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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.

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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.

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

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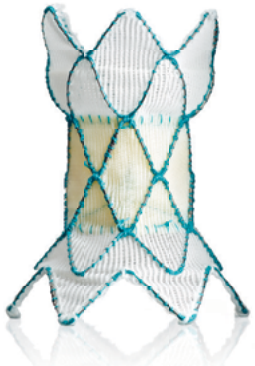

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WHAT IS THE MEDTRONIC HARMONY TPV CLINICAL STUDY?

The study is a multi-center prospective, non-randomized, interventional pre-market study in the United States. The purpose of the study is to evaluate the safety and effectiveness of the Harmony TPV system in patients who have congenital heart disease and are clinically indicated for pulmonary valve replacement. The trial will involve up to 40 subjects implanted at 10 study centers.

WHO CAN PARTICIPATE?

Patients who have pulmonary regurgitation:

- Severe pulmonary regurgitation by echocardiography, or
- Pulmonary regurgitant fraction ≥ 30% by cardiac magnetic resonance imaging

Patients who have a clinical indication for surgical placement of a RV-PA conduit or prosthetic pulmonary valve:

- Subject is symptomatic secondary to pulmonary insufficiency (e.g., exercise intolerance, fluid overload), or
- Right ventricular end diastolic volume index ≥ 150 mL/m^2, or
- Subject has RVEDV:LVEDV Ratio ≥ 2.0

HOW CAN I LEARN MORE ABOUT THE HARMONY TPV CLINICAL STUDY?

For additional information about the program, please contact Medtronic at:
RS.HarmonyTPVClinicalStudy@medtronic.com

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Review Article

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Transcatheter Pulmonary Valve Replacement

The Edwards Sapien Valve

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Abstract

Pulmonary valve replacement is one of the most common surgical procedures performed in older children and adults with congenital heart disease who have normally had at least one previous operation. The percutaneous alternative was first performed in man in 2000 when Dr. Bonhoeffer merged a surgically available bovine jugular vein valve (Venpro/Contegra) and a Cheatham-Platinum (CP) stent to create a percutaneous system for stenosed conduits; this valve was subsequently acquired by Medtronic and is now the Melody valve. The Edwards Sapien valve was originally designed for percutaneous aortic valve replacement (TAVI/TAVR), but its design makes it equally suitable for pulmonary implantation using a similar delivery system and it is indeed indicated for this purpose [1, 2]. The Edwards valve has evolved over recent years, increasing the range of sizes including the 29-mm Edwards XT and, more recently, the Sapien 53. The Edwards 3, incorporates a cuff/skirt outside of the frame to minimize paravalvular leaks; it was primarily designed for the aortic position where paravalvular leaks are generally more significant. Follow-up observations indicate that the performance and longevity of the Edwards percutaneous valve are comparable to surgically implanted bioprostheses which are also manufactured by Edwards Lifesciences; the catheter technique has reached a high level of sophistication to achieve successful and safe results in selected individuals. Some patients, however, would be better candidates for surgery, usually for anatomic reasons.

Transcatheter pulmonary valve implantation has some advantages over surgery, as it is less invasive, avoids repeat sternotomy and bypass, does not usually require intensive care, and results in a shorter hospital stay. Cost effectiveness is comparable, and because the Edwards valve is based on a well-established tissue valve technology, its longevity are performance are expected to be similar to that of surgery as the frame on which the valve is mounted is very robust with complete integrity maintained over at least 5 years from implantation.

Key Words:

Sapien • Edwards valve • Pulmonary valve replacement • Catheter intervention

Equipment

This consists of the Edwards valve itself, a dilator kit, introducer sheaths, balloon catheter, delivery system and the Atrion inflation device. In addition, diagnostic catheters, various balloons, guide wires, snares, and stents should be available.

Edwards Equipment

The Sapien Edwards valve, which comes in the Sapien XT and Sapien 3 versions, is balloon expandable and fashioned from bovine pericardium similar to tissue that has been used for surgical tissue valves for many years. Bovine pericardium consists of densely layered collagen and has clinically proven long-term durability. The bovine pericardium is carefully inspected and chosen for uniform thickness and quality. The

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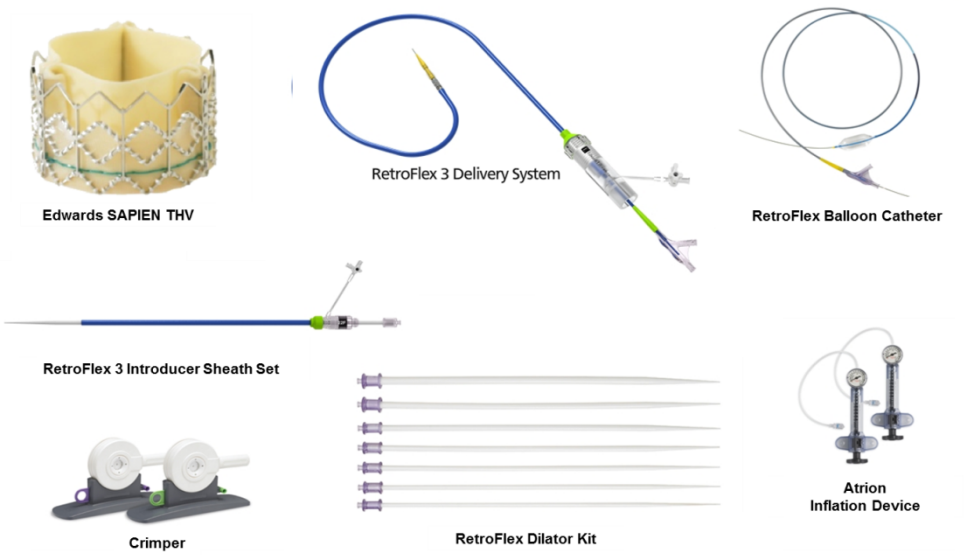

Figure 1: Edwards equipment.

valve tissue is treated with a patented Carpentier Edwards ThermaFix process that is designed to remove major calcium-binding sites in order to optimize valve longevity. The ThermaFix process uses (i) a heat process to remove glutaraldehyde molecules and (ii) a patented chemical process that removes 98% of phospholipids, as these are known calcium-binding sites; moreover, calcification of the valve is known to be the main reason for valve tissue degeneration but the long-term benefit of the ThermaFix still needs to be established. The pericardium is shaped into a three-leaflet valve, originally mounted on a stainless steel frame using polyethylene terephthalate fabric but the frame is now made from a Chromium-Cobalt alloy. In vitro durability testing simulating 5 years of implantation was successfully carried out for the valve components.

The pericardial leaflets are mounted on a laser-cut, biomedical grade Chromium-Cobalt frame consisting of 4 rows and 4 columns providing a high radial strength; this results in better hemodynamics by expanding into a round circle and is resistant to stress fractures. The latter was confirmed by a simulation process equivalent to 15 years of implantation. Due to the strength of the frame and for more uniform placement of the delivery system, Edwards developed a crimper to mount the valve on the delivery system. Originally, the Sapien valve came in 23- and 26-mm diameters. Edwards expanded the range, adding 20- and a 29-mm diameter options. The frame height, after implantation is 13.5 mm for the 20 mm valve, is 14.3 mm for the 23-mm valve, 17.2 mm for the 26-mm valve, and 19.1 mm for the 29-mm valve.

The original Sapien valve was mounted on a balloon that was part of the delivery system. Initially, this was known as the Retroflex and was upgraded to the RetroFlex 3 System, until recently. All the current models, except for the Edwards 3, can be delivered through the NovaFlex system; the Edwards 3 is delivered through a Commander delivery system. The change in design to the NovaFlex delivery system has made it possible to go through a smaller sheath by mounting the Edwards valve on the shaft proximal to the balloon for easy of entry into the patient and it is then placed across the balloon within the inferior vena cava. The NovaFlex ranges from 18 to 21 Fr in size and consists of a long catheter with a short, soft tapered tip for easy transition and to protect the Edwards valve during delivery. Proximal to the tapered tip is the balloon, over which the valve is placed for deployment. The balloon is volume and not pressure driven; the recommended volume of dilute contrast is placed in the Atrion QL inflation device to achieve the desired diameter for the size of valve being deployed..

The Edwards valve is crimped on to the shaft of the NovaFlex at the time of the procedure proximal to the balloon and using the Edwards crimper of the appro-

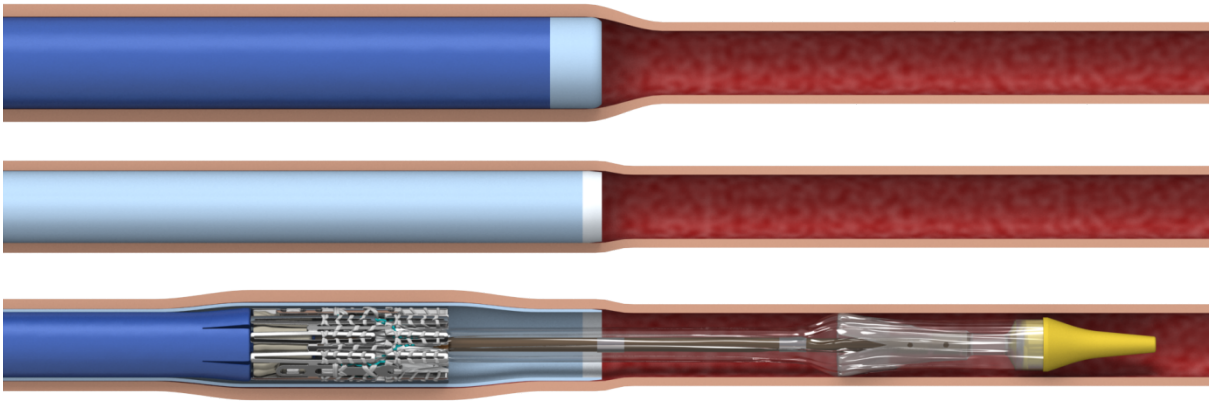

Figure 2: NovaFlex detail.

priate size for the valve that is being used. Proximal to where the valve is mounted on the shaft, there is a flared sheath which is part of the delivery system and designed to place the valve over the balloon when the system is inside the patient. Precise and fine placement of the valve on to the centere of the balloon is achieved by a rotating knob on the delivery handle. To inflate the balloon to a predetermined diameter, the Edwards Atrion inflation device is used with nominal volumes for the various size valves.

Edwards LifeSciences also manufacture a set of precisely tapered hydrophilic dilators as well as 35-cm hydrophilic introducer sheaths with a tri-seal valve in various diameters to accommodate the NovaFlex delivery system; however, nowadays, the expandable 16 Fr eSheath is preferred and uniformly suitable.

Edwards also provide the short Ascendra/Certitude sheath and delivery system designed for minimally invasive surgical implantation using a hybrid approach.

Additional Equipment

Diagnostic Catheters

A selection of catheters may be required to obtain angiography of the right ventricle, the right ventricular outflow tract (RVOT), and the pulmonary arteries, and to assess the degree of pulmonary and tricuspid regurgitation. Common types of catheters include the pigtail, multipurpose A2, the Gensini/MPB3, multitrack, balloon wedge/floatation, and pre-shaped coronary catheters for angiography during balloon interrogation of the RVOT.

Wires

Apart from the standard guide wires, it is important to have a hydrophilic wire and a selection of stiff exchange length wires, such as, the Amplatz stiff wires (Extra Stiff, Super Stiff, and Ultra Stiff by William Cook), the Lunderquist wire (William Cook) and the Back-up Meier wire (Boston Scientific).

Balloons

These are required for interrogating the RVOT, not only to assess the anatomy of the outflow tract but also to look at the impact on coronary artery patency, compression, and flow. Although compliant sizing balloons, such as the ones from St Jude Medical or NuMed, can be used, semi-compliant ones may be more appropriate; examples of these balloons include the Cristal (Balt) and BiB (NuMed) balloons. These balloons are also used for pre-stenting the RVOT when required. High pressure noncompliant balloons, such as the Z-Med and Mullins (NuMed) and the Atlas (Bard) are required to abolish resistant stenosis of the RVOT and these are usually used after stent placement and before valve implantation.

Stents

In many instances, pre-stenting is usual in order to cover areas of stenosis longer than the Edwards valve frame both in the context of a previous tissue homograft/xenograft conduit but also when there has been a trans-annular patch placed at the time of surgical repair. Pre-stenting not only helps to scaffold the RVOT, but it prepares the landing zone for the valve. Although pre-stenting is essential for the

Melody valve because of the fracture rate, this is not essential for the Edwards TM valve as the frame is very robust with no fractures recorded on bench testing or in clinical trials. The stent material does not seem to matter with respect to metal to metal interaction that may cause corrosion or valve dysfunction although there are Chromium-Cobalt stents, such as the Andrastent XXL which are both robust and material compatible. The stents used must be able to dilate to large diameters with predetermined shortening to allow for accurate placement and to cover the length of any narrowing. Although most of the time bare metal stents are used, it is essential to have covered CP stents (NuMed) either for primary use if there is the possibility of conduit rupture or for a bailout situation. If a longer covered stent is required above those available, these can be obtained from the manufacturer as a special order up to 55mm in length. Stents that are commonly used for the RVOT include:

a) Andrastent (Andramed)
b) CP bare metal and covered (NuMed)
c) Maxi LD (Ev3)
d) Palmaz (J & J)

These stents are often mounted on BiB, Cristal, or Z-Med balloons for deployment and delivered after RVOT interrogation to make sure that the stent or calcified material will not compress the coronary arteries.

Venous closure

Venous access closure devices are not essential but some operators prefer to use these; however, simple manual compression or the use of a FemStop is an acceptable, alternative option. Devices that are commonly used include the Perclose/Proglide or the ProStar both from Abbott Vascular. An alternative is to form a figure-eight suture at the site of skin entry using thick silk on a large curved cutting needle; this invaginates the skin applying pressure to the femoral vein entry point and achieves hemostasis. The suture can be removed after six hours.

Patient Selection and Preparation

Patients are selected for pulmonary valve replacement, according to accepted guidelines that include symptoms as well as supportive evidence of significant stenosis, regurgitation, or a combination of these; in other words, these patients would be equally candidates for surgery. Although some patients are suitable for either surgery or percutaneous pulmonary valve replacement some may carry a higher risk or are considered not to be surgical candidates either because of cardiac or non-cardiac conditions (e.g. Scoliosis, respiratory insufficiency, motor and/or developmental delay, psychological imbablance, amongst others). Some patients are asymptomatic but have objective evidence of significantly hemodynamic compromise. Those with symptoms often fall into NYHA class II or III.

Anatomic Situations

These include:

a) Truly native RVOT (usually stenosis due to dysplastic pulmonary valve or regurgitation following previous balloon valvuloplasty)
b) Trans-annular patch repair of native RVOT
c) Ventricle to pulmonary artery conduit (homograft or xenograft)

Physiologic Factors

a) Severe RVOT obstruction with a peak gradient of greater than 50 mm Hg
b) Severe pulmonary regurgitation with right ventricular volume over load, a right ventricular end diastolic volume of greater than 150 ml/m^2 on MRI, a regurgitant fraction of greater than 35% and a right ventricular ejection fraction of less than 40%
c) A combination of RVOT obstruction and regurgitation
d) Some patients may not have the above criteria but are nevertheless symptomatic with impaired CPEX. Sometimes restrictive right ventricular physiology contributes to this clinical presentation.

Clinical Scenarios

a) Repaired Fallot's tetralogy or pulmonary atresia with VSD
b) Repaired persistent arterial trunk

c) Post-Ross procedure (pulmonary autograft)
a) Post arterial switch/Rastelli in transposition of the great arteries
b) Post left ventricle to pulmonary artery conduit in congenitally corrected transposition
c) Any dysfunctional conduit/tissue valve between ventricle and pulmonary artery

General Criteria

There are no strict rules with respect to patient's age and weight, but as a guide, patients should be older than six years and weigh more than 25 kg as the delivery systems are still bulky.

It is essential for the entry veins to be of adequate size, that is, around 6 mm or more. Ultrasound evaluation of these is usually sufficient. Arterial access from the femoral or radial arteries is required to assess the coronary arteries during balloon interrogation of the RVOT.

There are some situations where percutaneous pulmonary valve implantation should not be considered:

a) If the coronary arteries are compromised or within 5 mm of the interrogating balloon
b) If the landing zone is too large for the available valve sizes; for non-stenosed outflow tracts, the valve size should be 10–15% larger to ensure anchorage and stability
c) Infection within the previous 6 months which includes systemic infection or endocarditis

Specific Observations/Investigations

Evaluation consists of clinical assessment as well as supportive investigations.

The ECG may show a broad, complex, right bundle branch block; if the QRS is wider than 180 msec, this usually implies significant right ventricular volume overload with arrhythmogenic tendencies although in many the QRS width is closer to 160 msec when other indications already exist. Holter monitoring is part of the work-up and the presence of ventricular tachycardia may be an indication for intervention although there are several mechanisms apart from mechanical right ventricular dysfunction. In general, however, the mechanical component is addressed first followed by electrophysiology if ventricular tachycardia persists following haemodynamic optimization.

A cardio-pulmonary exercise test (CPEX) provides quantitative workload capacity and is useful to demonstrate any progression over a period of observation and this helps to optimize the timing for intervention as well as to observe any benefits following intervention.

The echocardiogram/Doppler is the commonest investigation carried out to evaluate the RVOT obstruction as well as the effect of obstruction and regurgitation on the right ventricle. It provides information about the proximal pulmonary arteries, the velocity across the RVOT, the degree of pulmonary regurgitation, as well as the velocity and regurgitation of the tricuspid valve to estimate the right ventricular pressure and observe the degree of regurgitation. Transesophageal echocardiography is sometimes used during pulmonary valve implantation and may help with identifying the landing zone, but the valve leaflets are not easily seen due to scatter from the frame and if there is a suspicion of valve dysfunction, intra-cardiac echocardiography (ICE) is superior.

More specific and objective information is obtained on MRI/CT. These provide details of the RVOT including the diameter and length, spatial orientation of pulmonary an coronary arteries, quantitative RVOT obstruction and regurgitation, right ventricular function, and the right ventricular end diastolic volume correlated to body surface area. A right ventricular end diastolic volume of greater than 150 cc/m^2 is considered significant, as are an end systolic volume of more than 90 cc/m2, a regurgitant fraction of more than 35% and an RV ejection fraction of less than 40%. MRI is superior particularly for quantitative observations and these are important to assess progression but some patients with implantable devices, such as pacemaker/defibrillators are only suitable for CT.

Angiography and direct hemodynamic assessment can be done during the pulmonary valve implantation but increasingly this is carried out in advance during which balloon interrogation of the RVOT is carried out for more accurate measurement and to assess whether the coronary arteries could be compromised with stenting and/or valve implantation. If the balloon interrogation proves safe, the RVOT can be stented at the same time and for the pulmonary valve to be implanted a few months later. A gap between these pro-

cedures allows the stent to embed and to get a better idea of diameter in the event of recoil. If the latter is dynamic or significant (arbitrarily, a gradient of greater than 20 mm Hg), a second stent may be required. Right ventricular outflow tract preparation must be done prior to valve implantation and do not rely on post dilatation after the valve is implanted.

Procedure

Pulmonary valve implantation can be carried out under sedation although most are carried out under general anesthesia. A biplane system is preferable and the room must have adequate levels of sterility and air change to minimize risk of infection. The operators must adhere to strict sterile protocols throughout. Antibiotics are generally given to cover the procedure mainly to cover staphylococcal infections but this is not a substitute to good operator and patient preparation. The procedure is covered with heparin in therapeutic doses based on ACT measurement.

The femoral vein is accessed percutaneously high up to enter the external iliac vein. If the femoral veins are occluded or tiny or if there is absence of the IVC with azygos replacement, a right internal jugular approach is required. The jugular approach may also be preferred in patients with TGA or ccTGA.

A 5–6 mm skin incision is made at the entry site and if a closing device is planned this should be inserted at this stage. It is customary to place a 16–18 Fr short sheath to allow for angiography, balloon interrogation, or stenting of the RVOT if required. Right sided pressures are recorded and a right ventriculogram carried out to show the RVOT anatomy and pulmonary arteries, as this helps to determine which pulmonary artery to park the exchange wire in order to optimize the catheter course. In general, the left pulmonary artery is preferred when approaching from the femoral and the right pulmonary when approaching from the jugular but there are no hard and fast rules as this depends on the anatomy, approach, and operator preference. Arterial access with a 4–6 Fr sheath is obtained.

Once the RVOT is prepared with stenting, the PPVI procedure can proceed. Having a stiff exchange-length guide wire in a peripheral pulmonary artery is essential and this is placed through a MP

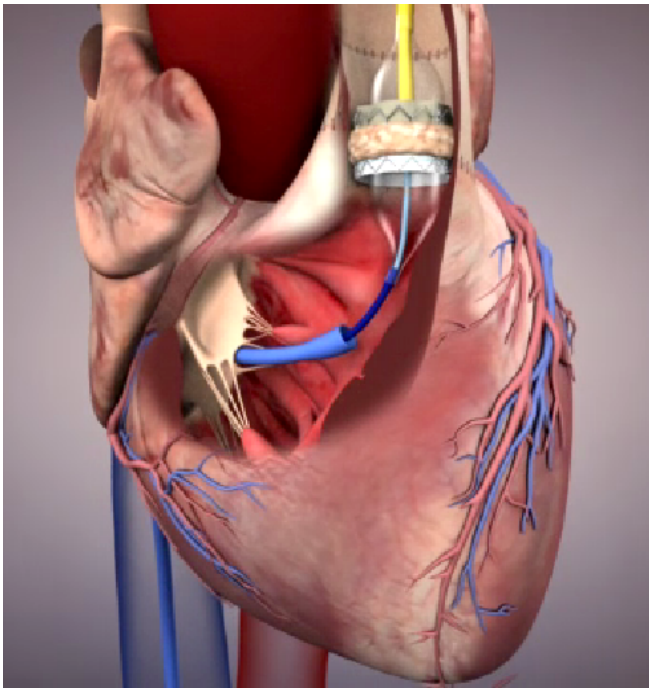

Figure 3: Animation of pulmonary valve implantation with the Edwards valve.

catheter; a Lunderquist 0.035" wire is commonly used. Over the wire, an appropriate Edwards introducer sheath, often nowadays this is the eSheath, is inserted having pre-dilated the track with the Edwards dilator kit. The Edwards XT or Sapien 3 valve is loaded and crimped on to the NovaFlex/Commander delivery system proximal to the balloon and making sure that it is orientated for pulmonary implantation—at least two people must see and confirm this. Choose the correct crimper for the valve size. The delivery system is then passed through the introducer sheath until the valve is well out of the delivery sheath in the upper part of the IVC. The valve is pushed forward on the proximal part of the balloon by releasing two catches on the delivery handle and pushing the flared sheath forward monitoring this on fluoroscopy - during this maneuver, it is essential to keep an eye on the wire position to avoid inadvertent withdrawal. Fine tuning of the valve position on the center of the balloon as judged by the radio-opaque markers, is achieved by the rotating knob on the delivery handle. It is best for this maneuver to be done in the IVC and not the RVOT. Once the valve is optimally placed on the balloon, the whole assembly is pushed over the wire towards the

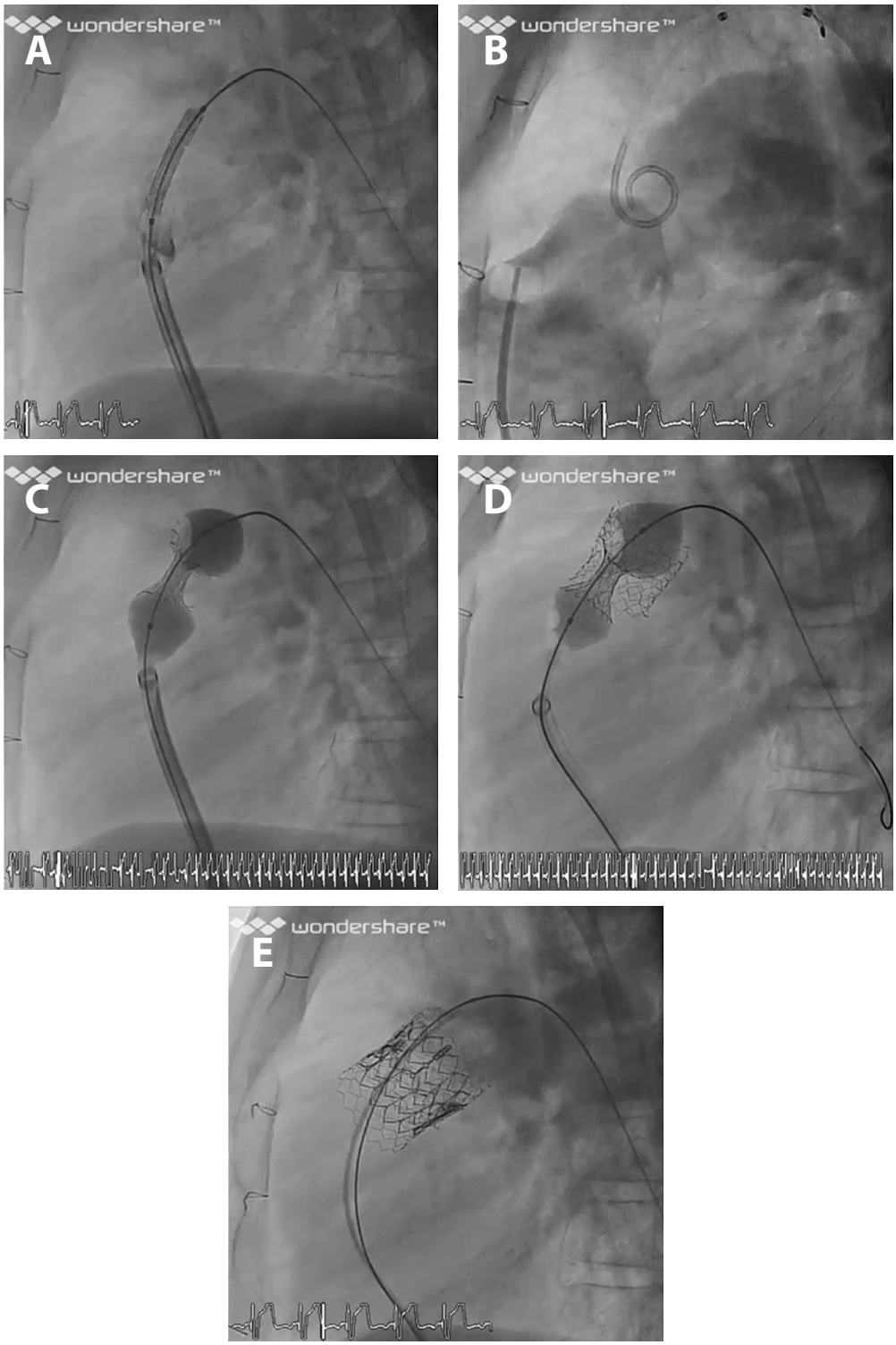

Figure 4 (videos): Sequence of angiograms in wide RVOT pre-stent, following two stents and a SAPIEN XT. Courtesy Dr Mansour Aljufan. Panel A. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017.016.14.vid.01. Panel B. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017.016.14.vid.02. Panel C. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017.016.14.vid.03. Panel D. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017.016.14.vid.04. Panel E. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017.016.14.vid.05.

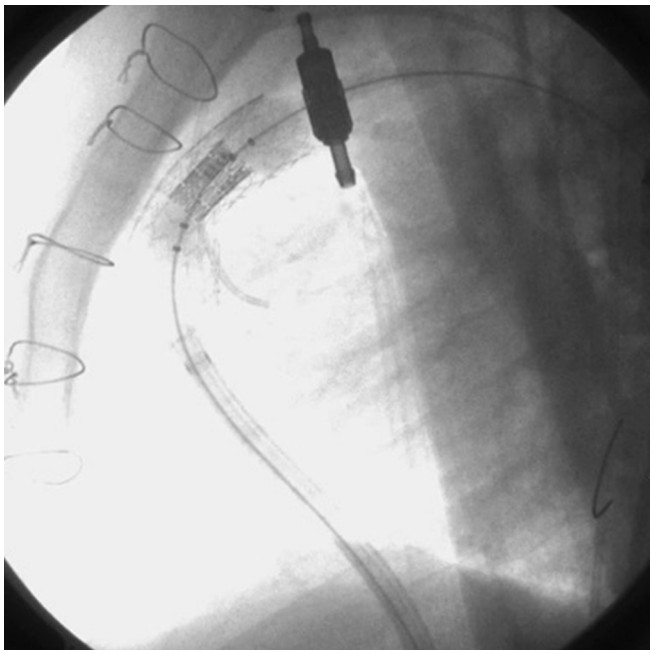

Figure 5 (video): Note slow balloon inflation and fine tuning of valve position to landing zone. Balloon bursts at full inflation but valve is fully deployed and stable. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017.016.14.vid.06.

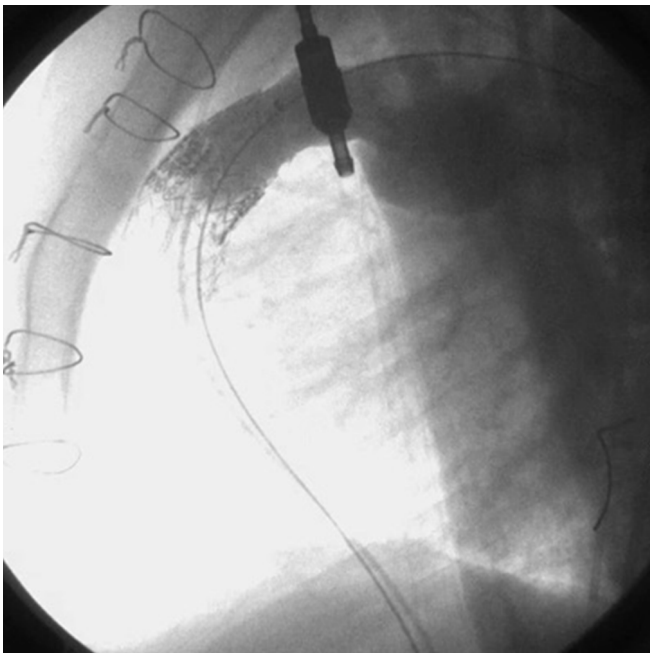

Figure 6 (video): Note circular Edwards valve configuration for optimal function. View supplementary video at http://dx.doi.org/10.12945/j.jshd.2017..016.14.vid.07.

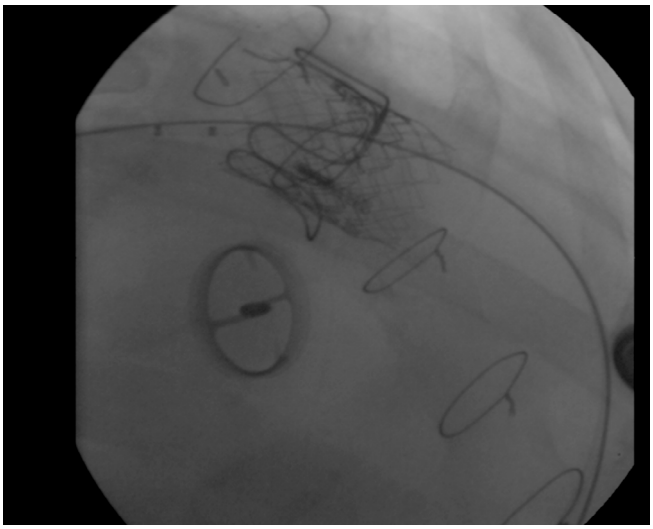

Figure 7: Valve-in-valve device with pre-stenting of RVOT. Courtesy of Dr. Eric Horlick.

landing zone. This may require perseverance and usually requires steady forward push but avoid rotation. It is essential to maintain the wire position in the pulmonary artery, although sometimes gentle traction is needed to straighten the course. Occasionally, it may be necessary to push the delivery system to create a loop in the right atrium in order to reach the landing zone, but this should be used only when necessary, as it may kink the wire or damage the delivery system and may cause damage to the heart. Once the valve is in an optimal position, the balloon is gently inflated to the predetermined volume for the valve size using the Atrion inflation device. The balloon is inflated gradually to give the operator chance to fine tune the valve position either by pushing the delivery system forward or pushing the wire to retract the system proximally. For large RVOT where there is marked movement during the cardiac cycle, fast ventricular pacing may be used to achieve stability; this can be assessed during balloon interrogation of the RVOT. If the procedure is being carried out under anesthesia, the operator can request apnea to minimize movement during valve deployment. It is important to inflate the balloon fully with the pre-determined volume. Occasionally, one may anticipate that a larger volume than the nominal may be required in which case the Atrion syringe may be filled with an additional 1–3 cc but only to give additional volume if it appears that

the valve may not be totally stable so it is important to deflate the balloon slowly and observe the valve carefully. It is common for the blood pressure and heart rate to fall during valve deployment but these recover quickly. Once the balloon is fully deflated, the delivery system is withdrawn under fluoroscopy making sure that there is no resistance against the Edwards valve. It may be necessary to adjust the wire to keep the balloon in the center of the valve during withdrawal. The gradient can be measured using a multi-track catheter over the wire and a pulmonary angiogram is performed to make sure the valve is competent. Mild regurgitation is acceptable especially when there is still a catheter across the valve, but if the leak is more than mild, it is important to establish if this is due to a paravalvular leak or leaflet dysfunction. A paravalvular leak, if significant, may be addressed by inflating the balloon to a larger diameter adding between 1–3 cc to the nominal volume. If the leak is due to valve dysfunction, ICE may be required to establish the reason. If this is due to a stuck leaflet, this may be mobilized using a pigtail catheter, but if the valve leaflet is damaged, a valve-in-valve device should be considered. With the NovaFlex/Commander system, the valve is pushed over the balloon against the leaflets and theoretically, damage can occur but in vitro testing has shown that this is not a problem.

If the hemodynamics are satisfactory and the valve is stable, the wire can be withdrawn and the procedure terminated. It is advisable for the dilator to be placed within the eSheath during withdrawal in order to avoid inadvertent pinching of the IVC wall as this may cause vessel tear with uncontrollable internal bleeding. It is customary to prescribe an antiplatelet agent for 6 months; many administer antibiotic prophylaxis for invasive procedures for the first 6 to 12 months, although this depends on local and national practice (Figures 4, 5 and 6).

If there is an existing failing bioprosthetic valve in the pulmonary position, an Edwards TM valve can be placed within the surgical valve; in this situation, pre-stenting is not usually required and coronary compression is not an issue. Pre-stenting may be needed if the obstruction extends beyond the bioprosthetic valve. What is essential is to find out exactly what type and size of bioprosthetic valve had been implanted and to know the exact characteristics of the valve, including the height, internal diameter and the leaflet design as this will determine the precise position of the Edwards valve within the bioprosthesis. In general, only one row or part of this of the Sapien is deployed proximal to the surgical valve ring and the majority of the implanted valve is distal to the surgical ring in order to open up the degenerated leaflets of the surgical valve.

Tips to reach RVOT

The delivery system is stiff and unwieldy and the course to reach the RVOT can be tortuous and in different planes, this making it difficult to deliver the mounted valve to the RVOT. A very stiff wire helps to rail road the valve but this can sometimes also proved a handicap particularly when the RVOT has been presented and the wire abuts against the stent preventing free movement of the valve in the RVOT. When difficulties are experienced delivering the Sapien from the IVC to the RVOT, there are several tips that can be considered:

a) Make the delivery system less stiff by withdrawing the catheter on the delivery system proximally. A variable degree of withdrawal can be checked to get the best of stiffness and softness for smooth movement of the valve. If the valve is in the right ventricle but cannot reach it's target in the RVOT, the catheter may only need to be withdrawn to the level of the tricuspid valve.
b) Balloon assisted wire anchoring. This is achieved by inserting a separate wire in the pulmonary artery where the stiff wire has been parked and a balloon is inflated in the pulmonary artery adjacent to the deployment wire in order to anchor this and achieve counter traction to help deliver the Sapien in the RVOT. The wire and balloon must be withdrawn before valve deployment.
c) Partial inflation of the balloon on the delivery system. This only requires 1 -2 cc of dilute contrast delivered through the Atrion and observed on fluoroscopy in order to create a smoother tip particularly if the RVOT is heavily calcified or if it has been presented.
d) Replace wire with a less stiff alternative. A very stiff wire may be more of an obstacle when the

valve is trying to reach the RVOT and it can be replaced with a less stiff valve so long as the distal tip of the delivery system is already in one of the pulmonary arteries.

Consider doing any of the above one at a time. A constant but gentle push on the delivery system with controlled counter traction on the wire are much more likely to be successful in reaching the RVOT than aggressive pushing and struggling.

Complications

The procedure is generally safe but the following complications may occur:

a) Vascular injury that may require surgery
b) Stent or valve displacement
c) Conduit rupture
d) Tricuspid valve damage
e) Arrhythmias which include heart block or ventricular tachycardia/fibrillation
f) Valve malfunction – may require a valve-in-valve device
g) Coronary occlusion
h) Infection
i) Death

Current Limitations

a) Anatomical features. As many as 70% of patients with Fallot's Tetralogy will require a trans-annular patch and this can become large and aneurysmal over the years. Although a 29 mm valve in the pulmonary position is adequate for haemodynamic purposes, some RVOTs can be much larger. For this reason, several options are being considered by manufacturers including the concept of a reducer designed to narrow the RVOT to allow placement of a 29 mm Sapien or to have a combined reducer with an integral valve to accommodate within the very dilated RVOT. There are several designs being evaluated at the moment, most of which using self expanding Nitinol technology.
b) Technical issues. The current loading design with the valve mounted on the shaft and eventually placed on the balloon within the patient has allowed for smaller introducer sheaths. This design works well for the aortic implantations and for the majority of pulmonary ones too. There are, however, 2 theoretical concerns when the Sapien is pushed over the balloon when orientated for placement in the RVOT
c) The valve is pushed over the balloon against the valve leaflets whereas for aortic implantation the leaflets are in-line and less likely to be damaged by the balloon. This is more theoretical although there are anecdotal reports of valve leaflet damage but the precise cause was not established.
d) The uncovered distal valve frame is pushed against the balloon and the sharp tips of the cells may potentially create pinhole punctures in the balloon which may impede full balloon inflation. It is always wise to have a Luer lock syringe with dilate contrast available in case balloon perforation has occurred and rapid injection is required to inflate the balloon and deploy the valve avoiding displacement from the target zone.

If operators are concerned about the above potential problems, an option is to mount the Sapien directly on the balloon outside the patient (instead of placing the valve on the catheter shaft) but this will mandate using a larger sheath; however, this is not usually an issue for pulmonary valves as the veins are large and stretchable and do not have the stenotic calcified lesions seen in the iliac arteries when the Sapien is used for TAVR.

Conclusion

The Edwards XT and Edwards 3 valves are very suitable for implantation in the pulmonary position. Their size range from 20 to 29 mm and this allows for broader indications; the XT valves are all delivered through a NovaFlex delivery system whereas the Sapien 3 uses the Commander delivery system [3-7]. The technique is well established. Pre-stenting is often performed except for some types of valve-in-valve implantation. Longevity is expected to be similar to surgical bioprosthetic valves and is likely to take over most cases for pulmonary valve replacement, although a few may still require surgery. The Compas-

sion and Premiere studies should give valuable data on the procedure as well as longevity and follow up.

Acknowledgements

We would like to thank Dr Mansour AlJufan for the videos shown in Figure 4 and to Dr. Eric Horlick for Figure 5.

Conflict of Interest

The author has no conflict of interest relevant to this publication.

Comment on this Article or Ask a Question

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CSI Asia-Pacific 2017 Abstracts

20th Annual Meeting, Miami Beach, Florida, January 16, 2017 – January 19, 2017

FEATURES OF PERIPARTUM DILATED CARDIOMYOPATHY

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Objective: To study the clinical course and prognosis of patients with peripartum cardiomyopathy form (PPCM).

Methods: A total of 50 PPCM patients aged 20 to 41 years (mean age 28,2 ± 0,8 years). All patients underwent: Holter ECG, echocardiogram, 6-minute walking test (6MWT) with the definition of NYHA class, and life prognosis. Studying the dynamics of the disease lasted from 3 to 175 months (med 67,4 ± 5,4 months), while the mortality rate was 34% (17 patients). Patients were divided into 2 groups: I- amounted 17 patients died in the period from 3 to 131 months of observation (36,6 ± 7,2 months.). II -33 patients, survivors in the 31 to 175 months (On average 83,1 ± 5,7 months; p <0.001) surveillance. The nature of therapy in these groups did not differ.

Result: A group of patients with lethal outcome, compared with patients surviving in the control period was characterized by significantly higher NYHA class: 3,6 ± 0,1 and 3,2 ± 0,1 ,respectively (p = 0,01), and disease duration was 7,8 ± 1,8 and 6,2 ± 1,2 months, respectively (p> 0.05). The length of the distance by 6MWT in the reference period in group I was 25.6% lower than in the group II, and amounted to 170.3 ± 15.7 m and 214 ± 12,1 m (p = 0.02) respectively. In group I there is a marked decrease in the ejection fraction (EF) of LV (32,6 ± 1,7% and 37,6 ± 1,8%; p = 0.01), which was accompanied by significant differences in the linear dimensions of the heart; EDD 6,8 ± 0,2 and 6,4 ± 0,09 sm (p = 0.04), ESD 5,9 ± 0,1 and 5,5 ± 0,3 sm (p = 0.01). In the analysis of ECG, a worse performance observed in group I; violation of AV conduction of I degree found in 5 (29.4%) and 4 (12.1%) pts, atrial fibrillation, paroxysmal in 3 (17.6%) and 1 (3.03%), Q wave in 3 (17.6%) and 1 (3.03%) cases, respectively, met group I and II, but was not statistically significant. Holter ECG showed that the PVCs of high grade was detected significantly more often in the deceased group (both P <0.05); Man 12 (70.6%) and 12 (36.4%), 6 (35.3%) and 3 (9.1%), an unstable ventricular tachycardia (less than 30 seconds) is set at 2 (11.8%) and 4 (12.1%), sustained at 1 (5.9%) (30 seconds) of cases recorded only in the deceased group.

Conclusion: The results of the study of the life prognosis of patients with PPCM with prolonged follow-up (67,4 ± 5,4 months) showed that mortality rates was 34% (17 cases). The case of fatal heart failure is characterized by relatively severe symptoms, accompanied by a deterioration of the main parameters of intracardiac hemodynamics and accompanied by a significant increase in the incidence of ventricular arrhythmias of high gradation.

TRANSCATHETER RECONSTRUCTION OF SUBAORTIC RIDGE WITH CLOSURE OF PERIMEMBRANOUS SUBAORTIC VSD WITH OR WITHOUT AR

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Background: Subaortic ridge (SAR) is almost always a progressive disease and recurrence after surgery may occur in nearly one third of patients.

Objective: To evaluate the safety and efficacy of management of PM VSD and SAR with or without AR using ADO type I.

Methods: During the period from 1/2/2014 to 1/10/2016, 29 of 318 patients (9.1%) with PM VSD were found to have SAR. The same protocol for catheter closure of PM VSD under TTE was done. The aortic disc of the device was pulled toward the defect capturing and/or compressing the ridge against the ventricular septum.

Result: The patients age ranged from 1.5-35 years (mean=6.1 years) and their weight ranged from 7-73 kg (mean=16 kg).Those patients almost always have VSDs with complex anatomy including their close proximity to the aortic valve with 20-30% of malalignment, prolapsing RCC &/or NCC was found in 22 patients (75.8%) with mild-moderate AR in 11 patients (38%) whose TTE follow up revealed improvement in the severity of the AR. Obstructive SAR was found in 8 of 29 patients (27.6%) with the mean LVOT PG of 25 mmHg. Successful VSD closure with capturing and/or compressing the SAR was achieved in

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24 patients (82.7%). Implantation failed in five patients due to deficient aortic rim in two patients and increased severity of AR in the other three patients.

Conclusion: Transcatheter closure of PM VSD with SAR using ADO type I is safe and effective with the very low incidence of complications.

STAGED SWISS CHEESE VSD CLOSURE

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An 8-year old male with cleft lip and palate presented with multiple muscular ventricular septal defects (VSD) diagnosed since 6 months of age. Anti-heart failure medical treatment with furosemide and digoxin were commenced by another cardiac center and was continued until the present time. Financial constraints prevented the performance of surgical correction, which was advised on numerous occasions.

2D echocardiogram showed multiple muscular VSDs with the most prominent being two muscular VSDs, measuring 7-8 mm and 5-6 mm located near the apex. There was some left to right shunting, left heart enlargement and signs of severe pulmonary hypertension (severe tricuspid regurgitation, right ventricular hypertrophy). He was planned for transcatheter closure of these 2 larger defects.

Under general anaesthesia and 100% oxygen support, the pulmonary artery pressure was documented at (103/50 mmHg, mean of 75 mmHg) 80% of systemic pressure. The Qp/Qs was 3:1 on oxygen. Left ventricular angiograms showed a midmuscular VSD (LV side 9.4 mm, RV side 6.6 mm, length 11.9 mm) and apical VSD (6.6 mm). The midmuscular VSD was accessed using a modified pigtail catheter. An AV loop was created from the femoral vein and the VSD was closed in standard fashion using a Cocoon VSD 12-7 mm through an 8F sheath. The position of the device was confirmed by angiography and transthoracic echocardiography. The apical VSD was crossed antegradely from the RV accessed from the internal jugular vein using a JR4 catheter over a glidewire with the tip positioned in the descending aorta. A 7F ductal delivery sheath was advanced from the right IJ over the wire and a 10-7 mm Cocoon VSD occluder was deployed under fluoroscopic and echocardiographic guidance. The patient tolerated the procedure without untoward events and was discharged with the following medications: aspirin (4 mg/kg/day), sildenafil (2 mg/kg/day), furosemide (0.5 mg/kg/day), captopril (1 mg/kg/day) and digoxin (10 mcg/kg/day). Repeat echocardiogram two days after the procedure showed the two devices in place without leak, but there were still another two muscular VSDs (4.5 mm and 6 mm) located between the two Cocoon VSD devices.

After two years from the transcatheter closure of the 2 muscular VSD, he was readmitted for transcatheter closure of the remaining muscular VSDs. Hemodynamic study on 100% oxygen showed the PA pressure at 90% systemic. The Qp/Qs was 2.2:1 with a PVR of 3.9 Wood units/m2. Left ventriculogram revealed two midmuscular VSDs measuring 5.8 mm (superior) and 5.5 mm (inferior).

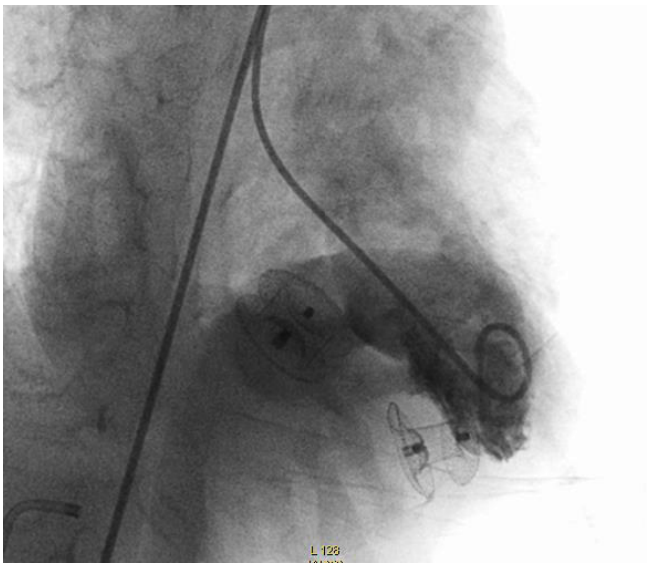

Figure 1.

The two VSDs were crossed and closed sequentially in standard fashion using a 6-7 mm Cocoon VSD occluder in each VSD. There was still some small residual VSD after these residual VSDs were closed, as is expected in this type of VSD.

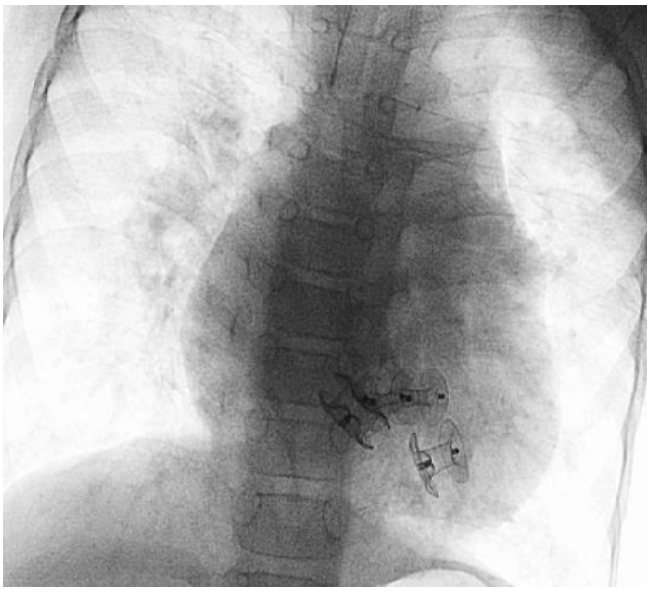

Figure 2.

The child tolerated the procedure without untoward events and was discharged with the following medications: aspirin, sildenafil, furosemide, captopril and digoxin. This case demonstrates the feasibility and safety of staged closure of Swiss cheese VSD using the Coccon device.

CATHETER CLOSURE OF CATHETER CLOSURE OF SINGLE PVL (PARAVALVULAR LEAK) MAY EXACERBATE PVL AT ANOTHER LOCATION: A REPORT OF TWO CASES

Takeshi Arita[1], Hidehiko Hara[2], Hirotaka Noda[1], Taku Yokoyama[1], Go Hashimoto[2], Hiromichi Sonoda[3], Akira Shiose[3], Ken-ichi Hiasa[4], Keita Odashiro[1], Koichi Akashi[1]

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Case 1: A 70-year-old female who underwent mitral valve replacement twice developed heart failure due to severe PVL at medial location. Small PVL was also noted at the lateral location. We performed catheter closure of medial PVL using Occlutech PLD device with marked reduction in PVL. Six months later, echocardiography revealed exacerbation of lateral PVL.

Case 2: An 85-year-old male with a history of mitral and aortic valve replacement developed heart failure due to PVL. Echocardiography revealed severe medial PVL and trivial lateral PVL. We performed transapical catheter closure of medial PVL using Occlutech PLD device with an elimination of PVL at the medial location. Two months later, he developed severe hemolytic anemia for which exacerbated lateral PVL is thought to be culprit.

In cases with multiple PVLs, single closure of PVL may exacerbate another PVL possibly due to altered hemodynamical load.

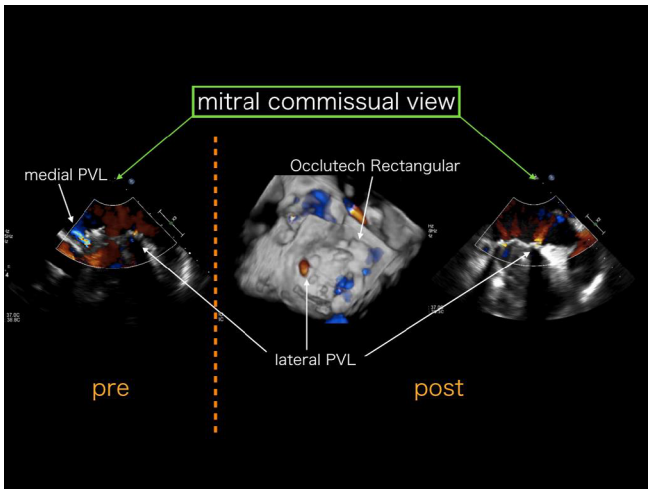

Figure 1.

PERCUTANEOUS ASD & VSD CLOSURE OF A 4 MONTHS OLD INFANT IN THE SAME SESSION

Ali Baykan / Nazmi Narin / Ozge Pamukcu / Kazim Uzum / Suleyman Sunkak

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Objective: Percutaneous closure of septal defects is a successful treatment modality that has been used for a long period of time in children. Our main objective in this case report is to present the transcatheter closure of atrial and ventricular septal defects of four months old infant in the same session. As far as we know this case is the youngest patient on whom percutaneous VSD closure was done in the same session with ASD closure.

History and Physical: Four months old boy with tachypnea, tachycardia diagnosed to have aneurysmatic perimembranous ventricular septal defect (VSD) sized 4 mm and atrial septal defect (ASD) sized 8 mm. Anti-congestive treatment was started but despite treatment, his symptoms continued and he was hospitalized 3 times for lower respiratory tract infections.

Indication for Intervention: Surgery was found as too risky because his lung parenchyma was not good and body weight was low. Therefore transcatheter closure was planned.

Intervention: VSD was closed with 4x4 Amplatzer® Ductal Occluder II device, ASD with 9 mm sized Amplatzer® Septal Occluder. In his first month control his complaints relieved and body weight was increased to 6.2kg.

Learning Points of Intervention: Percutaneous ASD and VSD closure is being done safely in children, but for the first time, percutaneous VSD closure was done in an infant with low body weight in the same session with ASD closure successfully. This case will be an encouraging example for the future.

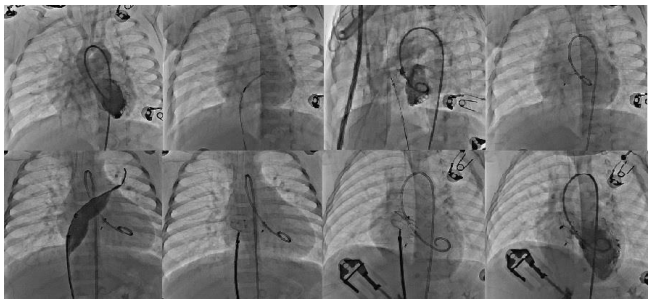

Figure 1.

EXPERIENCE ON PERCUTANEOUS TRANSLUMINAL MITRAL COMMISURIOTOMY IN SHAHID GANGALAL NATIONAL HEART CENTRE, BANSBARI, KATHMANDU, NEPAL

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Rheumatic Heart Disease (RHD) is the most common acquired heart disease in children in developing countries. RHD continues to be an important public health problem in Nepal. Approximately 25% of patients with RHD have isolated mitral stenosis (MS), and an additional 40% have combined MS and mitral regurgitation (MR). Based upon the nature and severity of MS, patients can be managed with medical management, percutaneous transluminal mitral commissurotomy (PTMC) or surgery. Since 1984, PTMC has revolutionized the treatment of patients with symptomatic MS. It has established itself as the procedure of choice for symptomatic MS patients. PTMC is recommended for symptomatic patients with severe MS (mitral valve area (MVA) ≤1.5 cm2) and favorable valve morphology in the absence of left atrial (LA) thrombus and or moderate-to-severe MR.

PTMC in Overall Patient at SGNHC: To serve the Nepalese patients with MS, PTMC service started in National heart centre in 2001. First PTMC in the centre was done on 14th April 2001. Till June 2016, 6023 PTMC were done in SGNHC. Government of Nepal provides free PTMC services to all the patients. In the first study published to evaluate the safety and efficacy of PTMC, two hundred patients from January 2003 to July 2004 were studied. Seventy four percent of the patients were female. Age ranged from 10 years to 61 years with the mean age 29 years. Mean MVA increased from 0.9±0.1cm2 to 1.8±0.2cm2. Mean LA pressure decreased from 21 to 7 mmHg. There was no mortality during the hospital stay or within the first month of the procedure. Two patients developed severe MR.

In another study, 1001 patients from March 2003 to March 2008 were studied. Seventy eight percent were female. Age ranged from 9 years to 68 years with mean age 31.2±12.4 years. MVA increased from 0.88±0.1cm2 to 1.67±0.2cm2. LA pressure decrease from 29.7 ± 8.6 to 12.8± 5.3 mmHg. Severe MR was noted in 2.1% patients. One had to undergo urgent mitral valve replacement (MVR) due to severe MR, two died of pulmonary edema due to severe MR. There were three deaths due to cardiac tamponade and one death in pregnant women who died due to abortion and septicemia.

In a recent prospective study, 262 patients who underwent PTMC during July 2013 to June 2014 were studied. Seventy four percent of the patients were female. Age ranged from 10 to 76 years with mean age of 33.2±12.5 years. Mean LA pressure decreased from 26.8 ± 8.9 mmHg to 15.6 ± 7.2 mmHg. MVA increased from 0.9 ± 0.17 cm2 to 1.6 ± 0.28 cm2. Moderate to severe MR was seen in 49(18.7%) patients after PTMC but none of them required emergency MVR. There was no mortality related to the procedure.

PTMC in Elderly: In a retrospective study in elderly (≥60years) patients, 49 patients underwent PTMC between March 2007 to March 2013 were studied. It accounts less than 2% of the total PTMC done during the study period. The MVA increased from 0.9±0.1 to 1.6±0.3 cm2 following PTMC. Mean LA pressure decreased from 25.4±6.6 to 12.9±4.5mmHg. Severe MR occurred in one patient. There were no other complications like death or pericardial effusion.

PTMC in Children: In a retrospective study performed from November 2009 to May 2013 to evaluate the safety and efficacy of PTMC in children. During the study period 2237 patients, among them 100 patients aged less than 15 years underwent PTMC procedure for severe MS. After PTMC, MVA increased from 0.7±0.1cm2 to 1.5±0.3 cm2 and mean LA pressure decreased from 29±7.9 mmHg to 13.9±6.2 mmHg.

PTMC in Juvenile Patients (Younger Than 20 Years Of Age): In a retrospective study of PTMC in 131 juvenile patients who underwent elective PTMC from July 2013 to June 2015 were studied. The mean MVA increased from 0.8±0.1 cm2 to 1.6±0.2 cm2 following PTMC. Mean LA pressure decreased from 27.5±8.6 to 14.1±5.8 mmHg. Post procedure severe MR was seen 3.8% patients. Among them one patient needed MVR after the PTMC, patient died after MVR.

PTMC in Pregnancy: A study was done among twenty two pregnant women from Jan 2003 to Dec 2007 to evaluate the safety and efficacy of PTMC with severe MS.PTMC was done during the 24.2±4.6 weeks of gestation. Mean age was 23±4.2 years and two patients were in AF. Fluoscopy time needed to complete the procedure was 7.5±4.8min. Procedure was successful in all patients. Mean MVA increased from 0.7±0.2cm2 to 1.8±0.2cm2. Mean LA pressure decreased from 28.1±4.3mmHg to 15.3±6.2mmHg.Twenty patient had a normal delivery whereas two underwent caesarean section. There was no maternal morbidity or mortality or intrauterine growth retardation.

Though there are multiple studies to study the safety and effectiveness of PTMC in our patients we still don't have any study about the long-term effect of PTMC in our patients. We need a long-term study to evaluate the safety and efficacy of this simple procedure in near future.

BALLOON DILATATION OF PULMONARY ARTERY STENOSIS FOLLOWING ARTERIAL SWITCH OPERATION FOR COMPLETE TRANSPOSITION OF THE GREAT ARTERIES

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History and Physical: This is a case of a neonate who consulted due to cyanosis. He was born to a 25 year old G2P1 mother via normal spontaneous delivery. He had unremarkable birth and maternal history but was noted to have cyanosis on the 2nd day of life. He was brought to the Philippine Heart Center and was subsequently admitted. Physical examination reveals oxygen desaturation at 64% with a grade 3/6 continuous murmur on the left upper sternal border. 2D-echocardiography revealed CHD, D- Transposition of the Great Arteries with intact ventricular septum, Patent Ductus Arteriosus and Patent foramen Ovale. He underwent Arterial Switch Operation with PDA ligation and immediate improvement of the oxygen saturations was noted at 80 %. However, 2 months post-operatively, he presented again with desaturations as low as 50%. Repeat 2-dechocardiography showed supravalvar pulmonic stenosis with a gradient of 93 mmHg across the stenotic area. He was referred to Pediatric Invasive Cardiology for Percutaneous Pulmonic Balloon Valvulotomy.

Physical examination revealed vital signs as follows: cardiac rate of 130s, respiratory rate of 42 cycles per minute with oxygen saturation

of 70-80%. He was awake with dusky oral mucosa. There was an equal chest expansion with no rales and wheezing. He had adynamic precordium, point of maximal impulse at 4th ICS, S1 normal, S2 single with 3/6 systolic ejection murmur at LMCL. Liver was not palpable with no abdominal masses. There were full equal pulses with dusky nailbeds.

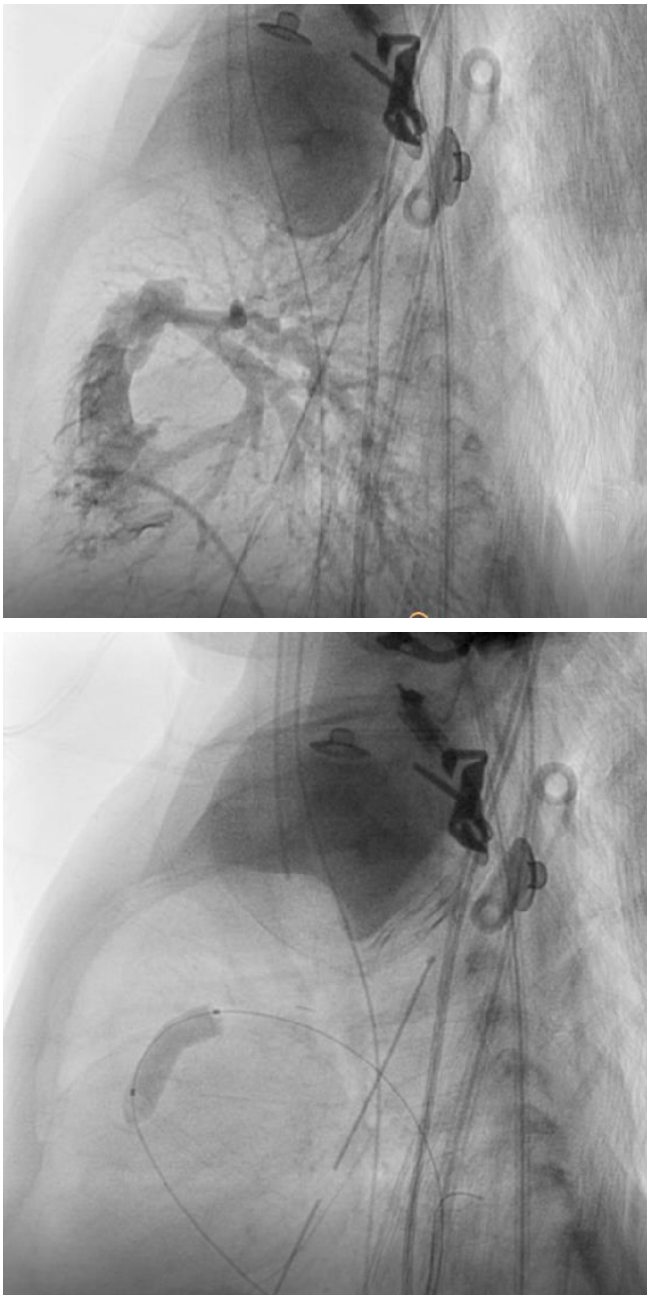

Figure 1.

Indication of Intervention: TOF is the most common form of cyanotic CHD. A 2002 meta-analysis of the incidence of CHD, which included 41 studies pertaining to TOF, suggested that the best estimate of incidence would be 577 cases of TOF per million live births. Surgical options for management of symptomatic neonates and young infants with TOF include both complete repair and interim Blalock-Taussig (BT) shunt. However, there is significant peri-operative morbidity that includes prolonged mechanical ventilation, increased inotrope requirement and end organ dysfunction. The additional disadvantages include the need for ventriculotomy and higher risk of reoperation. Due to the increased demands of postoperative care coupled with these disadvantages, many centres are reluctant to attempt primary repair of TOF in infants less than three months of age. This is particularly true for centers in the developing world where the resources are limited. The alternative to corrective operation is palliation with BT shunt in very young infants, which is still advocated. The limitations of this procedure include the risk of distortion of branch pulmonary arteries in up to 15 to 20% and shunt occlusion in another 3 to 6%. In addition, there is significant postoperative morbidity and mortality following neonatal BT shunt. Balloon pulmonary valvotomy has been previously attempted in TOF as a palliative measure. The right ventricular outflow tract (RVOT) obstruction in TOF is often at multiple levels: infundibulum, valve, annulus and, main and branch pulmonary arteries. Balloon pulmonary valvotomy can potentially offer reasonable interim palliation for infants with predominant valvar pulmonary stenosis (PS).

Intervention: Right heart catheterization was performed through a right femoral vein percutaneous puncture. A french 4 sheath was inserted and a french 4 pigtail catheter was manipulated under fluoroscopic guidance into the IVC, RA, RV and LA through the patent foramen ovale. Oximetry studies and pressure recordings were taken from selected vessel and chamber entered. RV angiogram was done using LAO, Cranial and lateral views showing opacification of the RV with passage of dye to the main pulmonary artery and to the aorta and its branches and PDA. Infundibular stenosis was noted on the right ventricular outflow tract. Confluent right and left pulmonary artery was also noted. The PDA was noted to be tubular and measured at 2 mm. PDA stenting was done using Omega Monorail 3x8mm. Exchange guidewire was inserted and placed in the peripheral pulmonary artery. The catheter was removed with the guidewire in place and replaced by TMP Ped pulmonary valvotomy balloon catheter measuring 6 mm x 20 mm was inserted and inflated until the waist disappeared. Two inflations of the balloon catheter was done.

Learning Points of the Procedure: Balloon dilatation of the pulmonary valve is an effective and safe palliation in tetralogy of Fallot. It promotes growth of the pulmonary vascular tree, reducing the need for trans-annular patching and is recommended in symptomatic infants of very young age, with a small pulmonary annulus (Z value below - 4 SD) and associated cardiac anomaly. (Eur Heart J 1998; 19: 595–600). The patient had improved oxygenation at 80-90 % discharged after with regular follow up awaiting total correction.

CLOSURE OF VENTRICULAR SEPTAL RUPTURE USING VENTRICULAR SEPTAL OCCLUDER AFTER MYOCARDIAL INFARCTION

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History and Physical: This is a case of a 64 years old female, newly diagnosed with diabetes mellitus, who came in due to chest pain.

Two months prior to admission, patient had sudden onset of severe chest pain. She was subsequently admitted at the National Kidney and Transplant Institute and managed as a case of Acute Coronary Syndrome. During this admission, the patient had episode shortness of breath associated with orthopnea and exertional dyspnea. Two-dimensional echocardiography was done which revealed ejection function of 62 – 69 %, concentric left ventricular hypertrophy with hypokinesia of the left ventricular apex with suspicious flow across the muscular interventricular septum indicating a ventricular septal rupture shunt. The patient was stabilized and was discharged improved.

Five days prior to admission, she was noted to have progressive bipedal edema. She was then readmitted at the NKTI. One day prior to admission, she was noted to have shortness of breath along with epigastric pain and vomiting. The patient was transferred to our institution for intervention.

On physical examination, the patient had stable vital signs, not in distress and ambulatory. Neck veins were distended. On chest examination, there was no lagging and retractions but with crackles on bilateral mid to lower lung field. The patient had adynamic precordium, point of maximal impulse at the 5th intercostal space left mid clavicular line, with thrill at the left parasternal area, no heave, S1 normal, S2 split, normal rate, regular rhythm, grade 4/6 holosystolic murmur over left parasternal and apical area. The abdomen was soft, not distended, no ascites but with palpable liver edge 3 cm below subcostal margin. The lower extremities showed grade II pitting bipedal edema with full pulses.

The assessment on admission was Atherosclerotic Heart Disease, Coronary artery disease, s/p Acute coronary syndrome (March 2016), Ventricular septal rupture, Congestive Heart failure, NYHA Functional classification II-III, Diabetes Mellitus type 2.

On admission, the patient was worked-up. She underwent coronary angiography with noted one vessel disease (LAD). On LV angiogram, contrast injection showed passage of dye from LV to RV through the muscular part of the interventricular septum. On the 6th day, the patient underwent ventricular septal rupture device closure using VSD occluder size 17/10. The patient was able to tolerate the procedure well. On the 18th hospital day, the patient then underwent PCI.

Indication of Intervention: The indication for closure of an interventricular septal defect after acute myocardial infarction causing hemodynamic compromise with evidence of loud holosystolic murmur and left ventricular dysfunction with lower extremities edema is warranted in our patient. The prognosis of post – AMI VSD is very poor, with mortality rates as high as 50 % at 1 week and 90 % at 2 months with conservative medical management. The patient had a history of AMI 2 months prior to admission and surgery is technically difficult owing to the myocardial tissue being soft and friable. Percutaneous closure device closure is a viable option in chronic period in patients with co morbidities and whose septal anatomy is favourable to device placement. The patient presented with ventricular dysfunction, with history of diabetes which put her to a high risk candidate for surgery. The septal anatomy of the ventricular rupture of the patient was at the muscular area, which is the only area recommended by the American Heart Association for device closure.

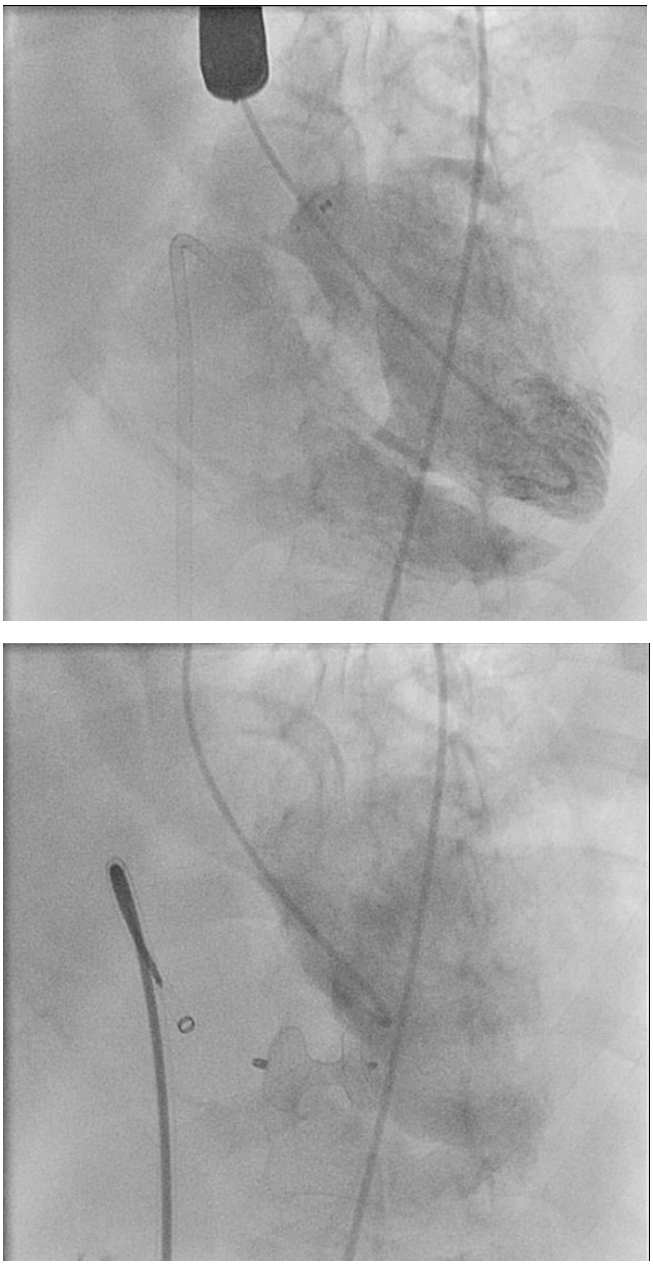

Figure 1.

Intervention: The patient underwent device closure of the muscular ventricular septal rupture on the 6th hospital day of admission. Left heart catheterization was performed via the right femoral artery percutaneous puncture and a French 6 sheath was inserted. A French 6 pigtail catheter was manipulated under fluoroscopic guidance into the descending aorta, ascending aorta and to the LV. LV angiography at LAO 35, cranial 35 showed a muscular ventricular septal defect. Right heart catheterization was performed through a right femoral vein percutaneous puncture. A French 6 sheath was inserted via the right femoral vein. A French 6 multi-snare catheter was then inserted and manipulated under fluoroscopic guidance into the IVC, RA and RV. An arteriovenous guide wire splint was then created. The

long Terumo guide wire 032 x 260 mm from the LV was manipulated thru the VSD to the RV, RA and to the IVC. The sheath was carefully advanced until its tip was placed in the ascending aorta. As soon as the sheath reached the ascending aorta, the arterial catheter was replaced via the guide wire with a pigtail catheter. The terumo guide wire was then pulled out by the snare to the right femoral vein. The introducer set was attached to the guide wire and pulled back to the IVC, RA, and RV thru the VSD and to the LV. A 6/8 mm VSD device occluder was then placed to occlude the VSD. Cineangiography post occlusion of VSD showed the device positioned within the VSD, with minimal shunting of contrast in the center of the device.

Learning Points of the Procedure: This is a novel case of percutaneous device closure of ventricular septal rupture post-MI in our institution. In a study done by Demkow et al, transcatheter closure has improved survival rates in selected patients in suitable anatomy. One of the challenges among interventional cardiologist is the margins of defect wherein the borders on may be necrotic and the poor clinical condition of the patient on presentation. According to Bialkowski et al, procedure failures were observed in acute post-MI VSD and satisfactory in subacute and chronic phase cases which was seen in our case. Therefore, proper patient selection should be done in order to have a favorable outcome.

LUTEMBACHER SYNDROME: A DOUBLE PROCEDURE (PERCUTANEOUS TRANSEPTAL MITRAL COMMISSURROTOMY AND ATRIAL SEPTAL DEFECT CLOSURE

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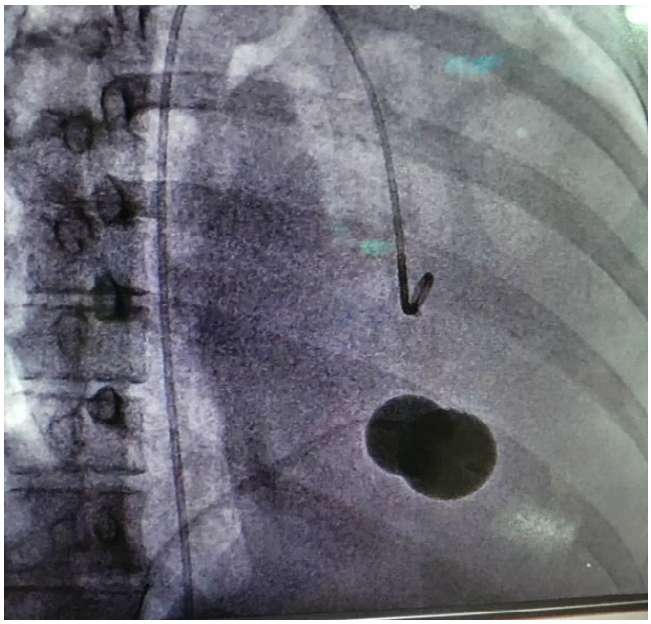
History and Physical: This is a case of a 45 year old female who came in due to easy fatigability. Patient was a diagnosed case of rheumatic heart disease since 1980 but lost to follow up. She had a history of repeated admission for one year prior to admission due to exertional dyspnea and congestion. Two months prior to admission patient was seen at the outpatient department and was noted to have difficulty of breathing, easy fatigability and bibasal rales hence she was admitted and started on medical management. She was discharged in an improved state with plan for interventional procedure. Patient was discharged as a case of rheumatic heart disease, mitral stenosis, atrial fibrillation in chronic ventricular response, NY functional classification II – III. Patient was re-admitted as a case of Lutembacher Syndrome, Atrial Septal Defect secundum type and Rheumatic Heart Disease with severe Mitral Stenosis two months after for interventional procedure.

On physical examination, the patient had stable vital signs with blood pressure of 110/60 mmHg, cardiac rate of 76 beats per minute, not in distress and ambulatory. No neck vein distention nor palpable masses noted. On chest examination, there was a symmetrical expansion with no crackles and wheezing. The patient had adynamic precordium, point of maximal impulse at the 5th intercostal space left intercostal space, no thrill, no heave, S1 normal, S2 split, normal rate, regular rhythm, grade 3/6 diastolic murmur at the apex. The abdomen was soft, not distended, no ascites. There were no cyanosis, no edema with good capillary refill time at < 3 seconds.

Indication of Intervention: The incidence of ASD in patients with mitral stenosis is 0.6-0.7% and the incidence of MS in patients with ASD is 4%. Lutembacher's syndrome is defined as the rare



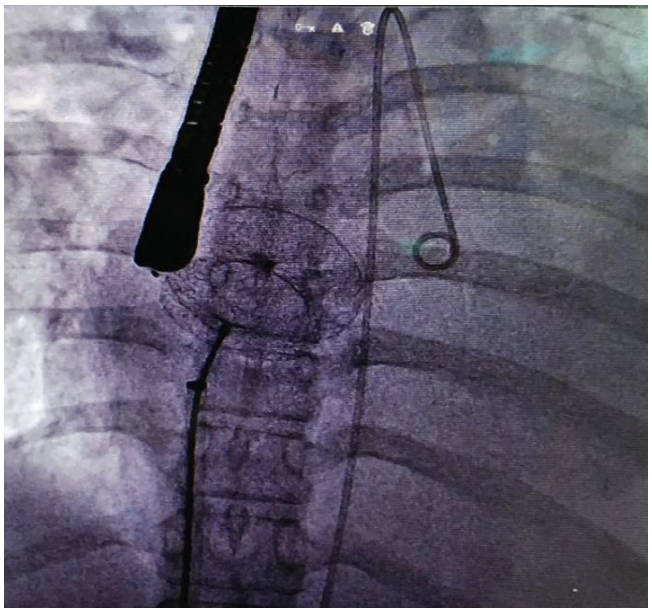


Figure 1.

combination of congenital atrial septal defect and acquired mitral stenosis. The haemodynamic effects of this syndrome are a result of the interplay between the relative effects of the atrial septal defect and mitral stenosis. Mitral stenosis augments the left to right shunt through the atrial septal defect. Because the mitral stenosis was, in fact, rheumatic in aetiology, the syndrome was defined eventually as a combination of congenital atrial septal defect and acquired, almost always rheumatic, mitral stenosis. Percutaneous transcatheter therapy has become the most widely accepted therapy, using balloon mitral valvuloplasty for mitral stenosis and the amplatzer atrial septal occluder for closure of an atrial septal defect. In a study of Uguro SU, et al , percutaneous correction is preferred to surgical correction as there is decreased morbidity compared to open- heart surgery.

There is also faster recovery with decreased length of hospital stay. Indications for percutaneous intervention in these patients include severe mitral stenosis causing hemodynamic instability that causes recurrent admission for the patients.

Intervention: The patient underwent pre - percutaneous mitral commissurotomy transesophageal echocardiogram which showed a mitral valve area of 0.41 cm2 by planimetry with mild mitral regurgitation. Left heart catheterization was done percutaneously using a 6 french pigtail catheter through a left femoral arterial sheath. The catheter was retrogradely advanced to the ascending aorta, aortic valve, and left ventricle. Pre-percutanous mitral commissurrotomy and atrial septal defect closure pressure recordings showed a low systemic arterial pressure of 89/60 mmHg and elevated LVEDP (17 mmHg). The PA pressure was elevated at 77/28 mmHg with no systolic pressure gradient across the pulmonic valve during pullback. The transmitral mean gradient is 10 mmHg. The Mullins catheter was directly inserted into the LA thru the interatrial septal defect and the coiled guidewire was inserted through the catheter into the left atrium. A size 26 mm Mitrapath balloon catheter was inserted over the guidewire and maneuvered sequentially across the interatrial septum and the mitral valve with the aid of a stylet. The balloon was inflated thrice at 23, 24 and 26 mm. The final gradient across the mitral valve was at 6.3 mmHg. Right heart catheterization was done percutaneously using a 7 french Counard catheter through a right transfemoral venous sheath and was advanced anterogradely into the RA, RV, PA and LA through the ASD. An Amplatz stiff wire was introduced as an exchange wire through the Cournard catheter and advanced into the right atrium and through the atrial septal defect into the left atrium with the tip extending beyond the level of the left upper pulmonary vein. The femoral vein sheath was then removed. The introducing sheath with the dilator was advanced over the exchanged wire into the left atrium and was positioned at the left atrium border while the dilator was removed. The delivery cable was passed through the loader and An ASD occluder was screwed clockwise onto the tip of the delivery cable. The device and the loader were then immersed in a saline solution and the occluder was pulled into the loader. The loader was introduced into the delivery sheath and was advanced into the left atrium. The retention skirt was deployed and pulled firmly against the interatrial defect. The position of the device was confirmed through transesophageal echocardiography. The device was adjusted until the retention skirt was well seated in the interatrial septum. The device was then released from the delivery cable and the system removed. Post PTMC intra-procedural 2D echocardiogram showed a mitral valve area of 1.0 cm2 by planimetry.

Learning Points of the Procedure: Percutaneous transcatheter closure of ASD and mitral valvotomy is the treatment of choice for Lutembacher syndrome until and unless the lesions are incongruous for the procedures. The patient was symptomatic with moderate to severe mitral stenosis with valve morphology favorable for PBMV.

CONGENITAL AORTA TO RIGHT ATRIAL TUNNEL: SUCCESSFUL TRANSCATHETER CLOSURE WITH A DUCTAL OCCLUDER

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Aorticocameral tunnels are extremely rare congenital extracardiac vascular channels, which connect the ascending aorta above the sinutubular junction to any of the chambers of the heart. The ascending aorta is reported to be the most common site of origin but rarely tunnel arising from the descending thoracic aorta has also been reported.

More than 90% of the aorticocameral tunnels communicate with the left ventricle, occasionally with the right ventricle, rarely with the atria. The most common of these infrequent conditions is the aorto-left ventricular tunnel (ALVT), followed in frequency by the aorto-right atrial tunnel (ARAT), aorto-right venticular tunnel (ARVT) and the aorto-left atrial tunnel. All of these conditions produce the physiology of congenital aortic insufficiency, but when the tunnel connects to a right heart chamber, an important left-to-right shunt is also produced[1].

History: This is a case of a 20 year old female, born term, with no signs of failure to thrive. At 4 years old, had consult with a private doctor due to recurrent cough, and an incidental murmur was noted. She was managed as a case of Rheumatic Heart Disease with monthly Benzathine Penicillin G IM injections. She was asymptomatic since then with no history of hospitalizations. Until 2 years PTA, patient started to have chest pains and palpitations, but still can do her activities of daily living without difficulty of breathing. With the persistence of chest pain described as squeezing in character, she sought consult at Philippine Heart Center-OPD and several diagnostic work ups were done. She was then advised for coronary angiography.

Patient was a nonsmoker and non alcoholic beverage drinker. No history of illicit drug intake.

Her current medications were Furosemide 20mg OD, and Enalapril 5 mg OD, with good compliance.

Physical Examination:
- Ambulatory and not in respiratory distress
- Vital Signs: CR: 70 bpm RR: 18 cpm O2Sat 99% BP: 90/ 60 mmHg Wt 43.7 kg Ht 153 cm BSA 1.36 m^2
- Anicteric sclerae, Pink palpebral conjunctivae
- No neck vein engorgement, no carotid bruit
- SCE, no retraction, bronchovesicular breath sounds
- Dynamic precordium, AB 6th ICS LMCL, no thrill/heave, normal rate, regular rhythm, S1 normal, S2 split, grade 3/6 continuous murmur heard best at the right mid parasternal border
- Flat abdomen, soft, nontender, no hepatomegaly, no masses
- No clubbing, no edema, equal peripheral pulses
- Grossly normal extremities

She was admitted at the wards. Complete blood count, protime, aPTT, serum creatinine were within normal limits. There was cardiomegaly with RA and RV prominence on the chest radiograph. Preoperative transthoracic echocardiogram showed anterior type of tunnel from the right coronary sinus to the right atrium.

A hemodynamic study with coronary arteriography was done and revealed angiographically normal coronary arteries. Ascending aortogram showed an anterior type of aorto to right atrium tunnel with a constricted and small opening at the right atrial end.

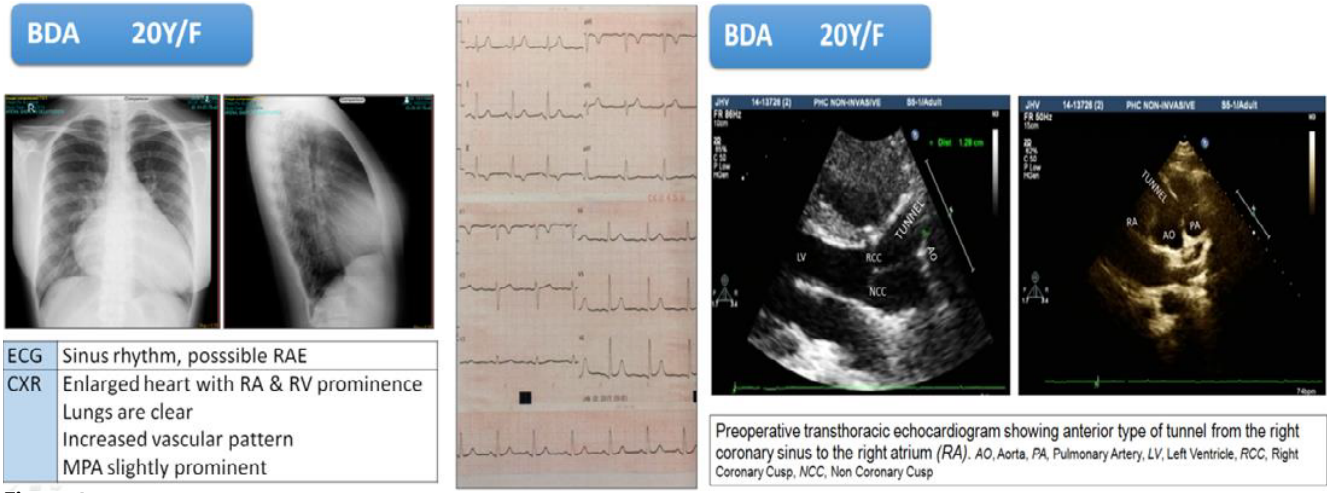

Figure 1.

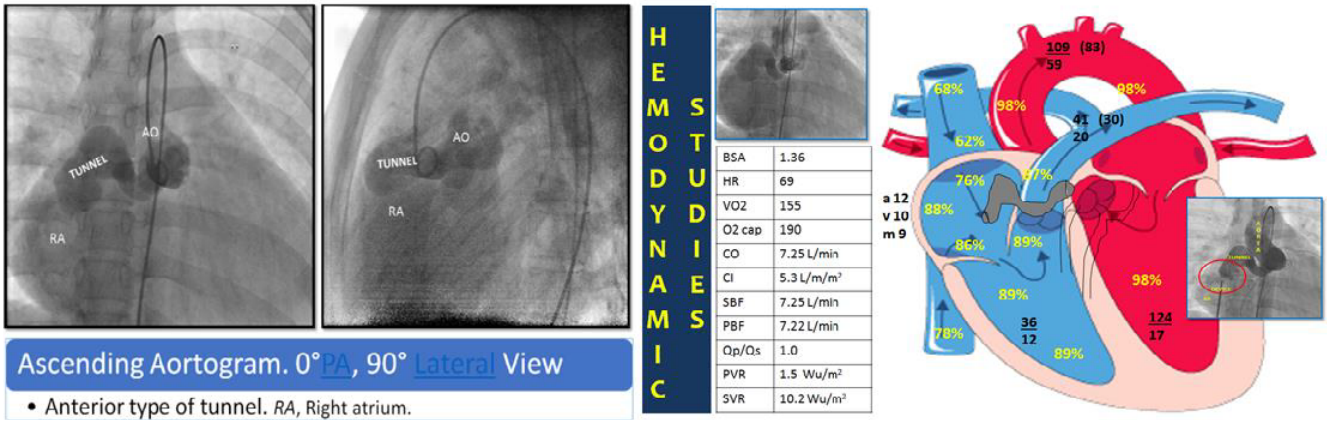

Figure 2.

The closure of an aorta-right atrial tunnel is recommended even in asymptomatic patients as there is only a low rate of procedural complications.

The continued patency of the tunnel leads to risk for biventricular volume overload, bacterial endocarditis, pulmonary vascular disease, aneurysm formation, calcification of the wall, aortic regurgitation and spontaneous rupture.

Treatment options are available according to the type of tunnel, its caliber, tortuosity, calcification, course and relation of the coronary ostia to the aortic orifice of the tunnel. They include:

1. Transcatheter closure
2. Ligation under controlled hypotension or repair with the patient under cardiopulmonary bypass

In this case, a transcatheter treatment is the option of choice due to the small opening of the right atrial end.

Placement of the Occluder Device:

- The right femoral vein and artery were cannulated using 6Fr sheaths using standard procedure & the patient was heparinized
- 6F Judkins catheter advanced retrogradely via the ascending aorta and cannulated the ostium of the ARAT from a peripheral access point
- A long Terumo glide wire 0.032 x 260 mm was used to cross the ARAT from the aorta to the RA, RV and to the MPA
- Snare system was inserted antegradely via the right femoral vein up to the MPA. The terumo glide wire was then pulled out by the snare to the right femoral vein
- An arteriovenous guide wire splint was then created
- The CDC6F delivery sheath with introducer was advanced over the wire to the IVC, RA, & to the tunnel
- The dilator & wire were then gently removed
- A 10/12 mm Cocoon PDA device occluder was then deployed at the exit site of the ARAT at the RA side
- Cineangiography post occlusion of ARAT showed the device positioned within the tunnel exit, with minimal shunting of contrast in the center of the device
- Device was then released from the delivery cable

Post intervention, there was no aortic insufficiency noted. The patient tolerated the procedure well and was discharged home after 24 hours of the procedure.

A repeat transthoracic echocardiogram was done three months post procedure and showed device in place with total occlusion of the tunnel. There was no aortic insufficiency noted.

Conclusion: Aorticocameral tunnels are extremely rare congenital cardiac anomalies. Imaging by TTE, MRI and angiography are of great help in diagnosis.

Surgical closure of tunnel along with repair of the associated cardiac defects has been achieved with satisfactory results in the past. However, with the availability of newer innovations and technology, transcatheter closure of tunnels with coils or duct occluders have become a better and more attractive alternative to surgery in selected cases without associated cardiac defects.

Reference:
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INTERMEDIATE TERM FOLLOW UP ON THE RESULTS OF TRANCATHETER CLOSURE OF DOUBLE COMMITTED SUBAORTIC VSD USING EITHER AMPLATZER DEVICE OR NIT OCCLUD LE COIL

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Background: Transcatheter ventricular septal defect (VSD) is a challenging treatment for doubly committed subarterial (DCSA) VSD.

Objective: To review intermediate term (3-5 years) results of transcatheter closure of DCSA VSD.

Methods: We retrospectively reviewed transcatheter closure of DCSA VSD using Amplatzer® device or Nit Occlud® Le VSD Coil.

Results: 69/73 patients (94.5%) had closure with median age and weight of 12 years and 37kg. There were 43 devices and 26 coils. The median VSD size in the device group was 6.1±1.8 mm vs 4.6±1.2mm in coil, p<0.001. Trivial to mild AR were found in 34.9% of device group vs 36.5% in coil group with moderate AR of 14% vs 15.4% respectively, p=0.922. Complete closure was 87.5% in device group vs 84.5% in the coil group, p =0415. At five years follow up trivial to mild AR were 46.9% in device group vs 48% in coil group with moderate AR of 3.1 % vs 0 %,p=0.772.

Conclusion: Device or coil can be used for transcatheter closure of DCSA VSD in DCSA. The degree AR appeared to be improved at five year follow-up with most of patients showing no or less than mild AR.

ASSOCIATION BETWEEN ELECTROLYTE IMBALANCE AT ADMISSION AND PROGNOSIS IN PATIENTS WITH DECOMPENSATED HEART FAILURE: LONG-TERM RESULTS

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Background: This prospective study baseline on the data of 52 consecutive patients admitted to the hospital due to acute decompensation of heart failure.

Heart failure physiology is extremely complex with a secondary sympathetic and neurohormonal activation. Electrolyte disorders are common and potentially fatal laboratory findings for emergency patients, hence more frequent monitoring of the serum electrolyte concentrations becomes very important for the patients with heart failure.

Objectives: The present study was conducted with the aim to estimate association between electrolyte levels measured at admission and morbidity/mortality within the first year after an episode of acute decompensation of heart failure.

Methods: All the patients were severely admitted to the cardiology department of the state hospital №24 named Katerine_II, attached to Russian National Medical University named N.I._Pirogov during the period of Febrary-June 2015.

Inclusion criteria: the patients were hospitalized for acute decompensation of congestive heart failure with compromised left ventricle function due to either low LVEF or mitral/aortic valve stenosis or regurgitation. On the other hand, the informed consent was obtained by each of them and the age of inclusion was more than 18 years old.

Exclusion Criteria: Acute de novo heart failure, patients with myocarditis, infective endocarditis, active cancer process. Also, patients with conditions causing electrolyte imbalance such as - vomiting, diarrhea, salt-losing nephropathy, diabetic ketoacidosis, cirrhosis, nephrotic syndrome, chronic kidney disease.

Results: Prevalence of electrolyte imbalance occurred in 19 patients 37%; hyponatremia 9 (17%); dyskalemia 10 (19%) among which hypokalemia 6 (12%) hyperkalemia 4 (8%). Known as an indicator of severity.

- In this study hyponatremia was associated with four times increased the 1-year mortality of any cases [RR 3.89 CI 1.55-10.24, p<0.05]. The same pattern is seen in patients with hypo- and hyperkalemia with a 20% and 30% 1-year mortality increase [RR 1,34, CI 0.88-2.07, p >0.05; RR 1.21 CI 0.66-2.24 p >0.05] respectively, although obtained results may not be considered statistically significant, perhaps it was due to a small sample size.

Conclusion: Hyponatremia have long-term prognostic value in patients hospitalized for acute decompensation of heart failure. It is a predictor of mortality, dyskalemia had the same trend thus statistically insignificant, perhaps due to a small sample size.

A NOVEL THREE DIMENSIONAL TRANSESOPHAGEAL ECHOCARDIOGRAPHIC COMPREHENSIVE MODEL OF AORTIC ROOT : PRELIMINARY EXPERIENCE IN AORTIC ANNULUS SIZING IN TAVR

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Background: A common use of 3D transesophageal echocardiography (TEE) is during TAVR procedures. The sizing of an aortic annulus (AA) is an important step in ensuring a successful TAVR procedure. A novel software, the eSie Valves package, relies on advanced machine learning technology to efficiently estimate a comprehensive model of aortic valve and aortic root from 3D TEE.

Objective: To test the accuracy of the eSie Valves package and True Volume TEE, these studies compared automated measurements using the eSie Valves package with MDCT to determine whether using 3D TEE data selects the same valve size as MDCT.

Method: In the pilot study in patients with aortic stenosis we are performing both 3D TEE and contrast MDCT prior to TAVR. 3D TEE (Acuson sc 2000)images were acquired with a one beat RES imaging to achieve high volume rates. The minimum and maximum AA diameter, AA area, perimeter, and other parameters were measured using the eSie Valves package and the standard MDCT method.

Results: In our preliminary study all 3D volumes that were acquired and analyzed showed that 3D TEE measurements are feasible and had excellent correlation with MDCT and excellent agreement between the two methods in selecting the prosthetic aortic valve size according to the standard sizing guidelines.

Conclusion: 3D echocardiographic imaging by the eSie Valves package is a novel technique having the potential to provide accurate and reproducible automated aortic annular measurements in echo and have good agreement in selecting the same valve size as MDCT.

MID-TERM FOLLOW-UP OF TRANSCATHETER CLOSURE OF PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECT IN CHILDREN USING AMPLATZER

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Background: Ventricular septal defect (VSD) is the most common form of congenital heart defects.

Objective: The purpose of this study was to evaluate the results of the early complications and mid-term follow-up of the transcatheter closure of the VSD using the Amplatzer VSD Occluder.

Methods: Between April 2012 and October 2013, 110 patients underwent percutaneous closure of perimembranous VSD. During the procedure, the size and type of the VSD were obtained from the ventriculogram. A device at least 2 mm larger than the measured VSD diameter by ventriculogram was deployed. Size of VSD, size of Amplatzer and device size to VSD size ratio were calculated. After confirmation of good device position by echocardiography and left ventriculography, the device was released. Follow-up evaluations were done at discharge as well as at 1, 6, and 12 months and yearly thereafter for VSD occlusion and complete heart block.

Results: We had 62 female and 48 male patients in our study. The mean age and weight of the patients at procedure were 4.3 ± 5.6 years (range 2 to 14) and 14.9 ± 10.8 kg (range = 10 to 43). The average device size was 7.0 ± 2.5 mm (range 4 to 14). The VSD occlusion rate was 72.8% at the completion of the procedure, rising up to 99.0% during the follow-up. The most serious significant complication was complete atrioventricular block which occurred in two patients. The average follow-up duration was 10.9 ± 3.6 months.

Conclusions: Transcatheter closure of the perimembranous VSD is a safe and effective treatment with excellent closure rates. This procedure had neither mortality nor serious complications.

Keywords: Perimembranous ventricular septal defect; Congenital heart defects; Amplatzer

A REVERSIBLE CAUSE OF CYANOSIS

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A 20-year-old male was referred to our institute for evaluation of easy fatigability and breathlessness. On physical examination, he had central cyanosis with 78% SPaO2 and clubbing. There were bilateral symmetrical pulses and cardiac examination was normal. Chest x-ray revealed homogenous tubular opacity in the left upper zone. Electrocardiogram (ECG) and two-dimensional echocardiographic study were normal. Contrast echocardiography was done by injecting agitated saline in the upper limb peripheral vein. Immediate (within 3 cardiac cycles) appearance of microbubbles in the LA confirmed the provisional diagnosis of pulmonary arteriovenous fistula (PAVF). Computed tomography of pulmonary angiography revealed a large PAVF arising from left pulmonary artery (Figure 1). There were no other features suggestive of hereditary hemorrhagic telangiectasia. Since patient was symptomatic with desaturation, he was taken for cardiac catheterization with intent to closure of the fistula. Selective left pulmonary artery (LPA) angiography with 6 Fr Pigtail revealed a large PAVF, draining into the LA via large vertical tubular vessel. A 6 Fr Judkins right (JR) catheter was advanced over the guidewire into the sac through the largest arterial feeder. The targeted arterial feeder measuring 15 mm was occluded by deploying a 18 x 20 mm duct occluder (Cocoon duct occluder, Vascular Innovations Co. Ltd.) using 10 Fr duct occluder delivery sheath (Cocoon Vascular Innovations Co. Ltd.) After device deployment, an additional PAVF was apparent on LPA angiography, in addition to mild foaming through the device. As oxygen saturation improved from 78% to 93%, the procedure was termed successful and the patient was discharged without procedural complication. 7 days post procedure patient presented with breathlessness and 3 episodes of hemoptysis for 3 days. On

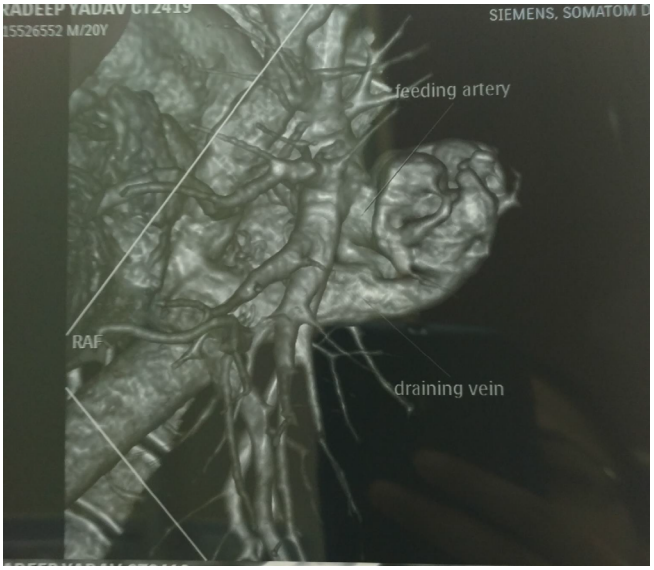

Figure 1. Computed Tomography of pulmonary angiography showing a large pulmonary arteriovenous fistula from left pulmonary artery with feeding artery measuring 14.5mm and draining channel measuring 12.5mm.

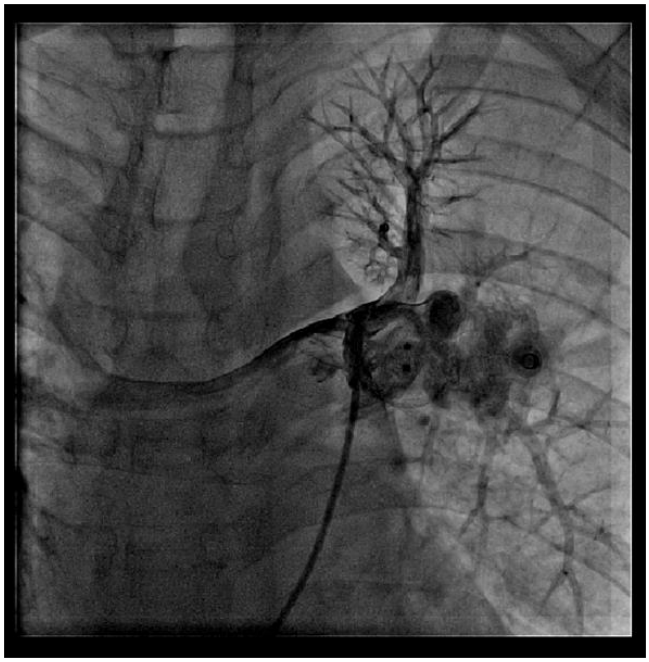

Figure 2. Duct occlude device in situ with mild foaming through the device.

examination chest was bilateral clear, with no murmur. Chest X-ray revealed homogenous opacity in left middle zone. His oxygen saturation at room air was 93%. In view of suspected pulmonary infarction patient was managed conservatively with cough suppressants, antibiotics and tranexaminic acid for 7 days. Patient improved on this treatment and was discharged after 10 days. At 1 year follow up patient is doing fine with no recurrent hemoptysis or breathlessness with oxygen saturation of 93%.

This case highlights that there can be multiple PAVF in a patient, whether all should be occluded is debatable. In our patient the small PAVF was not closed and at one year follow up patient is doing well with oxygen saturation of 93%. Retrograde approach to close the PAVF is other option if there are multiple feeders with single draining channel. Pulmonary infarction can occur post device closure of PAVF which can be conservatively managed.

CASE REPORT: CEREBRAL STENTRETRIEVER THROMBECTOMY OF AN EMBOLIZED VALVE FRAGMENT AFTER VALVE IN VALVE TAVI

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Case: Successful valve in valve TAVI was first reported by Grube et al in 2007 [1]. Until now the procedure has been established as a standard technique in elderly patients with multimorbidity who bear an enhanced risk for major cardiac adverse events following cardiac surgery [2].

We present a case of a 78 - year - old woman with a degenerated and severely stenosed Hancock II 21 mm bioprothesis which was implanted 2007 because of a symptomatic aortic valve stenosis. Since 2014 the patient presented aortic valve stenosis related clinical symptoms such as recurrent syncope and dyspnea at light exercise.

Transoesophageal reevaluation of the implanted Hancock II bioprothesis revealed a degenerative disease of the valve, the mean transvalvular pressure gradient was 50 mmHg, the valve opening area 0.50 square cm. Coronary artery angiography excluded an additional stenotic coronary artery disease. The Euroscore was 18.05 %.

The Heart Team decided to perform a valve in valve TAVI, a proven procedure [3,4,5], and implanted an Edwards Sapien XT valve. The implantation was performed transfemorally, the size of the implanted Sapien valve was 21 mm; the patient had a regular anaesthesia and was mechanically ventilated. The intraoperative transoesophageal evaluation after implantation displayed the prosthesis in a regular position and function; there was no mismatch, no relevant leakage of the valve, and the final peak transvalvular pressure gradient was within normal range (19 mmHg).

After cessation of anaesthesia the patient was extubated. However the patient failed to wake up and to resume spontaneous breathing. Soon a reintubation was required, and mechanical ventilation was reinstalled.

Following a neurological check we decided to perform computed tomography (CT) according to our stroke protocol. A noncontrast CT-scan of the brain ruled out an intracranial bleeding. Early signs of ischemic demarcation were also missing. However perfusion CT showed a decrease in the mean transit time (MTT) in the territory of the left middle cerebral artery (MCA) while the cerebral blood volume within the lesion was normal in most parts, suggesting the affected

brain parenchyma was still vital. Finally CT-angiography demonstrated an occlusion of the left MCA-bifurcation.

Subsequently systemic thrombolysis with 90mg of Alteplase was initiated. The patient was then transferred to the digital-substraction angiography unit of the Department for Radiology for emergency revascularization. Through a transfemoral access an 8F-balloon-aspiration catheter was placed in the left internal carotid artery (ICA). Digital subtraction angiography (DSA) revealed a persistent occlusion (Fig 1a). A 2.3F microcatheter was maneuvered behind the occlusion, then a Solitare2-FR 4x20 mm stentretreiver (EV3) was implanted. After 5 minutes the ICA was blocked by the balloon and the stent was retrieved during simultaneous aspiration. A white solid piece of tissue was recovered from the stent (Fig 2). The control angiogram showed a full restauration of blood flow (Fig 1b).

The pathological analysis proved a fragment of the degenerated Hancock II bioprothesis.

After extraction of the embolized material and restauration of a regular cerebral perfusion the patient recovered soon with full spontaneous awareness. Artificial ventilation was stopped.

The neurological follow up revealed a complete restitutio ad integrum.

Discussion: Cerebral microembolization is inherent to TAVI, and can occur during all stages of the procedure [6]. The incidence of periprocedural manifest stroke is reported to be around 2 - 3% [7,8]. In the majority of cases the embolized material cannot be identified. The stroke may be transient, but its impact is often persistent despite subsequent thrombolytic and antiplatelet medication.

The intention of this case report is to show that in case of stroke following valve in valve TAVI valve fragments may be the source of embolization requiring an active interventional management of this complication, since fragments cannot be targeted by thrombolytic therapy. Until now we have no data showing the incidence of cerebral embolizations on the basis of circulating valve fragments. The basis of an active management is an immediate CT angiography of the brain. On the basis of this case report a catheter based intracranial diagnostic and active intervention is gaining an important role in the acute management of periprocedural stroke in TAVI [9]. This is in line with new clinical trials demonstrating a better outcome for acute stroke treated with embolectomy compared to thrombolysis [10,11].

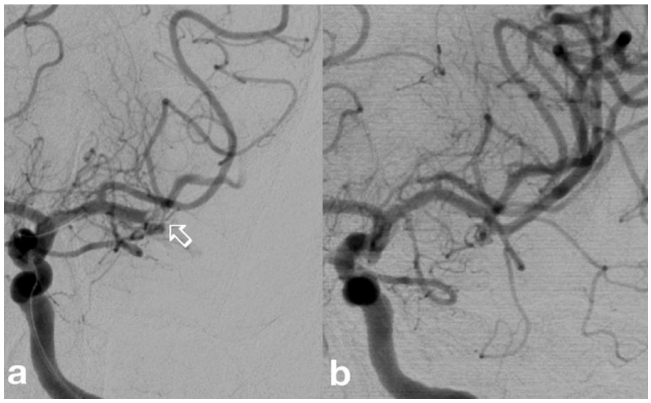

Figure 1. Digital subtraction angiography.

As shown in this case a complete regression of stroke can be achieved if the required procedure is done consequently and without time delay.

Considering this case also the routine use of mechanical cerebral protection device to prevent embolization of fragments of the degenerated implanted valve should be taken into consideration.

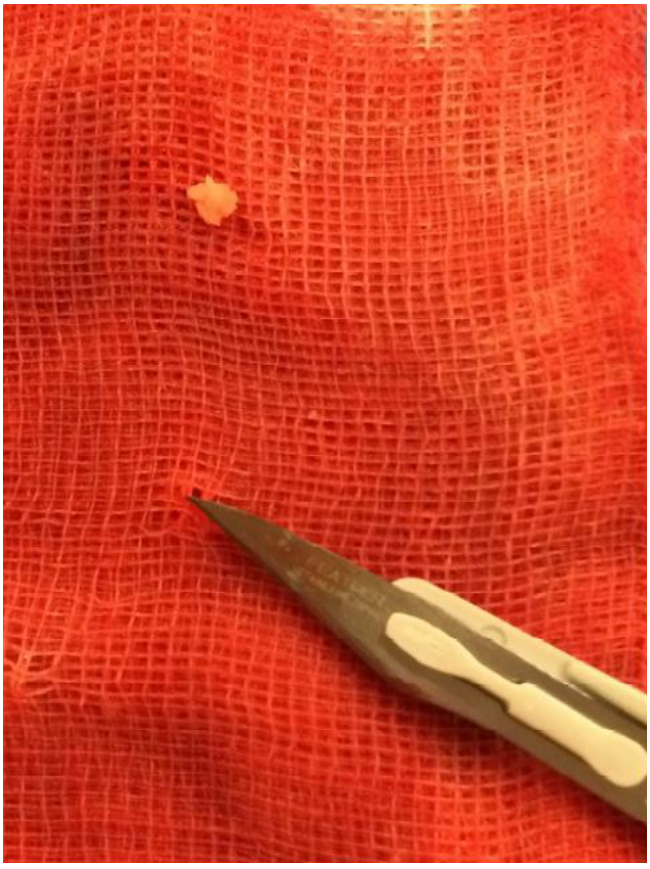

Figure 2. Embolized tissue fragment 2 x 2 square mm of the degenerated Hancock II bioprothesis.

CARDIAC MARKERS IN CHRONIC RENAL FAILURE PATIENTS

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Objectives: Patients with chronic renal failure are at a higher risk of cardiac event and have poorer outcomes. Early diagnosis and treatment of cardiac disease are important to improve their survival. The objectives were to determine the superior cardiac marker to predict all-cause mortality at 6 years, and to determine their optimal cut off values.

Methods: A prospective observational study was carried out. Patients were included if they presented to the ED with a chief complaint of chest pain and had chronic renal failure, defined as a serum creatinine of more than 130 umol/L. Creatine kinase (MB), Troponin T and Troponin I (using both Abbott and DxI-Beckman assays) were performed on the blood specimens drawn. All-cause mortality was traced from review of the patients' case records and checking of the registry of deaths.

Results: Seven hundred and fifty patients were recruited with a median age of 67. 60.2% of the study population were male. 87.5% of the population had CKD stage 4 and 5, with 32.4% on dialysis. The mortality rate at 6-year was 44.8%. Significant predictors were age ($p<0.0001$), absence of hypertension ($p=0.006$) and history of previous ischemic heart disease ($p=0.025$). Troponins T and I have higher AUC for all-cause mortality as compared to creatine kinase (MB). Troponin T had higher AUC when compared to troponin I by both Abbott and DxI assays. A cut-off of 0.08ug/L for troponin T had an AUC of 0.590 (sensitivity 54.8%, specificity of 58.2%, $p<0.0001$).

Conclusions: Troponin T is the superior cardiac marker for prognosticating all-cause mortality, with a higher cut-off recommended for patients with chronic renal failure, further research is necessary to examine the effect of previously known troponin, serial troponin testings and utilizing troponin levels to guide therapy.

EFFICACY OF EXPANDABLE HYDROGEL POLYMER COIL EMBOLIZATION FOR AORTOPULMONARY COLLATERAL ARTERY. -EFFICACY FOR REDUCTION OF NUMBER OF COILS AND PREVENTION FOR RECANALIZATION

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Background: Aortopulmonary collateral arteries (APCA) in single ventricular physiology is related to plural effusion or ICU stay period after TCPC. Although coil embolization is effective for those, it requires a large number of coils. In addition, bare platinum coil often causes recanalization.

Expandable hydrogel polymer coil (AZUR®) has unique characteristics represented by greater filling with fewer coils and is expected to prevent recanalization.

Objective: Reduction of the number of coils and prevention from recanalization by AZUR coil are retrospectively evaluated.

Methods: Study I: Total 11 vessels in 7 patients underwent coil embolization with AZUR for de novo APCAs from internal mammary artery (IMA) (AZUR group). They were compared with age matched patients who were treated with bare platinum coil (control group).

Study II: In 2 patients, AZUR was deployed in recanalized APCAs which have been previously treated with bear platinum coils. One patient had racemose hemangioma of the bronchial artery with fatal recurrent hemoptysis.

Results: Study I: The mean age of the patients were 5.6 years (2-17) and the mean diameter of IMA was 2.5 mm (2.0-2.8 mm). The number of coils was fewer in AZUR group as compared with control group (4.3±1.8 vs 6.5±2.8, $P=0.04$).

Study II: Complete occlusion by AZUR was demonstrated in both patients. Recurrent hemoptysis was stopped 2 years after coil embolization in the child with racemose hemangioma.

Conclusion: AZUR could contribute to reduce number of coils in APCAs and also be effective against recanalization even in Racemose hemangioma.

STRUCTURAL ACE - GENE POLYMORPHISM IN PATIENTS OF UZBEK NATIONALITY WITH DILATED CARDIOMYOPATHY

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Background: Dilated cardiomyopathy - a disease often genetically determined, depending on the nationality

Objective: To study the distribution of I/D polymorphism markers of ACE-genes in the Uzbek nationality with dilated cardiomyopathy (DC).

Methods: Study included 102 DC patients (39 female, 63 male), with clinical signs of II-IV FC heart failure NYHA. Duration of disease was 12.8±1.8 months. Control group included 65 healthy volunteers. All studied patients underwent clinical examination, Echocardiography, ECG, clinical-functional and laboratory methods of analysis and DNA extraction.

Results: The results obtained demonstrated prevalence of I/D genotype and absence of significant differences in frequency alleles I and D of ACE gene in individuals of Uzbek nationality suffering from DCMP. Control group had other pattern of genotype and alleles distribution of polymorph marker of ACE gene: DD- genotype was verified in 12 (20%) patients, ID genotype – in 14 (23,3%), II-genotype – in 34 (56,7%) ($P<0,01$; $\chi2=22,2$). D-allele was revealed in 41(34,2%) cases, I-allele – in 79 (65,8%) cases ($p<0,001$; $\chi2=22,8$). The results obtained in healthy subjects showed significant accumulation of I-allele and II –genotype I/D-polymorph marker ACE gene.

Conclusion: For the first time there was ID polymorphism of ACE gene in patients of Uzbek nationality with DC. There was shown prevalence of ID heterozygote genotype in the patients with DC and reliable prevalence of I-allele and II genotype in healthy subjects.

PERCUTANEOUS BALLOON VALVULOPLASTY FOR SEVERE PULMONARY STENOSIS IN INFANTS: A 10-YEAR INSTITUTIONAL EXPERIENCE AND LONGTERM OUTCOME

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Background: Although percutaneous balloon pulmonary valvuloplasty (PBPV) is the primary treatment for significant pulmonary valvular stenosis, it's widely considered to be difficult and relatively high risk for younger and severe stenosis children.

Objective: We retrospectively reviewed and analyzed the immediate and long-term outcome and safety of PBPV in neonates and infants with severe or critical valvular pulmonary stenosis.

Methods: One hundred and nine patients aged 2d~3y with critical or severe pulmonary valve stenosis admitted to our hospital from January 2005 to December 2014 underwent balloon valvuloplasty. Among them, 21 neonates had critical pulmonary stenosis, who had a tripartite right ventricle with moderate to severe tricuspid regurgitation (TR). Severe TR was seen in 12 and moderate TR in 6 out of other 88 patients of over one month of age. Right ventricular systolic pressure in all patients was equal to or greater than systemic pressure. 53 patients had PFO or small ASD with right-to-left or bi-directional shunt, 10 patients had PDA, 1 patient had multiple small muscular ventricular septal defects, and 1 patient had atrial septal defect, who had undergone the ASD occlusion two-year later. Dilatation with 2 balloons sequentially in one procedure was performed in 12 patients and dilatation with 1 balloon in the other patients.

Results: The pulmonary valvuloplasty was successfully performed in 105 of the 109 patients, and the dilatation success rate was 96.3%. In the four failure patients, balloon catheter could not be manipulated to cross the pulmonary valve in three patients, cardiac tamponade occurred in one patient. Immediately after dilatation, the systemic pressure gradient from right ventricle to pulmonary artery decreased from 50~132 (76.25±23.7) mmHg to 4~96 (25.29±19.2) mmHg (P<0.001). No significant complications in all patients during or post dilation except cardiac tamponade in one. During a 12 months to 9.6 years follow-up (mean 5.01 years), data showed that: (1) pressure gradient crossing pulmonary valve measured by echocardiography further decreased or remained stable in 103 cases, except one neonate and three infants, whose pressure gradient gradually increased, and needed a second dilatation and good results were gained. Re-dilatation rate was 3.73% (4/107). No case needed further surgery; (2) Tricuspid regurgitation reduced in all patients except for three whose RV were dysplasia; (3) Mild pulmonary regurgitation was seen in most patients post-dilatation, except moderate in six and severe in one. (4) All 10 PDAs closed spontaneously in 3~6 months of follow-up and muscular VSDs were closed as well in 3 months of follow-up. (5) All patients were doing well and were asymptomatic and acyanosis.

Conclusions: Balloon pulmonary valvuloplasty (BPV) is safe and effective in attaining both immediate and long term reduction of pulmonary valvular gradients and is currently the preferred therapeutic modality for valvular PS even in small baby patients with severe or critical stenosis.

A CASE OF SEVERE AS WITH SEVERE LVOT STENOSIS SUCCESSFULLY TREATED BY TAVR AND SUBSEQUENT PTSMA

Shohei Moriyama[1], Takeshi Arita[1], Taku Yokoyama[1], Hiromichi Sonoda[3], Akira Shiose[3], Yasuhiro Oga[2], Yusuke Takahara[2], Keiji Oi[2], Ken-ichi Hiasa[2], Kazumasa Fujita[1], Kei Irie[1], Hirotaka Noda[1], Mitsuhiro Fukata[1], Keita Odashiro[1], Koichi Akashi[1]
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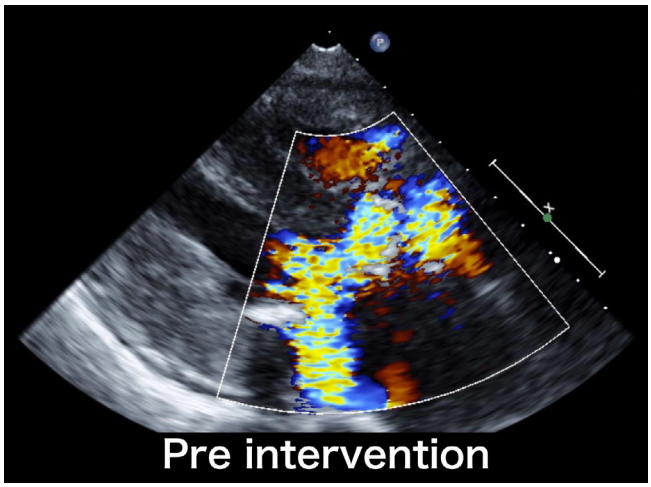
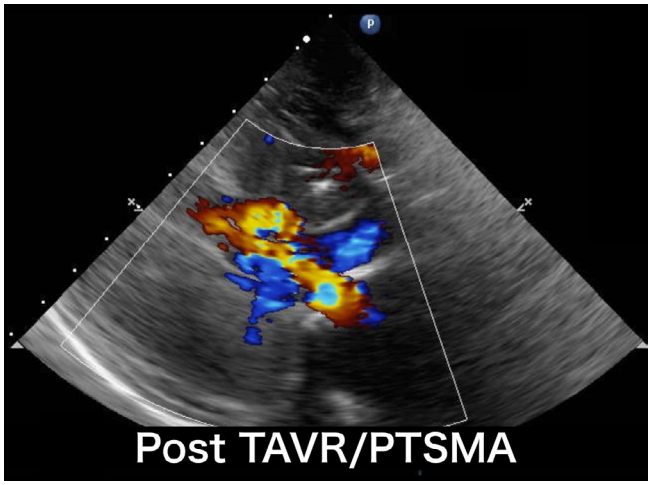
Aortic stenosis (AS) causes left ventricular hypertrophy which sometimes leads to left ventricular outflow tract stenosis (LVOTS) like hypertrophic obstructive cardiomyopathy.





We report a case of AS and concomitant LVOTS treated by balloon aortic valvuloplasty (BAV), TAVR and percutaneous transluminal septal myocardia alcohol ablation(PTSMA) sequentially.

A 84-years-old female presented with severe AS [aortic valve area (AVA) 0.5 cm2, mean gradient 63 mmHg] and LVOTS [peak gradient 166 mmHg,] , hypertension, hyperlipidemia, and heat failure. Her STS-PROM was 4.95% and significant frailty was noted. Due to high surgical risk, non-surgical approach was sought.

Medical therapy with cibenzoline and bisoprolol ameliorated LVOTS. However, subsequent BAV using 16 mm retrograde balloon exacerbated LVOTS with a LVOT gradient from 20 mmHg to 45 mmHg and worsening MR. One month following BAV, transfemoral TAVR using SAPIEN3® 23 mm was performed without any valve related complications. LVOTS was worsened with a pressure gradient from 76 mmHg to 117 mmHg and MR was mildly improved. One week later, elective PTSMA was performed by injecting 0.8 cc of ethanol into the first septal branch territory with an improved LVOT pressure gradient from 110 mmHg to 20 mmHg and improved MR.

Leaning points: LVOTS can accompany with severe AS. In those cases, single relief of valve resistance could exacerbate adjacent LVOTS hemodynamics. TAVR with concurrent or subsequent PTSMA should be employed for better improvement of obstructive hemodynamics.

COMPARISON BETWEEN BOLUS INTRACORONARY VERSUS BOLUS INTRAVENOUS INJECTION REGIMENS OF EPTIFIBATIDE DURING PRIMARY PCI IN PATIENTS WITH ANTERIOR STEMI

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Background: Eptifibatide achieve high local concentration via direct intracoronary injection as it promotes clot disaggregation, but it remains unclear if it is of superior benefit than the routine intravenous administration.

Aim: The current study aimed to examine the safety and efficacy of intracoronary versus intravenous bolus regimen dose of eptifibatide during primary PCI.

Patients and Methods: Prospective, controlled, randomized study enrolled 100 patients with acute anterior STEMI eligible for primary PCI equally divided into 2 groups (group A received bolus intracoronary eptifibatide and group B received it intravenous) followed by 12h continuous IV infusion. Predictors of myocardial salvage in the form of TIMI flow grade III, myocardial blush grade 3, ST segment resolution and left ventricular systolic function were evaluated with short term follow up for 1 month.

Results: Mean age of the study population was 50.95±8.45years, there was statistically insignificant difference between both groups regarding baseline characteristics regarding age (p=0.062), gender (p=0.488) and coronary artery disease risk factors (p>0.05), time from onset of pain to admission (p=0.86) or door to balloon (p=0.12). Group A achieved statistically significant better myocardial blush grade 3 (42% versus 10%, p=0.005), ejection faction 30 days after PPCI (46.11±7.81, versus 40.88±6.26, p=0.005) but statistically insignificant TIMI flow grade III (p=0.29) and ST resolution (p=0.34). Incidence of in hospital compilations and 30 days after discharge was statistically insignificant (p>0.05).

Conclusion: Regimen of intracoronary bolus eptifibatide achieved better myocardial salvage predictors and was as safe as intravvenous bolus during PPCI and at short term follow-up.

PERVENTRICULAR IMPLANTATION OF MELODY VALVE IN 12 KG BABY WITH PULMONARY HYPERTENSION AFTER POTTS SHUNT

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History and Physical: A baby-girl born with tracheoesophageal fistula, esophageal atresia and truncus arteriosus communis (TAC) underwent esophageal repair and fistula closure when 2 days old and weighing 3 kg. The cardiac procedure was postponed until the 3rd month of age due to pneumonia and sepsis. During the truncus repair, a 12 mm Contegra xenograft (Medtronic Inc, Santa Ana, CA) was implanted to reconstruct the right ventricle outflow tract. When she was 4.5 years old, her weight was only 12 kg and she was admitted to the cardiology department because of deteriorating exercise tolerance and poor weight gain.

Imaging: Echocardiography revealed severe right ventricle (RV) dysfunction and symptoms of elevated pulmonary pressure. Cardiac catheterization demonstrated suprasystemic pulmonary artery (PA) pressure, pathologic pulmonary arteries pattern and RVEDP 19 mmHg. The Contegra graft was distended to 21 mm in diameter and the PV was incompetent The baby was hospitalized and pharmacotherapy had to be gradually extended from bosentan and sildenafil to include continuous epoprostenol infusion, milrinon, digoxin, dopamine and oxygen therapy. Such a management did not prevent progressive heart failure with the eventual NT-proBNP level of 21 515 pg/ml. The patient was listed for lung transplantation and 8 mm Potts shunt has been created. The flow of blood in the Potts shunt was right to left in systole (with the difference between the upper and lower body saturation of 10 to 15%), however left to right in diastole with significant pulmonary insufficiency (PI). A conventional surgical pulmonary graft exchange was highly risky in terms of PAH, extremely depressed RV and the Potts shunt. Also percutaneous PV implantation was impossible because of low weight and poor venous access.

Indication For Intervention: The decision was made to implant the Melody valve in per-ventricular way in a hybrid room setting.

Intervention: Mild hypothermia was induced (34.5 C) for brain protection for potential periods of systemic hypotension. Through the limited, lower sternotomy the purse-string sutures were placed a little to the right from the subxyphoid area. This was also done to keep them away from the tricuspid valve apparatus and make all the maneuvers more applicable with a relatively stiff delivery system and limit any tension to the dysfunctional right ventricle. The RV wall was punctured, a wire was introduced to RPA. Positioning of the valve was preceded by angiography. The Melody valve (Medtronic Inc, Santa Ana, CA) hand-crimped onto a 22-mm Ensemble delivery system was then delivered over the wire into the right ventricular outflow and placed at the Contegra graft level using the overlapping of images. After confirmation of the positioning, the balloon in the balloon system was distended to 22 mm, withdrawn, and the RV was fixed. The valve was perfectly competent on repeated transthoracic echocardiograms. The patient was discharged home with bosentan and sildenafil therapy with no oxygen, 10-15% difference between the upper and lower body saturation.

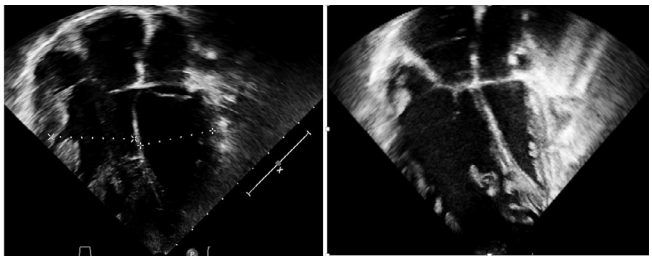

Figure 1. Echocardiography showing reverse remodeling of the both ventricle (on the left) 2 years after Potts shunt and Melody valve implantation into pulmonary position in 12 kg baby with PAH.

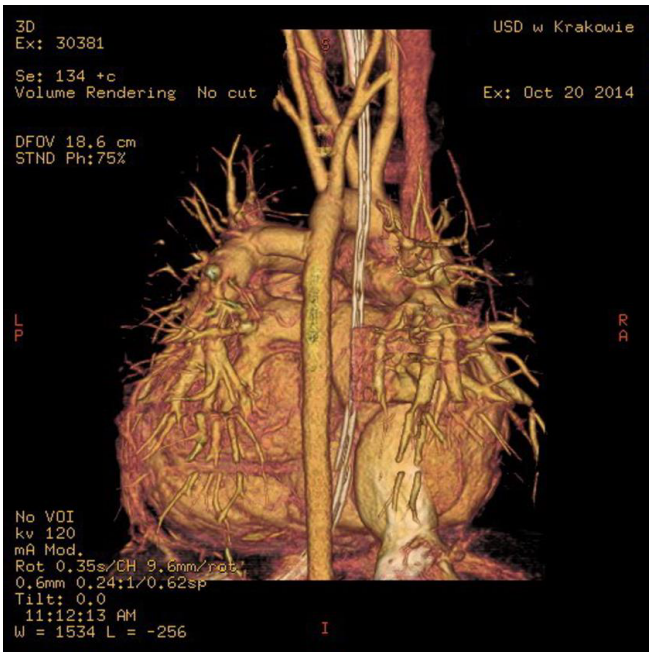

Figure 2. Angio CT scan demonstrating 8 mm Potts shunt in 12 kg baby with repaired common arterial trunk and PAH.

Learning Points of the Procedure: The 2-year follow-up showed not only the 4 kg body weight increase, spectacular improvement in the quality of life, fully competent Melody valve, no rhythm disturbances in Holter monitoring, but also no significant difference between the upper and lower body saturation and unsuspected reverse remodeling of the right ventricle. In conclusion, per- ventricular pulmonary Melody valve implantation is possible in a low-body-weight patient, when a surgical solution or femoral vessels are unsuitable, even if the patient presents with a significant right ventricular dysfunction. Potts shunt may be the treatment option in patients with iso or even infrasystemic RV pressure and significant RV dysfunction or distension to promote RV reverse remodeling.

PERCUTANEOUS PDA CLOSURE IN EXTREMELY LOW BIRTH WEIGHT BABIES

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Background: Patent Ductus Arteriosus (PDA) is an important cause of morbidity and mortality in preterms. As birthweight decreases, risks increase.

Objective: Main aim of our study is to emphasize the effectiveness and safety of percutaneous PDA closure even in extremely low birth infants.

Methods: In our center between the dates June 2014 – December 2015, PDA of eight patients less than 1 kg were closed percutaneously. To our knowledge this study includes the largest cohort of infants less than 1 kg in the literature, whose PDA were closed percutaneously.

Results: Symptomatic patients weighing less than 1 kg with PDA were included in the study. The mean patient age and weight was 16±5.9 days and 923±75.9 gr respectively. Mean PDA diameter was 2.48±0.5 mm. In all patients ADOII-AS device were used for PDA closure. There were no major complications reported. Left pulmonary arterial stenosis was detected in 2 patients which resolved spontaneously.

Conclusion: Interventional catheterization procedures are more commonly used in recent years. The advantages of percutaneous PDA closure include a high success rate, shorter length of hospital stay, reduced blood loss, low morbidity rate, and no traumatic scars. Since the length of hospital stay decreases with catheterization, it is much more cost-effective than surgery. We want to emphasize that in experienced centers percutaneous closure of PDA can be an alternative to surgery even in the extremely low birth weight babies.

PERCUTANEOUS VSD CLOSURE UNDER 1 YEAR OF AGE

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Background: Untreated large ventricular septal defects (VSD) are an important cause of congestive heart failure in early infancy. This population usually fails to grow and surgical closure is challenging because of congestion in their lungs prone to respiratory infection and their bad nutritional status.

Objective: The aim of this study was to share our experience in percutaneous VSD closure of children under 1 year of age.

Methods: We have performed VSD closure in 7 patients under 1 year of age between the September 2012 – May 2016 in Erciyes University Pediatric Cardiology Department.

Results: Age of patients ranged between 4–12 months. Weight of the patients during the procedure was between 5.3-9 kg. Mean VSD diameter was 3.19±0.47 mm. One defect was muscular, all others were perimembranous defects. All defects were closed with Amplatzer Ductal Occluder II(ADO-II). Mean fluoroscopy duration and total radiation dosage were 78.5±94.6 min, 2069±1395 cGy/min respectively. We did not face any major complications except in one patient where complete AV block was seen one month after the procedure. Pacemaker was implanted. No aortic regurgitation was seen in patients after device implantation.

Conclusion: The procedure of VSD closure, whether it is surgical or percutaneous, is very risky. The risks were higher when the children were smaller than 1 year of age and low body weight. Percutaneous VSD closure may be an alternative to surgery in early infancy that carry the similar risks but less invasive.

USING OF INTRACARDIAC ECHOGRAPHY DURING ASD CLOSURE

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Background: Transcatheter device ASD closure is a good alternative to open heart surgery. Most often the ASD closure is performed under transthoracic and transesophageal echocardiography. Although TEE provides exceptional images, it requires general anaesthesia and cannot be used in case of esophagus abnormality. These reasons explain the need to develop new imaging tools.

Objective: The aim of this study is to compare views obtained by different methods of intracardiac ultrasound (Ultra ICE, AcuNav).

Methods: 42 closure procedures were performed in the Philips Allura cathlab with a local or general anaesthesia, depending on age. To perform an intracadiac echocardiography (ICE) guidance we used the Ultra-ICE (iLab) by Boston Scientific in 39 cases and AcuNav by Biosense Vebster in 3 cases.

Results: By Ultra ICE we can get two cross-sectional views of the fossa ovalis in a 360˚ radial plane. The Ultra ICE allows to evaluate the length of the septum, the oval fossa perimetry, the all muscular edges, the right and left atria, tricuspid and mitral valves.

AcuNavTM scans in the longitudinal monoplane, providing a 90˚ sector image. By AcuNav we can get longitudinal and short-axis views of fossa ovalis. We can see right and left atrium, ascending aorta, inferior vena cava, superior and inferior muscular rims of fossa ovalis, and the diameter of the defect can be measured.

Conclusions: ICE provides clear visualization of heart structure, size and location of the defect and presence of rims. All device deployment steps can be monitored using ICE. The advantage of using AcuNav system is the possibility of acquiring doppler and color flow imaging.

A SEGMENTAL FEMORAL ARTERY OCCLUSION: A LESSON TO IMPLEMENT THE COMPREHENSIVE CARDIAC-CATHETERIZATION SYSTEM IN A DEVELOPING INSTITUTE

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History and Physical Examination: A 3-year-old boy diagnosed as Tetralogy of Fallot underwent cardiac catheterization for diagnostic study. Physical examination revealed central cyanosis, systolic ejection murmur at left upper parasternal border with clubbing of fingers. Oxygen saturation in room air was 70 percent.

During procedure, the left femoral artery was punctured with one attempt. Heparin 50 units/kg was given after insertion of 5F arterial sheath. The procedural time from vascular puncture was twelve minutes.

One day after cardiac catheterization, the deminished pedal pulse with cold left leg was recognized. Heparin was given at once. Heavy gauzes with compressive bandage dimension 3x4x5 cm was found at left groin. Twelve hours after heparin infusion, the computed tomographic angiography (CTA) revealed intraluminal thrombus (2.8 cm in length) causing complete occlusion of left common femoral artery with the reconstituted branches from left external iliac artery supplied to left popliteal and tibial artery.

The operative findings revealed constriction of the common femoral and superior femoral artery diameter of two and four millimeters, respectively. Thromboembolectomy was performed by 3F Fogarty catheter, however, no intraluminal clots were detected. Both vessels dilated up to five millimeters and pedal pulse was recovered at the end of operation. Enoxaparin was given following the heparin at one week. Two months after cardiac catheterization, the CTA demonstrated slight progression of common femoral-artery occlusion (3.6 cm in length) with the normal reconstructed flow to distal arteries (Figure 2). He has not received another vascular surgery, as he had not exhibited signs of claudication or limb ischemia.

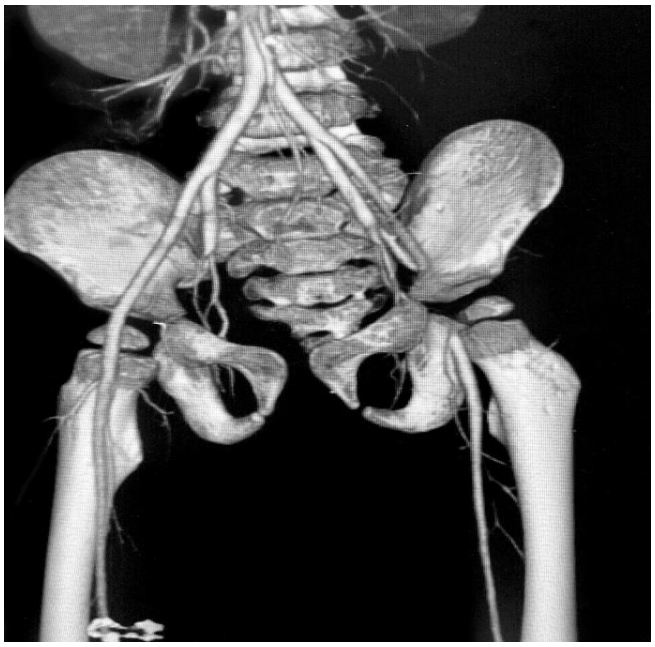

Figure 1. Postprocedural 36 hours CTA revealed complete occlusion of left common femoral artey, 2.8 cm in length.

Figure 2. Postprocedural 2 months CAT revealed complete occlusion of left common femoral artery, 3.6 cm in length with collateral arteries.

Indication for Intervention: Limb ischemia

Intervention: Surgical thromboembolectomy

Learning Points of the Procedure:

1. Excessive compression not only contributed vascular stasis but also precipitated arterial spasm which is the major mechanism of vessel-related thrombosis.
2. Late detection of vascular insufficiency had been an important factor on the thrombosis and ischemic progression.
3. Thrombolysis should be an appropriated treatment for the patients whom has no contraindications with the aim to improve vascular supply and avoid surgical complications.
4. Bolus heparin prophylaxis should be changed to 100 units/kg to achieve the best efficacy, particular in the high-risk patients.

MID-TERM RESULTS OF PERCUTANEOUS VSD CLOSURE WITH ADO II IN PEDIATRIC POPULATION

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Background: Nowadays percutaneous VSD closure is accepted as an alternative surgery but still no ideal device was determined for the pediatric population.

Objective: The aim of this study was to share mid-term results of percutaneous VSD closure with ADO II in pediatric population.

Methods: VSD closures of 49 patients with ADO-II device was performed in Erciyes University Medical Faculty Children Hospital, Pediatric Cardiology Department.

Results: Mean age of patients: 86.8±52.6 months. The youngest patient was 4 months old and the oldest patient was 18 years old. 19 patients were female and 30 were male. Weight of the patients was between 24.3±16 kg (Range: 5-76 kg). Mean diameter of VSD was 3.7±1,4 mm. Mean fluoroscopy and total procedure time were 37±19.3, 74.1±27 minutes respectively. We have used two ADOII-AS devices. VSD types were muscular in 6 patients, rest of the defects were all perimembranous type. No major complications like death, vascular complications, device embolizations were seen. One complete AV block was seen 6 months after the procedure and a pacemaker was implanted.

Conclusion: To our knowledge our study includes the largest series of pediatric patients on whom percutaneous VSD closure was done with an ADO II device. When all complications within the 42 months follow-up period are taken into consideration, the ADO II device is a good choice in selected cases for VSD closure even in the infants less than 1 year of age.

CLINICAL PROFILE, PROCEDURAL OUTCOME AND SHORT TERM FOLLOW UP OF PATIENTS UNDERGOING ENDOVASCULAR STENTING FOR COARCTATION OF AORTA

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Background: Endovascular stenting is considered the preferred option in managing coarctation of aorta in older children and adults. Covered stents are used in selected or high risk catergory of patients.

Aims: To study the clinical profile, procedural outcome and short term follow up of patients undergoing endovascular stenting of coarctation of aorta.

Methods: Between May 2013 and November 2016, 26 patients who underwent stenting of coarctation of aorta were retrospectively analyzed.

Results: 26 patients (eight females) aged 1-54 years (median 29), weighing 7.8 -86.4 kg (median 55.1), underwent stenting of COA. All except one had post-subclavian coarctation. 70% of patients had hypertension and were on treatment. Mean gradient at catheterization was 69.2 ± 29.4 mmHg and mean gradient post-procedure was 3.5 ± 4 mmHg. A total of 27 stents were deployed, Covered CP (17), Cook Formula (1), Advanta V12 Atrium (2), Intrastent Mega (3), Palmaz (2),Andrastent (1), Bare CP (1). Covered stents were used in 59.1%. The mean stent length and balloon diameter were 34.73 ± 11.56 mm and 16.3 ± 2.42 mm respectively. Pre-dilatation was done in two patients including one with near interruption. Post dilatation was needed in 35% of patients. Procedural complications included dissection in one patient needing a second covered stent and right femoral artery occlusion in another. Retroperitoneal hemorrhage in one resulted in mortality. Follow-up ranged from 1 month to 3.5 years. 36.4% required continuation of antihypertensive therapy even after stenting. Re-dilatation was required in 1 patient with pre-subclavian coarctation.

Conclusion: Stent implantation is a safe and effective alternative to surgical repair in COA. It provides immediate and near complete relief of pressure gradient which is sustained on short-term follow up. Systematic long-term follow up is required to look for restenosis, aneurysm formation and persistent systemic hypertension.

INITIAL PALLIATION OF TETRALOGY OF FALLOT: COMPARISON BETWEEN BT SHUNT AND RVOT STENT

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Background: Neonatal repair of symptomatic infants with Fallot-type (ToF) lesions remains the excep-tion in the UK. Initial palliation can be achieved by creation of a BT shunt, or RVOT stenting.

Aims: To compare the outcome of BTS and RVOT stent in the palliation of TOF.

Methods: 10 year retrospective review of the outcome of 101 ToF patients who required initial pal-liation (RVOT stent n=60 ; BTS n=41) prior to complete repair. Detailed assessment of PA growth in patients with comparable underlying anatomy.

Results: In the RVOT stent group vs the BT shunt group, there was a lower PICU admission rate (22% vs 100%) [p<0.001], a lower early mortality (1.7% vs 4.9%) [ns], a shorter initial hospital stay (7 vs 14 days) [p<0.004], and a shorter time to surgical repair (232 vs 428 days) [p<0.001]. In terms of PA growth after palliation, the benefit of RVOT stenting ver-sus mBTS was +0.599 z-score for the LPA and +0.749 z-score for the RPA. Rise in oxy-gen saturations was greater with RVOT stenting (p=0.012). There were 3 non-cardiac deaths in the RVOT stent group and none in the BTS group. There were no deaths after correction, and comparable bypass times and rate of transannular patching / conduit use. Overall mortality was comparable (8.4% vs 4.9%) [p = 0.69].

Conclusions: RVOT stenting is a safe and effective palliation in the initial treatment of infants with symptomatic Fallot-type lesions and provides superior growth of the pulmonary arteries.

FACTORS ASSOCIATED WITH COMPLICATIONS DURING TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS IN HASAN SADIKIN GENERAL HOSPITAL, BANDUNG, INDONESIA

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Background: Patent ductus arteriosus (PDA) forms about 5-10% of congenital heart diseases (CHD). PDA was the first example of CHD to be treated by transcatheter closure, which becomes an established form of treatment for the majority of patients with PDA and as a safe alternative to surgery.

Objective: This study is designed to determine factors that can predict the likelihood of incidence of all complications of transcatheter closure of PDA.

Methods: This was a retrospective cohort study. Pediatric patients with PDA who had a successful transcatheter closure were studied. Transcatheter closure report found at Diagnostic Invasive Division, Hasan Sadikin General Hospital from January 2014 to May 2016 were collected (n=114). Reports with incomplete data were excluded from the study. Multivariable logistic regression was used to identify predictors of complications of trancatheter closure of PDA.

Results: A total of 98 patients were enrolled in this study. There were 18 patients (18.4%) experienced complications of trancatheter procedure. Complications were seen more in those with type C defect (30.8%). The multivariate analysis shows that the size of ampulla and male gender were associated with incidence of complications of trancatheter closure of PDA (OR= 1.26; 95% CI: 1.01-1.56 and OR= 4.38; 95% CI: 1.32-14.45).

Conclusions: In our center, the size of ampulla and gender are independent risk factors for the incidence of complications of trancatheter closure of PDA.

PERFORATION BY CATHETER INTERVENTION FOR THE CALCIFIED OBSTRUCTION OR ARTIFICIAL CONDUIT-PLANNING BY MULTI-PLANAR RECONSTRUCTION IMAGE ON CARDIAC CT

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Background: Perforation is an essential technique to reopen the chronic occluded vessels. However, penetration of calcified obstruction or artificial conduit is still challenging.

Objective: To establish safety procedures to perforate calcified obstructions or ePTFE conduits.

Methods and Results: Before the catheter procedure, multi-planar reconstruction (MPR) image was performed for the planning of catheter intervention.

Case 1: 18 y/o male, SRV, post extracardiac (ePTFE)- TCPC, protein loosing enteropathy (PLE). Creation of Fontan fenestration was planned for reduction of CV pressure. While fixing Brockenbrough (BB) needle by snare catheter (snare assistant technique), stiff side of 0.014 inch guide wire advanced through tip of BB needle. Subsequently, perforation was dilated by 10mm balloon and then Palmaz stent was implanted. PLE improved.

Case 2: 41 y/o male. TGA, post Mustard procedure, SVC syndrome (calcified complete obstruction from SVC to RA). Steerable sheath was placed to fit occlusion as vertical. Then sharpened 0.014 inch guide wire advanced toward SVC. The perforation was dilated in stages by balloon catheter up to 18mm diameter.

Case 3: 41 y/o male, Right isomerism, SRV, po TCPC (lateral tunnel using ePTFE), Atrial tachycardia. To access common atria, perforation of the Fontan rout was planned. While fixing BB needle by snare assistant technique, BB needle gently advanced to common atria. The perforation was dilated by 5 mm balloon.

Catheter ablation was successful without complication. In all cases, MPR image could provide us with useful information to make a precise plan.

Conclusion: Snare assistant technique and steerable sheath is useful for back-up support. Stiff side of thin wire or sharpened wire could penetrate even the tough calcified lesions. MPR image on cardiac CT is a useful tool to make a feasible plan.

THE RISK OF LEFT VENTRICULAR SYSTOLIC DYSFUNCTION AFTER PERCUTANEOUS DEVICE CLOSURE OF PATENT DUCTUS ARTERIOSUS IN ADULTS

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Background: It has been reported that transcatheter closure of patent ductus arteriosus (PDA) is associated with deterioration of left ventricular ejection fraction (LVEF). However, the data remains sparse.

Objectives: To investigate the changes of LVEF after transcatheter closure of PDA in adult patients and explore the risk factors related to deterioration of LVEF after device closure.

Methods: The study was retrospectively analyzed in patients with isolated PDA and treated with transcatheter PDA closure by Cocoon™ device between January 2010 to March 2014. Determination of the risk factors of left ventricular systolic dysfunction has been explored by two-dimensional (2D) echocardiographic parameters pre-procedure.

Results: Thirty-three patients had successful device closure by Cocoon™ Ductal Occluder. The mean age was 38.5+12.0 years and 81.8% were female. The mean PDA diameter at its narrowest segment was 6.9 mm. According to the PDA classification, 51.6% of patients had type A, 35.5% had type B, 3.2% had type C and 9.7% had type E. The device size 10/12 were predominantly used in 45%. The 2D-echocardiography showed that the shunt occlusions were completed in 90% of patient at one month and 100% at 1 year. Post-procedure, the left ventricular ejection fraction (LVEF) decreased more than 5% in 74.2% of patients. However, left ventricular dysfunction after device closure was transient, LVEF has recovered mostly in 3-6 months.

Conclusion: Transcatheter device closure of PDA is associated with left ventricular systolic dysfunction post-procedure but it is transient with recovery at short-term follow-up.

MANUAL HEATING OF RADIAL ARTERY (BALBAY MANEUVER) TO FACILITATE RADIAL PUNCTURE PRIOR TO TRANSRADIAL CORONARY CATHETERIZATION

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Background: Transradial access (TRA) is increasingly being used for both diagnostic and interventional cardiac procedures. The use of TRA offers many advantages: decreased bleeding, vascular complications, reduced length of hospital stay, and reduced cost. However, the

small size of the radial artery limits the size of the equipment that can be used via this approach.

Objective: In this study we sought to investigate whether pre-procedural manual heating of radial artery facilitates radial artery puncture or not.

Methods: Patients undergoing transradial cardiac catheterization were randomized in a double-blind fashion to a subcutaneous combination of nitroglycerin+diltiazem or manual heating. The study endpoint was puncture score (score 1: easiest puncture-first try, score 2: puncture at second try, score 3: puncture at third try, score 4: puncture at forth or more try, score 5: radial puncture failed).

Results: 90 patients were enrolled (45 allocated to treatment group and 45 to heating group). Patients underwent ultrasound of the radial artery before the catheterization. Complications were rare: one hematoma (treatment group) and one radial artery occlusion (heating group). Baseline demographic and clinical characteristics were similar. The baseline radial artery diameter was similar in both groups. (2.41 ± 0.46 mm in heating group and 2.30 ± 0.48 mm in treatment group. However, puncture score was 1.47 ± 0.9 in heating group and 2.22 ±1.2 in treatment group (p=0.002), respectively.

Conclusions: Pre-procedural manual heating of radial artery facilitates radial artery puncture in patients undergoing transradial cardiac catheterization.

TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS IN PREMATURE INFANTS WEIGHING LESS THAN 2,500 GRAMS

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Background: Transcatheter closure of patent ductus arteriosus (PDA) in preterm babies remains a highly challenging procedure.

Objective: The aim of this study was to describe our experience with transcatheter device closure of PDA in symptomatic low birth weight premature infants.

Methods: Hospital records and catheterization reports of all premature babies who underwent transcatheter PDA closure since October 2014 in our hospital were reviewed. Basic demographics clinical information, echocardiographic, and angiographic data were recorded.

Results: Six premature infants (three boys and three girls) born at gestational ages ranging between 24 and 33 weeks (median, 28 weeks) were identified. All patients were symptomatic and received at least one course of indomethacin therapy. Median age and weight for procedure was 32 days (17-102 days) and 1,500 g (1,032-2,350 g), respectively. The mean minimal ductal diameter was 3.7 + 0.7 mm. Device used in this study were Amplatzer Ductal Occluder II additional size (ADO II AS) (n=4), Amplatzer Vascular Plug I (n=1), and Vascular Plug II (n=1). Complete closure was achieved in all patients with no major procedural complications.

Conclusions: It is currently feasible to undertake transcatheter PDA closure in carefully selected symptomatic premature infants.

SUCCESSFUL STENTING OF CHRONIC TOTAL OCCLUSION OF THE EPTFE GRAFT AFTER RIGHT PULMONARY ARTERY BYPASS SURGERY IN A GIRL WITH ABSENT PULMONARY ARTERY

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History and Physical: A 12-year-old girl was admitted to our hospital for endovascular treatment of chronic total occlusion of the right pulmonary artery (RPA) bypass graft. She first visited our hospital because of heart murmur when she was two years old. She was then diagnosed as having absent right pulmonary. She underwent RPA bypass surgery with 6mm ePTFE graft. The graft became stenotic easily because it passed anterior of the ascending aorta and then had a tight curve before it went into RPA between ascending aorta and superior vena cava. After the surgery, she underwent balloon dilation of the graft stenosis every two or three years. Pulmonary perfusion scintigraphy at 12 years of age suggested total occlusion of the RPA graft (right 3%, left 97%). Prominent second heart sound and ejection systolic murmur at upper left sternal border were audible.

Imaging: Computed tomography confirmed the diagnosis of total occlusion of the RPA bypass graft.

Indication for Intervention: She showed mild shortness of breath on exertion. Cardiac catheterization revealed elevated main and left pulmonary artery pressure (57/21[39] mmHg).

Intervention: The procedure was performed under local and intravenous anesthesia. An 8 French (Fr) sheath introducer was placed in the right femoral vein. Right ventriculography demonstrated total occlusion of the proximal RPA bypass graft. 6Fr AL-1 catheter could be stabilized at the orifice of the graft using 6Fr Brighttip sheath and4Fr Multipurpose catheter. A 0.018"

Treasure 12g guidewire was passed through the graft, and 0.035" Radifocus guide wire reached peripheral RPA. Intravascular ultrasound revealed severe thrombotic stenosis of the graft. The graft was dilated with 3 x 20 mm Sterling balloon, 3.5 x 13 mm NSE balloon, and then 5mm x 30mm Sterling balloon. RPA angiography revealed 50% patency of the graft and we finished the procedure. Oral aspirin and heparin infusion were administrated and then switched to aspirin and warfarin. She discharged eight days later, after checking the patency of the graft with ultrasonography and computed tomography. However, two months later, ultrasonography and pulmonary perfusion scintigraphy suggested re-occlusion of the RPA graft. After confirming the diagnosis of the occlusion by pulmonary artery angiography, we decided to perform stent implantation. Using a 10

French (Fr) sheath, 8.5Fr Parent sheath and 6Fr AL-1 catheter, 0.035" Radifocus guidewire was passed through the graft. Because of the tight curve in the middle of the graft, we chose self-expandable 7 x 60mm Smart stent. After predilation with 4 x 30 mm Sterling and 6 mm x 40 mm Sterling balloon, Smart stent was deployed to cover the 6mm ePTFE graft. Post-procedural angiography demonstrated a widely patent stent with good antegrade RPA flow. The pressure of the main pulmonary artery decreased from 67/27(46) mmHg to 49/10(27) mmHg after stent implantation. Clopidogrel was added to aspirin and warfarin, and she discharged from the hospital with good patency of the graft.

Learning Points of the Procedure: This is the first report of successful penetrating and stenting of chronic total occlusion of the ePTFE graft after RPA bypass surgery. Penetrating chronic total occlusion of the ePTFE graft at the pulmonary artery site with guidewire could be performed safely. Simple balloon dilation was not enough to maintain the patency of the occluded graft. Self-expandable stent might be a good option for pulmonary artery bypass stenosis/occlusion which runs anatomically complicated courses. Further study with a larger population is needed to investigate the effect of stent implantation in this setting and to establish adequate antithrombotic therapy in such cases.

Comment on this Article or Ask a Question

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