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Committed to Advancing Transcatheter Heart Valve Therapy

Edwards SAPIEN XT Transcatheter Heart Valve

Approved for Pulmonic Procedures

The SAPIEN XT valve is approved for pulmonic procedures in pediatric and adult patients with a dysfunctional, non-compliant right ventricular outflow tract (RVOT) conduit.

SAPIEN XT Valve Sizing—Pulmonic

23 mm	26 mm	29 mm
20-23 mm	23-26 mm	26-29 mm

Diameter of intended location within the conduit

Edwards Lifesciences is driving the innovation, collaboration, and education needed to bring transcatheter technology to more patients worldwide.

» Visit **Edwards.com/pulmonic** for more information

See adjacent page for Important Safety Information.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

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Important Safety Information

EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE WITH THE NOVAFLEX+ DELIVERY SYSTEM – PULMONIC

Indications: The Edwards SAPIEN XT transcatheter heart valve (THV) systems are indicated for use in pediatric and adult patients with a dysfunctional, non-compliant right ventricular outflow tract (RVOT) conduit with a clinical indication for intervention and: pulmonary regurgitation ≥ moderate and/or mean RVOT gradient ≥ 35 mmHg.

Contraindications: The THV and delivery systems are contraindicated in patients with inability to tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. Assessment for coronary compression risk prior to valve implantation is essential to prevent the risk of severe patient harm. Incorrect sizing of the THV may lead to paravalvular leak, migration, embolization and/or RVOT rupture. Accelerated deterioration of the THV may occur in patients with an altered calcium metabolism. Prior to delivery, the THV must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV. Do not use the THV if the tamper evident seal is broken, the storage solution does not completely cover the THV, the temperature indicator has been activated, the THV is damaged, or the expiration date has elapsed. Do not mishandle the NovaFlex+ delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. THV recipients should be maintained on anticoagulant/antiplatelet therapy as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solutions, or to the THV.

Precautions: Safety, effectiveness, and durability of the THV have not been established for implantation within a previously placed surgical or transcatheter pulmonic valve. Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate THV performance. Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, immediately flush the affected area with water and seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences. Patient anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: Echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin or sensitivity to contrast media, which cannot be adequately premedicated; pregnancy; and patients under the age of 10 years.

Potential Adverse Events: Potential risks associated with the overall procedure including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; respiratory insufficiency or respiratory failure; hemorrhage requiring transfusion or intervention; cardiovascular injury including perforation or dissection of vessels, ventricle, myocardium or valvular structures that may require intervention; pericardial effusion or cardiac tamponade; embolization including air, calcific valve material or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect arrhythmia; arteriovenous fistula; reoperation or reintervention; ischemia or nerve injury; pulmonary edema; pleural effusion, bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma or ecchymosis; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; fever. Additional potential risks associated with the use of the THV, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device malposition requiring intervention; valve deployment in unintended location; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; and mechanical failure of delivery system, and/or accessories.

Edwards Crimper

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

Contraindications: No known contraindications.

Warnings: The device is designed, intended, and distributed for single use only. **Do not resterilize or reuse the device.** There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

Precautions: For special considerations associated with the use of this device prior to THV implantation, refer to the SAPIEN XT transcatheter heart valve Instructions for Use.

Potential Adverse Events: No known potential adverse events.

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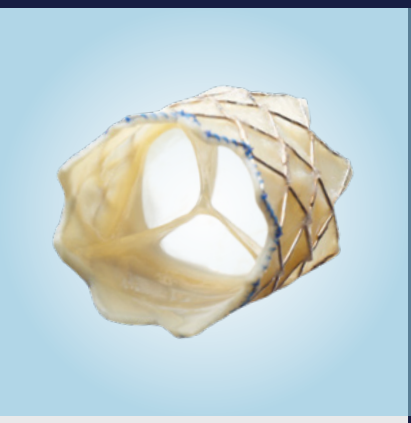
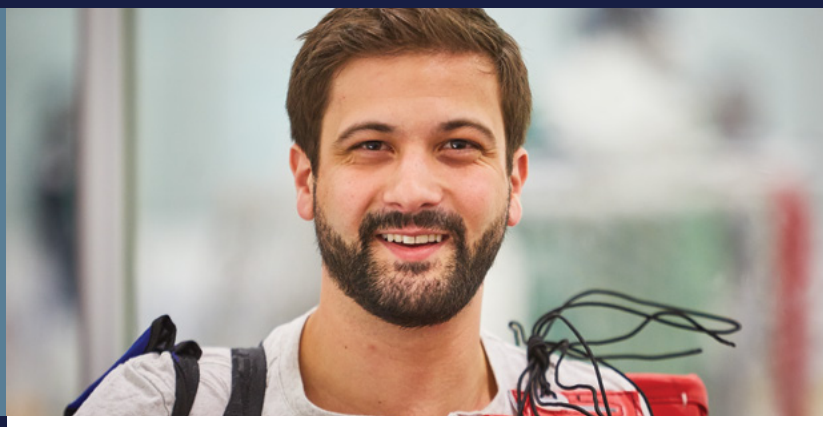


Melody™

Transcatheter Pulmonary Valve (TPV) System



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88.8%

freedom from reoperation*

*US IDE Study

Proven Valve Competence

98.1%

of subjects with ≤ mild PR*

Designed Specifically for Pulmonary Valve Replacement

The Melody valve is the longest studied transcatheter pulmonary valve at seven years post-implant.

The Melody TPV System first received CE mark in September 2006.

The Melody TPV System received Health Canada approval in December 2006 and US approval under an HDE on January 25, 2010 (H080002).

PMA approval received January 27, 2015 (P140017).

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Further, Together

Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System

Important Labeling Information for the United States

Indications: The Melody TPV is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has ≥ moderate regurgitation, and/or a mean RVOT gradient ≥35 mm Hg.

Contraindications: None known.

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.**
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- 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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Important Labeling Information for Geographies Outside of the United States

Indications: The Melody™ TPV is indicated for use in patients with the following clinical conditions:

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR
- Patients with stenotic prosthetic RVOT conduits or bioprostheses where the risk of worsening regurgitation is a relative contraindication to balloon dilatation or stenting

Contraindications:

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- 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
- Known allergy to aspirin or heparin
- Pregnancy

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.

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.

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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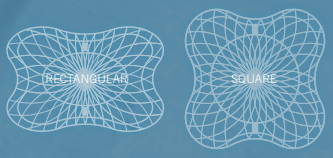

PLD

Occlutech Paravalvular Leak Device

Paravalvular leak closure

The Occlutech PLD is an ideal device for closing paravalvular leaks as it offers a range of outstanding features

- User-friendly and easy to use.
- Optimal positioning by two gold markers.
- Repositionable and fully retrievable.
- Optimized concave shape facilitates placement around the implanted valve.
- Available with wide range of sizes for closing from small leaks to large leaks.
- Available with different design options for different PVL morphologies: Rectangular and Square.

The Occlutech PLD is available with two types of connections between the discs, **W**aist or **T**wist. Example shown on a Occlutech PLD Square.

Perfecting Performance

Occlutech

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Feasibility of Fully Automated Motion Compensated Overlay for Transcatheter Aortic Valve Implantation

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Abstract

Background: Automated motion compensation of aortic root overlay on fluoroscopy during transcatheter aortic valve implantation (TAVI) could ensure accurate device positioning at minimal contrast cost, thereby reducing complication rates.

Objectives: To describe the feasibility of software that automatically compensates for cardiac and respiratory motion on X-ray, which may allow greater device control during TAVI.

Methods: Twenty four TAVI cases (25,607 frames) from four independent institutions using either the Medtronic CoreValve (n=8) or Edwards Sapien valve (n=16) were post-processed with the software. For each case, the algorithm applied three steps: (i) Generation of an anatomical roadmap using X-ray (Vascular Outlining, or VO) or 3D segmentation of CT data, (ii) Correlation to pigtail catheter, and (iii) Real-time motion compensation.

Results: VO motion compensation was activated 84% of all frames yielding a relative displacement error of -1.09 ± 2.65 mm. Similarly, CT-aided motion compensation was activated 84% of frames yielding a relative displacement error of -0.77 ± 2.92 mm.

Conclusions: We have shown feasibility of the first fully automated motion compensation method for real-time continuous visualization of the target aortic anatomy during TAVI procedures. Our method has the potential to improve valve positioning accuracy and reduction in deployment variability.

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Key Words

Aortic stenosis • TAVI • TAVR • Imaging modalities • Non-invasive imaging

Introduction

With over 250,000 procedures conducted worldwide in the last decade, transcatheter aortic valve implantation (TAVI) has gained widespread acceptance for the treatment of aortic valve disease [1]. As outcomes continue to improve, TAVI is expected to be performed in younger, lower-risk patients [2] and will grow the number of procedures further. Correct positioning of the artificial valve is crucial for TAVI outcome [3]. Current implantation of prosthetic aortic valves

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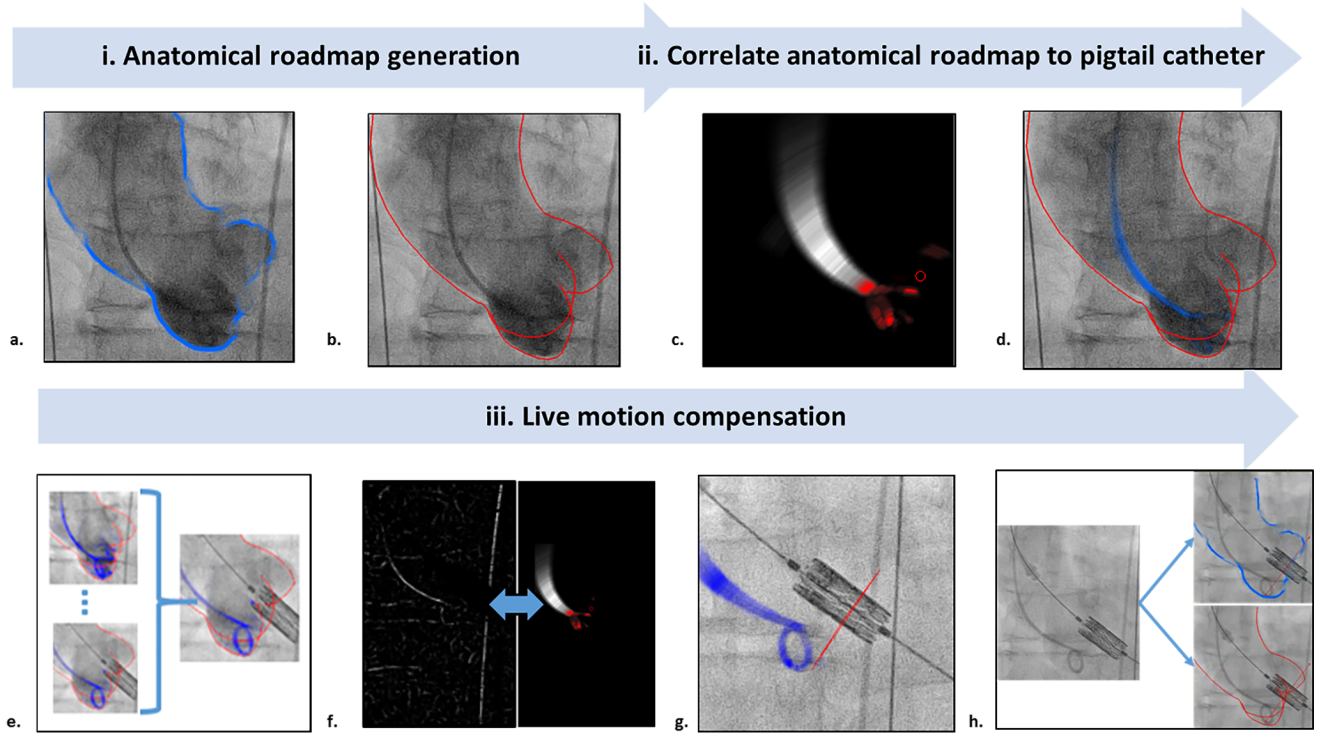

Figure 1. The three steps of motion compensation: i. Anatomical roadmap generation: ***(Panel A)*** Vascular Outlining (VO) based on the angiographic image, ***(Panel B)*** Computed-Tomography (CT) segmentation registered to the angiographic image. ii. Correlate anatomical roadmap to pigtail catheter: ***(Panel C)*** The reference map for the pigtail is extracted, ***(Panel D)*** The spatial relation between the pigtail reference map ***(blue)*** and the anatomical roadmap ***(red)*** is set. iii. Live motion compensation: ***(Panel E)*** The pigtail reference map best matching the current pigtail shape is selected, ***(Panel F)*** Live fluoroscopic image is filtered ***(left)*** and matched to the pigtail reference map ***(right)***, ***(Panel G)*** Fluoroscopic view of the matching result, ***(Panel H)*** The transformation is applied to the anatomical roadmap resulting in a dynamic motion-compensated roadmap, either VO ***(blue)*** or CT ***(red)***.

outside the optimal depth range still occurs in 21% of the cases [4], resulting in high-degree atrioventricular block (10-30%) and paravalvular leak (4-35%) [5]. We have created a fully-automated software that enables anatomical roadmap overlays on live fluoroscopic images compensated for cardiac and respiratory motion without workflow disruptions, which may allow for greater control over valve placement. This paper describes how our technology works and reports on the results of the feasibility study performed.

Method

Our algorithm comprises three steps:

i. **Anatomical roadmap generation.** Angiograms with contrast injections are automatically identified and the frame best opacifying the aortic root is selected by the algorithm, upon which two types of anatomical roadmaps are generated:
   1. Vascular Outlining (VO): The outline of contrast is detected in the X-ray image (Figure 1a).
   2. Computed Tomography (CT) aided: The automatic CT segmentation [6, 7] is registered to the angiographic image (Figure 1b).

ii. **Correlate anatomical roadmap to the pigtail catheter.** The pigtail catheter is routinely locked in an aortic valve cusp and its motion reflects overall aortic valve motion. The software searches for the pigtail catheter (Figure 1c) and sets the spatial relationship with respect to the anatomical roadmap (Figure 1d). This correlation process is performed for all angiograms producing a series of references (Figure 1e).

iii. **Live motion compensation.** Each live fluoroscopic image is filtered to enhance pigtail-like objects, which is then matched to the references (Figure

Table 1. VO and CT-aided motion compensation results.

			VO MC			CT-aided MC		
Valve type	Pigtail catheter cusp position	Number of cases	Frames with activated MC (%)	Relative displacement error (mm)	Absolute displacement error (mm)	Frames with activated MC (%)	Relative displacement error (mm)	Absolute displacement error (mm)
CoreValve	Lowest	8	82	-1.10±2.61	2.00	85	-1.13±2.91	2.15
Sapien	Lowest	4	87	0.09±2.56	1.97	98	-0.15±2.45	1.50
	Middle	12	89	-1.24±2.72	2.71	80	-0.09±3.02	2.48
Total	-	**24**	**84**	**-1.09±2.65**	**2.24**	**84**	**-0.77±2.92**	**2.22**

1f-g). The anatomical roadmap is then transformed accordingly to obtain a real-time dynamic motion-compensated roadmap (Figure 1h). Motion compensation is deactivated automatically if the pigtail catheter is obstructed, such as by the TEE probe, and activated when the pigtail catheter is successfully found again.

The live motion compensation is real-time up to 30 frames per second using an Intel® Xeon E5-1620 v3 CPU 3.50GHz.

Automatic Motion Compensation Evaluation Protocol

The use of a motion compensated overlay occurs during the device positioning and deployment phase, so we post-processed X-ray data of 24 cases during this phase to evaluate the algorithmic performance. None of these datasets were used for algorithm development.

First, the percentage of frames in which motion compensation was correctly activated by the algorithm was determined. Secondly, the relative and absolute displacement error were determined for every X-ray frame by comparing the manually annotated pigtail catheter and aortic root position with the algorithmic roadmap position, where a negative relative displacement error denotes deeper positioning by the algorithm. Continuous variables were given as mean ± standard deviation and categorical variables were given as percentages.

Results

For all 24 cases (25,607 frames) we evaluated the performance of motion compensation (Table 1). VO motion compensation was activated 84% of all frames yielding a relative displacement error of -1.09 ± 2.65mm and 2.24mm absolute displacement error. CT-aided motion compensation was activated 84% of all frames yielding a relative displacement -0.77 ± 2.92mm and 2.22mm absolute displacement error.

The relative and absolute displacement error increased for the larger and hence more obstructive CoreValve and also increased when the pigtail catheter was positioned in the more obstructive middle position (Table 1). Overall VO and CT-aided motion compensation demonstrated similar performance.

Discussion

We have used the pigtail catheter as a contrast-independent landmark for motion compensation during TAVI without any need for software interaction. To our knowledge, only one approach has successfully tracked the aortic valve plane by using the calcifications on the aortic valve as contrast-independent landmarks [8]. A clinical trial correlated this approach with a promising reduction in the incidence of conduction disorders [9]. The feasibility of the approach was limited by the need to manually annotate the calcifications after every repositioning of the C-arm. Additionally, not every patient may have sufficient visible calcifications [10]. All currently available CT fusion solutions provide static overlays only.

Of the two motion compensation methods evaluated: VO has the advantage of requiring only a well-contrasted aortic root angiogram representing the current aortic anatomical situation. CT-aided motion compensation provides a richer 3D view, with the ability to integrate pre-procedural planning in the live roadmap.

A major limitation of the study design was the post-processing of data. Actual clinical use of motion compensation is needed to determine the impact of the motion compensated anatomical roadmap on valve positioning. Another limitation of the technology is its dependence on the pigtail catheter maintaining its position locked in one of the aortic valve cusps. It is important not to lose this position as the device is advanced, as the relationship between the pigtail and the valve plane is assumed constant. Whereas this is common in clinical practice during valve positioning, the pigtail is typically pulled in the last phases of deployment, implying that the motion compensated overlay may not be used for guidance if any final adjustments are required. Further studies are warranted to examine whether these limitations are clinically acceptable. Of note, the live overlay is automatically disabled when detecting pigtail retrieval, to avoid erroneous guidance.

The implications of this work are perhaps greatest for enhancing the learning curve amongst new operators and for physicians performing TAVIs on lower-risk patients with potentially fewer X-ray-visible anatomic landmarks. Prospective studies of impact of this technology on contrast usage and positioning accuracy are warranted.

Conclusion

We have shown feasibility of the first fully automated motion compensation method for real-time continuous visualization of the target aortic anatomy during TAVI procedures. Our method has the potential to improve valve positioning accuracy and reduction in deployment variability and contrast usage.

Conflict of Interest

- Nick Assink – Master student located at Philips Healthcare)
- Maria-Louisa Izamis – Employee of Philips Healthcare
- Olivier Nempont – Employee of Philips Healthcare
- Marco Verstege – Employee of Philips Healthcare
- Cherif P. Sahyoun – Employee of Philips Healthcare
- Alexander Haak – Employee of Philips Healthcare
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- John C. Messenger – Research funding and in-kind support from Philips Healthcare
- Gerhard Schymik – In-kind support from Philips Healthcare
- Navid Madershahian – In-kind support from Philips Healthcare
- Thorsten C. Wahlers – In-kind support from Philips Healthcare
- Peter G. Eshuis – Employee of Philips Healthcare

Comment on this Article or Ask a Question

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Current Interventional Management Strategies for Coronary Arteriovenous Fistulae

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Abstract

Coronary arteriovenous fistulae are uncommon abnormal connections between one of the coronary arteries and a heart chamber or another blood vessel, usually pulmonary vasculature or other venous vessels. Clinically significant fistulae may lead to ischemia of the segment of the myocardium perfused by the affected coronary artery. Therefore, closure of such fistulae is indicated. Transcatheter closure if feasible is recommended and can be achieved using different occlusion devices. This paper discusses the clinical classification of fistulae and the interventional approach to eliminate such fistulae with some case examples. The availability of new coils and catheters render the interventional approach safe and effective.

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Key Words

Coronary fistula, Coil occlusion, Congenital heart disease, Interventional therapies

Coronary artery fistula is defined as an abnormal connection between one of the coronary arteries and a heart chamber or another blood vessel, usually pulmonary vasculature or other venous vessels. It is estimated to account for 0.2-0.4% of total congenital cardiac anomalies [1]. In 1908 Maude Abbott published the first pathological account of this condition [2].

Bjork and Crafoord in 1947 performed the first successful surgical closure of a coronary fistula in a patient with a preoperative diagnosis of patent ductus arteriosus [3].

In general, most coronary artery fistulae are small and do not cause any symptoms. Most are clinically undetectable and are found incidentally on echocardiography performed for other reasons or in adults undergoing coronary angiography performed for an unrelated cause. Most fistulae resolve spontaneously without causing any complications. Only those fistulae that are about three times the size of a normal caliber of a coronary artery may cause symptoms or complications and require management. Symptoms may include the following:

- Dyspnea on exertion
- Angina
- Fatigue
- Palpitations

Due to steel phenomenon, large fistulae may lead to ischemia of the segment of the myocardium perfused by the affected coronary artery. The mechanism is related to the diastolic pressure gradient and runoff from the coronary vasculature to a low-pressure receiving cavity/vessel. If the fistula is large, the intracoronary diastolic perfusion pressure progressively diminishes.

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Prior to the era of echocardiography, the right coronary artery was considered to be the major site of origin of the fistulae (40-60%), followed by the left anterior descending (30-60%) then circumflex and a combination thereof. However, currently, we believe more fistulae originate in the left anterior descending artery. The right side of the heart (ventricle, pulmonary arteries, right atrium, coronary sinus, etc) is the major drainage (termination) site of most fistulae (90%) [4, 5].

Prior to 1990's, surgical ligation was considered the treatment of choice with external ligation of the fistula preferred if possible. However, if the fistula is posteriorly located behind the heart, internal closure of the termination site on cardiopulmonary bypass offered a safe alternative [6]. Recurrence rate after surgical closure is about 10% [7].

Since the report by Reidy et al. [8], percutaneous closure in the cardiac catheterization laboratory has become the most common option for management of large fistulae. To enable successful and safe closure, it is imperative to define the anatomy of the fistula by selective coronary angiography. Detachable balloons, coils, devices, and vascular plugs all have been used successfully to close coronary fistulae [9, 10].

The purpose of this paper is to discuss the management decisions and details of transcatheter closure techniques.

Management Decisions

As mentioned above, small fistulae in an asymptomatic patient need not be closed. However, if the fistula is large or if the patient is symptomatic, closure is recommended. The decision process in managing fistulae depends on: site of origin of the fistula (proximal vs distal) [11], size of the fistula, patient's symptoms, presence of any complication caused by the fistula (angina, heart failure, endocarditis, rupture, etc), age of the patient, the anatomy of the fistula and presence of other indications to undergo an invasive procedure. The current recommendations by the AHA/ACC guidelines [12] include for Class 1: patients with continuous murmur should undergo exact delineation of the origin and termination of the fistula by either echocardiography or CT/MRI; patients with large fistulae should undergo closure (surgical or percutaneous) after delineation of the exact anatomy and finally, small-moderate fistulae with complications (ischemia, arrhythmias or ventricular dysfunction of unexplained etiology) should undergo closure. Last but not least, the approach of elimination of the fistula (surgical vs. transcatheter) depends on the expertise of the physicians involved in the management of the patient.

Proximal Fistulae

If small in size with no symptoms, observation is recommended and no medications. However, if the fistula is medium or large with or without symptoms, closure is recommended (surgical vs. transcatheter) followed by antiplatelets for at least one year.

Distal Fistulae

If small in size with no symptoms, observation is recommended with no medications. However, if medium in size with or without symptoms one has two options: closure followed by antiplatelets for one year or observation while receiving antiplatelets indefinitely. If the fistula is large with symptoms, closure is recommended, 6 hours post-closure, heparin should be started to keep PTT at 1.5 times normal while warfarin is started. Patients should be discharged home on Warfarin to keep INR around 2.5 for a period of 6-12 months [11]. Also, these patients should receive antiplatelets indefinitely. If the fistula is large with no symptoms, one has two options: either observation while receiving antiplatelets indefinitely or closure. If fistula is closed, one should treat as large fistula with symptoms.

Another important factor in the decision-making process is the size of the patient.

Fistulae in small patients

If small-moderate in size, they can be left alone until the patient is bigger. Spontaneous regression of fistulae has been reported [13], however, if the fistula is big and leading to cardiac symptoms, closure is recommended. Elective closure of moderate-large sized fistulae that are not causing symptoms is reasonable and can be performed once the child is an appropriate weight (approximately >15 kg).

If fistula is associated with other cardiac lesions (most commonly tetralogy of Fallot, patent ductus ar-

teriosus, atrial septal defect), the fistula can be closed at the time of repair of the primary cardiac lesion.

Transcatheter Closure Techniques

Once a decision is made about the need for closure of the fistula, it is very important to plan the procedure appropriately. We recommend the following:

1. Discussion of the case with an interventional adult cardiologist colleague. We can't overemphasize the importance of collaboration with adult cardiologists when it comes to the coronary circulation. They need to be involved in the planning of the case.
2. Discussion of the case with an interventional radiologist to see what equipment may be needed. Interventional radiology uses many coils and catheters that are not readily available in the congenital cardiac catheterization laboratory. We have found over the years that getting help from interventional radiology has contributed to the success of the procedures.
3. If the patient is an adult age (over 18-21 years), we advise to admit the patient post-procedure into an adult unit equipped with continuous cardiac monitoring (telemetry) and with staff familiar with EKG's and management of cardiac ischemia. We believe this is an important aspect of managing such patients. The pediatric units, for the most part, are not familiar with cardiac ischemia/enzymes, and they may miss important events in these patients that could lead to catastrophe.
4. When placing coils/devices to occlude fistulae, it is very important to delineate the myocardial branches to ensure that coils/devices are beyond the last viable myocardial branch. Obviously, occlusion proximal to such branches will result in cardiac ischemia.
5. Available coils: coils are made of different materials, available in various lengths, diameters, shapes and several methods of delivery. Coils are available in lengths from 1 to 300 mm and in diameters ranging from 1 to 27 mm. Available coil shapes include J- or C-shaped, helical, conical, tornado, straight, and complex three dimensional (3D) shapes. Coils may be bare or fibered with material such as Dacron, nylon fibers, polyester, wool, silk, or polyvinyl acetate (PVA) embedded within them to increase thrombogenicity. Steel was the initial material used for coils then came Platinum and different alloys that made them softer, more radio-opaque and non-ferromagnetic enabling future MRI follow-ups [14]. The methods of coil delivery had evolved over the last five decades in response to the need for a safer and more controllable deployment as well as to solve the technical problems encountered in old methods. Among the early methods were the pushable, injectable and liquid coils delivered by pushing wires or injecting saline or contrast after loading the coils in the delivery catheters [14]. The first detachable coil was described in 1977. Current detachable coils are deployed by a variety of mechanisms including mechanical, by electrolysis, and by hydrostatic means. The disadvantage of the mechanical detachment is that there is often friction between the coil and the microcatheter, during embolization through tortuous vessels, this friction can limit delivery, or the coil can rotate or flip at detachment [14]. Deployment of coils can be done by a wide range of catheters, the current assortment of microcatheters widely used may not be all well suited for several anatomic variants, including excessive vascular tortuosity. The most commonly used microcatheters for coiling are Excelsior SL-10 and 10-18 (Stryker, Kalamazoo, MI, USA), Echelon 10 and 14 (Medtronic, Minneapolis, MN, USA) and Headway 17 (Microvention TERUMO, Tustin, CA, USA). As mentioned above, these catheters are readily available in radiology departments engaged in aneurysm coiling. The proper coil for embolization should be sized 20 to 30% larger than what the target vessel measures on pre-deployment angiogram to prevent distal embolization or migration. Placement of an undersized coil risks its distal embolization away from the intended location. Attempting to place an oversized coil may result in the coil not forming the intended shape or even straightening in the vessel [14]. In general, dense packing of the target vessel is recommended to achieve complete embolization. The key to inducing complete thrombosis is cross-sectional occlusion which can be done by different techniques [15]. A scaffold technique involves initially deploying a higher radial force coil followed by a

softer coil or an anchoring technique where a distal coil is anchored in a branch vessel then packed proximally [15]. This prevents distal migration and results in a tighter coil pack. An inflated compliant occlusion balloon may be used distal to the coil delivery catheter to prevent unwanted distal embolization, especially in high-flow fistulae. Then the balloon can be deflated and withdrawn after the deployment of the first coil that acts as a future basket for further coils [14].

6. The Amplatzer family of devices have been used for percutaneous closure of fistulae. The muscular device, the Duct occlude and the vascular plugs (I, II, IV) all have been used successfully for the closure of these fistulae [16-20]. The advantage of the plugs over the conventional devices is the need for a smaller sheath/catheter for deployment, thus making retrograde delivery possible. For deployment of devices (muscular VSD device or the PDA device), perhaps the best approach is to form an arteriovenous wire loop and deployment of the device from the venous side (see example below). However, for the vascular plugs, it is possible to deploy them from the retrograde approach using the corresponding guide catheter or small delivery sheath.
7. Finally, we want to emphasize the importance of anticoagulation and antiplatelet therapy post device/coil closure of fistulae. As discussed above [11], in some patients intravenous heparin has to be initiated about six hours after closure and bridging to Warfarin and antiplatelet therapy thereafter. This is extremely important to avoid the unfortunate complication of thrombus propagation proximal to the devices/coils [21].

Techniques

Fistulae can be closed either in a retrograde fashion (approach from the arterial system) or from the venous side (direct access if possible or after establishing an arteriovenous wire loop). Each technique has its own merits.

Retrograde approach

Access should be obtained via the right femoral artery and vein. We usually insert a 4-5Fr sheath in the artery in children and 6Fr in adults. For the vein, a corresponding size can be used. On occasions, we also obtain access in the contralateral femoral artery. We do this if we use a 4-5Fr diagnostic coronary catheter for closure. The purpose of this is to perform control angiography for assessment of the position of coils/devices prior to release. However, if we use a guide catheter, one may not need additional access. After a careful hemodynamic assessment is performed, selective coronary angiography is performed in the affected coronary artery. Usually, we perform at least two angiograms in different orthogonal views. The purpose of the angiograms is to delineate the exact anatomy of the fistula (origin, course, termination and viable myocardial branches). If the flow is brisk due to the size of fistula, one may need to balloon occlude the fistula with an end-hole balloon catheter advanced over a wire into the fistula and injection via this catheter after removal of the wire. We find this technique to be helpful in delineating the termination site and also in delineating the myocardial branches distal to the balloon (see case below).

Case example:

Four year young female child presented with continuous murmur heard shortly after birth. Echocardiography revealed the presence of moderate-large sized coronary artery fistula arising from the left anterior descending artery (LAD) and terminating in the right ventricle. She has been followed conservatively until age four years, when it was decided to close it on an elective basis. Her weight was 16.4 kg. A 4Fr sheath was inserted in the right femoral artery and a 5Fr sheath in the right femoral vein. Selective left coronary angiography was performed using a 4Fr JL diagnostic catheter (Figure 1A). Then a 150cmx6cm Excelsior SL-10 Microcatheter (Stryker, Kalamazoo, MI, USA) was inserted inside the JL. The Transend floppy tip guidewire, 0.016" (Stryker, Kalamazoo, MI, USA) was used to navigate the tortuosity of the coronary artery until the wire reached to the right ventricle (Figure 1B). Then over this wire, a 4Fr balloon-tipped catheter was exchanged and positioned in the distal coronary artery. With balloon inflation, hand injection delineated the fistula better (Figure 1C). Then over the same wire, the balloon-tipped catheter was exchanged for the JL and then the Excelsior Microcatheter was fed over this wire all the way to the dis-

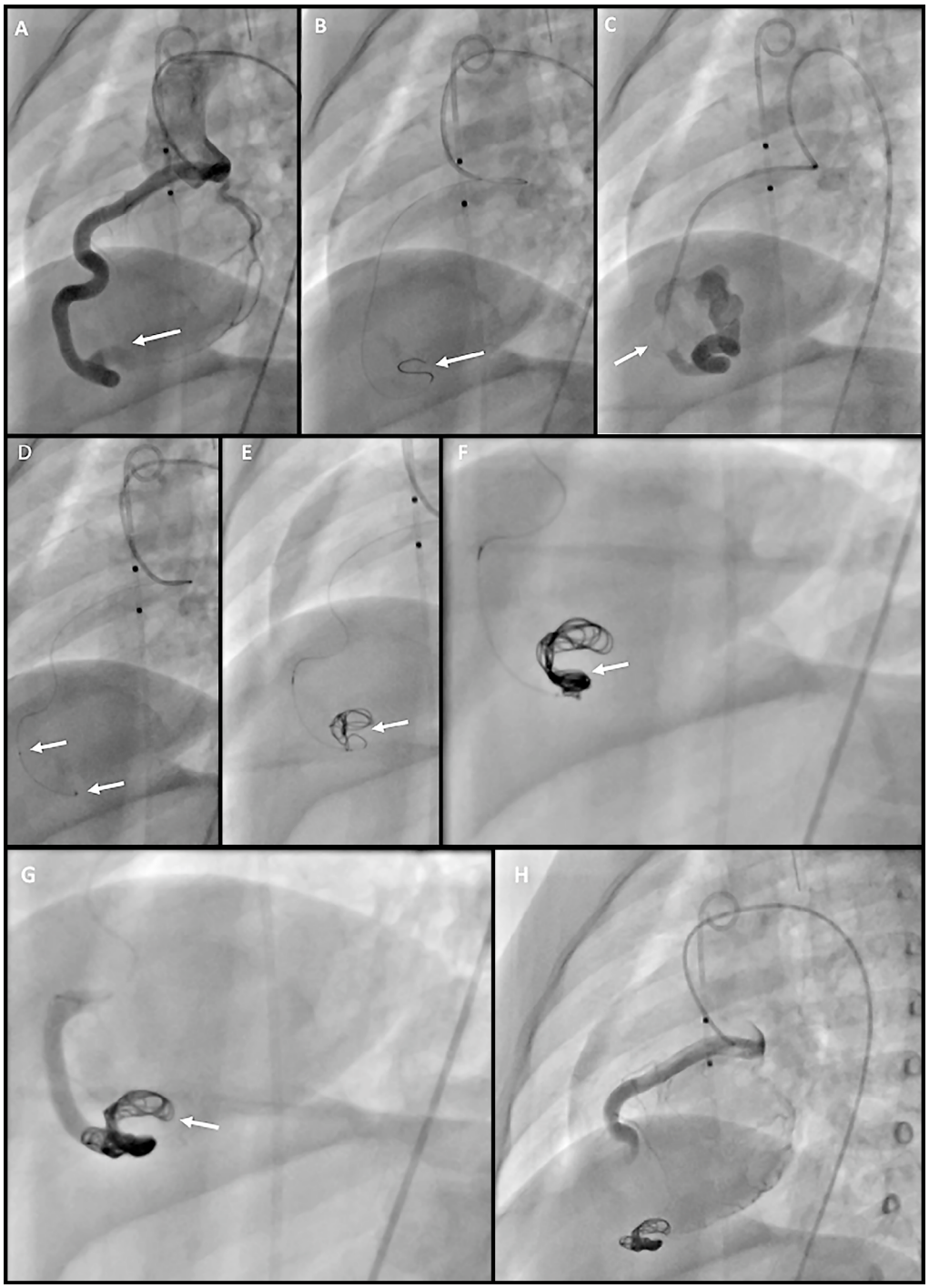
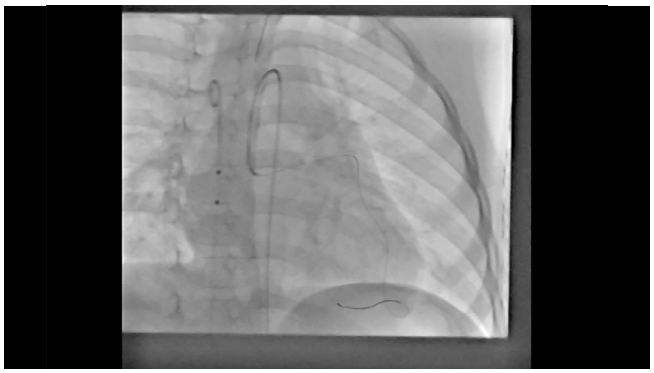


Figure 1. Selective Left Main Coronary Artery Angiograms in a 4 yr. young female child with left anterior descending (LAD) coronary artery to right ventricle (RV) fistula. ***Panel A***. Dilated LAD terminating with a fistula to the RV ***(arrow)***. ***Panel B***. Diagnostic JR catheter in left main and an 0.016"Transend guide wire all the way to RV ***(arrow)***. ***Panel C.*** A 4Fr. Balloon tipped catheter was advanced in LAD. Balloon inflated to block flow ***(arrow)*** and this delineated fistula better. ***Panel D.*** Cine fluoroscopy of the Excelsior Microcatheter in fistula. Two radio-opaque markers delineating position of the Microcatheter ***(arrows)***. ***Panel E***. Cine fluoroscopy after deployment of first Target detachable coil ***(arrow)***[8mmx20cm]. ***Panel F.*** Cine fluoroscopy after 4 additional Target detachable coils were deployed ***(arrow)***[second coil was also 8mmx20cm, 3rd and 4th coils were 4mmx8cm and last coil was 6mmx20cm]. ***Panel G.*** Angiogram just after the deployment of the five coils revealed no flow distal to coil. ***Panel H.*** Final angiogram shows flow stopped proximal to coils.



Video 1. Video which illustrates the case mentioned in figure 1. View supplemental video at https://doi.org/10.12945/j.jshd.2018.043.17.vid.01.

tal part of the fistula (Figure 1D). The first coil used (Figure 1E) was 8mmx20cm Target detachable coil (Manufactured by Boston Scientific for Stryker Neurovascular). The advantage of such coils is its electrically released mechanism. Subsequently, four additional Target detachable coils were deployed (the second coil was also 8mmx20cm, 3rd and 4th coils were 4mmx8cm and last coil was 6mmx20cm (Figure 1F). Repeat angiography between coil deployment was done to assess residual flow. Final angiogram after the fifth coil revealed good coils position and no residual flow (Figure 1G, H).

The patient was allowed to recover in the intensive care unit. After six hours and due to the sluggish coronary flow at the end of the procedure (Figure 1G, H), heparin drip was initiated at 15 units/kg/hr keeping PTT at 1.5 times normal. The same evening, the patient received 75mg aspirin and 2mg Warfarin. She was discharged home after 2 days on 75mg aspirin and 2 mg Warfarin. For video of the case, see Video 1.

Anterograde Approach

As mentioned above, a closure can be done from the venous side either by creating an arteriovenous wire loop [16] or via direct access of the fistula from the venous side [22].

The wire loop technique: to do so, one has to cross the fistula from the arterial side and advance a wire until it exits into the right side and then snare and exteriorize from either the femoral vein or jugular vein depending on the location of the fistula.

Case example:

We previously have published this case [17]. 12 days young female baby, 2.4 kg presented in florid congestive heart failure due to a very large left main coronary (LMC) artery to the right ventricle fistula. Her right femoral artery was occluded due to a prior cardiac catheterization. Access was achieved from the left femoral artery 4Fr, left femoral vein 4Fr, and right internal jugular vein 8Fr. The initial hemodynamic assessment revealed systemic pulmonary artery pressure and infinite Qp:Qs ratio. Angiography in the left main coronary artery revealed the presence of huge LAD to right ventricle fistula (Figure 2A, B). The fistula was crossed easily from the arterial side using a 0.035" floppy tip guidewire. The wire was advanced all the way to the main pulmonary artery and snared using a 4Fr., 10mm gooseneck snare (Microvena) and was exteriorized from the right jugular vein (Figure 2C, D) creating an arteriovenous wire loop. An 8Fr. Mullins sheath was advanced over this wire from the jugular vein through the right ventricle into the fistula and into the distal LAD. The first device used was a 12mm Amplatzer muscular VSD device (AGA Medical, Plymouth, MN)[Figure 2E). A total of 7 Flipper coils (five of them were 5mmx8cm, and two were 5mmx10cmm (Cook Medical, Bloomington, IN) were deployed from the arterial side to create a nest behind the VSD device (Figure 2F, G). Repeat angiogram still revealed significant residual shunt (Figure 2H). Due to the heavy contrast load used (7ml/kg), the procedure was terminated. The baby remained stable without a rise in troponin or lactate but remained intubated with the continued moderate residual flow by echocardiography. Therefore, two days later the baby was brought back to the catheterization laboratory and a right carotid artery cut down was used and an 8Fr. sheath was inserted. A 10/8 mm Amplatzer Duct Occlud (AGA Medical)(Figure 2I) and a 9mm Gianturco Grifka Vascular Occlusion Device (Cook Medical)(Figure 2J) were deployed proximal to the coils and muscular VSD device. Repeat angiography revealed good devices positions and minimal residual flow (Figure 2K, L). Repeat hemodynamics revealed that the pulmonary artery pressure dropped to 40% systemic and the Qp:Qs ratio decreased to 2.7:1. The baby was extubated two days later. She was transferred back to referring institution on 4mg/kg aspirin orally. She was

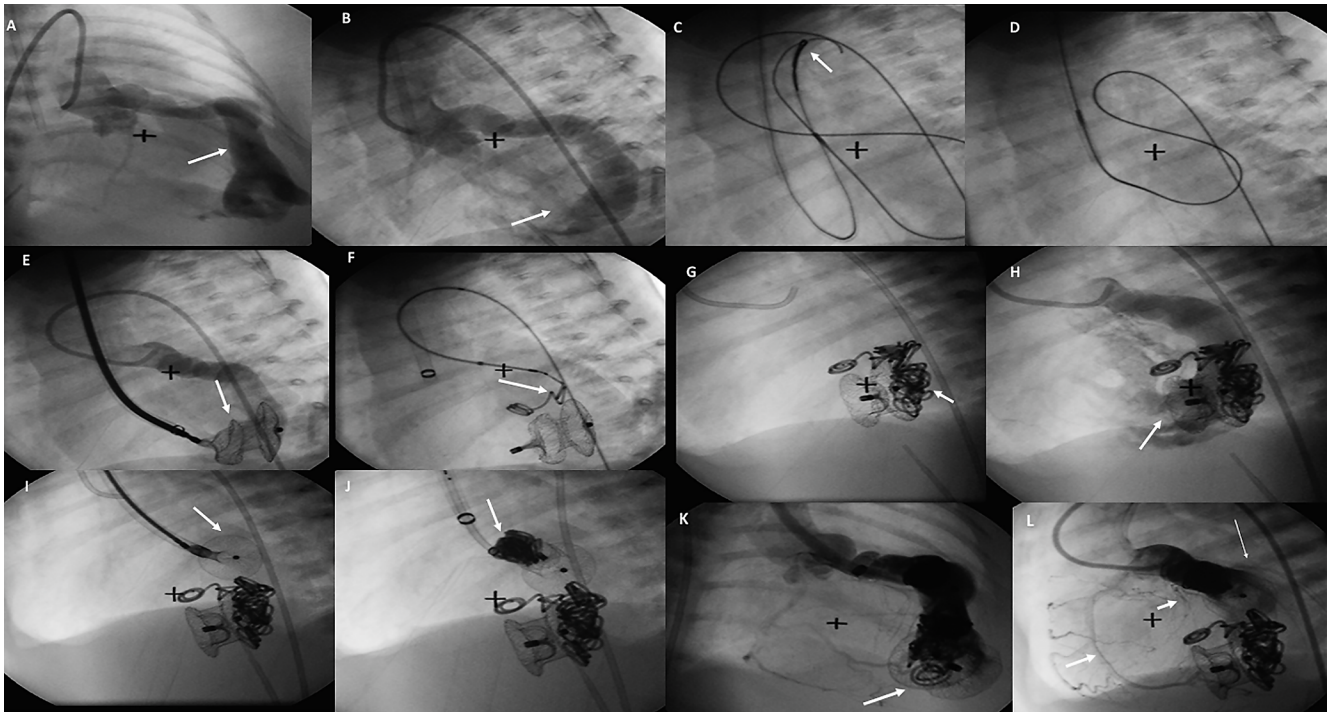


Figure 2. Selective left main coronary angiograms in a 2.4 kg 12 days young baby with large left main coronary artery (LMC) fistula terminating in right ventricle (RV). ***Panel A***. Angiogram in right anterior oblique (RAO) view showing large LMC artery fistula draining into RV. ***Panel B***. Repeat angiogram in left anterior oblique (LAO) view showing drainage to RV ***(arrow)***. ***Panel C.*** Cine fluoroscopy after passing an 0.035" guide wire from fistula to RV to main pulmonary artery where it was snared using a gooseneck snare ***(arrow)***. ***Panel D.*** Forming of an arteriovenous wire loop with exit into the right internal jugular vein. ***Panel E.*** LMC artery angiogram after deployment of a 12mm Amplatzer muscular VSD device ***(arrow)*** from the right internal jugular vein. ***Panel F.*** Cine fluoroscopy after deployment of 1st Flipper coil (5mmx8cm) from the arterial side ***(arrow)*** proximal to the device. ***Panel G.*** Cine fluoroscopy after deployment of additional 6 coils from the arterial side ***(arrow)***[four of them were 5mmx8cm and two were 5mmx10cmm] to create a nest behind the VSD device. ***Panel H.*** Angiogram revealed residual flow through the fistula to the RV ***(arrow)***. ***Panel I.*** Cine fluoroscopy during deployment of a 10/8mm Amplatzer Duct Occlud ***(arrow)*** from right carotid artery cut-down proximal to the coils and VSD device. ***Panel J.*** Cine fluoroscopy during deployment of a 9mm Gianturco Grifka Vascular Occlusion Device (GGVOD) ***(arrow)*** proximal to the PDA device. ***Panel K.*** Final angiogram in RAO view showing near complete occlusion of fistula ***(arrow)***. ***Panel L.*** Angiogram in LAO view showing devices with coils in good position with near complete occlusion. Thin arrow shows opacification of circumflex, fat short arrow shows LAD and fat long arrow shows right coronary artery.

discharged home after ten days from the procedure. She had been doing well since then. Echocardiography at one month revealed complete closure of the fistula and normal cardiac function.

<u>The direct access technique</u>

If the fistula could not be crossed from the arterial side to close retrogradely or to create wire loop, one may attempt to cross directly from the venous side (fistula exit) [22]. The following case illustrates this technique.

Case Example:

A 76-year-old gentleman was referred to us due to symptoms of increased shortness of breath. He was known to have a circumflex to pulmonary artery fistula for ten years prior to this procedure. He was a previous smoker. Pulmonary function test revealed a mild form of chronic obstructive pulmonary disease. Cardiac catheterization was performed via the right femoral artery using 7Fr. sheath and right femoral vein using 6 Fr. sheath. Hemodynamics revealed slightly elevated pulmonary artery pressure with a mean of 26mmHg and Qp:Qs ratio of 1.4:1. Angiogra-

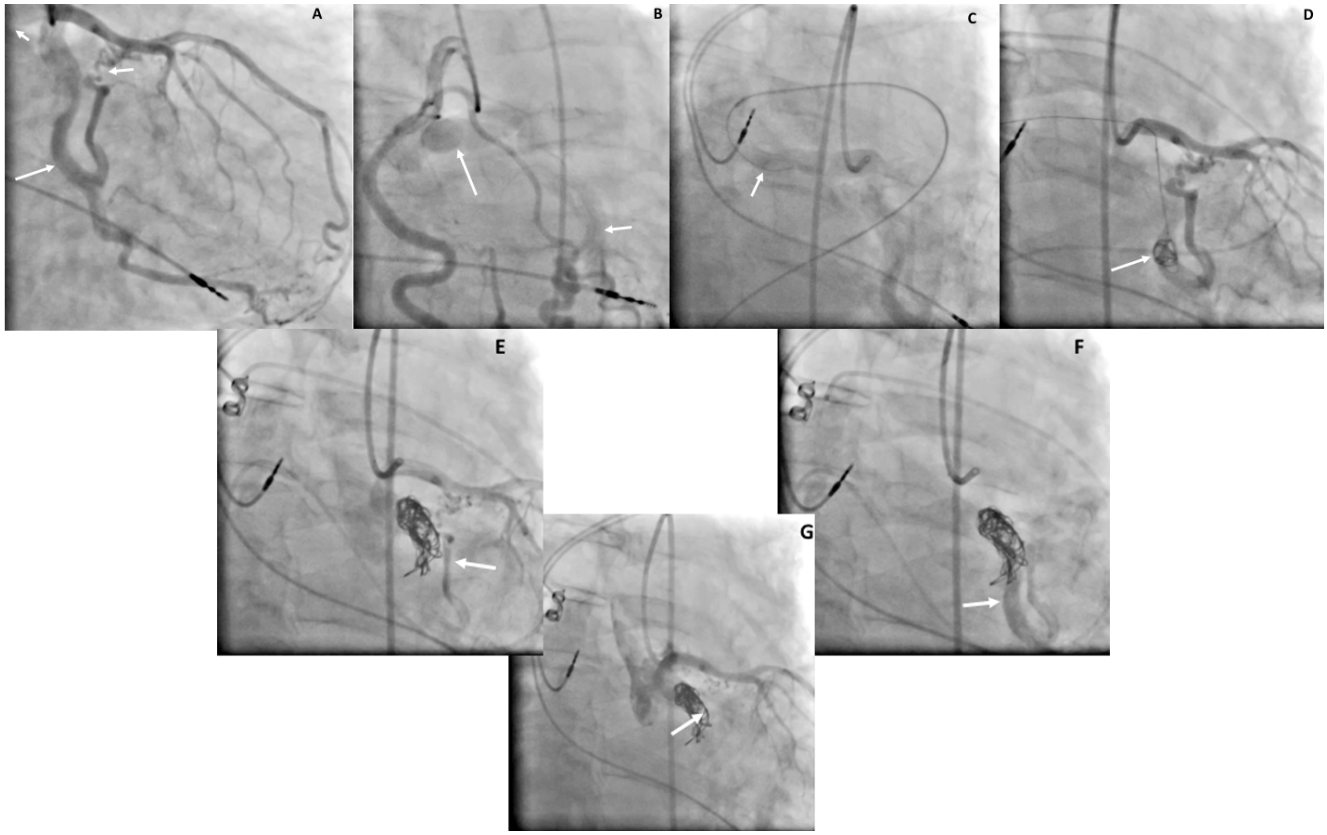


Figure 3. *Panel A*. Selective left main coronary angiogram in a 76 yr. old gentleman showing very narrow and tortuous circumflex *(medium arrow)*. There is a fistula arising from circumflex *(long arrow)* and this fistula drained to the right pulmonary artery *(short arrow)*. *Panel B.* Selective right coronary angiogram showing the posteromedial branch draining into a fistula *(short arrow)* that drains into the fistula that arose from the circumflex, all drain into the right pulmonary artery *(long arrow)*. *Panel C.* Angiogram in LMC artery where fistula drains into mouth of right pulmonary artery, where a 5Fr. JR catheter was positioned *(arrow)*. *Panel D.* Cine fluoroscopy during deployment of 12mmx30cm Target detachable coil *(arrow)* using the Excelsior Microcatheter. *Panel E.* angiogram after deployment of additional 7 Target detachable coils (2nd coil: 10mmx30cm; 3rd and 4th coils: 9mmx20cm; 5th, 6th and 7th coils: 4mmx8cm and 8th coil: 3mmx4cm) showing filling of the circumflex *(arrow)*. *Panel F.* few frames later showing contrast up to the coils *(arrow)* and *(Panel G)*, few frames later no residual flow in fistula and good coils position *(arrow)*.

phy in the left main coronary artery revealed normal LMC and LAD. The circumflex origin was very narrow and very tortuous. At mid circumflex, a fistula arose and drained to the right pulmonary artery (RPA). The fistula size was double the size of the circumflex (Figure 3A). Angiography in the right coronary artery revealed normal artery with minimal coronary artery disease; however, the distal branch (posteromedial coronary artery) drained via smaller channels and connected with the circumflex fistula and all drained to the RPA (Figure 3B). Multiple attempts to cross the fistula from the LMC artery failed. Therefore, a 5Fr. JR catheter was used from the venous side to the RPA and crossed the exit site of the fistula (Figure 3C). A 0.016" guidewire (Transend) was used to navigate the fistula. The wire and a 150cmx6cm Excelsior SL-10 Microcatheter were advanced all the way to the origin of the fistula from the circumflex. The wire was removed and a total of eight Target detachable coils were deployed in mid-distal fistula (1st coil: 12mmx30cm; 2nd coil: 10mmx30cm; 3rd and 4th coils: 9mmx20cm; 5th, 6th and 7th coils: 4mmx8cm and 8th coil: 3mmx4cm (Figure 3D, E, F). Repeat angiography revealed complete closure of fistula (Figure 3G). The patient had recovered overnight and a repeat echocardiography the next day revealed complete closure of the fistula. He was discharged home after 24 hours from the procedure on his medications of warfarin and aspirin.

Follow-up

It is mandatory to follow patients with coronary arteriovenous fistulae life-long. Such patients may be at increased risk for acute or late-onset coronary thrombosis [21-26], Patients with distal fistulae with dilated proximal conduit are especially at increased risk for such complications. We propose that such patients receive life-long antiplatelet therapy. The issue of anticoagulation needs to be taken into consideration as discussed above. Further, these patients need to undergo coronary imaging every few years based on symptoms or even periodic CT coronary angiography. Other factors may increase the risk of coronary thrombosis such as smoking, diabetes, hypertension, and hyperlipidemia. Patients with fistula drainage to the coronary sinus may be at higher risk of coronary thrombosis [27]. To best understand the long-term sequelae of coronary fistulae closure, there is an ongoing registry by the CCISC (Congenital Cardiovascular Interventional Study Consortium) collecting data on these patients.

Conflict of Interest

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

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Patent Foramen Ovale Closure for Recurrent Stroke Prevention: A Network Meta-Analysis of Randomized Controlled Trials

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Abstract

Background: Patent foramen ovale (PFO) has been shown to be associated with recurrent strokes. Randomized controlled trials (RCTs) evaluating the benefit of transcatheter closure of PFO over medical therapy in patients with cryptogenic stroke showed inconsistent results.

Objectives: We aimed by performing network meta-analysis to evaluate three different treatment strategies for stroke prevention, namely, PFO closure, antiplatelet therapy and oral anticoagulation.

Methods: We searched PUBMED and Cochrane database for RCTs comparing PFO closure to medical therapy in patients with PFO and cryptogenic stroke. Three different strategies were evaluated; PFO closure, antiplatelet therapy alone and oral anticoagulation. A Bayesian network meta-analysis was performed to calculate odds ratios (OR) and 95% credible intervals (CrI). The outcome of this study was recurrent stroke events at the longest follow up period reported.

Results: We included 4 RCTs with a total of 2821 patients. There was significant reduction of recurrent strokes with PFO closure when compared to antiplatelet therapy alone (OR 0.29, CrI 0.07-0.84). On the other hand, there were no statistically significant differences between PFO closure and oral anticoagulation (OR 0.52, CrI 0.1-1.92) or between anticoagulation and antiplatelet therapy (OR 0.55, CrI 0.13-2.14).

Conclusion: In patients with PFO and cryptogenic stroke, transcatheter PFO closure is associated with significant reduction in recurrent strokes when compared to antiplatelet therapy alone. This benefit was not statistically significant when PFO closure was compared with the use of oral anticoagulation.

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Key Words

Patent foramen ovale • Stroke • Network meta-analysis

Introduction

The presence of patent foramen ovale (PFO) has been shown to be associated with increased incidence of stroke. [1–3] Therefore, PFO closure has the potential of prevention of recurrent stroke events in patients with PFO and cryptogenic stroke. Randomized controlled trials (RCTs) that evaluated the benefit of transcatheter PFO closure in recurrent stroke prevention showed inconsistent results. [4–9]. One of the differences between those trials is that oral anticoagulation was permitted in the medical therapy arm in some of the trials, [4, 6, 9] which could have contributed to the discrepancy in the results. Hence, in the current study we aimed by performing network meta-analysis to compare three different strategies for recurrent stroke prevention, namely, PFO closure, antiplatelet therapy alone and oral anticoagulation.

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Methods

We searched PubMed and Cochrane Central Register of Controlled Trials for trials comparing PFO closure to medical therapy from inception through October, 2017. Only studies in the English language or studies with an English translation were included. Citations were screened at the title/abstract level and relevant citations were retrieved as full reports. References from the included studies were also manually searched for relevant studies.

Studies were eligible for inclusion if they were randomized controlled trials that compared PFO closure to medical therapy in patients with cryptogenic stroke and PFO. If the medical therapy arm in any study included patients on antiplatelets and/or oral anticoagulation, the study was included only if recurrent stroke was reported separately for each group of patients. Studies were excluded if they were non randomized trials or if outcomes of patients on antiplatelets and patients on oral anticoagulation were not reported separately. Moreover, patients who received PFO closure plus anticoagulation and patients who did not receive any antithrombotic therapy in any of the included studies were excluded from the final analysis.

The outcome of the present study was recurrent strokes at the longest follow up period reported in each study. In the CLOSURE I trial, [6] the outcome included was recurrent strokes or transient ischemic attacks. Data were independently extracted from the included trials by the first and second authors (G.M. and D.S.) on a pre-specified data sheet. Any discrepancy was discussed until there was complete agreement on all the results in the final data sheet.

Network meta-analysis was performed using a Bayesian Markov chain Monte-Carlo model. [10] Dichotomous outcome variables were compared with odds ratios (OR) and 95% credible intervals (CrI). The more conservative random effect model was adopted for final interpretation of the results. Vague (non-informative) priors for between-study heterogeneity were applied to the random effects analyses. Analyses using the fixed effect model was also performed and was only shown in the forest plot diagram. Three chains with different starting variables were used. To achieve convergence, a burn-in phase of 10,000 simulations was performed then 20,000 simulations were performed for the final analyses. Convergence was confirmed by assessing whether the Monte Carlo error is less than 5% of the standard deviation of the effect estimates or between study variance and by visual inspection of Gelman Rubin graphs. [11, 12] The heterogeneity between trials was determined from the median between-trial variance $\tau 2$. A $\tau 2$ estimate of 0.40 was interpreted as a high degree of heterogeneity. [13] Consistency between direct and indirect evidence was assessed by plotting the posterior mean deviance of the individual data points in the inconsistency model against their posterior mean deviance in the consistency model. Consistency was suggested when each data point had a posterior

Table 1. Characteristics of included trials.

				Medical therapy		
Trial name	Mean age (years)	Female (%)	PFO closure device	Antiplatelets	Oral Anticoagulation	Follow up duration
CLOSE [5]	44	42	All available devices	aspirin, clopidogrel or aspirin/dipyridamole	Coumadin or direct oral anticoagulants	5.4 years
CLOSURE I [6]	46	48	STARFlex Septal Closure System	Aspirin	Coumadin	2 years
REDUCE [7]	45	40	HELEX and Cardioform Septal Occluders	aspirin, clopidogrel or aspirin/dipyridamole	N/A	3.2 years
RESPECT [8]	46	45	Amplatzer PFO Occluder	aspirin, clopidogrel or aspirin/dipyridamole	Coumadin	5.9 years

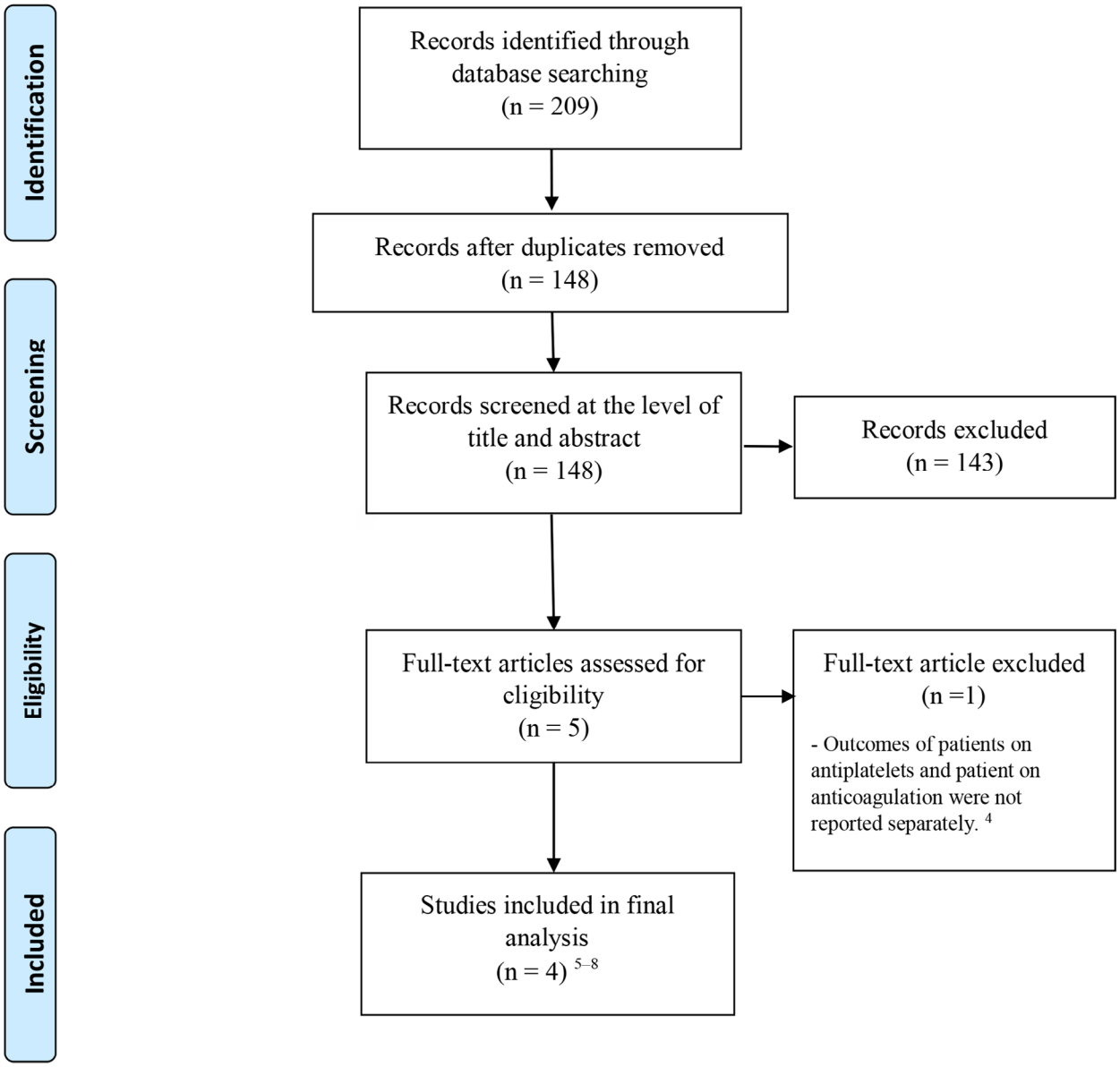

Figure 1. Flow diagram of study selection process according to PRISMA.

mean deviance contribution close to one. [12, 14] All statistical analyses were performed using WinBUGS 1.4 (MRC Biostatistics Unit, Cambridge, UK) [15] and the Microsoft Excel-based tool (NetMetaXL). [12]

Results

The process of citation screening and publication selection according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flow chart is demonstrated in Figure 1. Initial screening was performed on 148 articles. Five trials were then fully retrieved for review and four trials were included in the final analyses. Two trials compared PFO closure to antiplatelet therapy and/or oral anticoagulation [6, 8], One trial compared PFO closure to antiplatelet therapy alone, [7] and one trial compared antiplatelet therapy one time to PFO closure and a second time to oral anticoagulation. [5] Characteristics of trials included in our study are shown in Table 1.

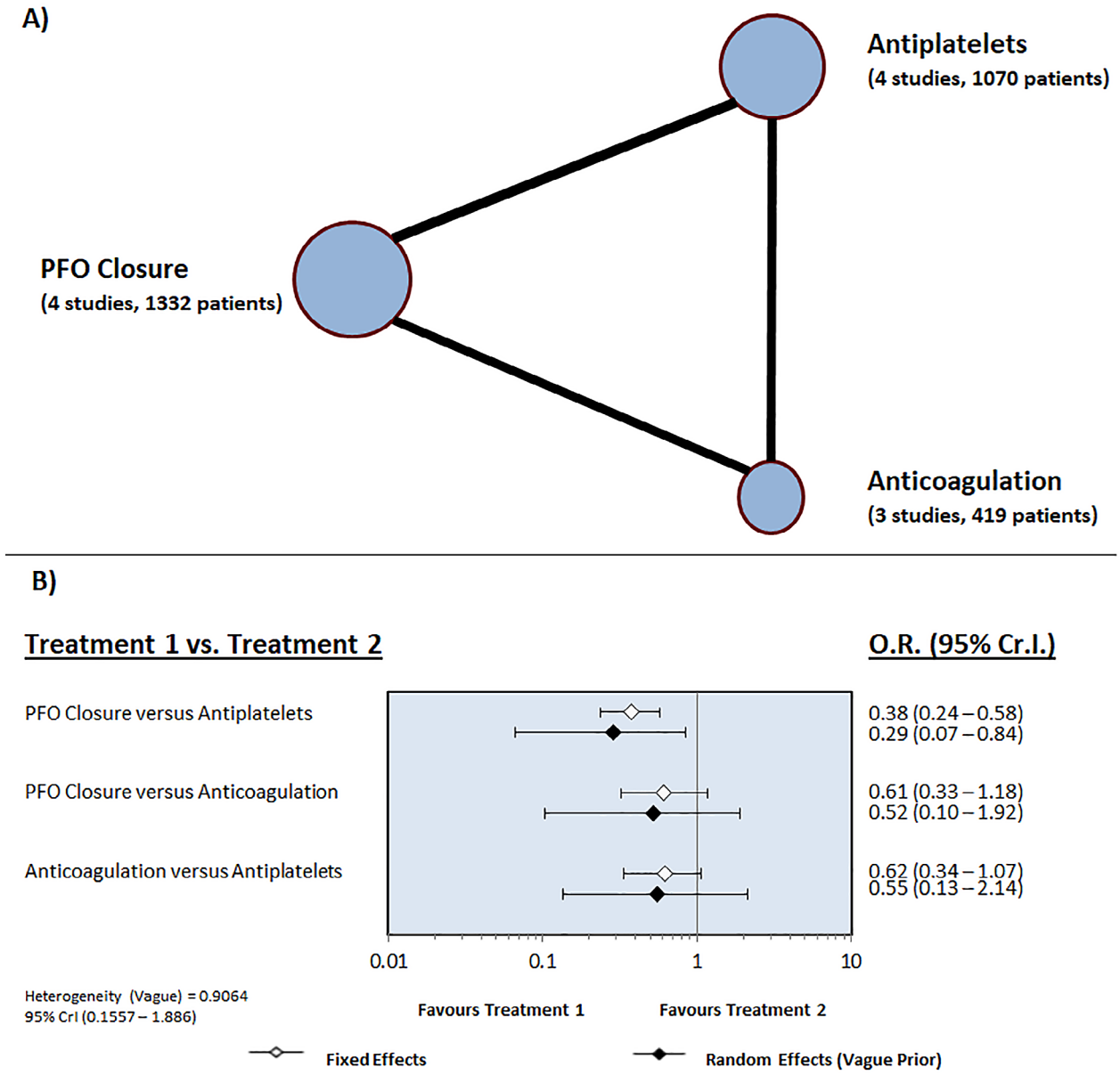

Figure 2. *Panel A.* Diagram of different treatment arms for recurrent stroke prevention. *Panel B.* Forest plot of mixed treatment comparisons showing statistically significant reduction of recurrent strokes with PFO closure only when compared to antiplatelet therapy. Both fixed and random effect models are shown.

The network included a total of 2821 patients. PFO closure was performed in 1332 patients, 1070 patients received antiplatelet therapy alone and 419 patients received oral anticoagulation alone (Figure 2A). There was significant reduction of recurrent strokes with PFO closure when compared to antiplatelet therapy alone (OR 0.29, CrI 0.07-0.84). On the other hand, the reduction in recurrent stroke when PFO closure was compared to oral anticoagulation was not statistically significant (OR 0.52, CrI 0.1-1.92). Moreover, the difference between oral anticoagulation and antiplatelet therapy in recurrent stroke reduction was also non statistically significant (OR 0.55, CrI 0.13-2.14). Heterogeneity assessment by τ2 was 0.9. Network com-

parisons of different treatment modalities are shown in Figure 2B. Plotting the posterior mean deviance of the individual data points in the inconsistency model against their posterior mean deviance in the consistency model suggested reasonable consistency between direct and indirect evidence.

Discussion

The present study is a network meta-analysis comparing three different strategies for recurrent stroke prevention in patients with PFO and cryptogenic stroke, namely, PFO closure, antiplatelet therapy and oral anticoagulation. The main finding of our study is that PFO closure is associated with significant reduction in recurrent strokes when compared to antiplatelet therapy alone.

Trans catheter PFO closure has been compared to medical therapy in randomized trials to evaluate the benefit in recurrent stroke prevention in patients with cryptogenic strokes. In the CLOSURE I [6] and the PC [4] trials as well as the early results of the RESPECT trial, [9] there was no significant benefit of PFO closure over medical therapy. However, when PFO closure was compared to antiplatelet therapy alone in the REDUCE [7] and CLOSE [5] trials, there was significant reduction in recurrent stroke events in patients who underwent PFO closure. Hence, the inclusion of patients on anticoagulation in the medical therapy arm might have contributed to the absence of difference between PFO closure and medical therapy.

A recent updated meta-analysis comparing PFO closure to medical therapy, whether antiplatelets or oral anticoagulation, PFO closure was associated with significant reduction in recurrent strokes. [16] In our study, however, we aimed to evaluate the benefit of PFO closure compared to antiplatelet therapy and oral anticoagulation separately. Based on the results of our study, there is clear benefit of PFO closure over antiplatelet therapy alone. On the other hand, when compared to oral anticoagulation, the benefit of PFO closure is less evident and needs further investigation.

There are limitations to our study that should be considered. There was marked heterogeneity between the results of the trials. However, we used the more conservative random effect model for interpretation of the results. Another limitation is the exclusion of the PC trial as outcomes were not reported separately for patients on antiplatelets and patients on anticoagulation in that trial. A third limitation is that we were unable to perform subgroup analysis based on factors like age, atrial septal aneurysm and shunt size that might have an impact on recurrent strokes. A fourth limitation is that the only outcome evaluated was recurrent strokes because there were no sufficient data on other outcomes that was stratified based on medical therapy used. Finally, the number of patients in the oral anticoagulation arm is small. Therefore, the results pertaining the use of anticoagulation should be taken with caution and more trials are needed to validate our findings.

In conclusion, when compared to antiplatelet therapy alone, PFO closure is an effective treatment strategy for recurrent stroke prevention in patients with PFO who had a cryptogenic stroke. This benefit was not statistically significant when PFO closure was compared with the use of oral anticoagulation.

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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Retrieval of a Partially Deflated Balloon: A Novel Approach

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Abstract

A rare complication of balloon dilation in the catheterization laboratory is the inability to deflate the balloon catheter. In the literature, methods described for deflating the balloon all involve puncture or rupture of the balloon while it is within the patient. Here we present a case in which a novel approach was used in order to puncture and deflate the balloon outside of the patient. We further looked at how balloons rupture when overinflated and the potential risks associated with doing this inside of a patient.

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Key Words

Catheterization • Pulmonary artery stenosis • Balloon malfunction

Introduction

The inability to deflate an angioplasty balloon is a known, albeit uncommon, complication of balloon dilation procedures. Typically, methods for balloon deflation in the literature include over-inflation of the balloon in order to rupture it, inserting the stiff end of a wire through another catheter in order to puncture the balloon or insertion of a needle through the chest wall. These procedures are potentially a high risk in that they involve either rupture of the balloon within the patient or transcutaneous needle puncture. We describe a case in which an alternative approach was used for retrieval of a partially deflated balloon.

Case Presentation

A 3-year-old female with a history of tetralogy of Fallot with Pulmonary Atresia status-post full repair presented with significant continued branch Pulmonary Artery (PA) stenoses. Her past medical history included being an ex-28 week premature infant, chronic lung disease, central sleep apnea, and right femoral vein thrombosis. She had two previous cardiac surgeries (a modified Blalock-Taussig shunt (BTS) in the neonatal period; central pulmonary arterioplasty and VSD repair with 14mm RV to PA conduit at 9 months of age). She also had three previous catheterizations which included angioplasty of left (L)PA and right (R) PA, as well as implantation of a Valeo 9mm x17mm stent (Bard Peripheral Vascular, Tempe, AZ) in the LPA, mounted on a 7mm balloon. Despite this, she had evidence of continued branch PA stenosis with RPA peak gradient of 43 mmHg and LPA peak gradient of 46 mmHg by echocardiogram. She was referred to the catheterization laboratory to evaluate her branch PAs with possible angioplasty and/ or stent implantation.

In the catheterization laboratory, access was first obtained in the right internal jugular vein with a 4 Fr sheath and the left femoral vein with a 6 Fr sheath, as the patient had a history of right femoral vein occlusion. Initial hemodynamics showed the RV pressure to be 82% of the systemic pressure and there was significant intimal proliferation within the LPA stent down to 4.1mm compared to 6.7mm distally. A 0.018" Platinum Plus Guidewire (Boston Scientific Corp., Marlbor-

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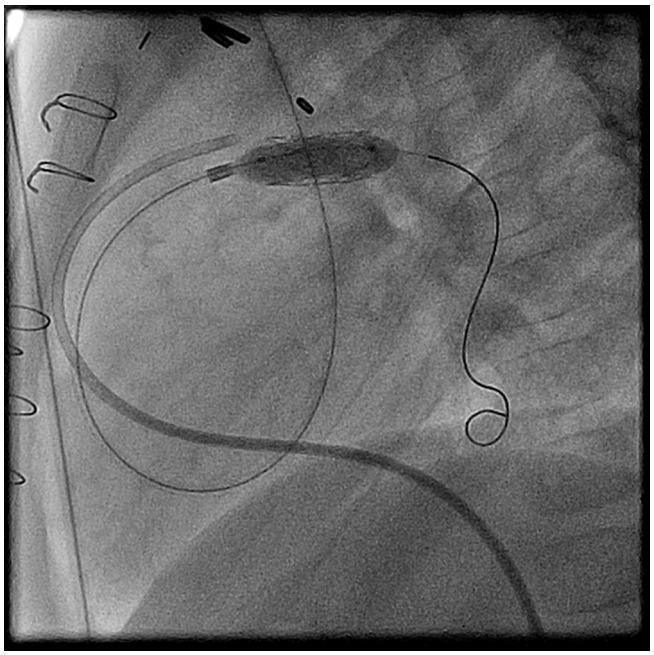

Figure 1. Partially inflated balloon within LPA stent. The 7mm x 2cm Sterling Balloon has been inflated within the LPA stent, but cannot be fully deflated.

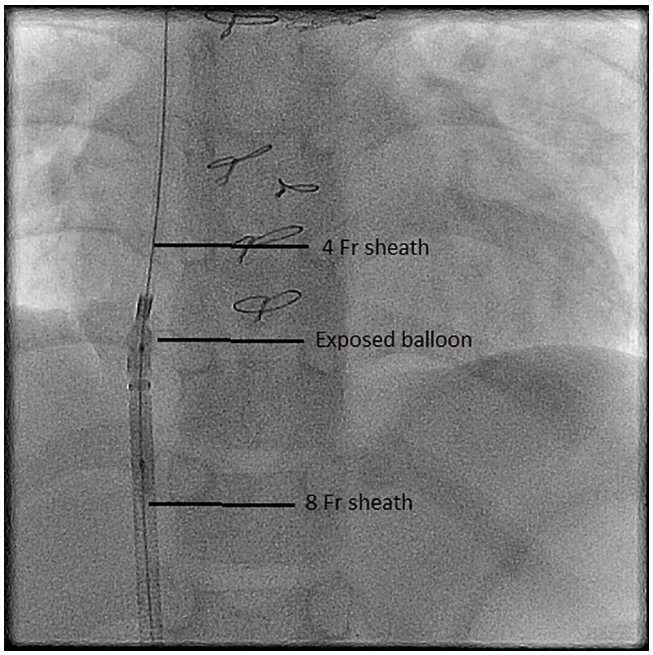

Figure 2. Balloon partially pulled into sheath. The partially deflated balloon has been snared and mostly pulled into the 8 Fr sheath with a portion of the balloon exposed in right atrium. Note that the width of the balloon is similar to the width of the 8 Fr sheath.

ough, MA) was positioned from the RIJ sheath into the distal LPA across the LPA stent. The initial short RIJ sheath was exchanged for a 63 cm long 4 Fr sheath (Cook Medical, Bloomington, IN), positioned across the LPA stent. A 7mm x 2cm Sterling Balloon (Boston Scientific Corporation, Marlborough, MA) was advanced through the long sheath, over the wire and positioned within the LPA stent. The balloon was inflated several times until it was positioned well within the stent. After the balloon was inflated a fourth time, however, the balloon catheter could not be fully deflated and could not be housed in the 4 Fr sheath (Figure 1). Of note, we had previously resheathed the balloon by using an inflate-deflate method involving applying positive and then negative pressure to the balloon while pulling the balloon into the sheath to keep the sheath in the pulmonary artery.

Because the balloon could not be resheathed, the sheath, balloon and Platinum Plus wire were all pulled into the right atrium to straighten the curve. Negative pressure was applied many times to the balloon with no success in deflation. The 6 Fr sheath in the LFV was exchanged for an 8 Fr 90cm long sheath in an attempt to snare and cover the deflated balloon. The distal tip of the Platinum Plus wire was snared in the right atrium through this 8 Fr sheath and the balloon was pulled into this larger sheath. Unfortunately, the balloon could not be completely pulled into the 8 Fr sheath, but the profile of the balloon extruding from the sheath was nearly the same width as the 8 Fr sheath (Figure 2). The 8 Fr sheath, snare, balloon, Platinum Plus wire and 4 Fr sheath were then pulled down and out of the left groin with part of the balloon uncovered by the sheath (Figure 3). The partially inflated balloon was exposed and punctured with a needle and deflated manually. It could then be pulled back into the 4 Fr RIJ long sheath and safely removed (Figure 4).

Discussion

The inability to deflate an angioplasty balloon is a known, albeit uncommon, complication of balloon dilation procedures [1]. This complication was first

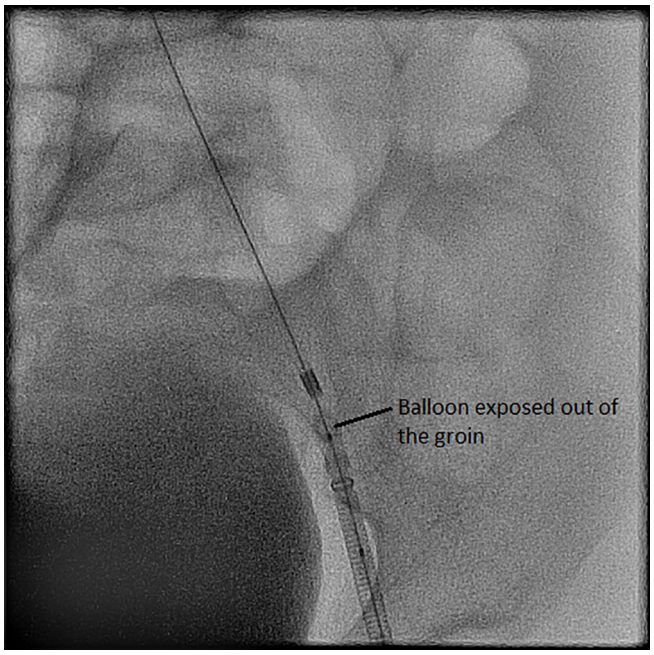

Figure 3. Balloon pulled out of the groin. The balloon, mostly within the 8 Fr sheath, has been pulled out of the left groin so that it could be exposed and popped manually.

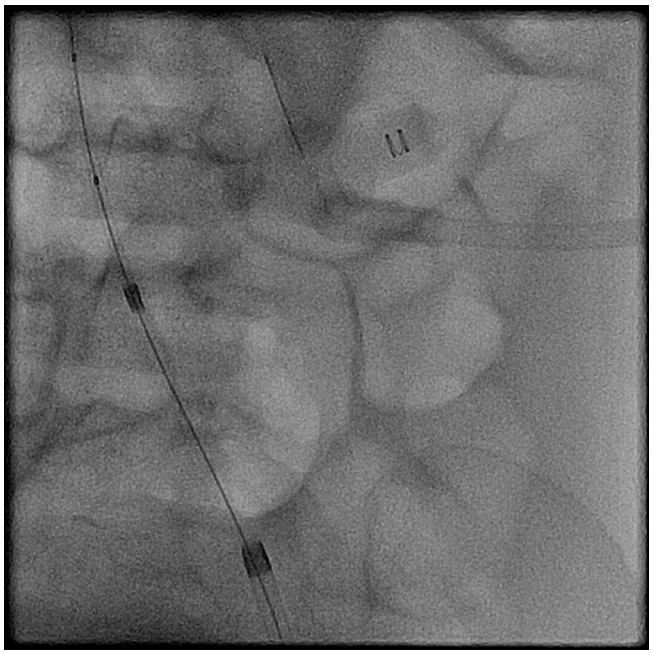

Figure 4. Deflated balloon within sheath. After the balloon has been manually deflated, it has now been pulled back into 4 Fr RIJ sheath so that it can safely be removed from the body.

described in the early literature for the balloon atrial septostomy procedure [2-6]. In some cases, successful deflation of the balloon was eventually achieved by use of the stiff end of a wire advanced either through the second lumen of the balloon catheter or through a second end-hole catheter. With the wire held in position just past the tip of the catheter, the balloon was pulled back onto the wire in order to puncture the balloon [2,5]. In other cases, the balloon was punctured by a fine needle introduced percutaneously, either transhepatically or through the chest wall [3,4]. Both of these approaches have significant risks associated with them. With the first approach, there is the risk of vessel/cardiac damage from the wire. With the latter, there are obvious risks through transcutaneous needle access of the balloon of damage to the heart and surrounding structures. According to Hijazi et al., when a balloon septostomy catheter does not deflate, the first thing to do is to pass a guide wire in the balloon lumen to clear any obstruction. This maneuver was not performed in our case. If this does not work, an injector should be connected to the balloon and 3-5 cc of contrast injected under pressure using 300 psi in order to rupture the balloon [7]. With this approach, rupture of the balloon at high pressure has the risk of embolization of the balloon fragments[8]. Finally, if this does not work, one can try using the stiff end of a guide wire through a second catheter [7].

In order to test the technique of balloon rupture, we overinflated a series of balloon catheters ex vivo to see at what pressure the balloons burst and how they tore. First, we manually burst a series of balloons by slowly over-inflating the balloon with a BasixTouch inflation device (Merit Medical, South Jordan, UT) until the balloon burst. It should be noted that balloon rupture mechanisms are subject to variations due to balloon materials system fatigue. Table 1 lists the sizes and types of balloons tested as well as the burst pressures and type of hole or tear created. During manual over-inflation, all Sterling balloons as well as the Opta Pro, Palmaz Blue and Valeo balloons had longitudinal tears. The Dorado Balloon burst with a pinhole tear in the proximal balloon. The Atlas Gold Balloon did not burst, but the high pressure created a connection between the wire lumen and the balloon lumen within the catheter. This balloon remained unable to deflate. We additionally burst a Miller-Edwards Balloon Septostomy Catheter (Edwards Life sciences, Irvine, CA).

Table 1. Manual burst pressures.

Manual Burst					
Size (mm x cm)	**Type**	**Burst (atm)**	**Burst (psi)**	**Listed Burst (atm)**	**Type of hole/ tear**
5 x 2	Sterling	26	382	14	Longitudinal
5 x 2	Sterling	27	397	14	Longitudinal
6 x 2	Sterling	24	353	14	Longitudinal
7 x 2	Sterling	27	397	14	Longitudinal
16 x 2	Atlas Gold	35	514	18	Hole between wire and balloon lumens
8 x 2	Opta Pro	17	250	10	Longitudinal
7 x 2	Dorado	27	397	22	Proximal Pinhole
6 x 1.7	Palmaz Blue	22	323	10	Longitudinal
7 x 1.8	Valeo	27	397	14	Longitudinal
Miller-Edwards BAS balloon		6	88		Complete rupture of balloon

Atm= atmospheres; psi= pounds per square inch

Table 2. Power burst pressures.

Power Burst					
Size (mm x cm)	**Type**	**Burst (atm)**	**Burst (psi)**	**Listed Burst (atm)**	**Type of hole/ tear**
5 x 2	Sterling	27	401	14	Longitudinal
6 x 2	Sterling	33	481	14	Longitudinal
8 x 2	Sterling			12	Hole between wire and balloon lumens
9 x 2	Sterling	33	484	10	Longitudinal
12 x 2	Atlas Gold			18	Hole between wire and balloon lumens
6 x 2	Opta Pro	25	364	10	Longitudinal
9 x 1.7	Valeo	20	300	12	Longitudinal
9 x 1.7	Valeo	21	309	12	Longitudinal
10 x1.7	Valeo			12	Longitudinal
5 x 2	Dorado			24	Proximal pinhole
6 x 2	Dorado	37	537	24	Proximal pinhole
7 x 2	Tyshak Mini	26	383	4	Longitudinal
16 x 5.5	BIB	Outer- 11; Inner- 25	Outer- 167; Inner- 370	5/5	Longitudinal

At 6 mL of fluid and at a pressure of 6 atm, the balloon burst and the fragment completely ruptured off of the catheter (Figure 5)(Table 1).

Next, we tested the balloon bursts in the manner Hijazi et al. proposed using a pressure injection. When we did this in the manner described, the power

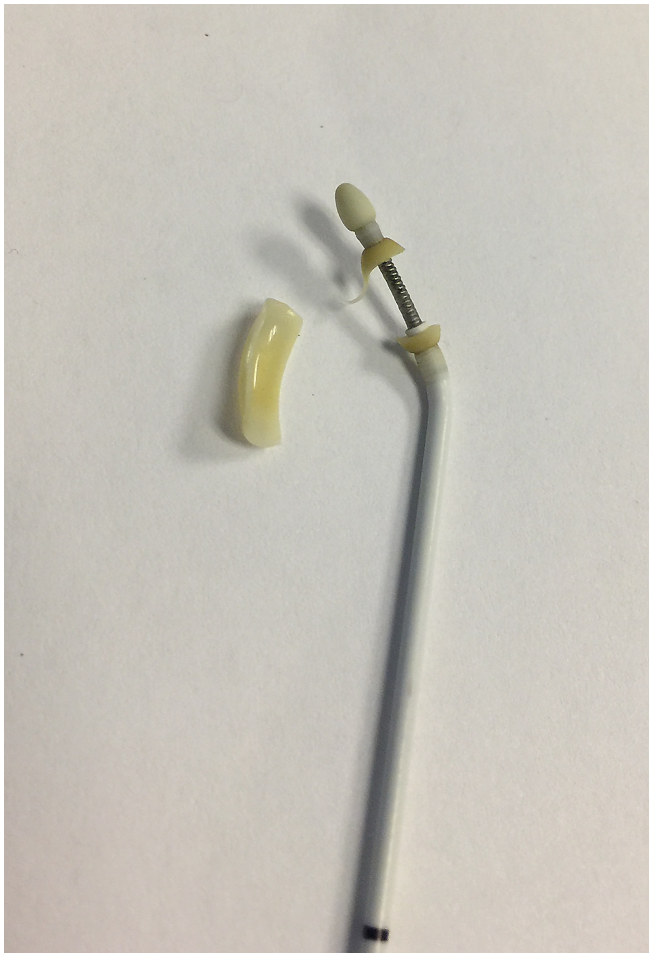

Figure 5. Complete rupture of BAS balloon. Shown is a ruptured Miller-Edwards Balloon Septostomy Catheter with balloon fragment seen.

kept auto-stopping due to the peak pressure limit of 300 psi. When we changed the peak pressure limit to 600 psi, we were able to burst the balloons. Table 2 similarly lists the sizes and types of balloons tested as well as the burst pressures and type of hole or tear created, again keeping in mind that balloon rupture mechanisms are subject to variations due to balloon materials system fatigue. Unfortunately, not all burst pressures were captured. Both Dorado balloons developed pinhole tears in the proximal balloon. Additionally, the Atlas Gold as well, as one Sterling balloon, developed a hole between the wire and balloon lumens. However, these balloons did eventually deflate (Table 2).

In our patient, by covering the balloon with the larger sheath, the balloon was able to be positioned outside of the body where it could be punctured. Multiple factors contributed to the success of this technique and may not be applicable in many other situations. In our case, the balloon was not stuck fully inflated to its maximal diameter and thus could be safely pulled back into the right atrium. If there was a structure proximal to the balloon that was narrower than the partially inflated balloon, it could not have been pulled safely into the right atrium, making our technique more difficult. In the selection of the size of the second venous sheath, careful attention needed to be paid to the size of the partially deflated balloon. While our intent was to fully pull the partially inflated balloon into the larger sheath, luckily the exposed balloon was nearly the exact size of the sheath, making it safe to remove from the vessel orifice partially exposed. An even larger sheath could have been used to fully cover the balloon. This technique could not be performed if the angioplasty was being performed on the arterial side. Finally, if the balloon did not partially deflate, it could not have been pulled out of the stent and would have obstructed flow to the LPA. In this scenario, one of the other techniques to rupture the balloon in its position could be employed.

Conclusion

We report a novel approach to removal of a balloon that could not be fully deflated. Utilizing this method does not involve puncture or rupture of the balloon while it is still inside the patient. A second venous access point opposite to the site where the balloon catheter enters often can straighten the balloon catheter and assist in its retrieval — the largest size sheath that can be placed safely should be considered to fully cover the balloon. While there are limitations to this approach, removal of a partially deflated balloon in this manner offers a safe alternative to the traditional removal techniques. As new balloon catheters emerge, it is important to know how they will rupture if one plans to rupture the balloon within the patient as there may be a risk of balloon embolization, pinhole balloon rupture or creation of a connection between the wire and balloon lumens. If the patient is stable, it may be worthwhile to first attempt balloon

rupture outside of the patient with the same type of balloon. However, it should be noted that in vivo rupture mechanics of the balloon can differ when they are subjected to the stresses of use during catheterization. Perhaps more important than the specifics of this technique, is the notion that when faced with difficult clinical situations, the interventional cardiologist needs to think outside the box.

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 Repair of Anterior Mitral Leaflet Perforation in a Patient with Mechanical Aortic Valve Using Antegrade and Retrograde Approaches: Case Report

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Abstract

Mitral leaflet perforations after surgical aortic valve replacement may be iatrogenic or due to endocarditis. We present a 20-year-old female who underwent surgical mechanical aortic valve replacement 8 months prior to this presentation for bicuspid severe aortic valve stenosis. She presented with acute decompensated heart failure with dyspnea and New York Heart Association (NYHA) functional class of III-IV. Transthoracic (TTE) and transesophageal echocardiography (TEE) demonstrated severe mitral regurgitation (MR) through an anterior mitral leaflet perforation. The patient refused surgical repair and percutaneous closure of the perforation was decided and performed using both antegrade and retrograde approaches. In this report, we emphasize the details and challenges of the procedure.

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Key Words

Mitral leaflet perforation, Mechanical aortic valve, Catheter-based Mitral valve interventions

Introduction

Anterior mitral leaflet perforation complicating bicuspid aortic valve has been reported and are mostly iatrogenic or related to infective endocarditia [1]. For patients with clinical symptoms, surgical re-intervention is generally the accepted approach [2]; however, reoperation after aortic valve replacement may be associated with an increased risk of mortality and morbidity. Very few sporadic cases of percutaneous closure of perforated anterior mitral leaflet have been reported [3-5]. We describe a case of successful percutaneous closure of an anterior mitral leaflet perforation in a patient who previously had a mechanical aortic valve replacement. We present this case to emphasize the role of double antegrade and retrograde approaches through both femoral arterial and venous accesses and the challenges of the procedure.

Case Report

History

A 20-year-old female was diagnosed with bicuspid aortic valve (AV) and severe aortic stenosis (AS) complicated by infective endocarditis and mechanical AV

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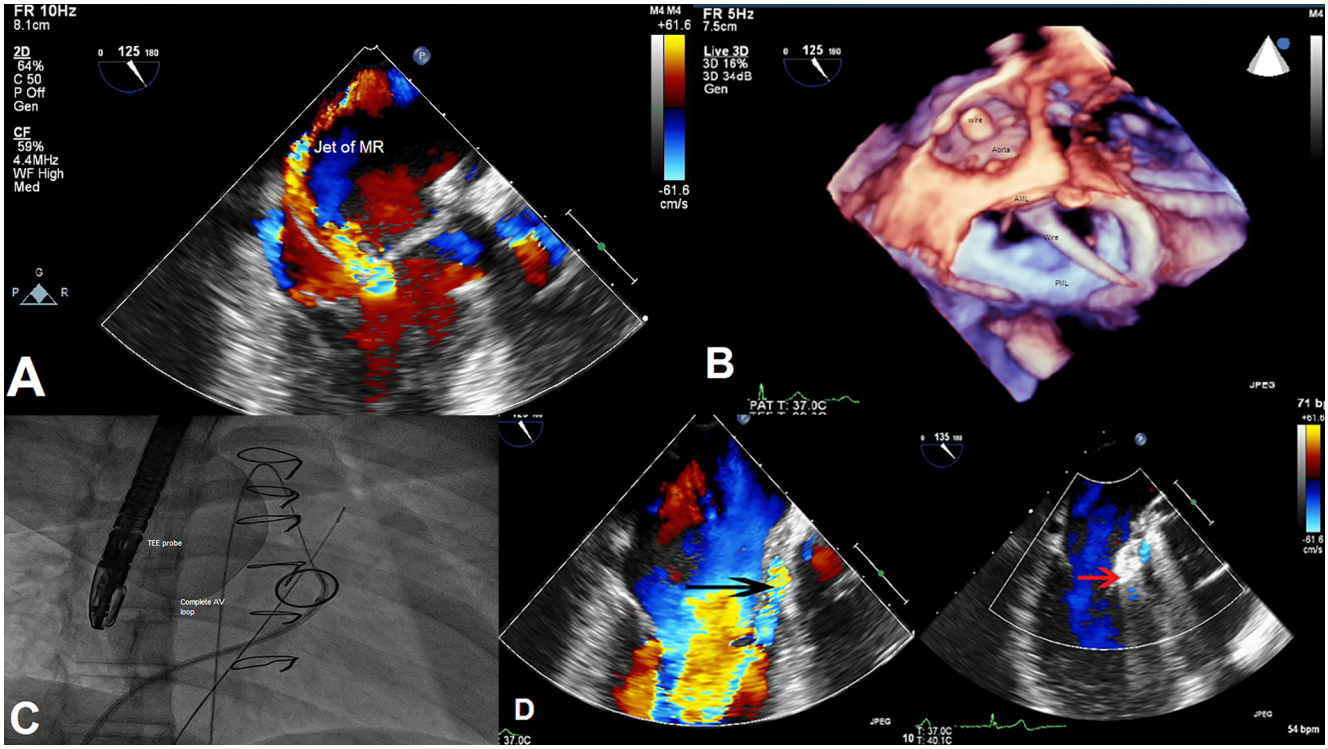

Figure 1. *Panel A.* TEE showing severe mitral regurgitation through the AML perforation. *Panel B.* 3D-TEE showing the wire passing from the AV to AML perforation. *Panel C.* Fluoroscopic view showing the complete arteriovenous loop and delivery sheath introduction. *Panel D.* 2D-TEE view during passing the mechanical aortic valve with the wire, showing moderate aorticregurgitation(left); after device implantation and removal of the wires, there is no aortic regurgitation (right).

replacement was done. Eight months later, she presented to our center with progressive SOB with NYHA class III-IV. Cardiovascular examination revealed 4/6 holosystolic murmur at the apex. Transthoracic echocardiography revealed severe mitral incompetence (Figure 1A). Transesophageal echocardiography (TEE) showed 5x5mm anterior mitral leaflet (AML) perforation through the A2 segment with moderate pulmonary hypertension (estimated systolic pulmonary artery pressure of 50 mmHg). The aortic valve showed a mean gradient of 18 mm/Hg across the AV with no valvular or paravalvular leaks. The left ventricular ejection fraction (LVEF) was 55% and the left ventricular end systolic diameter was 46 mm. Several blood cultures were taken and they showed no bacterial growth. As the patient refused redo surgery, she was referred for a possible percutaneous closure of AML perforation.

Procedure

The procedure was performed under general anesthesia with three-dimensional TEE guidance (PHILLIPS iE33 Cardiovascular Ultrasound, USA) and periprocedural prophylactic antibiotics were given. The challenges were crossing the defect in the A2 segment, selecting the appropriate device and the AML behavior after device deployment. Very low transseptal puncture was intended to create a straight tract without tension on the AML during closure. We anticipated that crossing the defect from the LA side will be extremely difficult due to leaflet's movement away from and parallel to the crossing wire with each heartbeat. In addition, crossing through the mechanical aortic valve may carry the challenge of hemodynamic instability or mechanical disruption of the valve. Arterial and venous femoral accesses were secured and heparin was given. Transseptal access was done; tip deflectable catheter (Agilis St Jude) 8.5 F was introduced

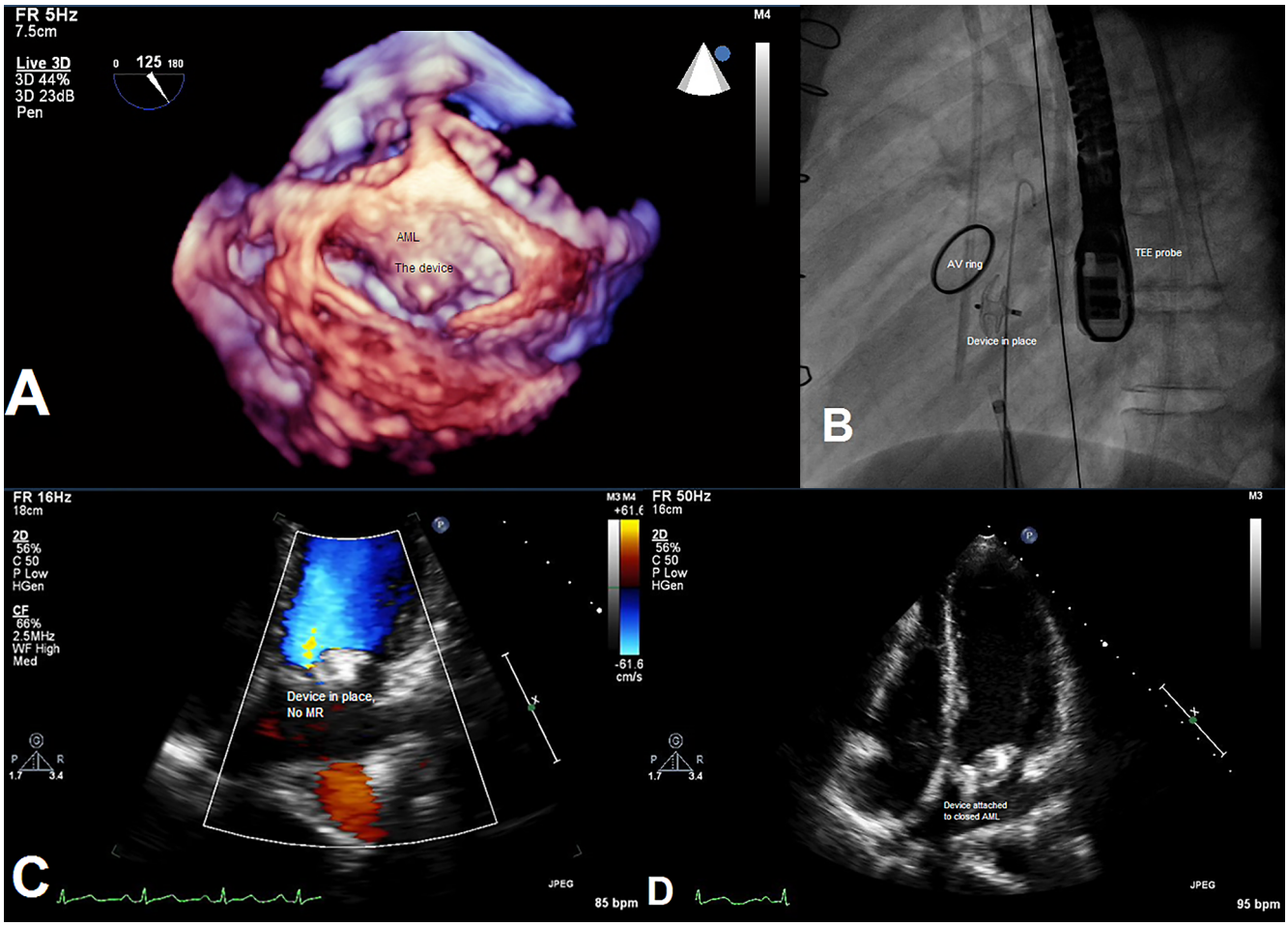

Figure 2. *Panel A.* 3D-TEE showing the device located within the AML sealing the perforation. *Panel B.* Fluoroscopic view showing the device after its release in the AML. *Panel C.* Colour-TTE apical view after 6 months following the procedure with no residual MR. *Panel D.* 2D-TTE apical view showing the device fixed in the AML 6 months after the procedure.

for effective negotiation in the LA cavity and through the anterior mitral leaflet perforation (Figure 1B, 1C).

With the help of 2 dimensional (2D) TEE at a 120-degree angle with slight clockwise rotation, the mechanical AV and the AML perforation were visualized at the same view helping to cross the defect. Real-time 3D imaging was used to monitor device implantation. Retrograde crossing using cut pigtail catheter and 0.035" Terumo glide wire across one orifice of the aortic valve was successful, avoiding the central slit orifice (Figure 1D). The cut pigtail, with a suitable curve, successfully passed to the LV cavity then was carefully pulled back to the level of the AML, and the wire was easily oriented through the hole of the AML. This step ended by snaring the wire in the LA forming the complete arteriovenous (AV) loop (Figure 1C). A Tourque Vue 6F sheath (St Jude Amplatzer) crossed the atrial septum to the AML perforation and was forwarded to the ascending aorta, crossing the mechanical aortic valve with extreme caution as harm may affect the AML, creating more injury or disrupting the mechanical aortic valve. The device chosen for closure needs to be light enough not to affect the AML mobility and needs to be fixed away enough from the closure line to avoid creating new MR through the normal MV orifice. We selected an atrial septal defect closure device (Amplatzer septal occluder, St Jude) size 4 mm with the large disc (16mm) designed to be in the LV side for better stability. During and after crossing the defect, monitoring with real-time 3D-TEE imaging was

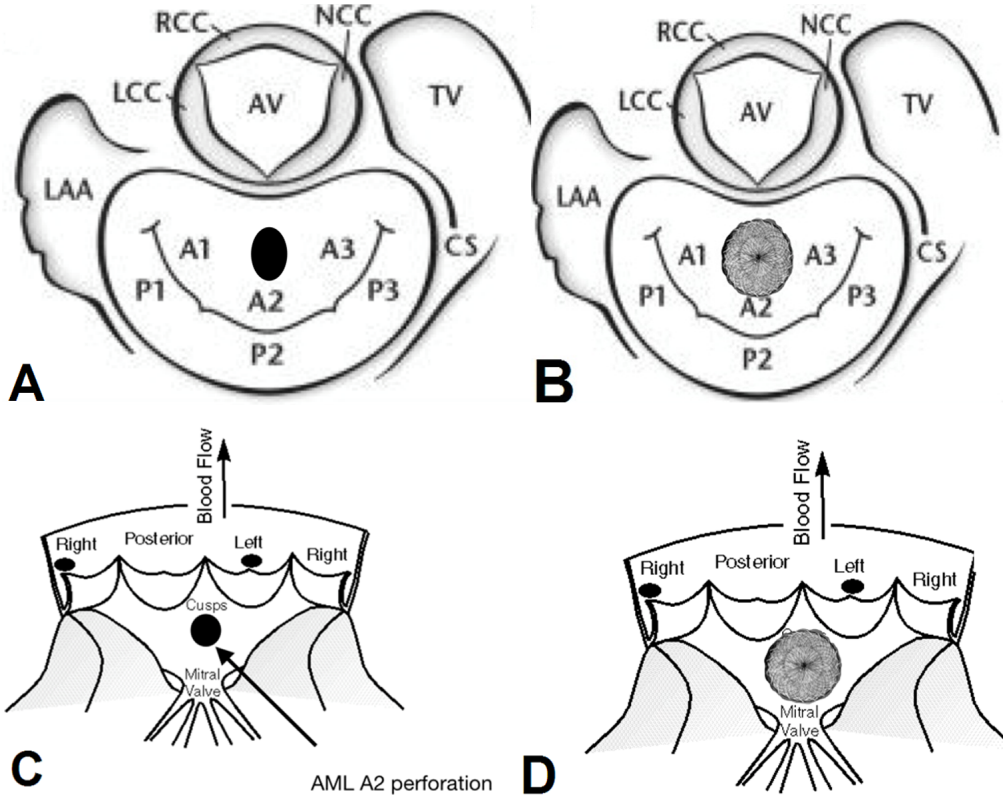

Figure 3. *Panels A and C.* A cartoon showing the location of the anterior mitral leaflet perforation and its relation to the aortic valve, it was 5X5 mm in diameter and 8 mm away from the mitral valve closure line. ***Panels B and D.*** Same cartoon showing the ASD closure device in place and its relation to the MV closure line and also relation to aortic valve.

helpful through device deployment. The device was partially opened through the aortic valve then fully opened in the LVOT with good secured traction of the delivery system to close the second disc sandwiching the AML. The device showed no interference with the mitral valve closure mechanism and the anterior mitral leaflet moved freely. TEE showed no residual mitral incompetence; no diastolic gradient across the mitral valve and no LVOT systolic gradient (Figure 2A and 2B).

Follow up

The patient's clinical course was excellent as she had significant symptomatic improvement with NYHA class I and her follow-up echocardiography showed no residual MR, no diastolic mitral valve gradient and estimated systolic pulmonary artery pressure of 35 mmHg after 6 months following the procedure (Figure 2C and 2D).

Discussion

Mitral leaflet perforations are generally rare and mostly due to infective endocarditis [1, 6]. Other causes can be iatrogenic and would have occurred during surgery for the aortic valve, or due to autoimmune diseases like systemic lupus, erythematosus, or antiphospholipid syndrome [7]. During aortic valve surgery, anterior mitral leaflet perforation can happen due to the fibrous continuity between the anterior mitral leaflet and the aortic valve [8]. Furthermore, the middle of the anterior mitral leaflet corresponds to the anatomical location of the commissure between the left and non-coronary sinuses of the aortic valve [8]. Because of this close anatomical proximity, either of the two valves may be injured during intervention for the other [8]. In a review of the complications in 475 cases after repair of aortic valve insufficiency done by Dyck et al. [9]; they reported two cases of perforation of the base of the anterior mitral leaflet. In

some patients, the mechanism of injury to the mitral valve anterior leaflet is aortic valve regurgitation, with the regurgitant jet being directed towards the mitral valve anterior leaflet, eroding the tissue and leaving the surface more prone to infection [8].

As endocarditis is sometimes associated, infection must be excluded in all patients with leaflet perforation. Perforations in the anterior leaflet may be the only mechanism of mitral regurgitation and if it is large, it may cause severe heart failure and warrant intervention whenever they are diagnosed [1, 2].

In this reported case, multiple blood cultures drawn over two weeks were negative, and no vegetations were seen on TEE. In our case, the perforation may have been either iatrogenic, possibly because of surgical aortic valve replacement, or as a complication of the endocarditis that was diagnosed preoperatively. Surgery is the standard treatment for patients with mitral leaflet perforations [8]; but because of the higher risk related to the redo surgery and the patient's preference, percutaneous procedure was adopted.

Percutaneous closure carries multiple challenges which include crossing the leaflet perforation, which can be done from either the LA side or the ventricular side, the site of transseptal access, feasibility of crossing and negotiating the mechanical aortic valve, and how much the device can affect the closure mechanism of the mitral valve. We chose a very low septal puncture to avoid stretching the leaflet during manipulation. Then we decided to use either IM catheter or cut pigtail for negotiating the perforation from the LVOT as it was faster and easier. For the mechanical aortic valve, we avoided any excessive tension on the valve and made sure to stay away from the central slit to avoid impairment of both discs simultaneously. The best selection of the closure device was a double disc device with a distance no more than 4mm between the discs, and it is best to have a larger disc towards the high-pressure chamber (LV). Also, there must be enough distance between the edge of the device and the closure line of the mitral valve. We used an atrial septal occluder device size 4 mm with an LV disc of 12 mm and waist thickness of 3 mm. Because of the extreme difficulty of crossing, we preferred keeping a safety wire during device deployment to maintain access in case of accidental loss of the access (Figure 3A-D).

In the study of Velasco S., et al. [3], they used an 8X4-mm Amplatzer Vascular Plug III with no follow up reported. In the study of Raczkiewicz S., et al. [4], they reported using a 6 mm × 3 mm PLD rectangular (Paravalvular Leak Device, Occlutech). They reported five months follow up by transthoracic echocardiography with no residual regurgitation. In the study of Javed U., et al. [5], they used 5mm Amplatzer atrial septal occluder.

In our case, we used an Amplatzer ASD device, however, a small Amplatzer duct occluder II, (5 to 6 mm with a short waist), could be another option since it's made of micronitinol with a low chance of hemolysis. It can be delivered through a much smaller delivery sheath which could minimize trauma to the mitral valve as well.

Summary

Percutaneous repair of mitral leaflet perforation caries many challenges and is only reserved for appropriately selected patients who have a high risk for surgery or in patients who refuse it. The main challenge during the procedure is the safe crossing through the defect using both the antegrade and retrograde approach. TEE guidance of the procedure is mandatory and real-time 3D is very helpful. Further research is needed to establish mid- and long-term follow up of this approach.

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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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Left Main Protection and Emergency Stenting During TAVR with Self-Expandable Valve

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Abstract

Left main (LM) obstruction is rare but life-threatening complication of transcatheter aortic valve replacement (TAVR) which occurs by displacement of left coronary leaflet toward the ostium or by direct occlusion by the covered skirt of the prosthesis. We report an 88-year old lady with severe aortic stenosis, short distance from annulus to left main origin, shallow/low sinus of Valsalva, and calcification of the left aortic leaflet undergoing TAVR with a self-expandable valve. Instead of recently described "Chimney" stenting with protrusion of a very long stent segment from LM above the prosthesis leaflets and behind the valve frame, a "T-stenting" with stent protrusion only into the left sinus Valsalva was used to secure the LM patency.

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Key Words

Emergency left main stenting, TAVR

Introduction

Left main (LM) obstruction is rare but life-threatening complication of transcatheter aortic valve replacement (TAVR) which occurs by displacement of left coronary leaflet over the ostium or by direct occlusion by the covered skirt of the prosthesis [1, 2]. Since this complication may be anticipated if a careful evaluation of aortic computed tomography (CT) scan is performed, LM can be protected up front by placement of a guiding catheter into the LM ostium and advancing a guidewire with undeployed stent into the left anterior descending artery (LAD) [2]. If LM occlusion occurs, the stent can be immediately withdrawn and deployed to reestablish LM patency. Importantly, because of the valve height during the TAVR with a self-expandable valve such as Evolut R (Core Valve Evolut R, Medtronic, Dublin, Ireland), the guiding catheter is located behind rather than above the valve frame. In case of LM occlusion, a "chimney" stenting with protrusion of a very long stent segment from the LM ostium above the prosthesis leaflets and behind the valve frame, has recently been described [3]. We herein present an alternative "T-stenting" strategy with stent protrusion extending only into the sinus of Valsalva toward the valve frame without leaving any stent segment behind the valve frame.

Case report

The patient was an 88-year-old lady with symptomatic severe aortic stenosis (gradient 69/37 mm Hg, AVA 0.4 cm2) and preserved left ventricular ejec-

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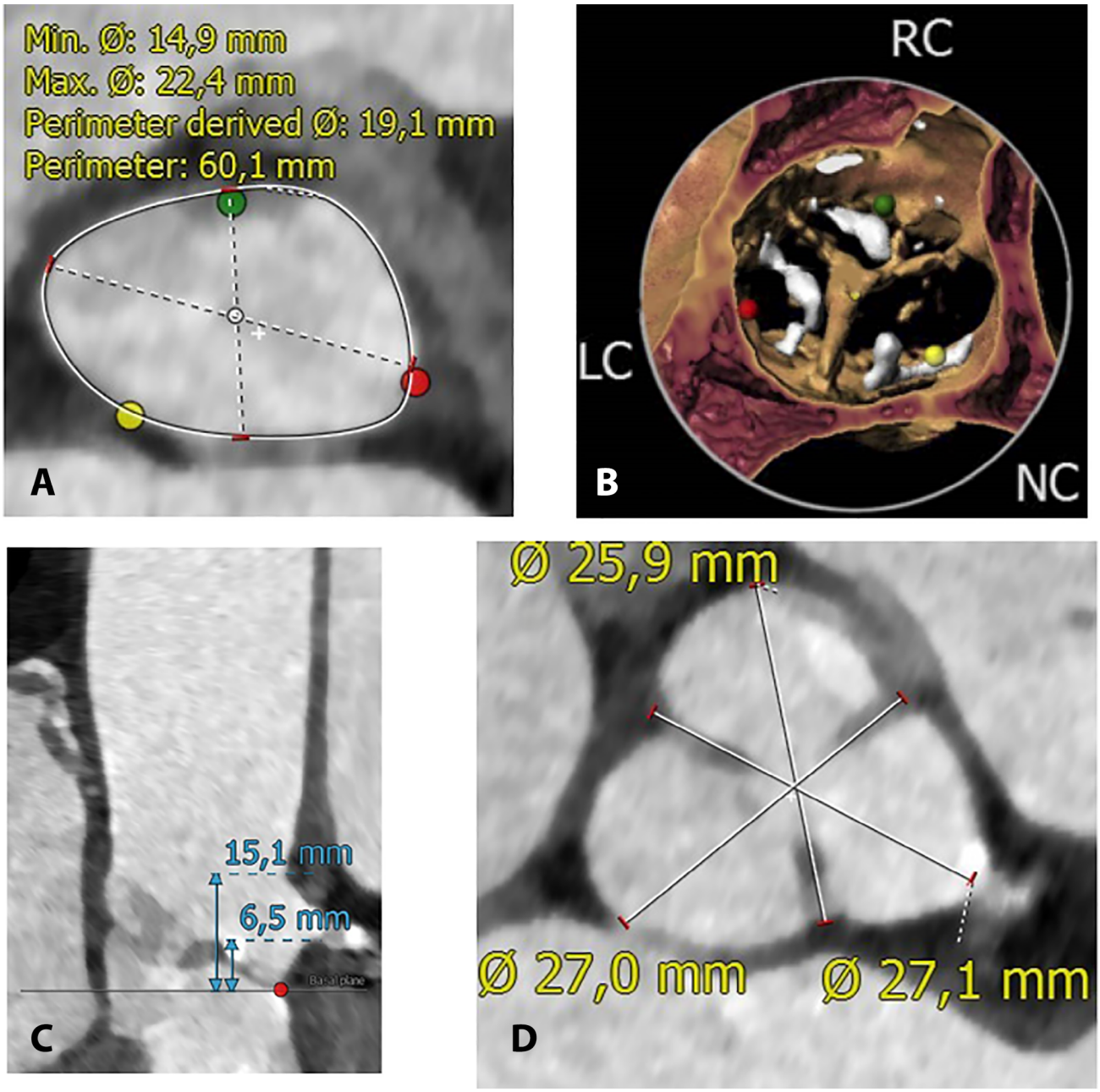


Figure 1. CT measurements of aortic annulus *(Panel A)*, aortic leaflet calcification *(Panel B)*, height of left coronary ostia/left sinus of Valsalva *(Panel C)* and diameters of sinuses of Valsalva *(Panel D)*.

tion fraction (72%) who was referred for TAVR by the Heart Team because of very high surgical risk (Euroscore II 15.30%, STS 11.06%). Coronary angiography showed diffuse calcification and moderate proximal and mid LAD disease. Pre-procedural CT scan revealed aortic annulus perimeter of 60.1 mm, short distance from annulus to LM origin (6.5 mm), shallow sinuses of Valsalva (average 26.7 mm), a borderline height of left sinus Valsalva (15.1 mm) and a calcified nodule on the left coronary cusp (Figure 1). Because of threatened LM occlusion during valve placement, an EBU 3.5 6 Fr guiding catheter (Medtronic, Dublin, Ireland) was placed via left radial artery to cannulate LM. A .014" BMW guidewire (Abbott Vascular, Abbott

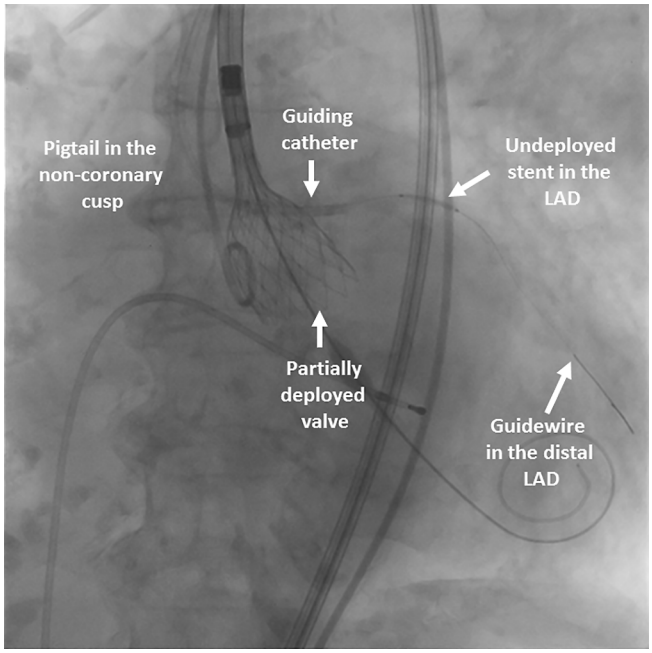
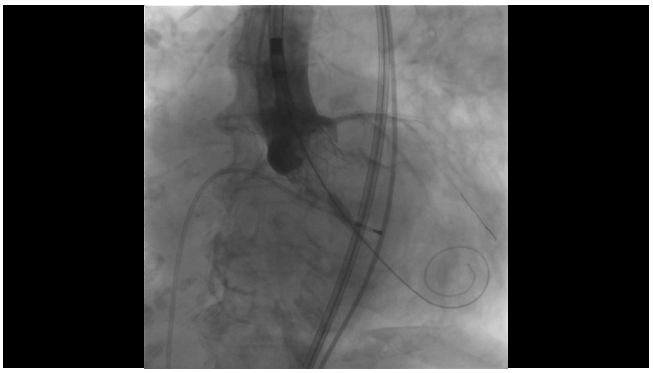
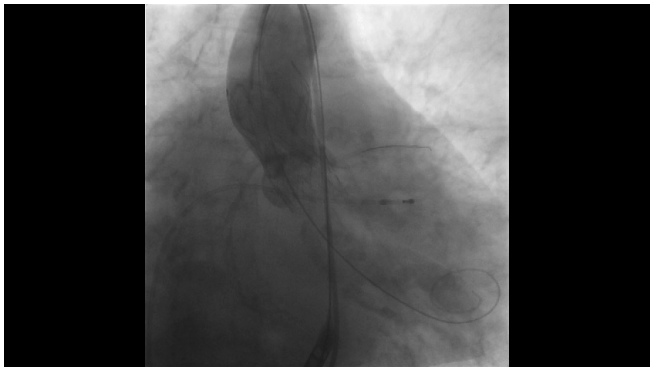


Figure 2. Valve deployment to the point of no recapture with the guiding catheter lying behind the valve frame, and guidewire with undeployed stent in the left anterior descending artery.

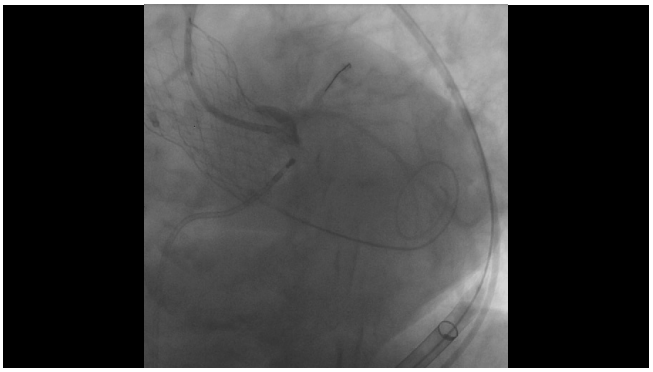
Park, Illinois, USA) was advanced into LAD followed by placement of undeployed drug-eluting stent Orsiro 3.5x15 (Biotronik, Berlin, Germany). Using the right femoral artery, a 26 mm self-expandable Evolut R valve (Core Valve Evolut R, Medtronic, Dublin, Ireland) was deployed without predilation (Figure 2). Left coronary flow, assessed prior to full deployment, was preserved (Video 1). However, after full deployment, aortography revealed decreased left coronary compared to right coronary flow despite pulling the stent back to the guiding catheter while still maintaining guidewire position (Video 2). Guide injection showed that left leaflet was displaced close to the LM ostium (Video 3). The stent was re-advanced to the LM, protruded proximally close to the valve frame and deployed (Video 4). After placement of an LM stent which extended into the proximal LAD, a haziness was noticed at the distal edge. Stented segment was initially extended with a 2.5x12 Orsiro (Biotronik, Berlin, Germany). Since haziness persisted, additional 2.5x15 mm Orsiro was deployed distally and this resulted in a good angiographic result (Video 5). Aortogram revealed widely patent LM, LAD and circumflex artery with normal flow (Video 6). Except for



Video 1. Aortogram before complete valve deployment. Both coronary arteries are well perfused. View supplemental video at https://doi.org/10.12945/j.jshd.2018.008.18.vid.01.

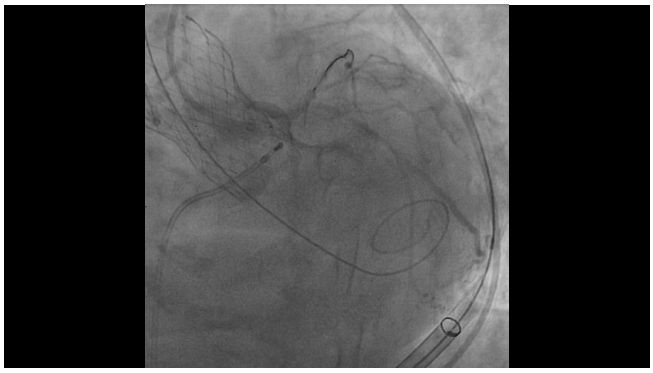


Video 2. Aortogram with decreased left compared to right coronary flow after complete valve deployment despite moving of the stent from LAD back to the guiding catheter. View supplemental video at https://doi.org/10.12945/j.jshd.2018.008.18.vid.02.

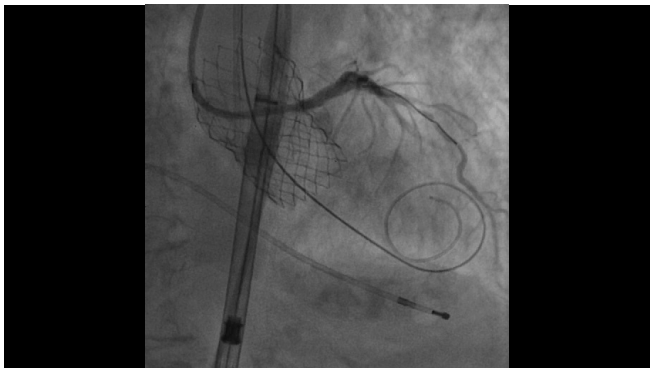


Video 3. Injection through the guiding catheter revealed a mass protruding toward the LM ostium. View supplemental video at https://doi.org/10.12945/j.jshd.2018.008.18.vid.03.

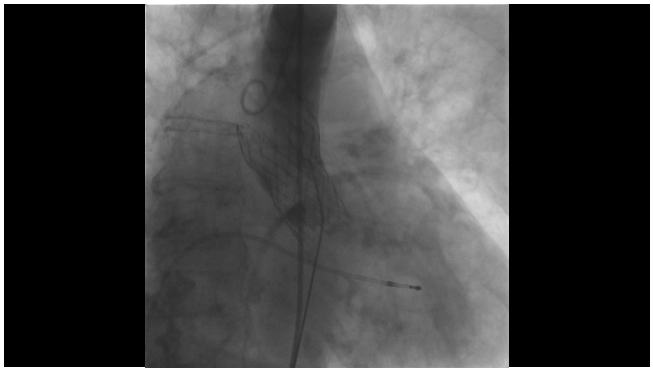
the need for a permanent pacemaker, the hospital stay was uneventful and the patient was discharged with dual antiplatelet therapy including acetylsalicyl-



Video 4. Stent deployment from the LM toward the valve frame. View supplemental video at https://doi.org/10.12945/j.jshd.2018.008.18.vid.04.



Video 5. Post procedural guide injection showed widely patent LM, LAD and left circumflex artery with normal flow. View supplemental video at https://doi.org/10.12945/j.jshd.2018.008.18.vid.05.



Video 6. Final aortogram with comparable left and right coronary flow. View supplemental video at https://doi.org/10.12945/j.jshd.2018.008.18.vid.06.

ic acid and clopidogrel. Post-procedural CT scan after three weeks revealed widely patent LM stent protruding across the sinus of Valsalva close to valve frame with its proximal part in a "T-stent" shape. (Figure 3). Twelve months after the intervention, the patient continues to be asymptomatic.

Discussion

Several anatomic factors derived from preprocedural CT scan including low LM ostium, shallow sinuses of Valsalva, severe leaflet calcification with large bulky calcium nodules, high native leaflet length/curved coronary sinus height ratio as well as extreme valve oversizing and "valve-in-valve" procedure, have been identified as high risk features for coronary occlusion during TAVR [2, 4]. A potential risk of coronary occlusion may also be assessed before TAVR using aortic valve predilatation with simultaneous aortogram. If the coronary occlusion is documented, upfront LM protection is mandatory [4]. We did not use this technique because we perform a vast majority of TAVR without predilatation. If we predilate, we always use a small balloon (18-20 mm) to minimize manipulation of the calcified native valve. Predilatation with a smaller balloon would probably underestimate the likelihood of actual LM occlusion during TAVR. Moreover, based on the CT scan, we have already decided to use upfront LM protection. Admittedly, according to CT-derived measurements, a 23 mm rather than 26 mm Evolut R should have been used. Some oversizing with this self-expandable prosthesis was selected because annulus perimeter was at the very upper limit for the 23 mm valve, the native valve was highly calcified, and we have already decided for upfront LM protection.

The optimal strategy for LM protection during TAVR, particularly when using self-expandable Evolut R valve, remains to be defined. The "chimney" technique is generally considered in patients with low sinotubular junction due to potential occlusion of the respective sinus of Valsalva after valve deployment. In our patient, the height of the left sinus of Valsalva was just above the recommended 15 mm. We, therefore, decided for a less complex "T-stenting" and protrude LM stent only above the displaced leaflet and toward the valve frame. Accordingly, the proximal part of the stent was not behind the valve frame. This avoids possible unfavorable interaction between the LM stent and self-expanding valve frame which

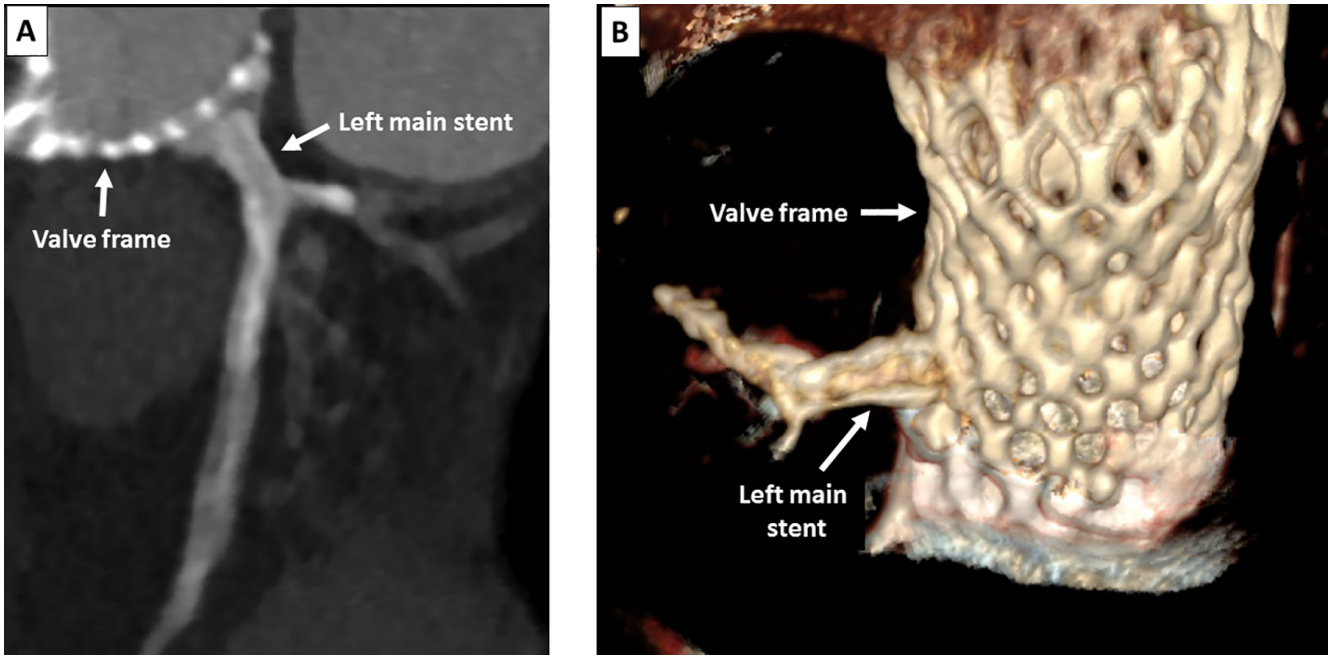


Figure 3. Post procedural computed tomography scan after 3 weeks showing widely patent LM stent protruding toward the valve frame *(Panel A)* together with three-dimensional reconstruction *(Panel B)*.

may also happen after the procedure. We also believe that smaller stent protrusion may facilitate left coronary engagement in the future and may theoretically reduce the risk of stent thrombosis. Of note, using our "T-stenting" technique, we were able to deliver an additional two stents to the LAD through the LM stent without any problems. Retrospectively, we believe that additional LAD stenting was required because there was a distal edge dissection from the initial LM stent which extended into the diffusely diseased proximal and mid LAD. Beside "chimney" and our "T-stenting" techniques, the third option to prevent LM occlusion during TAVR is the recently described "BASILICA" technique with modulating of the native valve leaflet. A single leaflet tear, which would prevent coronary occlusion, is made by leaflet wire traversal and snaring followed by slicing. To our knowledge, this technique has been described so far in only six "valve-in-valve" procedures and one native aortic stenosis. We did not use "BASILICA" because of the lack of experience and fear to increase stroke risk when manipulating with a heavily calcified cusp. However, when discussing any of the herein described LM protection techniques during TAVR, it is important to notice that the number of reported patients is still very limited and long-term efficacy and safety remains to be proven.

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Conflict of Interest

Marko Noc and Branko Cveticanin have no relevant conflict of interest.

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Oscar Mendiz reports proctorship for CoreValve (Medtronic) and consultation fees from Abbott Vascular.

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