interventions has reached a plateau. Conversely, the so-called Structural Heart Disease (SHD) interventions have emerged as the new kid on the block.

The name SHD is now reserved to those acquired or congenital cardiovascular pathologies that involve the major central cardiovascular structures outside the scope of acquired atherosclerotic coronary and peripheral vessels pathologies [4-5]. The origins of the SHD interventions initially arose within the pediatric cardiology arena. It started by creating atrial septal defects in newborns with transposition of the great arteries [6], followed by balloon valvuloplasty [7] of the pulmonic valves. It was later extended to the adult population with percutaneous balloon aortic as well as mitral valvuloplasties. From the late 1980's to the early 2000's, a handful of interventional pediatric cardiologists and few adult coronary interventionists performed these SHD interventions. With the advent of transcatheter valve replacement, the field has been revolutionized in a very dramatic way, generating interest by both coronary interventionalists and

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cardiac surgeons alike.

Structural heart disease deals with a large anatomical variation of many different cardiovascular structures, with various shapes and locations and a multitude of possibilities on how to access. This demands a core-knowledge different than traditional interventional training, one that is not solely based on angiography but requires the complete physiologic and 3D anatomic understanding of cardiovascular structures. The crux of the question remains: what is really needed to become a SHD Interventionist? Presently, there is no board certification in SHD, and no other formal or official guidelines for training. The majority of current specialists are trained by industry and "physician proctors" on the specific use of each individual device and are familiar with the various aspects of catheter-based therapies. This includes interventional cardiologists, interventional radiologists, pediatric cardiologists, cardiac surgeons and vascular surgeons who may master one procedure but not another. Only 50% of the US training programs in coronary interventions provide some exposure to these types of procedures; in addition, there are only few centers (usually academic), which offer a formal, full year of designated SHD training [4-5]. In most cases, this training program is offered to candidates who have completed their full training in: a) internal medicine, general cardiology and interventional cardiology, b) general surgery and cardiothoracic surgery, c) pediatrics and pediatric cardiology.

There is a consensus agreement among interventional cardiology training program directors that in the near future a training curriculum will be officially established and applied, as is the case with medicine, cardiovascular diseases and interventional cardiology [8-9]. At the moment, we only have some expert consensus recommendations on what would be required for training [4-5]. Lately there have been also some recommendations on operator and institutional requirements, but mostly for transcatheter valve repair and replacement [10-13].

What is certain is that the training should not consist solely on how to perform specific procedures by teaching on how to use any specific device. Such a curriculum will need to include, among others:

A. Master the anatomy, physiology, pathology and clinical patient management of SHD.
B. The development of technology and procedural skills of transcatheter therapy in SHD, and more importantly, to teach trainees to think outside the box. How to perform all kinds of access; know the type and performance characteristics of wires, catheters and devices.
C. Extensive training in all imaging modalities used at the diagnosis and treatment of SHD. This will include fluoroscopy, two-dimensional and real-time 3 Dimensional transthoracic (TTE) and trans-esophageal (TEE) echocardiography, intracardiac echocardiography (ICE), 3D/4D Computed Tomography (CTA), Cardiac Magnetic Resonance imaging (CMR), Positron emission tomography (PET scanning) and the use of Fusion imaging technology.
D. The team approach: Perhaps, one of the most important aspects to be taught to trainees is learning on how to work in a multidisciplinary team. SHD requires contributions from many experts and at all levels of patient care, from the diagnosis and assessment to procedural performance. Like in the Apollo 11, success depends on the function of each team member.

At present, there is no official government budget for the training of SHD interventionalists. Usually, the costs of training are covered by their respective clinical departments or by industry grants. We believe that the time has come for full support, like other ACGME programs, with the possibility for combined efforts with the Federal Government and Industry. Undoubtedly, with increasing age of the population and the prevalence of SHD and the improving results in current SHD interventions, there will be a continually growing demand for the SHD interventionalist, and, optimistically, training standards and their means of financing. Finally, the Apollo 11 returned home, and remains until today a symbol of human victory. Let us hope that SHD procedures are another glorious human victory. We believe that these small steps are becoming now one giant leap the field of Structural Heart and that their respective procedures will be here to stay.

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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