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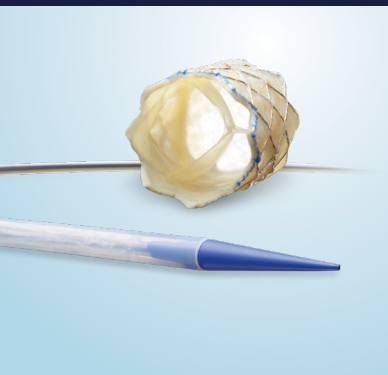
Melody™ Transcatheter Pulmonary Valve, Ensemble™ II Transcatheter Valve Delivery System

Important Labeling Information
for the United States

Indications

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

Contraindications

None known

Warnings/Precautions/Side Effects

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

- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.

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

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

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

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

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

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

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

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

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

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

Important Labeling Information
for Geographies Outside of the United States

Indications

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

- Patients with regurgitant prosthetic right ventricular outflow tract (RVOT) conduits or bioprostheses with a clinical indication for invasive or surgical intervention, OR

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

Contraindications

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath

- Implantation of the TPV in the left heart

- RVOT unfavorable for good stent anchorage

- Severe RVOT obstruction, which cannot be dilated by balloon

- Obstruction of the central veins

- Clinical or biological signs of infection

- Active endocarditis

- Known allergy to aspirin or heparin

- Pregnancy

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

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

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

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

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

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Predictors of Procedure Time Prolongation During Percutaneous Transcatheter Closure of Atrial Septal Defect - A Retrospective Study

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Abstract

Background: Percutaneous transcatheter closure (PTCC) of atrial septal defect (ASD) may convert to a long procedure. We aimed to identify predictors of prolonged procedure.

Methods: Under transesophageal echocardiography and fluoroscopy guidance, 81 children with ASD underwent PTCC. Retrospectively, medical charts, echocardiographic recordings, catheterization reports and fluoroscopic films were reviewed. Demographics, echocardiographic measurements of ASD, dimensions of the device and hemodynamic data were collected. Prolonged procedure was defined as the duration from device deployment out of the delivery sheath to its release exceeding 10 minutes. A statistical model was designed using stepwise logistic regression analysis. Receiver operating characteristic curves were plotted to find the best cut-off for significant predictors.

Results: The procedure was prolonged in 25 patients. By monovariate analysis, the significant predictors for prolonged procedure were smaller, and younger patients, larger ASD, smaller left atrial (LA) dimensions and device waist ratios to weight, patient's length, and LA dimensions. By multivariate analysis, the significant predictors were deficient septal rim toward superior vena cava (SVC) and device waist diameter in relation to patient's length (best cut-off: < 12 mm and > 0.13, respectively). In three cases (3.7%) the device embolized; retrospectively possibly the cause is small used device and in one combined with vigorous physical activity.

Conclusions: A short septal rim toward superior vena cava and large device waist size in relation to patient size and/or LA dimensions may predict prolonged procedure during PTCC of ASD.

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Introduction

Percutaneous Transcatheter Closure (PTCC) is the current preferred treatment option for secundum atrial septal defect (ASD) [1]. The advantages of currently used devices include relatively easy deployment, easy retrievability, and the ability to close even large and fenestrated defects [2-5]. Contraindications of PTCC are elevated pulmonary vascular resistance and acute infections.

During the PTCC of ASD, sometimes the procedure may get unduly prolonged. The causes for such prolongation and the potential of procedure failure are related to the patient variables (clinical situation, demographics of the patient, etc.) or to the cardiac or

atrial septal anatomy (cardiac chamber size, defect size and position, septal thickness, presence of extra structure close to the defect, etc.) [6, 7]. In rare cases, device-related factors (Cobra like deformity during deployment) and delivery system deformity (kinking or distortion) is the reason behind procedure prolongation. These causes of prolongation may *happen* separately or in combination. Such unexpected situations might increase the fluoroscopy time, radiation dose, risk of complications and procedural failure.

Though some factors leading to procedure prolongation have been reported sporadically [8], our aim was to find the patient demographic, cardiac anatomical and device-related factors that could foresee procedure prolongation. Additionally, we report procedure failure and complications.

Methods and Patients

In a retrospective, cohort study, all children < 18 years (n = 89) who were referred for PTCC of their ASD between October 2010 and October 2015 were included in this study.

Under general anesthesia, patients were intubated, a trans-esophageal-echocardiography (TEE) (Philips Medical Systems, iE33, Andover, MA, USA), was performed by one of the two experienced pediatric cardiologists (MES, MOG) before starting catheterization. The ASD and the atrial septum were evaluated in terms of defect size, number and position, total septal length, measurement of all rims around the defect, and the relation of the defect to the adjacent structures, including the venae cavae, atrioventricular valves, pulmonary veins and the coronary sinus. In particular, measurement of rims toward the atrioventricular valve (AV), pulmonary veins, ascending aorta and the rims toward inferior and superior vena cavae were performed [9-10]. The patient was sent for surgical closure if the ASD was too large that the occluder device which will be used will affect the adjacent structures, if there are more than two deficient rims (< 5 mm) [1], if the rim was deficient and flimsy toward the inferior vena cava or if the patient had other associated cardiac lesions.

In our practice, the size of the occluder device (Amplatzer Septal Occluder [ASO] or Occlutech) was selected by adding 1 to 2 mm to color Doppler size of the ASD [8, 11]. No balloon sizing of the defect was performed. At the beginning of the study period, the choice of the closure device (ASO; AGA Medical Corporation, Golden Valley, MN, USA, or Occlutech, Flex II, Helsingborg, Sweden) was based on availability and patient age and size. However, during the study period, we did not continue with this selection criteria and device type selection depended on availability and operator preference.

All procedures were performed by two experienced interventional paediatric cardiologists (MES, MOG). After right heart catheterization and confirmation of normal pulmonary artery pressure, the occluder device was deployed through the delivery sheath of recommended size under fluoroscopy and real-time TEE. The device was released after careful confirmation of good positioning and presence of septal tissue between the device discs followed by a gentle Minnesota wiggling [12, 13]. Additionally, we made sure that the device was neither distorting the ascending aortic configuration nor impinging on the venae cavae and pulmonary veins, and that it was not affecting the atrioventricular valve function. Within 24 hours after catheterization, all patients underwent repeat transthoracic echocardiography, chest radiography, and electrocardiography (ECG).

The Institutional Review Board at King Fahad Medical City, Riyadh approved this study (IRB Log No. 15-408). Informed consent was waived based on the retrospective study design.

Data collection

Medical charts, echocardiographic recordings performed before, during and after the procedure, catheterization reports and recorded fluoroscopic films of all patients were reviewed. Demographic data (age, sex, weight, height and body surface area) were collected.

Echocardiographic parameters

In the pre-procedural Transthoracic Echocardiography (TTE) the defect size, number of defects (single versus multiple) and position, total septal length, measurement of the rims around the defect (rims toward the atrioventricular (AV) valves, ascending aorta, pulmonary veins, and venae cavae) were estimated.

Moreover, the presence of additional features were noted: aneurysmal tissue (a bulge > 10 mm in the atrial septum that moved back and forth), septal mal-alignment (deviation of the rims > 1.5 mm from each other), presence of prominent Eustachian valve and/or Chiari's network, double septal contour (structure parallel to atrial septum usually in the left atrium), flimsy septal portion (thin floppy, pliable septal tissue). The left atrial (LA) dimensions (coronal, lateral and anteroposterior lengths) were measured and the left atrial volume was calculated [14]. From an apical four-chamber view, the tricuspid and mitral valve annuli were measured. The right and left ventricle sizes were measured from the parasternal long axis view. The Z-values were calculated for all cardiac structures. The degree of inter-ventricular septum flattening (0, 1, 2, 3) was documented, as an indicator of right ventricular volume overload [15, 16].

Hemodynamics, catheterization and device-related variables

The right ventricular and mean pulmonary artery pressure, the systemic-to-pulmonary shunt ratio (Qp:Qs), size, number and type of the device (Amplatzer vs. Occlutech) and durations of fluoroscopy and the procedure were documented. The fluoroscopy films of all patients were reviewed offline. The duration of device deployment was calculated from starting of the deployment of the left atrial disc out of the delivery sheath until the final release of the device. If the deployment time exceeded 10 minutes, the procedure was considered prolonged.

Statistical and data analysis

The patients were divided into two groups according to the duration of deployment time: group I ≤ ten minutes; group II > ten minutes, defined as prolonged procedure. Ten minutes was selected as a cut-off-time between short and prolonged procedure depending on the fact that time from deployment to release of the device was six to eight minutes in the majority of our cases. Therefore, we decided that ten minutes for device deployment (not the total procedure time) would be a rational cut-off limit to define short and prolonged procedure as the operator might consume additional two to four minutes due to different reasons which are not related to the procedure itself.

The groups were compared statistically to identify the demographic, echocardiographic (anatomical), and device-related or hemodynamic factors that predict procedure prolongation. The data are expressed as the mean ± the standard deviation (SD). The differences between the means were calculated using Student's t-test. The differences in categorical variables were analyzed using Chi-square tests. Receiver Operating Characteristic (ROC) curves were designed to determine the cut-off values for the significant numeric variables that give the highest sensitivity and specificity. A stepwise binary logistic regression model was designed, taking procedure prolongation time or non-prolongation as dependent variable. All significant numerical and non-numerical parameters in univariate analysis were taken as independent variables. In addition, the model was subjected to goodness-of-fit tests and a model without multicollinearity was preferred over one with multicollinearity.

Univariate and multivariate stepwise logistic regression was used to identify the most significant predictors of procedure prolongation. Moreover, the odds ratios were calculated. The level of statistical significance was set at $p \leq 0.05$. All statistical analyses were performed using IBM, SPSS Statistics version 22 (SPSS, Inc., Chicago, USA).

Results

Eighty-nine patients with ASD were referred for PTCC. After pre-procedure TEE, eight patients were not considered for PTCC of the defect due to large defect in relation to patient size (that the occluder device which will be used will affect the adjacent structures) in three patients, deficient rims around the defect (< 5 mm, mainly the rim toward inferior vena cava) in three patients, and sinus venosus defect type in two patients.

Percutaneous transcatheter closure of the ASD was performed on 81 patients. Using the criteria described in the methods section, the procedure durations were short in 56 patients (group I) and prolonged in 25 patients (group II). Tables 1 and 2 show the differences between the two groups with respect to general demographics, variables related to the defect, cardiac chambers, and atrioventricular valves dimensions, degree of ventricular septum flattening,

Table 1. Demographic and echocardiographic characteristics of patients in two groups (short vs. prolonged procedure time).

Groups	Group I (n = 56) Short procedure time	Group II (n=25) Prolonged procedure time	P-value
General demographics			
Age	6.98 ± 3.92	4.47 ± 3.86	**0.009**
Male	41.8%	41.7%	0.990
Weight (kg)	21.9 ± 11.8	15.14 ± 8.06	**0.013**
Height (cm)	114.62 ± 20.04	96.92 ± 16.77	**< 0.001**
Body surface area (m²)	0.8 ± 0.3	0.6 ± 0.25	**0.005**
Defect related variables			
ASD size	11.8 ± 3.99	12.17 ± 3.91	0.706
ASD size/patient's weight	0.64 ± 0.28	0.93 ± 0.37	**<0.001**
ASD size/patient's length	0.10 ± 0.03	0.13 ± 0.04	**0.014**
Aneurysm deviation > 10 mm	16.1%	16%	0.994
Prominent eustachian valve	5.5%	8.3%	0.629
Chiari network	10.9%	12.5%	0.838
Double contour	1.8%	8.3%	0.164
Flimsy rims	18%	37%	0.065
Septal malalignment	3.6%	4.2%	0.910
Margins around the defect			
SVC rim length	13.13 ± 2.98	11.66 ± 2.91	**0.050**
Superior rim length	11.73 ± 3.43	12.46 ± 4.27	0.426
AV valve rim length	12.35 ± 5.06	10.9 ± 3.82	0.211
Aortic rim length	6.09 ± 2.08	5.55 ± 1.94	0.290
IVC rim length	12.19 ± 4.27	11.2 ± 3.4	0.339
LA, MV, LV dimensions			
LA (coronal) length	35.82 ± 6.77	31.71 ± 6.8	**0.015**
LA (lateral) length	25.62 ± 5.25	22.33 ± 5.63	**0.014**
LA (A-P) length	20.47 ± 3.92	19.04 ± 4.54	0.160
LA (coronal) length, indexed to BSA	46.73 ± 11.05	54.25 ± 14.18	**0.013**

Table 1 (cont.).

Groups	Group I (n = 56) Short procedure time	Group II (n=25) Prolonged procedure time	P-value
LA, MV, LV dimensions (cont.)			
LA (Lateral) length, indexed to BSA	33.16 ± 7.48	38.08 ± 9.89	**0.017**
LA (A-P) length, indexed to BSA	26.95 ± 7.3	32.67 ± 9.59	**0.005**
LA volume cm³	19.9 ± 10.4	14.8 ± 10.6	**0.050**
MV annulus (Z-score)	−0.02 ± 0.81	−0.18 ± 1	0.476
LVEDD size (Z-Score)	−1.2 ± 1.5	−0.86 ± 1.54	0.363
LV SF	33.63 ± 3.56	35.38 ± 5	0.081
TV, RV dimensions, degree of septal flattening			
TV annulus size	24.67 ± 3.32	22 ± 3.28	**0.001**
TV annulus size (Z-score)	1.14 ± 0.59	1.04 ± 0.83	0.528
RV size (Z-score)	8.94 ± 1.59	8.38 ± 2.05	0.198
Degree of septal flattening ≥ 2	16.4%	41.7%	0.016

Data are presented as mean ± standard deviation or as number (percentage) of patients. ASD = atrial septal defect. SVC = superior vena cava. AV = atrioventricular valve. IVC = inferior vena cava. LA = left Atrium. A-P = anterior-posterior. MV = mitral valve. LVEDD = left ventricular end diastolic dimension. LVSF = left ventricle shortening fraction. TV = tricuspid valve; RV = right ventricle.

device-related parameters, hemodynamic parameters, and procedure-related details.

The patients in group II were significantly younger, lighter and shorter than those in group I: (4.5 years SD 3.9 vs. 6.9 years SD 3.9; p = 0.009), (15.1 kg SD 8.06 vs. 21.9 kg SD 11.8; p = 0.013), (96.9 cm SD 16.8 vs. 114.6 cm SD 20.04; p < 0.001).

Defect (ASD), atrial septum and adjacent structures

The ratio of ASD size (mm) in relation to the patient weight (kg) and length (cm) was significantly larger in group II patients: (0.93 SD 0.37 vs. 0.64 SD 0.28; p < 0.001), (0.13 SD 0.04 vs. 0.1 SD 0.03; p = 0.014), respectively. Incidence of all non-numerical variables was higher in group II but these differences did not reach statistical significance.

Table 2. Device-related characteristics and hemodynamic and procedural characteristics of patients in two groups (short vs. prolonged procedure time).

Groups	Group I (n = 56) Short procedure time	Group II (n=25) Prolonged procedure time	P-value
Device related variables			
Device waist size	13.13 ± 4.21	14.28 ± 4.89	**0.281**
Device LA disc size	26.32 ± 4.86	25.06 ± 6.46	0.334
Device waist diameter / patient's weight	0.71 ± 0.31	1.04 ± 0.44	**< 0.001**
Device waist diameter / patient's height	0.12 ± 0.04	0.15 ± 0.05	**0.003**
Device waist diameter/total septal length	0.44 ± 0.56	0.41 ± 0.11	**0.791**
Device waist diameter/LA coronal length	0.37 ± 0.11	0.46 ± 0.14	0.003
Device waist diameter/LA lateral length	0.53 ± 0.18	0.67 ± 0.23	**0.006**
Device waist diameter/LA (A-P) length	0.66 ± 0.22	0.77 ± 0.25	**0.039**
LA disc size/LA coronal length	0.75 ± 0.16	0.81 ± 0.2	0.218
LA disc size/LA Lateral length	1.07 ± 0.28	1.19 ± 0.42	0.134
LA disc size/LA (A-P) length	1.33 ± 0.32	1.38 ± 0.45	0.580
LA disc size/total septal length	0.88 ± 1.06	0.72 ± 0.19	0.469
Hemodynamic-related variables			
RV systolic pressure	27.91 ± 7.38	32.48 ± 9.87	**0.027**
PA mean pressure	16.48 ± 3.9	19.78 ± 6.79	0.008
PA Systolic pressure	24.27 ± 5.65	26.39 ± 8.06	0.186
PA Diastolic pressure	9.77 ± 3.37	11.65 ± 4.09	0.037
Qp:Qs	1.74 ± 0.68	1.8 ± 0.71	0.733

Table 2 (cont.).

Groups	Group I (n = 56) Short procedure time	Group II (n=25) Prolonged procedure time	P-value
Procedure-related variables			
Time between device deployment & release(min)	6 ± 2.1	40.72 ± 57	**< 0.001**
Procedure time (min)	49.8 ± 18.13	93.32 ± 45.4	**< 0.001**
Fluoroscopy time (min)	10.92 ± 6.71	25.92 ± 15.36	**< 0.001**

Data are presented as mean ± standard deviation or as number (percentage) of patients. LA = left atrium. A-P = anterior-posterior. RV = right ventricle. PA = pulmonary artery PA. Qp:Qs = pulmonary flow : systemic flow.

Procedure failures and complications

Device embolization occurred in three patients (3.7%), within one week in one patient and the next day, after closure, in two patients. The first patient had a central 11 mm defect which was closed by 10.5 mm Occlutech, Flex II device. The closure procedure went smooth. The patient presented to the emergency department with chest pain one week after closure of the defect. The symptoms started on the previous day after jumping on the trampoline. Echocardiography revealed that the device embolized to the left ventricular outflow tract. In the second patient, there was central 12 mm defect with some aortic rim deficiency (5 mm) and double septal contour. The defect was closed by 12 mm Amplatzer septal occluder. Next day, echocardiography before discharge revealed that the device embolized to the left atrium. Both patients were referred for surgical removal of the device and defect closure. In the third patient, there was an eight mm central defect and double septal contour. The defect was closed by 9 mm Amplatzer septal occluder. Next day, chest X-ray before discharge revealed that the device embolized to the descending aorta. It was retrieved through a percutaneous trans-arterial approach and the defect closed successfully by using a bigger (12 mm) *Amplatzer septal occluder*.

Cardiac chambers and valve annulus measurement

The left atrium (i) coronal, (ii) lateral and (iii) antero-posterior lengths and (iv) its volume was significantly smaller in Group II**.** These differences were found

Table 3. Univariate analysis and multivariate stepwise logistic regression analysis for prolonged procedure time.

Variables	Univariate analysis			Multivariate analysis		
	P-value	Odds ratio	95% CI	P-Value	Odds Ratio	95% CI
Demographics-related variables						
Height (cm)	0.013	3.5	1.27-9.62			
Body surface area (m2)	0.027	2.96	1.11-7.89			
ASD size/weight	0.008	3.79	1.37-10.45			
ASD size/length	0.042	2.78	1.02-7.59			
Device waist size/patient's weight	0.004	4.8	1.58-14.55			
Device waist size/patient's length	0.004	4.8	1.58-14.55	0.006	7.28	1.78–29.85
Left atrium & anatomy-related variables						
LA coronal length		0.07	2.45	0.92-6.53		
LA lateral length	0.012	3.64	1.3-10.23			
LA coronal length, indexed	0.046	2.7	1.0-7.26			
LA lateral length, indexed	0.046	2.7	1.0-7.26			
LA A-P length, indexed	0.065	2.5	0.93-6.71			
Device waist diameter/LA, A-P length	0.046	2.7	1-7.26			
Device waist diameter/LA coronal length	0.013	3.5	1.27-9.62			
Device waist diameter/LA lateral length	0.008	3.79	1.37-10.45			
SVC rim size	0.006	4.54	1.46-14.08	0.011	6.89	1.56-30.44
Tricuspid valve annulus size	0.008	3.93	1.4-11.07			
Hemodynamics & procedure related variables						
PA mean P	0.04	2.8	1.03-7.61			
Procedure time (min)	<0.001	16.36	5.02-53.31			
Fluoroscopy time (min)	<0.001	10.47	3.46-31.71			

CI = confidence interval; LA = left atrium; A-P = antero-posterior; SVC = superior vena cava; LVEDD = left ventricular end diastolic dimension; RV = right ventricle; PA = pulmonary artery

in absolute and indexed measurements (relative to body surface areas). The values of the four respective parameters after indexing in group II versus group I, respectively, were as follows: (i) left atrium coronal 54.2 mm SD 14.18 vs. 46.7 mm SD 11.05 (p = 0.013); (ii) left atrium lateral 38.08 mm SD 9.8 vs. 33.16 mm SD 7.48 (p = 0.017); (iii) left atrium anteroposterior 32.67 mm SD 9.59 vs. 26.9 mm SD 7.3 (p = 0.005); and (iv) left atrium volume 19.9 cm^3 SD 10.4 vs. 14.8 cm^3 SD 10.6 (p = 0.05). Only the absolute left atrium antero-posterior dimension was not significantly different between the two groups. Further, the degree of septal flattening was more in patients in Group II (41.7% vs. 16.4, p = 0.016), indicating greater right ventricle volume overload caused by larger Qp:Qs.

Device related parameters

The ratios of the device waist diameter to the patient weight and length were significantly larger in group II: respectively (1.04 SD 0.44 vs. 0.71 SD 0.31, p < 0.001) and (0.15 SD 0.05 vs. 0.12 SD 0.04, p = 0.003). Moreover, the ratios of the device waist diameter to left atrial coronal, lateral and antero-posterior lengths were significantly larger in group II: respectively (0.46 SD 0.14 vs. 0.37 SD 0.11, p = 0.003); (0.67 SD 0.23 vs. 0.53 SD 0.18, p = 0.006); (0.77 SD 0.25 vs. 0.66 SD 0.22, p = 0.04).

Hemodynamic parameters and procedure times

The right ventricle systolic pressure and the mean pulmonary artery pressure were significantly higher in group II: respectively (32.48 mmHg SD 9.87 vs. 27.91 mmHg SD 7.38; p = 0.027), (19.78 mmHg SD 6.79 vs. 16.48 mmHg SD 3.9; p = 0.008). Additionally, the total procedure time, the fluoroscopy time and time between the beginning of device deployment and release were significantly longer in group II: respectively (93.32 min SD 45.4 vs. 49.8 min SD 18.13; p < 0.001), (25.92 min SD 15.36 vs. 10.92 min SD 6.71; p < 0.001), (40.72 min SD 57 vs. 6 min SD 2.1; p < 0.001).

### Predictors of procedure prolongation

Monovariate analysis revealed that the significant predictors of prolonged procedure were as follows: smaller and younger patients, larger ASD size, smaller LA dimensions, and larger device waist ratio to body weight, body length and LA dimensions (Table 3). Multivariate analysis by backward stepwise logistic regression revealed that deficient septal rim toward superior vena cava (odds ratio: 6.89 [95% CI 1.56 – 30.44], p = 0.011; best cut-off value < 12 mm) and large device waist diameter in relation to patient body length (odds ratio 7.28 [95% CI 1.78 – 29.85], p = 0.006; best cut-off value > 0.13) were significant predictors for prolonged procedure (Table III).

The Receiver operating characteristic (ROC) curves

ROC curves for the SVC rim length and for the ratio of the device waist diameter to patient length revealed that the cut-off points that gave sensitivity close to 95% and the highest specificity were rim length 12 mm and ratio 0.13 (Figures 1 and 2). The ROC curves for the ratio of device waist diameter to left atrial coronal, lateral and anteroposterior lengths are presented in Figure 3. The best cut-off values were 0.4, 0.59 and 0.67, respectively.

Discussion
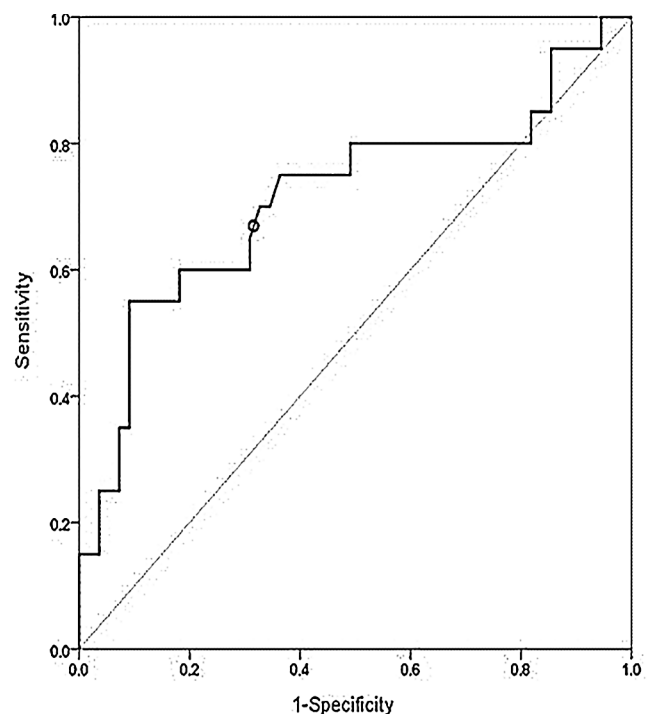
Figure 1. ROC curve for the SVC rim size. Area under the curve was 0.63 (95% confidence interval 1.56 - 30.44, p = 0.011). The circle represents the optimal cut-off values which give the best sensitivity and specificity. ROC = Receiver-operating characteristic; SVC = Superior venae cava.
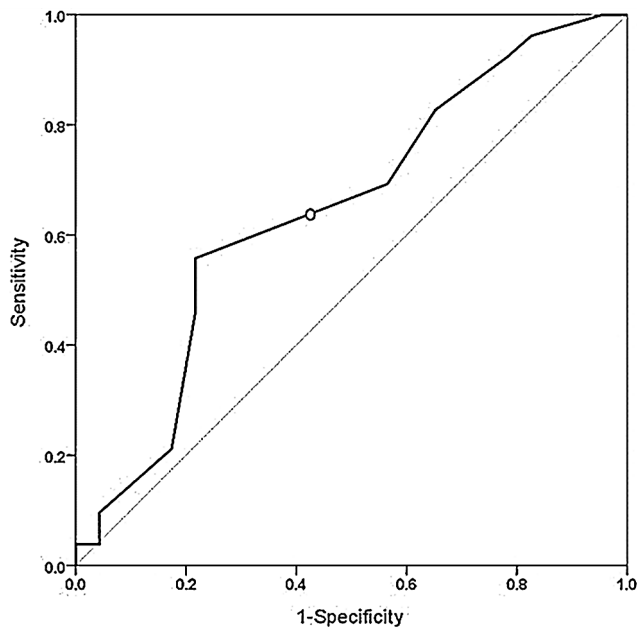
Figure 2. ROC curve for the ratio of the Device Waist Diameter to Patient's Length. Area under the curve was 0.72 (95% confidence interval 1.78-29.85 , p = 0.006). The circl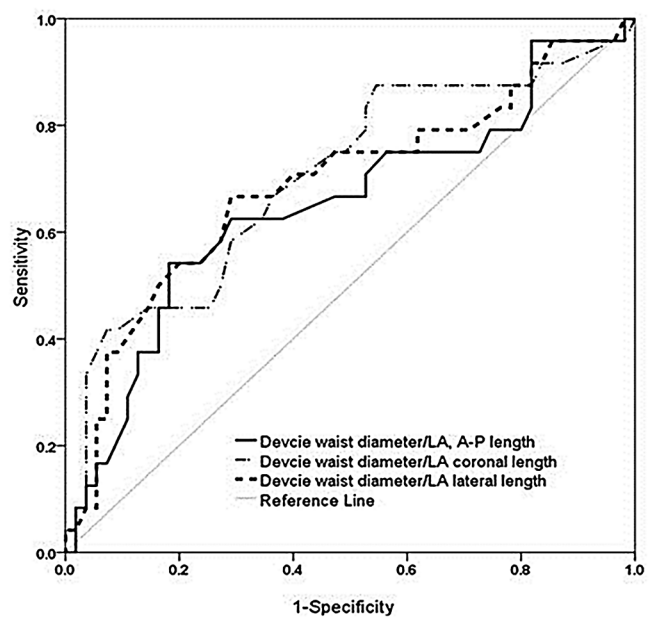e represents the optimal cut-off values which give the best sensitivity and specificity. ROC = Receiver-operating characteristic.

Figure 3. ROC curve for the ratio of the Device Waist Diameter to LA Anterior-posterior Length, LA coronal length, LA lateral length. Areas under the curve were 0.65 (95% CI = 1 - 7.26, p = 0.046), 0.70 (95% CI =1.27 - 9.62, p = 0.013), and 0.689 (95% CI = 1.37 - 10.45, p = 0.008) respectively. ROC = Receiver-operating characteristic; LA = Left atrium; CI = Confidence Interval.

The results show that shorter septal rim towards superior vena cava and larger closure device waist diameter in relation to body height were predictors of procedure prolongation during percutaneous transcatheter closure of the atrial septal defect. The best cut-off values for these predictors were 12 mm and 0.13, respectively. Monovariate analysis revealed that the ratio of device waist diameter to left atrium (LA) dimensions may also predict procedure prolongation.

The findings support the common knowledge that the complexity of any intervention is increased by small patient size [17]. The relations of device waist diameter to weight and length are significant predictors. It has been reported that patient weight can be used as a guide for device size selection. The criteria proposed that device diameter (in mm) to weight (in kg) ratio should be less < 1.5 [18]. In the current study, multivariate analysis showed that the device waist diameter in relation to the height of the patients seems to be statistically more important than its relation to weight. *Ko et al.* reported that a larger defect, smaller

posterior-superior rim, smaller retro-aortic rim and smaller ratios of the LA dimensions to the device size predicted the need to apply modified methods for ASD device closure, leading to prolongation of the procedure. Based on their results, they speculated that the relationship between device size and left atrial anteroposterior dimension is the most important one [8]. It is interesting that though we defined prolonged procedure differently (length of deployment time > ten minutes), we came to a similar result. The relationship between the device waist size and the left atrial anteroposterior dimension seems to be an important variable; a ratio > 2:3 predicted an increase in the complexity and duration of the intervention.

The most common site for erosions after ASD transcatheter closure is the free wall of the left atrium or the posterior aspect of the aorta [19], which represent the two boundaries of the anteroposterior axis of the left atrium. This could indicate that oversizing the device in relation to the left atrial anteroposterior diameter may increase the risk of procedure difficulties and prolongation.

It has been argued that the relation between the device left atrial disc volume and the left atrial volume might be a more sensitive predictor [20]. In this study, we used the device diameter in relation to left atrial dimensions. The volume of the left atrial disc is the result of its diameter and thickness. The thickness of the disc is a constant and the changes in its volume is the result of the changes in its diameter which constantly related to device waist diameter. However, volumes relations could be a more useful predictor.

In this study, we defined procedure prolongation as deployment time beyond ten minutes. This cut-off time limit was selected depending on our experience, where the time from deployment to release of the device was six to eight minutes in the majority of the cases. Thus, we decide ten minutes would be a rational limit to define short and prolonged procedure as the operator might consume additional short time. The deployment time could be affected by repeated attempts to deploy the device, using different deployment methods (balloon-assisted deployment, right pulmonary vein etc.), using more than one device, loss of device memory (Cobra deformity), delivery sheath distortion, and difficulty of getting clear TEE images to confirm proper and stable device positioning. All these variables are influenced by the experience of the operator and the echocardiographer. Skilled operators and experienced echocardiographers can achieve shorter deployment times. However, the effect on deployment time due to the operator experience would be relatively same in all procedures. Equipment failure during procedure can also prolong the deployment time however we did not experience such type of difficulty in this study.

The study showed that the rim toward superior vena cava as a significant predictor for procedure prolongation. The ROC curve resulted in a cut-off value of the rim < 12 mm. We find this value is far much longer than what is usually considered to be deficient (i. e. 5 mm) [1]. Such result may need to be studied further.

Device embolization occurred in three patients (3.7%). The first patient came to the emergency department one week after closure with a complaint of chest pain. The symptoms started on the previous day after jumping on the trampoline. Echocardiography showed that the device embolized to the left ventricular outflow tract. The embolization was con-

sidered to be due to a relatively small device and the vigorous physical activity which should be avoided at least for three months after the procedure. In the second patient, echocardiography before discharge, next day, revealed that the device embolized to the left atrium. Similarly, in the third patient, chest X-ray before discharge revealed that the device embolized to the descending aorta. Retrospectively, we could assume that embolization could have been avoided by using bigger closure devices to get better device fixation and stability; especially in the presence of double septal contour in the two patients and short aortic rim in one.

Three patients who were eventually referred for surgical closure of the defect (two after device embolization and one because of device mal-position which was irretrievable due to distorted sheath) and one had device embolization which was retrieved percutaneously. All patients belonged to the prolonged group and have an SVC rim (8, 9, 9, 11 mm) shorter than the cut-off length (12 mm). This finding may indicate that while the three other variables are only predictors of procedure prolongation, a shorter SVC rim might predict the risk of embolization in addition to procedure prolongation.

Limitations of the study

The major limitations of this study are its retrospective nature and the relatively small number of patients. An additional limitation is that the results are from a single center experience. The effect of rim deficiency toward inferior vena cava was not studied as such, as patients with such rim deficiencies were sent to surgery without further attempts at PTCC.

The prolonged procedure group was significantly younger than the other group. It also differed from the other group in other variables that could be used as predictors, but the differences between the groups were not statistically significant, possibly because of the relatively small number of patients.

Conclusions

This study reinforces previously published literature reporting that the percutaneous transcatheter closure of atrial septal defect is riskier and may unexpectedly convert into a difficult and prolonged pro-

cedure in younger and smaller patients. The relationship of the closure device diameter to body size and left atrial size can be used as a predictor of the risk of experiencing difficulties and prolongation. The septal rim toward the superior vena cava is another predictor of procedure difficulty and prolongation, and it might even predict the risk of embolization. Further studies on larger patient populations are needed to confirm our findings.

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Conflict of Interest

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

Comment on this Article or Ask a Question

Pulmonary Arteriopathy in Patients with Mild Pulmonary Valve Abnormality without Pulmonary Hypertension or Intracardiac Shunt

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Abstract

Background: The natural history of pulmonary artery aneurysms (PAA) without pulmonary hypertension, intracardiac shunt or significant pulmonary valvular disease has not been well studied. This study looks to describe the outcome of a cohort of adults with PAA without significant pulmonic regurgitation and stenosis. Imaging modalities utilized to evaluate pulmonary artery (PA) size and valvular pathology are reviewed.
Methods: Patients with PAA followed at the Ahmanson/UCLA Adult Congenital Heart Disease Center were included in this retrospective analysis. The criteria for patient inclusion were PAA size ≥ 2.5 cm without intracardiac shunting, more than mild pulmonary valve stenosis and regurgitation, or pulmonary hypertension. PAA size gathered from initial imaging was compared to the most recent to quantify PAA growth over time. CT, MRI and echocardiography results were compared.
Result: Eleven patients were included; Eight females and mean age of 57 (range 25-80). Eight patients were > 50 years of age. Five patients had PAA > 4 cm and were ≥ 50 years old. PAA size increased at a mean rate of 0.5 cm over a mean follow-up of 10 years. Echocardiography demonstrated significant correlation to CT/MRI (r=0.93, p<0.001).
Conclusion: Most PAA cases are present in patients older than 50 years. Long-term follow-up suggests a benign course without episodes of dissection or rupture despite 6/11 patients with PAA ≥ 5 cm. PA dilation progresses slowly over time and does not appear to cause secondary events. Echocardiography correlates well with magnetic resonance imaging and computed tomography and is useful in measuring PAA over time.

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Introduction

Pulmonary artery aneurysm (PAA), as an isolated finding, is a rare condition of unclear clinical significance that is not well described in the literature. Deterling and Clagett [1] reported an occurrence of eight PAA in 109,571 post-mortem examinations, corresponding to an estimated prevalence of one PAA per 13,696 necropsies. Greene and Baldwin [3] described four criteria for defining PAA: 1) Dilation of the pulmonary artery (PA) (including or excluding the branches), 2) lack of intracardiac shunt, 3) lack of chronic cardiac conditions and 4) lack of systemic arterial disease.
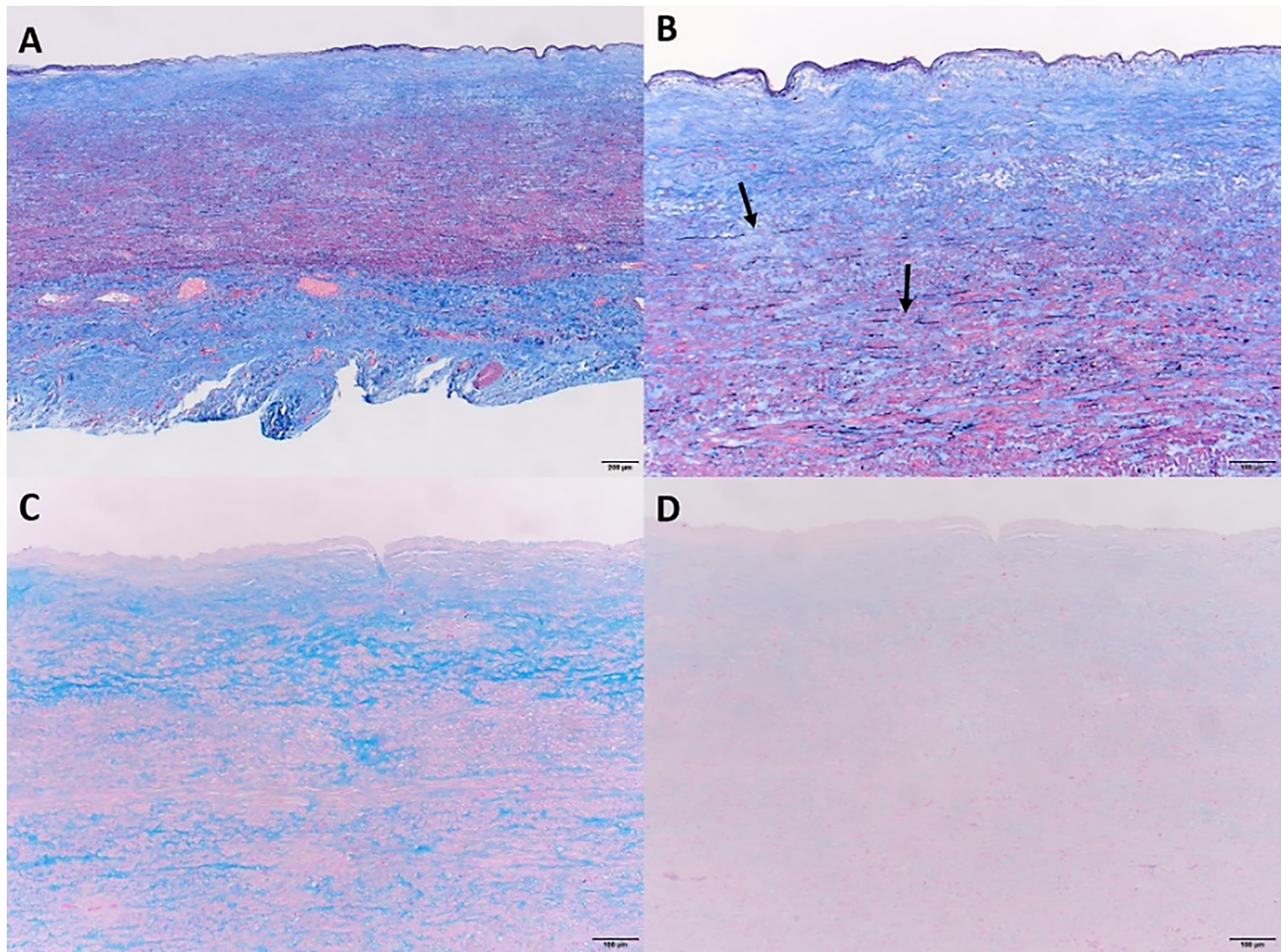
Figure 1. Pulmonary artery histology from a patient with Pulmonary artery aneurysm. *Panel A*. Trichrome/elastin stain demonstrating severe elastic fiber loss (40x) consistent with grade 3 arteriopathy (Niwa et al, Circulation 2001). *Panel B*. At high power, there is disruption (arrow) and fragmentation of the remaining elastic fibers (trichrome/elastin, 100x). *Panel C*. The alcian blue stain highlights translamellar mucoid extracellular matrix accumulation (100x). *Panel D*. The extracellular mucoid matrix materials (glycosaminoglycans) are digested following treatment with hyaluronidase (100x).

When pulmonary aneurysms do occur, they are usually secondary to a variety of factors, most commonly pulmonary arterial hypertension and/or congenital cardiac shunts. Less commonly pulmonary artery aneurysms may be secondary to infection (syphilis and tuberculosis), congenital arteriopathy (e.g. Marfan and Turner syndrome), auto-immune conditions (Behcet's) or congenital pulmonary valve abnormalities (Tetralogy of Fallot with absent pulmonary valve, pulmonary stenosis and/or regurgitation) [2]. Pulmonary artery dilation may be present in patients with pulmonary valve stenosis, however, catastrophic complications such as dissection or rupture are rare (Roberts WC et al. AJC 2017, Adodo et al. Ann Thorac Surg 2017, Koretzky Circulation 1969). The histopathologic characteristics are similar to those seen in the aortas of those with congenital aortic valve disease [9]. The association between aortic dilation and congenital aortic stenosis is well known, however, the degree of aortic dilation is not directly related to the degree of valvular stenosis. This suggests a congenital etiology to the aortopathy in bicuspid aortic valve patients that may be independent of valvular hemodynamics. Could a similar logic exist for congenital pulmonary valve stenosis? The definition of an aneurysm is "focal dilation of a blood vessel involving all
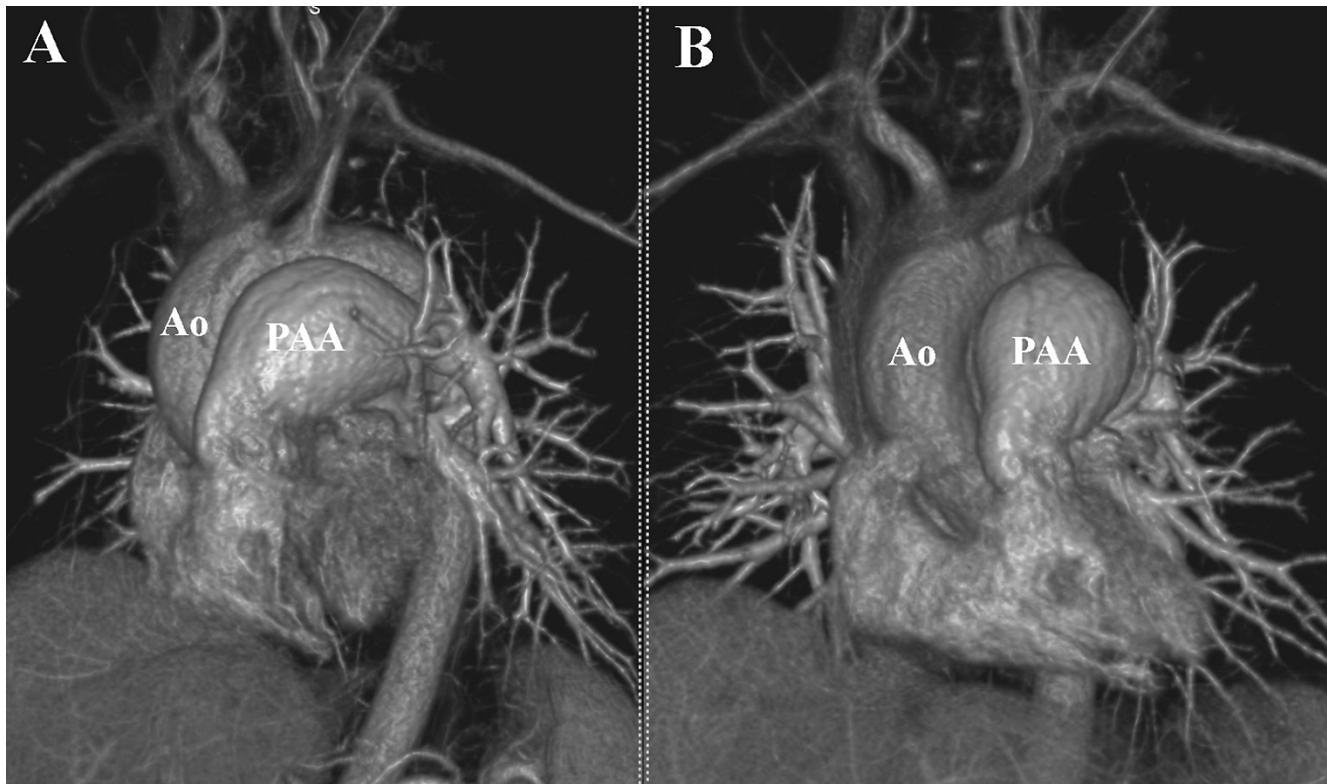
Figure 2. Cardiac MRI with feraheme contrast of a patient with Pulmonary Artery Aneurysm demonstrating severe dilation of the main pulmonary artery. *Panel A*. Left anterior oblique view. *Panel B*. Frontal view.

three layers of the vessel wall" [4]. There have been several suggested definitions for pulmonary artery aneurysm. Nguyen et al [5] defined a PAA as the "focal dilation of the artery beyond its maximal normal caliber". There is no clear consensus on the upper limit of normal size for the main pulmonary artery in adult patients. In this study, we considered PAA to be a dilation of the main and/or proximal branch pulmonary artery of ≥ 2.5 cm. The histopathologic characteristics of PAA include fragmentation and loss of elastin fibers (Figure 1). Patients with PAA are generally asymptomatic and the diagnosis is often made incidentally on chest or cardiac imaging. This study seeks to describe the imaging modalities utilized to make the diagnosis of PAA and monitor for growth or complications, the natural history of this condition and review the existing literature. Moreover, commonly utilized imaging modalities for the diagnosis and follow-up of PAA, such as echocardiography and cross-sectional imaging with computed tomography (CT) and/or magnetic resonance imaging (MRI), are compared (Figure 2).

Methods

A retrospective review of the Ahmanson/UCLA Adult Congenital Heart Disease Center database was performed to identify a cohort of patients with PAA. The criteria for patient inclusion were dilated main and/or branch pulmonary artery ≥ 2.5 cm, lack of significant pulmonary valvular disease, absence of congenital cardiac shunt and/or pulmonary hypertension, and absence of a clear secondary etiology. Transthoracic echocardiographic and cross-sectional imaging (CT and/or MRI) imaging data were gathered and compared. The first recorded PAA size from each imaging modality was compared to the most recent PAA size allowing estimation of rate of growth over time.

Results

Eleven patients with PAA were identified from a total of 4,857 patients in the Ahmanson/UCLA Adult Congenital Heart Disease database. Patients with

Table 1. Baseline and follow-up imaging characteristics of 11 pulmonary artery aneurysms (PAA) patients. Mean follow-up duration is 10 years.

| Patient	Gender	Age (years)	Initial PAA size (cm)	PAA size at latest follow-up (cm)	Follow-up duration (years)	Rate of PAA growth (cm/year)
1	M	65	3.7	3.8	12	.01 cm/year
2	M	30	5	5	5	0 cm/year
3	M	77	4.5	5	15	.03 cm/year
4	F	53	3.8	3.8	1	0 cm/year
5	F	52	4.8	5.3	18	.03 cm/year
6	F	80	7.3	7.5	2	0.1 cm/year
7	F	71	3.1	4.3	11	0.1 cm/year
8	F	25	2.8	3.9	14	0.08 cm/year
9	F	69	5.9	6.5	13	0.05 cm/year
10	F	70	4	5.4	16	0.09 cm/year
11	F	43	4.6	4.7	5	0.02 cm/year

greater than mild pulmonary valve stenosis or regurgitation and any of the secondary causes of pulmonary artery aneurysm were excluded. All patients had mild pulmonary valve stenosis and 9/11 had mild pulmonary regurgitation. Eight of the eleven patients were female, mean age 57 (range 25-80) (Table 1). Eight of the eleven (73%) were above 50 years of age. Five patients (46 %) had PAA > 4 cm and all were ≥ 50 years old. PAA size increased at a mean rate of 0.5 cm over a mean follow-up of 10 years, and an increase in PAA size was noted in nine patients. PAA size increased at <0.1 cm/year in all patients (Figure 3). For the assessment of PAA size, echocardiography demonstrated a significant correlation to CT/cMRI *(r=0.93, p<0.001)*. There were no instances of pulmonary artery dissection or rupture despite 6/11 patients with PAA > 5 cm. Additionally, there were no instances of coronary artery compression and no evidence of progressive pulmonary valvular abnormalities over 10 years.

The mean systolic gradient across the pulmonic valve measured by Doppler was 7.3 (+/- 3 mmHg) and 7/11 patients had evidence of pulmonary valve systolic doming by echocardiography. Ten patients underwent cardiac MRI imaging at some point in their care, of these eight had evidence of pulmonary valve doming, and one patient had a bicuspid pulmonic valve. A bicuspid aortic valve was present in one patient who also had dilation of the ascending aorta and whereas another patient had pectus excavatum and mitral valve prolapse without dilation of the aorta. Pulmonary ejection sounds were auscultated in eight patients and pulmonary ejection murmurs were heard in all eleven patients. Pulmonic valve clicks or murmurs led to further investigation and discovery of PAA by echocardiography in nine patients. Incidental discovery occurred by chest CT in one patient with frequent pulmonary infections and another patient with a thyroid cyst.

Discussion

Pulmonary arterial aneurysm (PAA) may occur in a variety of settings and is often associated with pulmonary arterial hypertension or congenital cardiac shunts. The condition has been described in patients with pulmonary valve pathology, but long-term data on clinical significance and progression is lacking. This study sought to delineate the long-term outcomes in a cohort of adults with no more than mild pulmonary valve dysfunction and PAA. Long-term follow-up suggests a benign course without catastrophic complications of rupture or dissection despite 6/11 patients having a PAA ≥ 5 cm. The dilation of the pulmonary artery occurred slowly over time and did not seem to cause any secondary clinical complications such as
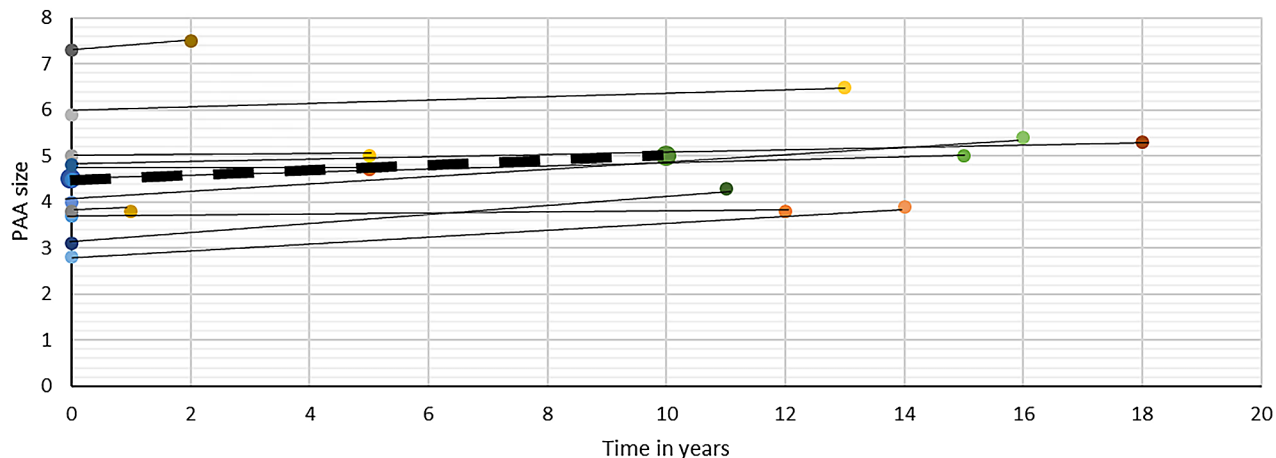
Figure 3. Rate of change in Pulmonary Artery Aneurysm size in 11 patients over time. The bold and dashed line is the mean rate of growth in the entire cohort over 10 years.

progressive pulmonary valve regurgitation or coronary artery compression.

Niwa et al. [9] described the histopathologic characteristics of thirteen patients with PAA and compared the findings to seventy-three patients with aortic aneurysms due to a variety of causes. One patient with PAA and pulmonary valve stenosis was included and had evidence of advanced (grade 3) medial wall abnormalities of collagen deposition, ground substance and loss of elastin fibers (Figure 1). There are rare reports of aortopathy in patients with pulmonary valve stenosis and PAA. In 1959, Evans and Dauncey [7] described a case of aortic dissection in a patient with moderate pulmonary valve stenosis with "post-stenotic" pulmonary artery dilation. However, the occurrence of congenital pulmonic and aortic valve disease is unusual. In congenital aortic or pulmonic valve stenosis, the relationship of severity of stenosis to the degree of arterial dilation and histopathologic abnormalities has been questioned. Niwa et al. [9] suggest that aortic and pulmonic arterial dilation are independent of the degree of valvular stenosis or regurgitation and more likely due to an inherent congenital arteriopathy. This assertion is supported by the eleven patients described in this cohort, all of whom had pulmonary artery dilation in the absence of significant pulmonic valve stenosis. Therefore, "post-stenotic" pulmonary arterial dilation

is not included in this cohort given the absence of significant pulmonary valve stenosis.

Patients were generally diagnosed because echocardiographic imaging was performed to evaluate for pulmonic valve ejection sound and/or systolic flow murmurs in the pulmonic position. There were two incidental diagnoses made on chest imaging to evaluate other conditions.

In regard to imaging modalities, it was encouraging to note that echocardiography correlated well with cross-sectional imaging by MRI or CT. Echocardiography is widely available, cost-effective and does not involve radiation. Given the slow rate of PAA growth (~ 5 mm over 10 years), yearly imaging is unnecessary.

The following limitations are present in our study. The sample size for this study is eleven patients. No definitive claims can be made with a small sample size. This study is also retrospective. Even though the current progression of the patients in our study is good, we can't be sure that they will continue on the same trajectory.

Conclusions

Pulmonary artery aneurysms are described in patients with congenital pulmonary valve pathology of mild functional significance. Most cases were present in patients older than 50 years. Long-term follow-up

suggests a benign course without dissection or rupture despite the majority of patients with PAA > 5 cm. Pulmonary arterial dilation progresses slowly over time and does not appear to cause any secondary clinical events. Echocardiography correlates well with MRI or CT and is useful in measuring PAA over time. Yearly imaging is unnecessary given the slow rate of progression.

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Conflict of Interest

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

Comment on this Article or Ask a Question

CSI Asia-Pacific

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1. PERCUTANEOUS TRANSLUMINAL MITRAL VALVULOPLASTY IN POST MITRAL VALVE REPAIR AND AORTIC VALVE REPLACEMENT PATIENT

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A 34-year-old male, who underwent Aortic Valve replacement with mitral valve repair for rheumatic heart disease (RHD), Severe AR with moderate MR in 2007. Patient had NYHA class III Symptoms along with palpitation for 10 to 12 years. Hence he was taken for AVR and MV repair. Pre operation echo revealed RHD, Severe AR, Mod MR, Dilated LV (LVIDd/s 7.8/6.0cm), Dilated LA(4.3cm) and LVEF=55%. Intra-operative findings revealed Dilated LA and LV, thickened aortic leaflets with lack of centre coaptation, Thickened AML and PLML with rolled edges, mild commissural fusion, mild to moderate sub-valvular changes. He underwent AVR with ATS 20mm and Bilateral commissurotomy and papilotomy of P2, 27mmSJM ring angioplasty ring. Post repair no leak on saline test. Echocardiography after three month of surgery revealed Normally functioning aortic prosthetic valve, Mitral valve area of 1.6cm2.

In March 2017, after 10 years of AVR and MV repair, patient presented with of extertional dyspnea. He underwent echocardiography which revealed normally functioning Aortic Valve (peak gradient across Aortic valve 15mmHg, Mean gradient =7mmHg), commissural fusion with MVA of 0.7cm2, as shown in Fig 3, no significant subvalvar pathology or calcification of the valve, dilated LA. In view of suitable morphology of MV for percutaneous transluminal mitral valvuloplasty (PTMC) with Boston score (Wilkins score) of 7, he was considered for PTMC. Heart team discussion was done. Team decide to attempt PTMC so that MV replacement (MVR) may be delayed for few more years. IV heparin infusion was started and warfarin was stopped. Three hours before the procedure heparin was stopped. Three hour after the PTMC IV heparin was started and continued until INR was in theurapeutic range.

Through right femoral vein approach patient underwent PTMC with 26mmAccura balloon inflated to 26mm.Pigtail catheter was not kept in the ascending aorta as the metallic Aortic valve was the landmark for the septal puncture. Procedure was successful with single inflation. Medial commissure was split and lateral commissure was partially split.
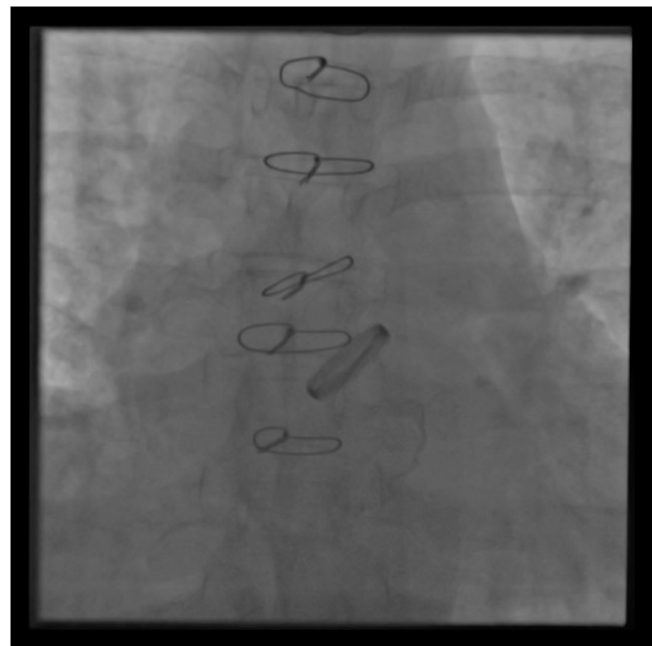
1. Figure 1. Prosthetic Aortic valve with Mitral valve ring.
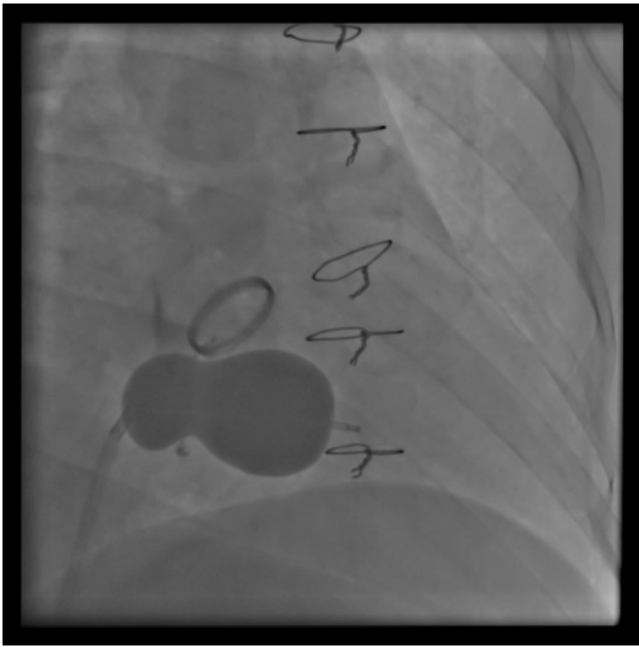
1. Figure 2. Balloon Dilatation during PTMC.

MVA increased from 0.6 to 1.3 cm2 as shown in Fig 2, MV gradient decreased from 17mmHg to 7mmHg, mean left atrial pressure decreased from 15 to 7 mmHg. There was no increase in MR. During the procedure patient went into vasovagal reaction. Patient discharged after therapeutic range of INR was achieved. Patients is currently under follow with NYHA I symptom.
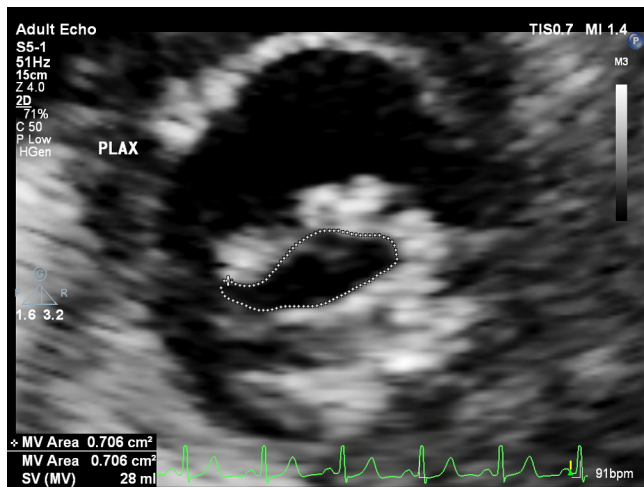
1. Figure 3. MVA=0.7cm2 before PTMC.

Conclusion: In patients with suitable valve morphology, PTMC can be done successfully in MS following MV repair for severe MS. This may help to delay the need for MVR in younger patients.

1. Figure 4. MVA=1.3cm2 post PTMC.

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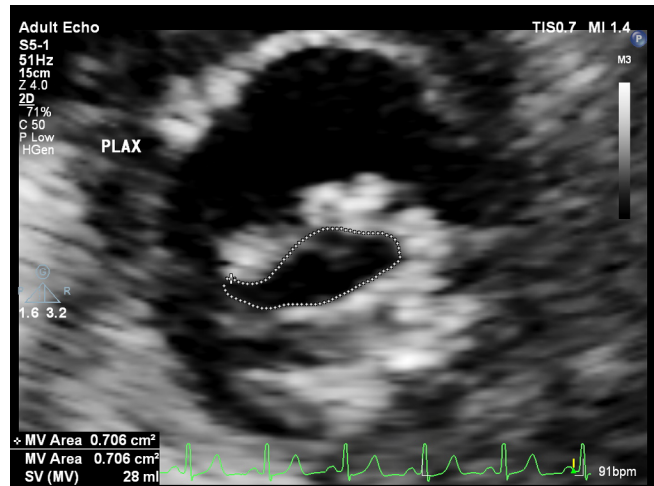3. Iung B, Vahanian A. Rheumatic mitral valve disease. In: Otto CM, Bonow RO, eds. In: Valvular Heart Disease: A Companion to Braunwald's Heart Disease 4th ed. Philadelphia: Saunders; 2013:255–277.
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2. EXPERIENCE ON TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS IN NEPAL

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Background and Aims: In the current era, transcatheter closure of patent ductus arteriosus (PDA) using either coils or device is a well-established procedure.We want to describe our experience in PDA device closure in Nepal.

Methods: It was a retrospective study done with the hospital catheterization laboratory records. Patients age, gender device used any adverse outcome were analyzed.

Results: In Nepal first PDA device closure was done in March 2007. Till Novemebr 2017, 223 PDA device closure were done in four centres of Nepal. Most of the cases (203) were done in national heart Centre. During the study period 211 patients were attempted for transcatheter closure of PDA in national heart centre. Six patient were thought to have unfavorable size or shape, and transcatheter occlusion was not attempted. In one patients attempt was made to close the duct with cook coil which embolized to pulmonary artery. One patient device was retrieved as there was no significant decrease in the pulmonary artery pressure. Among the 203 PDA device closures most 149 procedures were done in the year 2016 and 2017. In 203 patient PDA was successfully closed. Among the 203 patients 155 were female and 48 were male. Age ranged from 0.4 years to 69 years with the mean of 13.5 years. The PDA was closed by Amplatzer duct occluder in 178 patients, Life tech PDA occluder in 14 patients, Hyperion PDA occlude in seven patients, Amplatzer muscular VSD in four patients. Most of the cases we did the antegrade technique.In few cases when we cannot cross the PDA through the pulmonary artery retrograde technique was used.In one case we closed a residual PDA after there was a PDA after the surgical closure.

Conclusions: Transcatheter closure of PDA can be done safely with high success rate in Nepal.

3. DEVICE CLOSURE OF NON ISCHEMIC, NON TRAUMATIC LEFT VENTRICULAR PSEUDOANEURYSM: A RARE PRESENTATION

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Introduction: Pseudoaneurysm of the LV cavity has been reported after myocardial infarction and myocardial surgery. It has been associated with mitral regurgitation and a high mortality. Conventional surgery however carries significant mortality, especially when combined with mitral valve replacement; and medical treatment carries an even higher mortality. We report a case of non ischemic and non traumatic pseudoaneurysm which was treated with device closure.

Case Report: 45 years old lady presented with history of dyspnea on exertion, chest pain since last 3 years with progressive worsening since last 3 months presently in NYHA class 3. Investigations done revealed cardiomegaly on

chest X-Ray. Echo revealed large apical pseudoaneurysm with preserved left ventricular function. Cardiac MRI done revealed presence of lobulated psuedoaneurysms from LV with enhancing wall suggestive of scar and fibrosis. The larger psuedoaneurysm was measuring 10x6.6x5.0 cm in maximal dimensions with a narrow neck ,3 mm in diameter and 4 mm in length, arising from the apex communicating with the LV cavity with movement of blood and also having intracavitary filling defect suggestive of a thrombus.There was also presence of another lobulated pseudo aneurysm measuring 3.1x2.8 cm in maximal diameter with a narrow neck of 4mm diameter and 15mm length arising from sub-mitral lateral wall extending in the atrioventricular groove communicating with the left Ventricle and indenting the Left Atrium. Coronary angiogram was done which revealed normal coronaries.

She was planned for device closure in view of narrow neck and pseudoaneurysm was successfully closed with Amplatzer vascular plug 3 size 12mm. Post device closure echocardiogram revealed complete occlusion of the pseudoaneurysm sac which was later confirmed on CT angiography.

Discussion: Pseudoaneurysm are mostly ischemic or traumatic (post surgical). This case was unique in the sense that there was no history of any surgical procedure and also that coronaries were normal. Percutaneous approach is attractive option as it carries less morbidity as compared to standard surgical approach.

4. COARCTATION OF AORTA IN ADULTS: CHALLENGES FACE

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Introduction: Coarctation of the aorta is a common congenital defect, which although normally detected and surgically repaired in childhood may present in adolescence or adulthood. Most common presentation is hypertension. Presentation can be complicated by associated lesions. The natural history of untreated coarctation is that of premature death from stroke and coronary heart disease or sudden death. We present three cases of unusual presentation and challenges thus faced.

Case Reports:

Case 1: A 45 year old post aortic valve replacement presented with dyspnea on exertion (NYHA class IV). Evaluation revealed severe prosthetic valve dysfunction with severe Pulmonary arterial hypertension. Patient was taken up for cath to assess hemodynamics but surprisingly found to have associated coarctation of aorta with almost atresia subsequently underwent stenting of coarctation. Post procedure the gradient across the prosthetic aortic valve also decreased significantly.

Case 2: A 65 years old post angioplasty to LAD and LCx presented with chest pain. Angiogram done revealed normal coronaries but had coarcation of aorta. patient had deranged renal function and developed anuria. Subsequently patient was taken up for coarctation stenting. After the procedure the renal function improved dramatically.

Case 3: 42 years old presented with history of recurrent admissions for pulmonary edema. Evaluation revealed severe aortic regurgitation. He was planned for aortic valve replacement. He was taken up cath for evaluation of coronaries but found to have near atresia of arch which was then relived by stenting of coarctation. Severity of AR decreased post procedure.

Discussion: Coarctation in adults though usually presents with uncontrolled hypertension but it can be complicated by presence of associated lesions like aortic regurgitation or complications like renal failure and also it can overestimate the severity of associated lesion as in our case it overestimated the severity of prosthetic valve dysfunction in first case and Aortic regurgitation in second case.

5. PERCUTANEOUS ASD CLOSURE OF CHILDREN LESS THAN 10 KG

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[4] Erciyes University; Pediatric; Pediatric Cardiology
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[7] Erciyes University; Interventional; Kayseri

Background: Traditionally the procedure of percutaneous ASD closure is used to be done in children more than 15 kg.

Main limitation factor for small children is the size of delivery system and how to manage in a state of complication.

Objective: The aim of this study was to discuss the success, efficacy and safety of the percutaneous closure of symptomatic ASD in children less than10 kg.

Method: Study was performed in 2 Pediatric Cardiology centers: Erciyes University and Gaziantep University. Total 32 patients were included. Demographic and angiographic data of these patients were gathered retrospectively from patients' records.

Results: Median weight of patients was 9,0 (8,2-9,5) kg, median age of patients was 19 (12,5-31,5) months. Female/male ratio was 21/11. Median mean pulmonary pressure was 25 (20,5-33) mmHg. The median value of measured defect sizes measured during angiograph was 13,0 (10,75-15,0) mm. Median value for preferred device size was 13,0 (9,0-15,0) mm. Weight/defect and body surface area/defect ratios were calculated. The ratio of weight per defect size was 0,64 (0,56-0,85) also ratio of body surface area per defect size was 0,030 (0,028-0,040).

Additional medical problems of patients were growth hormone deficiency, Mucopolysacharidosis, Down syndrome in 3 patients. Additional heart problems of patients were severe pulmonary stenosis in 4 patients, large PDA in one patient, VSD in 2 patients. Pulmonary valvuloplasty, PDA closure, and percutaneous VSD closure were done in those patients in the same session with ASD closure. Types of devices used were: Amplatzer Septal Occluder in 26 patients, CeraFlex Septal Occluder in 2 patients, Figulla FlexII Atrial Septal Occluder in 3 patients, Memopart Septal Occluder in 1 patient.

After successful positioning, before deploying the device in one patient device was retrieved because of compression to the aorta.

No major complication was seen.

Conclusion: In experienced centers percutaneous ASD closure can be done effectively and safely in symptomatic children less than 10kg.

6. ATTACH-&-RAISE TO THE ATRETIC PULMONARY VALVE WITH AN ENDHOLE CATHETER IS A GUARANTEE FOR SUCCESSFUL RADIOFREQUENCY VALVOTOMY IN NEONATES OF PULMONARY ATRESIA WITH INTACT VENTRICULAR SEPTUM

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Background: For neonates of pulmonary atresia with intact ventricular septum(PAIVS), Z score of tricuspid annulus is above -4.0, and without severe sinusoidal RV-coronary communication, a transcatheter perforation of the atretic PV appeared to be an optimal initial intervention to pave a way for final 2 ventricle circulation. However, the hypoplastic and tortuous RV outflow tract usually make this procedure difficult and risky.

Method: 1999 through 2017, there have been 15 PAIVS neonates received radiofrequency valvotomy (RFV) procedure in this Children's hospital. The procedure began with hot air cooking and hand molding of a 4F JR catheter, usually 1.5 or 2.0 cm of its first curve, to make it soft and compliant as much as possible. Assisted with a 0.035 Terrumo wire, we advanced it patiently until attached at the atretic PV, and even pointed and raised it. Aftewards, exchanging to an RF wire, and connect to the energy generator to perform RFV. Following a successful RFV, we used monorail catheters to perform balloon pulmonary valvuloplasty.

Result: In the first year, we failed in 2 cases. Afterwards, all 13 cases were successful. The initial 5 cases required 5-12 attempts of RFV procedure. However, all the later 8 cases were successful within 3 attempts. There was no mortality. We believe the key break through technique was making all possibility to get a firm attachment on the PV by the end-hole catheter.

Conclusion: Attach-&-raise to the atretic pulmonary valve with an endhole catheter is a guarantee for successful RF valvotomy in neonates of PAIVS.

7. SERIAL PULMONARY ARTERY STENTING USING VARIOUS STENTS AND TECHNIQUES IN A YOUNG PATIENT WITH REPAIRED COMMON TRUNCUS ARTERIOSUS

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History and Physical Findings: A female baby with common truncus arteriosus (CTA) type II received surgical repair at her age of 3 days. However, severe bilateral pulmonary artery (PA) stenosis developed soon after operation. Balloon dilatation was performed at her age of 2 months but the PA recoiled easily. We implanted bioabsorbable stents (Abbott BVS 3.5x18mm) at bilateral PAs and post-dilated up to 4.0 mm. Systolic right ventricular (RV) pressure decreased from 71 to 45 mmHg. However, follow-up echocardiography showed progressive increase in RV pressure. At her age of 5 months, we repeated cardiac catheterization and realized the PA diameter remained around 4 mm while bilateral bioabsorbable stent integrity had been disrupted. Because hemodynamic instability due to low cardiac output during the procedure, we implanted a metallic stent (Express SD 7x20mm premounted stent) for left PA stenosis using "jail technique". However, general condition remained unstable after unilateral PA stenting. We then arranged further cardiac catheterization for right PA stenting (Express 6 x 18 mm stent) using "Y-stent technique" 3 weeks later. Distal right PA was totally obstructed by an intimal flap after stenting, and rescued by an inflated balloon to reattach the flap to the vessel wall. Unfortunately, significant stenosis with obstruction was detected at RV outflow tract 6 months later. We sent the patient to surgery at her age of 11 months. During operation, the stents were explanted, and the outflow tract and branch PAs were extensively reconstructed. Follow-up echocardiography after redo operation revealed significant restenosis at bilateral PA junctions. The patient also developed significant edema and hepatomegaly since her age of 20 months.

Indication for Intervention: Stenting for bilateral recurrent postoperative PA stenosis

Intervention: Bilateral PA stenting was performed using "kissing stent technique" (2 premounted stents (GENESIS 2910) were inflated simultaneously). The effect was dramatic. Systolic RV pressure decreased from 104 to 17 mmHg. Although reperfusion lung edema developed in the following few days after the procedure, the condition was fairly managed by aggressive diuretics treatment and ventilator support. The patient was discharged home 7 days after stenting. Follow-up echocardiography revealed no obstruction across the RV outflow tract and bilateral PAs. The patient experienced much improvement in exercise tolerance after the procedure.

4ᵗʰ cardiac catheterization, 21m/o, BW:8.6kg

Before	After
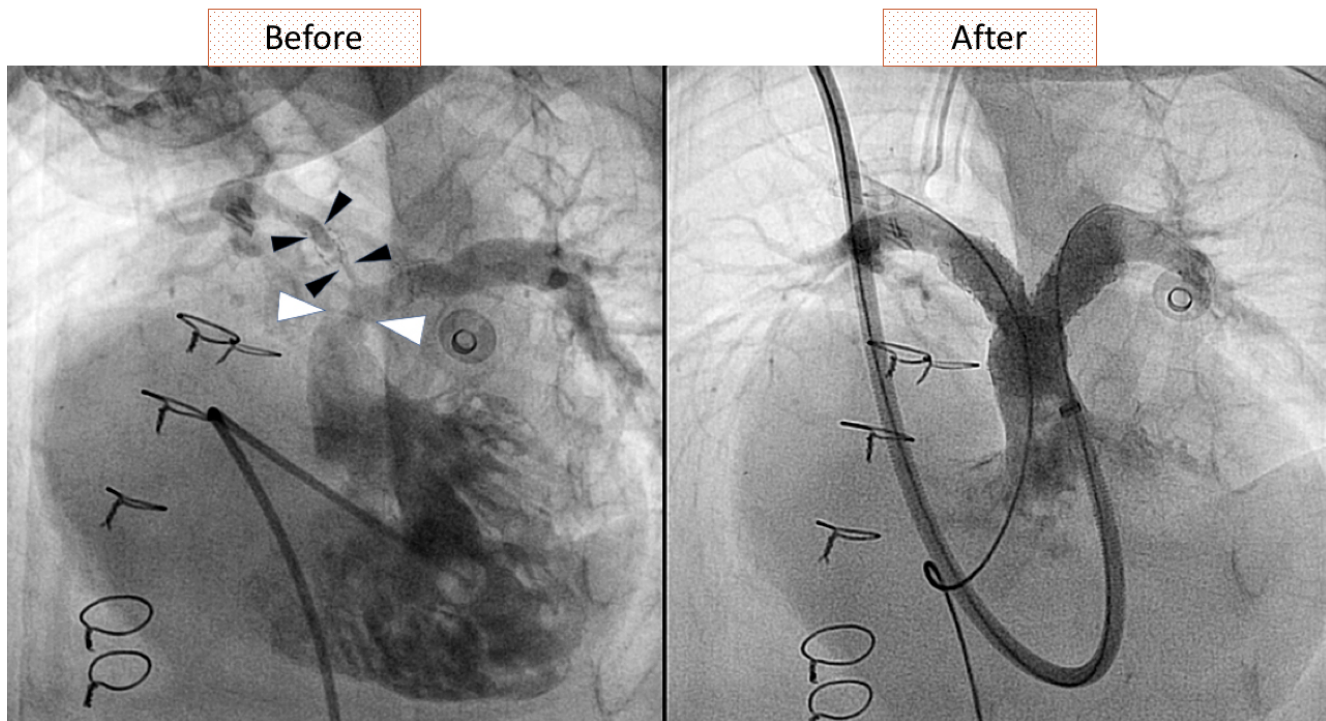
7. Figure 1

Learning Points of the Procedure: Kissing stent technique using stents dilatable to adult size can be an effective treatment for young patients with recurrent postoperative complex PA stenosis.

8. PERCUTANEOUS REPAIR OF POST-INFARCTION VENTRICULAR SEPTAL RUPTURE IN A PATIENT WITH MYOCARDIAL INFARCTION AND REFRACTORY HEART FAILURE

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History and Physical: A 62-year-old male suffered from acute chest pain and dyspnea for one week. He had the history of hypertension and was a smoker. He visited emergent department and desaturation without cardiogenic shock was noted. Physical examination revealed grade IV/VI pansystolic murmur over left lateral sternal border and bilateral crackles.

Imaging: Electrocardiogram revealed sinus tachycardia with poor R wave progression. Chest X-ray revealed pulmonary edema with bilateral pleural effusion. Echocardiography revealed hypokinesia of left ventricular (LV) apex and anterior wall with aneurysm formation, LV ejection fraction around 40 %, and the presence of two sites of ventricular septal rupture (VSR), which were located at middle inferoseptal wall (Figure 1A) and apical septal wall (Figure 1B). Computed tomography angiography findings were compatible with echocardiography. (Figure 1C and 1D). Coronary angiography revealed total occlusion of middle left anterior descending (LAD) artery (infarcted related artery) and chronic total occlusion of proximal right coronary artery.

Indication for Intervention: Surgical intervention with coronary artery bypass graft and VSR repair was suggested. However, he declined our suggestion.

Intervention: We performed percutaneous coronary intervention over middle LAD with a drug-eluting stent deployed on the 5th day after admission. Then, due to refractory heart failure, we performed percutaneous ventricular septal defect (VSD) occluder implantation on the
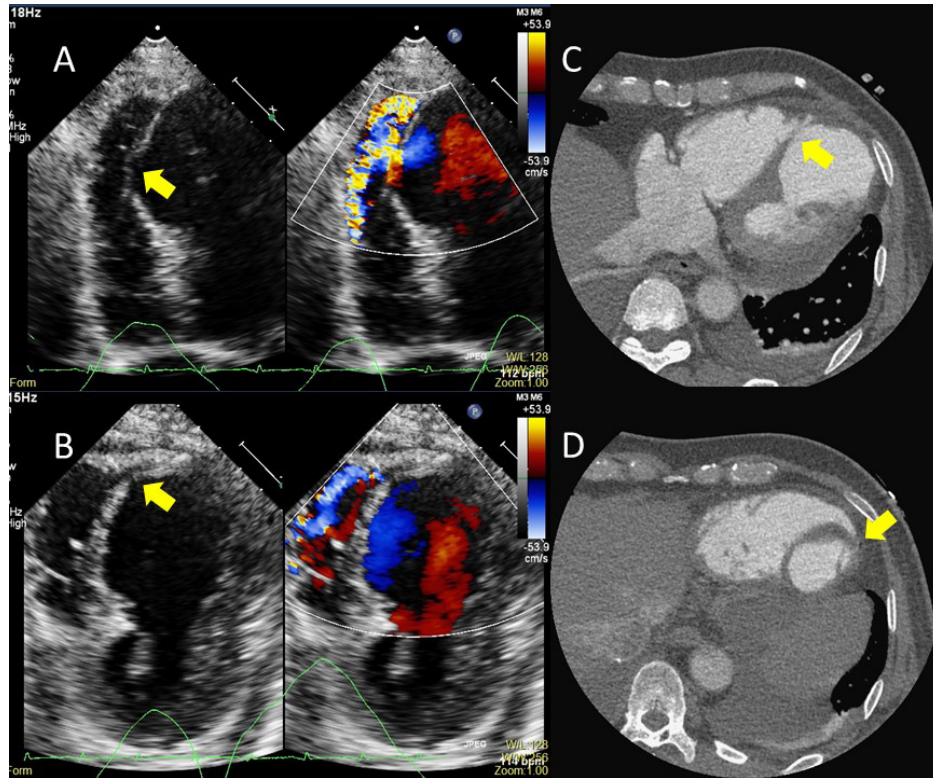
8. Figure 1.
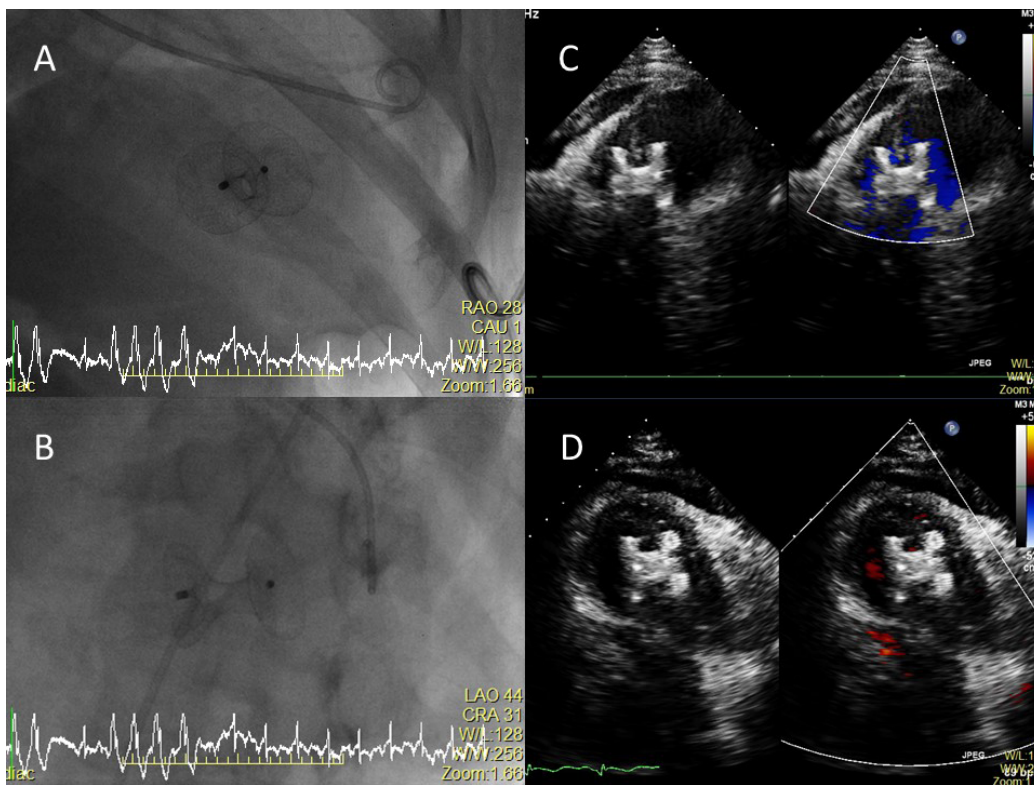
8. Figure 2.

21st day after admission. The patient was under general anesthesia. We approached the middle inferoseptal VSR from right femoral artery route by a 6 Fr. JR 4 guiding catheter and a 0.032inch*260cm guidewire. The guidewire crossed the middle inferoseptal VSR successfully and moved into inferior vena cava. A Snare kit was indwelled from right femoral vein into pulmonary artery. The guidewire was captured by the Snare kit and then it was externalized into right internal jugular vein. The measured size of VSR was 11.4mm by a 34mm sizing balloon and 12mm by real-time transesophageal echocardiography (TEE). A 10 Fr. delivery system was indwelled from right internal jugular vein into left ventricle by the guidance of the guidewire. Then a 20mm AmplatzerTM P.I. Muscular VSD Occluder was deployed to the middle inferoseptal VSR site successfully. The position was confirmed by the left ventriculography. (Figure 2A and 2B). His hemodynamic status improved immediately after implantation. TEE on the next day (Figure 2C) and the 12th day (Figure 2D) after intervention revealed that the site of implantation was optimal with much decreased interventricular shunt. He was discharged uneventfully on the 35th day after admission.

Learning Points of the Procedure: Interventional closure of post-myocardial infarction VSR is an alternative treatment option to surgical repair, with the advantage of immediate shunt reduction to prevent haemodynamic deterioration. A meta-analysis revealed that the successful device implantation rate was 89%, the overall inhospital/30-day mortality was 32%, and the major complications included device embolization, ventricular perforation and arrhythmias.1

Reference:
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9. TREATMENT PREFERENCES OF HEMODYNAMICALLY SIGNIFICANT PATENT DUCTUS ARTERIOSUS IN NEONATES < 2500 GM AT THE ERA OF TRANSCATHETER CLOSURE: WHAT ARE NEONATOLOGISTS' CONSIDERATIONS?

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Background: Transcatheter closure and surgical ligation of hemodynamically significant patent ductus arteriosus (PDA) are both treatments of choice for premature neonates when medical treatment fails or are contraindicated. However, factors regarding to which treatment option to be preferentially adopted by neonatologists remain unclear.

Objective: The aim of this study is to evaluate factors which may determine the treatment preference for neonatologist toward hemodynamic significant PDA in neonates < 2500 gm.

Methods: The retrospective study was conducted in one level 3 hospital from December 2016 to August 2017. Hemodynamically significant PDA in neonates < 2500 gm managed by either transcatheter closure or surgical ligation were included.

Results: There were 23 neonates included (8 with transcatheter closure, and 15 with surgical ligation). In surgical group, 10 (66.7%) procedures were performed within 8 hours after the decision was made by neonatologists, while all transcatheter closure were performed > 12 hours after decision making. Patients receiving surgical ligation had smaller birth body weight (BW) (median 763 (min.350-max. 1278) v.s. 1170 (680-2120) gm, p<0.05), younger age at procedure (10 (1-24) v.s. 25 (11-41) days, p<0.001), lower BW at procedure (738 (350-1230) v.s. 1318 (718-2190) gm, p<0.05), and less likely to having finished ibuprofen treatment ≥ 2 times (13.3% v.s. 87.5%, p<0.05). Besides, PDA associated comorbidity (66.7% v.s. 12.5%, p<0.05) and general comorbidity (93.3% v.s. 50%, p<0.05) were more prevalent in patients receiving surgical ligation. Transcatheter closure generally took longer procedure time (69 (37-104) v.s. 26 (10-45) minutes, p<0.001), but the intubation days after procedure were shorter (5 (0-17) v.s. 27 (1-82) days, p<0.05) than surgical group. No procedure failure was noted in both groups. Short-term complications were more common in surgical group. After excluding 8 (53.3%) surgical cases with comorbidities (ongoing infection, pulmonary hypertension requiring inhaled nitric oxide, and acute kidney injury with anuria) which were considered as

contraindications for transcatheter closure, the other 7 surgical cases had lower BW and more pre-procedural comorbidities comparing to those received transcatheter closure.

Conclusion: In the era when transcatheter PDA closure for premature neonates is safe and effective, we found that neonatologists generally prefer to send patients to surgery if there have been significant comorbidities prior to the intervention and if the patient was considered "too small". However, still a substantial portion of patients who received surgical ligation may be eligible for considering transcatheter closure.

10. REFRACTORY KAWASAKI DISEASE WITH SUPERGIANT LCA AND RCA ANEURYSMS IN A 1-YEAR-9-MONTH OLD MALE TODDLER

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History and Physical: This 1-year-9-month old male toddler was admitted to a certain hospital because of suspected group A streptococcus infection related acute tonsillo-pharyngitis on September 12, 2016. During the hospitalization, he had high fever over 5 days with clinical symptoms including bilateral non-exudative conjucntivitis, strawberry tongue and fissured lips, generalized maculopapular rash and plaques, extremities change, and neck lymph node enlargement over 1.5 cm, and typical Kawasaki disease was diagnosed. The initial echocardiograms showed RCA 2.8 mm, LCA 3.1 mm on September 14, 2016. Initial lab data showed CRP of 15.17 mg/dl, WBC of 9100/cumm, Hb of 10.4 g/dl, PLT of 123k/cumm, Albumin of 1.9 g/dl, GPT of 155 U/L but no pyuria. He totally received IVIG treatment twice and methylprenisolone pulse therapy at the 3rd course. He had fever for 20 days totally. A RCA giant aneurysm was detected by echocardiogram follow-up, and he was receiving aspirin treatment there. Nine months after discharge, the patient visited VGHTC-PCV OPD for follow-up of Kawasaki disease with coronary artery aneurysm. At our VGHTC hospital, echocardiography showed LCA and RCA giant aneurysms. Then, MDCT showed LCA super giant aneurysm 2.6cm and RCA giant aneurysm 1.2cm. Now, we prescribe Aspirin and Warfarin treatment for the patient. The patient is under close follow-up at our PCV OPD.

Imaging:
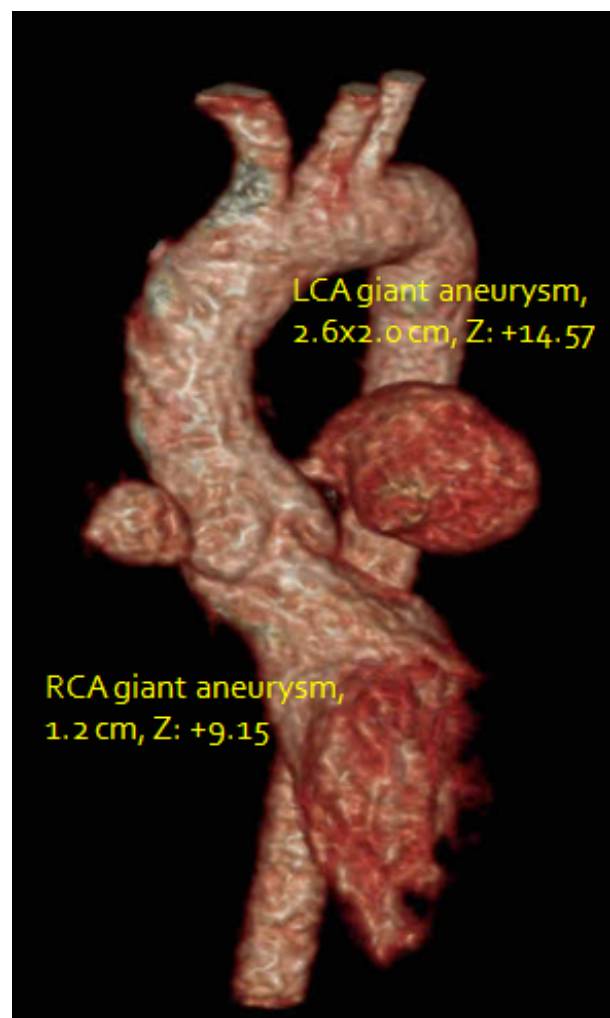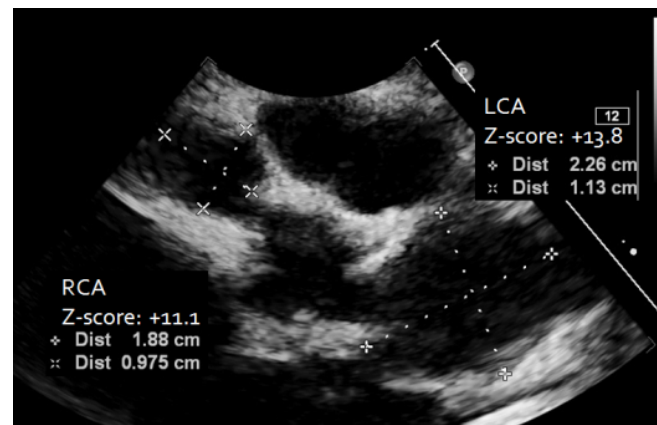
Indication for Intervention: According to 2017 AHA guidelines, further imaging with angiography (CT, MRI, invasive) may be considered for diagnostic and prognostic purposes during the first year and may be considered for periodic surveillance every 1 to 5 years thereafter (Class IIb;Level of Evidence C).

Intervention: Due to the patient's parents worry and the risk of intervention, we decided to arrange the MDCT rather than catheterization angiography.

Learning Points Of The Procedure: MDCT is also a good choice to evaluate the sizes and number of coronary artery aneurysms under the safer condition.

11. RENAL VEIN STENTING IN A FILIPINO TEENAGER WITH NUTCRACKER SYNDROME – FIRST REPORTED CASE IN THE PHILIPPINES

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Nutcracker syndrome, also known as left renal vein entrapment is often a neglected cause of microscopic or gross hematuria. We present a case of a 15-year old female who presented with recurrent flank pain associated with hematuria. Whole abdominal CT scan revealed a decreased in the abdominal aorta:superior mesenteric artery angle measuring approximately 280 (normal value: 38-560) with resultant compression of the left renal vein and tortuosity of the second lumbar vein suggestive of nutcracker

syndrome. Renal duplex ultrasound showed compression of the left renal vein by the abdominal aorta and the superior mesenteric artery with an anteroposterior (AP) diameter of 0.13cm. There is note of renal vein distention (transverse AP diameter of 0.80 cm) after the area of compression. The patient underwent endovascular treatment of the renal vein using a 14 mm x 60cm self-expanding stent (Boston Scientific, Epic). Post left renal vein stenting duplex scan was done which revealed a patent stent and increased in the transverse AP diameter of the renal vein to 0.92 cm with normal venous flow. There were no immediate post-operative complications and resolution of symptoms after 3 days. At one-year follow-up, the patient has no recurrence of flank pain and hematuria. This is the first reported case of renal vein stenting in the pediatric population in the Philippines.

12. CUTTING BALLOON ATRIAL SEPTOSTOMY IN AN ADULT FILIPINO FEMALE WITH END-STAGE FENFLURAMIN-INDUCED PULMONARY ARTERIAL HYPERTENSION – FIRST REPORTED CASE IN THE PHILIPPINES

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Group 1 Pulmonary arterial hypertension (PAH) is a debilitating, progressive disease resulting to recurrent morbidity and early mortality despite advance medical therapy. Atrial septostomy creates a right-to-left interatrial shunt, decreases right-sided heart filling pressure, and improves left-sided heart filling with eventual goal of improving systemic oxygen delivery due to improved cardiac output. This procedure has been proven as an effective therapeutic option providing notable clinical and hemodynamic improvement and increased survival in patients with advanced PAH.

We present a case of a 38-year-old female known case of Group 1 Pulmonary arterial hypertension (PAH) for 9 years who initially presented with syncope, shortness of breath, and bipedal edema. Patient also had prior intake of Fenfluramine (Bangkok), a diet pill known to cause PAH. Her 2D echocardiography at that time showed severely dilated right atrium and right ventricle with ventricular volume and pressure overload and severe pulmonary hypertension. Subsequent diagnostic right heart catheterization confirmed severe pulmonary hypertension with right atrial pressure (RAP) of 15 mmHg and mean pulmonary artery pressure (PAP) of 72 mmHg. Despite the patient's compliance with medical therapy consisting of

oxygen, Furosemide, Bosentan and Sildenafil she remained severely symptomatic at rest (NYHA functional class IV) with poor quality of life. Due to her refractory right-sided heart failure requiring frequent hospitalization patient underwent atrial septostomy. The septostomy was created with a transeptal puncture then followed by graded dilation initiated by a cutting balloon catheter then ended by serial static balloon dilation. This was guided by 3D echocardiography. A 10 mm atrial septal defect was created with a drop in RA pressure to 10mmHg and final oxygen saturation of 80-84% from right to left shunting. There was relief of shortness of breath after 72 hours from the procedure. The patient was maintained on oxygen, Bosentan and Sildenafil. At six-month follow-up, patient has shown sustained improvement in 6 minute-walk test and heart failure symptomatology.

This is the first successfully performed atrial septostomy in an adult in the Philippines as a therapeutic option for severe end stage PAH in a setting where heart-lung transplantation is not yet available.

13. A CHALLENGING WATCHMAN LAA CLOSURE CASE

Jiandong Ding

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History and Physical: A 66-year old woman presenting with nonvalvular Atrial Fibrillation (AF). Hypertension was the only risk factor. She suffered from AF for 20 years and was treated intermittently under anticoagulant therapy because of abnormal fluctuations of INR when taking warfarin. She had a heavy past medical history: cerebral embolism that leading to left limb hemiplegia in 2007. In 2008, she suffered from spontaneous cerebral hemorrhage and finally she recovered without any sequela. Anticoagulant therapy was stopped and switched to aspirin, leading to a recurrent ischemic stroke in 2014. Then, the patient was put under dabigatran (110 mg twice a day). CHA2DS2-VASC score was estimated 5 and HAS-BLED score 6.

Imaging:

1) Baseline transesophageal echo rule out thrombus.
2) Baseline transesophageal echo measurements (Fig1).

Indication for Intervention: The patient with AF was at extreme high risk of stroke for many reasons: high CHA2DS2-VASC score, previous stroke on aspirin and was also at high risk of bleeding with the previous occurrence of a cerebral bleeding and high HAS-BLED score. The patient fulfilled FDA indication for Watchman:indicated for OAC, not suitable for warfarin, appropriate rationale for non-pharmacologic approach.

Intervention: Under general anesthesia, TEE guidance was performed. Location of the transseptal puncture was selected and confirmed by TEE. A double-curved access sheath was advanced into the left atrium and LAA angiography was performed. The max width of LAA ostium was 28mm by LAA angiography. A 33mm Watchman® device was selected for implantation. At first, the device was too proximal in the LAA and protruded into the left
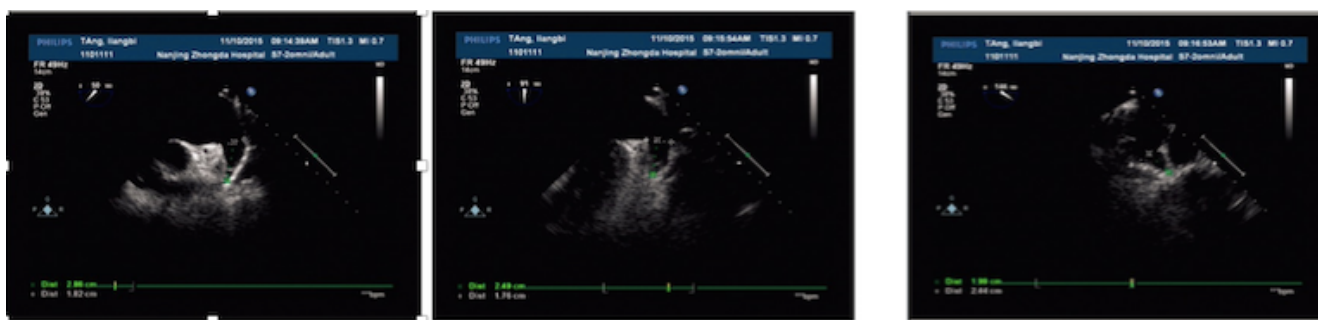
Angle	Max Width	Max Length
45 degrees	23	33
90 degrees	24	30
135 degrees	24	27

13. Figure 1.

atrium, shoulder was 11mm, full implant recapture, then, the device was too distal in the LAA and residual flow in the left atrium, partial retrieval and redeployment. Finally, the attachment of the device was checked with a Tug test and the device was deployed. The final angiogram and TEE showed a well-seated device, with no residual flow, that completely closed the LAA ostium (Fig2, mov1,2).

Learning Points of the Procedure: Coumadin ridge (ligament of marshall) separates LAA and LUPV. If coumadin ridge protrudes far into LA, must push probe in and flex to see LAA without acoustic artifact.

When original sizing is done (outpatient TEE or CT), patient is often NPO, so LAA may be small. LAA may expand with hydration during watchman implant, needs remeasuring after volume load.

Attempt to cover all proximal trabeculations as trabeculated areas increase risk of thrombus formation.

Avoidance of pericardial tamponade: Echo guided transseptal puncture, pigtail catheter in front of sheath, slow deployment of device.

Avoid embolization: proper position and size of device.

Avoid periprocedural stroke: Adequate anticoagulation (ACT > 220), proper de-airing

14. SUCCESSFUL STENTING OF OBSTRUCTED GLENN CIRCULATION ON DAY 5 POSTOPERATIVE DAY IN A 8-MONTHS-OLD GIRL

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[2] Southampton University Hospital; Consultant Cardiologist; Child Cardiology
[3] Southampton General Hospital; Interventional Congenital Cardiology; Child Cardiology

History and Physical: Superior vena cava (SVC) stenosis can be a rare but significant complication in patients undergoing Cavo-pulmonary anastomosis. Rarely hemodynamically significant obstruction can lead to SVC syndrome which carries a significant morbidity for these patients. Treatment options for SVC stenosis include surgical relief or catheter-based interventions, including balloon dilation or endovascular stent implantation.

Eight months old girl with Tricuspid atresia, large unrestrictive VSD and severe subpulmonary stenosis underwent a Superior Cavopulmonary anastomosis, BT shunt takedown, Atrial septectomy and augmentation of right pulmonary artery. Unfortunately, postoperatively she continued to have low saturations with high central venous pressures. On further assessment clinically and echocardiographically, significant Glenn obstruction was strongly suspected.

Indication for Intervention: Diagnostic catheter on day 5 postoperative period suggested mean SVC pressures of 27 mm Hg with marked arterial waveform. Angiography suggested the Glenn anastomosis was compressed anteriorly probably by the aorta, as was the proximal left pulmonary artery.

Intervention: Following urgent MDT review she went back to the catheter lab next day and stent implantation was successfully performed into the left pulmonary artery using a 7 x 12 mm Cook Formula stent inflated to about 6mm and an 8 x 12 Cook Formula stent placed across the Glenn anastomosis. The final result of this was a significant fall in her mean SVC pressure to 17mmHg with good flow seen through both stents.

Learning Points of the Procedure:
• Superior vena cava obstruction can be successfully relieved by transcatheter stent implantation in patients post Superior Cavopulmonary anastomosis as early as day 5 postoperative period.
• Technical success and efficacy in relieving associated symptoms are high.

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15. MID-TERM FOLLOW-UP RESULTS OF TRANSCATHETER INTERATRIAL SEPTAL DEFECT CLOSURE

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Background: Transcatheter Interatrial Septal Defect Closure using Amplatzer was done in different centers. Experience of operator for select of best size of Amplatzer in this procedure could decreased complications.

Objectives: We studied immediate and midterm results of transcatheter closure of atrial septal defects (ASDs) using Amplatzer septal device closure.

Materials and Methods: The study included one hundred thirty seven patients (thirty one men, one hundred-six women; mean age 8 ± 7.3 years; range 1–65 years) who underwent transcatheter closure of secundum ASD between Oct 2014 and Oct 2016 in our center. All the patients were evaluated by transthoracic echocardiography before and during the procedure and in adult patients, transesophageal echocardiography was performed before and during the procedure. Closure of ASDs was performed under general anesthesia with transesthorasic echocardiography guidance. Follow-up controls were done at the day after procedure, one week, 1, 3, 6, and 12 months and annually thereafter. The median follow-up periods of ASD were 15 months.

Results: The mean ASD and device size were 14.5± 3.3 and 16.3 ± 4.2 mm respectively. The mean procedural and fluoroscopy times were 21.3 ± 4.7 and 5.1 ± 1.9 minutes. Immediate complication such as mortality, bleeding, fatal arrhythmia and device embolization did not occurred in any patients during and after the procedure. Cardiac arrhythmia were occured in 4 patients during the first month after the procedure. Late device embolization did not occurred during the follow-up. No residual shunts were seen after procedure. Transient ischemic attack was occured in one patient during the procedure and in one patient 2 days after the procedure without long term complication.

Conclusion: Transcatheter closure of ASDs using the Amplatzer devices is an efficacious and safe therapeutic option and had low complications and could done in suitable patients.

16. PROCEDURAL AND SHORT OUTCOMES OF TRANSCATHETER RADIOFREQUENCY-ASSISTED PULMONARY VALVOTOMY AND BALLOON VALVULOPLASTY OF PATIENTS WITH PULMONARY ATRESIA WITH INTACT INTERVENTRICULAR SEPTUM

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Background: Pulmonary atresia-intact interventricular septum (PA-IVS) is a rare congenital heart disease. To improve cardiac circulation, the goal now is to carefully select patients to achieve a biventricular repair via transcatheter radiofrequency-assisted pulmonary valvotomy and balloon valvuloplasty (TRFAPV-BV) and to avoid early open heart surgery. Success rates of >80% have been reported. Due to its rarity, no single institution can provide a consistent interventional guideline. There is much to be learned from a multicentered approach to collecting longitudinal experience to a challenging clinical case.

Objective: We report our procedural and short-term outcomes in our patients who have undergone TRFAPV-BV with an emphasis on possibly identifying the predictors for survival and the need for additional transcatheter right ventricular outflow tract (RVOT) reintervention.

Methodology: This is a retrospective, descriptive, cohort study of all patients with PA-IVS who underwent TRFAPV-BV from Decemeber 2013 to April 2016. The hospital medical records of each patient was reviewed. Transthoracic two dimensional echocardiogram reports and clips, and cardiac catheterization reports pre and post-TRFAPV-BV were reviewed. In addition, each patient's clinical course through medical records were examined until their most recent clinical follow-up.

Results: There are 29 pediatric patients diagnosed with PA-IVS between December 2013 to April 2016. Out of these 29 patients with PA-IVS, 9 pediatric patients had a tripartite right ventricle underwent TRFAPV-BV, in whom 8 were described as successful, 89% (8/9). This study observed that the following paremeters had a favorable outcome: tricuspid valve (TV) annulus z-score > -2.5, tripartite right ventricle, absence of ventricular to coronary connections, tricuspid to mitral vale ratio >0.5 and right-to-left ventricular pressure ratio of >1. Moreover, parameters after TRFAPV-BV of higher residual gradient across pulmonary

valve and lower pulmonary valve annulus z-scores may be predictive of the need for subsequent RVOT reintervention.

Conclusion: Using these parameters might predict good survival of patients and anticipate the need for a subsequent RVOT reintervention.

17. ENDOVASCULAR INTERVENTIONS IN HYPOPLASTIC LEFT HEART PHYSIOLOGY

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[2] Topchibashev Research Centre of Surgery (Azerbaijan)
[3] Dragomanov National University (Ukraine)

Objective: To present experience of endovascular procedures in newborns with hypoplastic left heart physiology.

Methods: Since 2012 to 2017yy. 15 patients with hypoplastic left heart physiology underwent hybrid procedures. All patients were newborns (1-9 days of life) in a critic condition. Body weight comprised 2.24±0.14kg. Ascendig aorta dimensions < 2 mm.

All 15 patients underwent bi-lateral banding of pulmonary arteries combined with stenting of Ductus arteriosus. In 2 patients used self expandable stent; in 13 - balloon expandable stent. In 3 patients intervention completed with Rashkind procedure.

Results: 4 of 15 patients made an unevenrtful recovery; 11 - died. In-Hospital mortality comprised 73.3%. One patient three years later underwent favorable re-stenting of Ductus arteriosus.

Causes of mortality: septic complication - in 2 patients; stent & istmus of the aorta thrombosis with consequent coronary insufficiency - in 4; stenosis of stent with occlusion of istmus of the aorta - in 1; left atrium perforation during Rashkind procedure - in 1; bleeding - in 1; fatal cardiac rhythm disturbances - in 3 patients.

Conclusion: Despite of high mortality hybrid procedures are the only choice of option in newborns with hypoplastic left heart physiology in critic condition & serve like a bridge for following intervention

18. POST-DILATATION TO PREVENT STENT MAL-APPOSITION AND JAILING IN AORTIC COARCTATION AND PULMONARY STENOSIS

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History and Physical:

Case 1: A 16-year-old boy with CoA. He previously underwent percutaneous stenting for recurrent CoA. The center of the first stent had been placed at the most stenotic site, apposing the aortic wall and avoiding jailing of the left subclavian artery. Follow-up CT angiography revealed deformity of the descending aorta at the proximal site, which might have been caused by the protrusion of the primary stent against the posterior wall of the aorta. An additional stent in the proximal site was proposed to prevent aortic wall injury.

Case 2: A 11-year-old boy with hypoplastic left heart syndrome. He underwent total cavopulmonary connection at the age of 2. Stenting(P3008) was performed for postoperative central PS at the age of 9. The proximal end of the stent protruded over the SVC anastomosis. Post-dilatation for the protruded part was proposed to prevent obstruction of systemic venous flow.

Imaging:
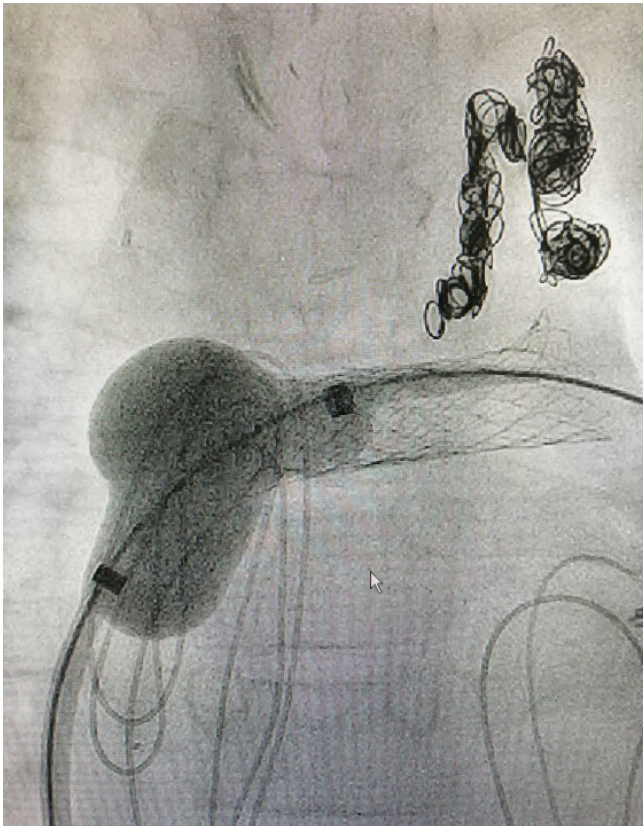
Intervention:

Case 1: After hemodynamic assessment, femoral arterial access was replaced with a 14-Fr sheath in a surgical "cut-down" manner, and a stent (P4010) was placed to cover the proximal end of the first stent. Because the additional stent remained incompletely apposed to both the anterior aortic wall and subclavian artery, a Coda 32-mm balloon (Cook Medical, Bloomington, IN) was advanced to the proximal end of the second stent and manually inflated to prevent stent mal-apposition and partial jailing of the left subclavian artery. Angiography and hemodynamic evaluation after the post-dilatation using the Coda balloon demonstrated complete apposition to the vessel wall and no measurable residual gradient.

Case 2: After placing a 14-Fr sheath at femoral vein, post-dilatation using a Coda balloon 32-mm was performed for the proximal end of the stent. Angiography after the procedure demonstrated complete apposition to the anastomosis. Both procedures were uncomplicated. The stent was briefly and successfully apposed to vessel wall with origin of side branch vessels opened, relieving obstruction and deformity of the vessel.

Learning Point of the Procedures: Aortic coarctation (CoA) and pulmonary stenosis (PS) are often located in curved segment and adjacent to the origin of other vessels. Stenting for such lesions is sometimes accompanied by stent mal-apposition and partial jailing of side branch vessel, which may be related with thrombosis or branch vessel occlusion. We performed post-dilation using Coda balloon to appose the stent to vessel wall. Coda balloon is a spherical semi-compliant balloon catheter intended for temporary occlusion of large vessel and post-dilatation of stent graft in adult. Apposition using Coda balloon is a quite simple and effective resolution in stenting for CoA and PS.

19. IMPERFECT PDA STENTING IN A BABY GIRL WITH TETRALOGY OF FALLOT

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History and Physical: 7-day-old female baby was a victim of tetralogy of Fallot with small patent ductus arteriosus (PDA). After delivery, cyanosis (SpO2=75-80%) was noted with a Gr II/VI systolic murmur at her left middle sternal border. Prostaglandin E1 (PGE1, 5 ng/kg/minute) was given to maintain adequate pulmonary blood flow.

Imaging and Indication: Computed tomography demonstrated small pulmonary arteries (McGoon index:1.0). Therefore, we plan to do PDA stenting for her first-stage operation.

Intervention: Left innominate artery cineangiogram showed a small PDA connected between left subclavian artery (LSCA) and bification of bilateral pulmonary arteries. (Figure A) We passed a Rinato coronary wire to his distal LPA via the PDA and then deployed a REBEL (4 x 8 mm) and a MULTI-LINK8 (3.5 x 15 mm) stent at his PDA. However, compromised LSCA flow and thrombosed stent (no flow) were noted 10 minutes after stent implantation. NC QUANTUM APEX balloon (4 x 15 mm) was advanced to redilate the two stents and successfully restore the flow.

Another Rinato wire was advanced to left innominate artery, through the mesh of the implanted stents, finally to her LSCA. NC Sprinter balloon (3.5 x 15 mm) was used to dilate the mesh at the origin of LSCA. Cineangiogram confirmed the patency of LSCA origin. (Figure B) She was
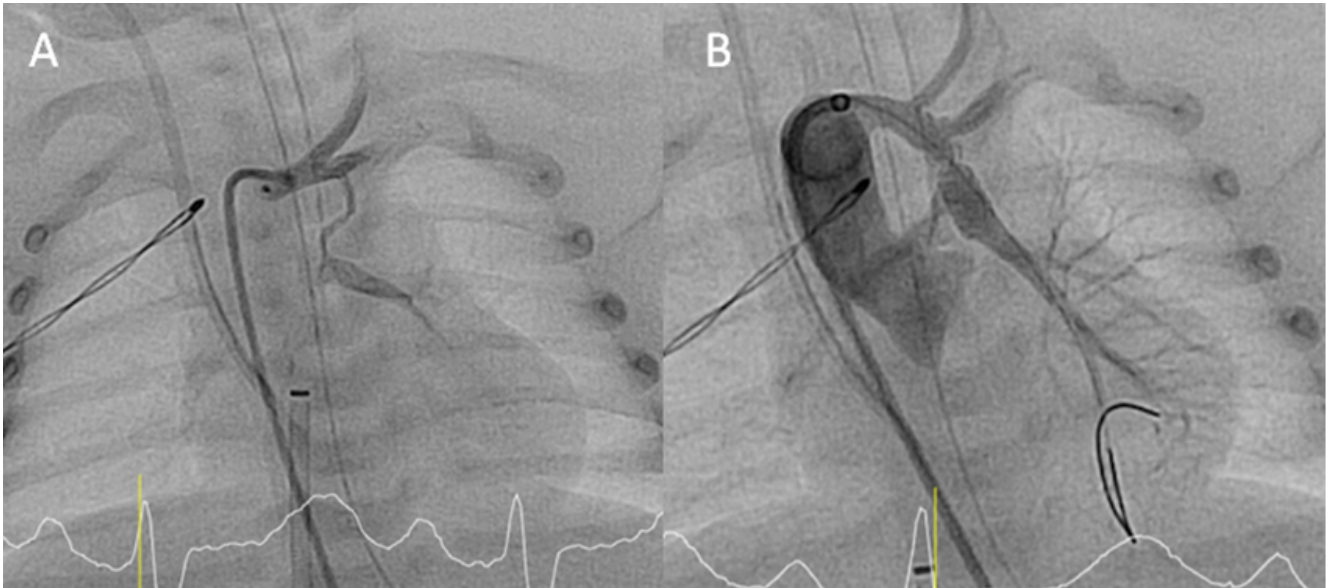
19. Figure 1.

discharged with a saturation of 90% 14 days after the procedure.

Learning Points Of The Procedure: PDA stenting is a good alternative of shunts for the cyanotic patients with TOF. However, PDA shortening may occur during the procedure. Careful implantation by using the relatively short stents might avoid disasters. Unexpected disturbance of LSCA flow can be rescued by the dilatation of mesh on the stent.

20. TRANSCATHETER CLOSURE OF AN SINUS VENOSUS TYPE ATRIAL SEPTAL DEFECT

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History and Physical: A 2 year-8-month-old boy was noted to have congenital heart disease since infancy. The physical examinations revealed a toddler with poor body weight gain and systolic murmur.

Imaging: (See Figures 1-4)

Indication for Intervention: Failure to thrive.

INTERVENTION:
  I. Under intracardiac echocardiography guidance (ICE)

  II. The defect was sized first by 24 mm Amplatzer sizing balloon.

  III. An 12 mm Amplatzer septal occluder was deployed

20. Figure 1.

over the defect through a 7 Fr Amplatzer TorqVue 45 degree delivery system by standard technique.

IV. After the stability was tested by wiggle maneuver, the device was then releases.

V. The defect was completely closed, and the right middle pulmonary vein was drainage into left atrium between right and left discs.
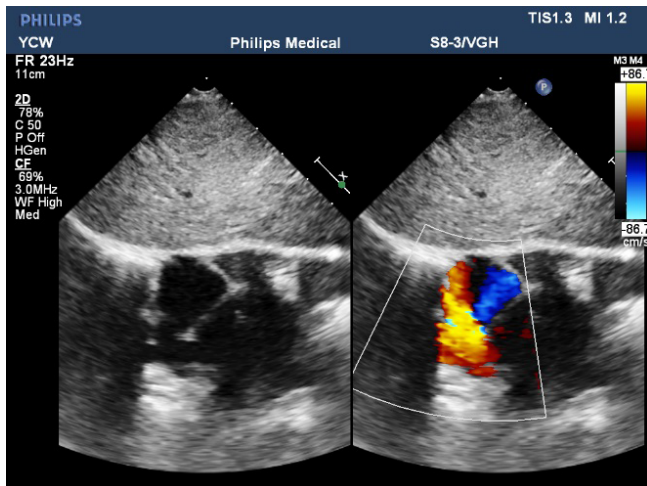
20. Figure 2.

20. Figure 3.

20. Figure 4.

<u>Learning Points of the Procedure:</u>
I.   Sinus venosus type ASD can be transcatheter closed.

Pulmonary vein can be drained between two discs of the septal occlude.

21. OUTCOMES OF TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS IN CHILDREN WEIGHING LESS THAN 6-KILOGRAMS AT THE PHILIPPINE GENERAL HOSPITAL

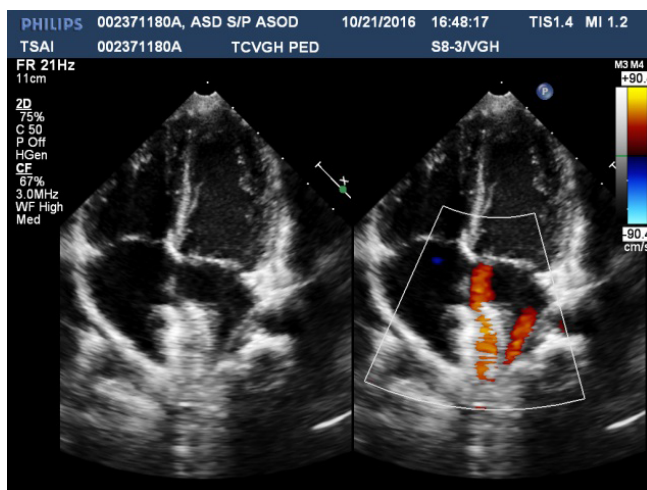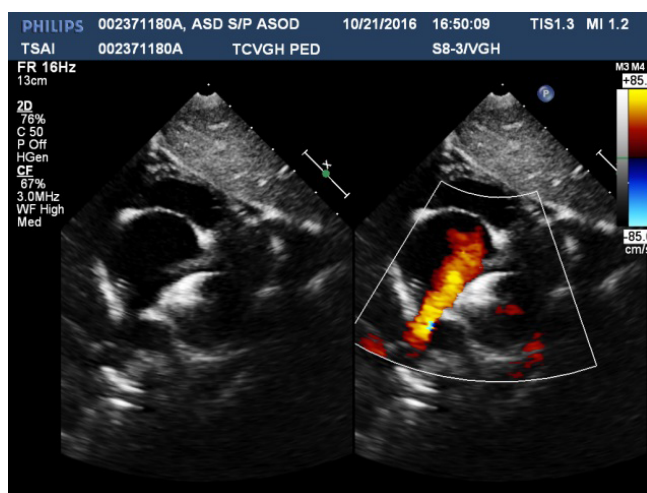*Jethro Macallan[1], Jonas Del Rosario[2]*
[1] Philippine General Hospital; Pediatrics Section of Cardiology; Pediatric Cardiology
[2] University of the Philippines; St. Luke's Medical Center; Philippine Children's Medical Center

<u>Background:</u> Advancement in the field of cardiac catheterization and interventional cardiology in the form of transcatheter closure (TCC) of patent ductus arteriosus has replaced surgical ligation and/or transection as the primary treatment modality in symptomatic patients with a PDA. Different devices from the initial Ivalon plug to the Rashkind double umbrella, Sideris buttoned device, Gianturco coil or Duct-occlud device, and Amplatzer Duct Occluder (ADO) has been developed. Shape and size variability of ductus arteriosus and small patient size necessitated development of new devices or modifications for currently available devices. In the Philippines, there is limited published data on TCC of PDA in children less than six kilograms. For this analysis, outcomes in the form of technical success and occlusion rates as well as complications will be evaluated.

<u>Objective:</u> To determine the outcomes of transcatheter closure of patent ductus arteriosus in patients weighing less than 6 kilograms

<u>Methodology:</u> We conducted a retrospective study of forty five (45) patients (male 14, female 31; mean age 8 ± 3 months, range 2months to 1 year old; mean weight 5.0 ± 0.78 kilograms, range 3.4 to 5.9 kilograms) with echocardiographic evidence of PDA underwent transcatheter closure of PDA. Aortic angiogram was performed to evaluate the PDA. A second aortic angiogram was performed after device deployment. Echocardiography was repeated at 24 hours-, 1 month and 6months intervals to assess for occlusion and complications.

<u>Results:</u> A total of 45 patients were included in the study. The mean narrowest diameter of PDA was 3.5 ± 1.2mm (range 2mm to 5.6mm). Of the 41 patients with successful

deployment of device, residual shunt was noted in one patient at 6-month echocardiographic follow-up. The number of females was more than males. The overall technical success rate was 91%. The occlusion rate regardless of the type of device was 98% with a significant residual shunt rate of 2%. Minor and major complications were 11% and 11% respectively.

Conclusion: Transcatheter closure in children less than 6kg regardless of the device that was used is effective and safe in the Philippine setting

22. BREATH TAKING RETRIEVALS OF EMBOLIZED DEVICES

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Objective: This study was aimed to discuss the various techniques employed to retrieve the embolized devices during interventional cardiac catheterization procedures.

Background: Embolization of the devices may be due to many reasons varying from improper estimated size to problems with image quality just before device release. Once embolized the retrieval depends upon the type, site, size and position of the device. Additionally availability of the appropriate sheaths, variety of snares, bioptomes, balloons, biplane fluoroscopy and lot of patience is the prerequisite for device retrieval.

Methods: In this total 11 devices were embolized from august 2010 to October 2017.Of these 7 were ASD, 3 PDA and one of them was VSD device.

Snares, sheaths, multiple catheters, balloons and wires were used to retrieve all the devices with reasonable results. The hemodynamic data and vita signs were carefully monitored during the procedures along with surgical back up.

All devices were removed successfully with variable time interval and fluoro exposure. The smallest patient in whom device was removed was 1 year of age. Various fluoro projections techniques were used to retrieve embolized devices. In certain situations balloon was inflated distal to device to change the position for favorable capture. There was no mortality or morbidity due the procedures. Patient's rhythms remained stable and no cardiac arrest was recorded.

Conclusion: Device embolization can be prevented with accurate preprocedure assessment and thorough estimation of position, stability, and residual flow judgment on color with good imaging. Device retrieval is safe if all the required equipment and expertise is available.

23. TRANSCATHETER INTERVENTION IN PATIENTS WITH COARCTATION OF AORTA IN A TERTIARY CARDIAC INTERVENTION CENTRE IN SRI LANKA:PATTERNS OF PRESENTATION, ECHOCARDIOGRAPHIC FEATURES AND FINDINGS AND OUTCOME FOLLOWING INTERVENTION

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Background: Coarctation of Aorta is a congenital abnormality which can have poor outcome without early intervention. Transcatheter intervention has made it the preferable modality of therapy for CoA over surgery.

Objective: To ascertain the patterns of presentation, clinical, echocardiographic features, modality of intervention and outcomes of coarctation of aorta patients whom presented for transcathter intervention.

Methods: A retrospective analysis of patients' records were done from 2002-2017, in a tertiary cardiac specialist centre in Sri Lanka. 50 patient were included. Successful outcome was defined by a drop in pressure >50% or <20mmHg.

Results: Number of CoA patients n=50. Their age ranged from 8 -50 years. Mean age was 23.2 years. Males were 54%(n=27) of the populace. Majority, 54%(n=27)] had asymptomatic hypertension. Amongst those symptomatic, shortness of breath was the commonest n=10(43.4%). Headache was seen in n=4(17.3%). Most, n=25(50%) had LVH on 2D-echo. All had preserved EF>60% on initial workup. Eighteen (36%) had additional echo structural abnormalities. Valvular abnormalities were the commonest n=13(72.2%). Bicuspid aortic valves were seen in n=4(22.2%), AR & MR were each observed in n =3 (16.6%). COA narrowest diameter was 1.5mm, and the maximum diameter was 15.4mm. Mean was 4.77mm. Eighteen(36%) underwent only balloon dilation, while n=25(50%) underwent direct stenting. The pre-procedural mean PG was 62.93mmHg and post- procedural PG was 11.79mmHg, the reduction was statically significant (P=0.00). Assessed separately the mean PG before intervention in the balloon dilation patients were 63.88 ±

33.87mmHg,and 62.24±21.55mmHg in the direct stented patients. Post intervention PG was 20.33 ± 22.5mmHg & 5.64±9.7mmHg in the balloon dilation and direct stenting group respectively. However there was no statistical significance between the mean pressure gradient difference(42.59mmHg & 54.71mmHg respectively) following intervention in between both arms (P=0.775). Majority showed interventional success n=41(93.2%). Procedural failure was seen n=3(6.3%) of the analyzed populace, of which n=2 belonged to the balloon dilation arm. Majority, n=39(78%) were free of complications.4 patients had complications, Aneurysm formation and dissection were each noted at n=1(2%). Only n=10(20%) maintained long term follow up. Of those followed up, mean duration of follow up was 84.8± 56.9months. Most n=9 had preserved EF. Most n=9 showed insignificant residual PG across CoA .Five remain symptomatic, n=3 complaining of shortness of breath and n=2 complaining of chest pain. Most n=6, had good control of blood pressure. Only 1 patient developed TIA.

Conclusion: Transcatheter intervention in CoA appears to show immediate significant successful results, indicating it as an effective procedure. Balloon dilation alone or direct stent insertion has good immediate outcome, though our study did not show superiority on immediate success. Overall transcatheter management of CoA is a safe procedure. Complications though uncommon can be life-threatening. Long term residual persistence of symptoms and hypertension necessitate the need for better follow up.

24. PERCUTANEOUS PULMONARY VALVE REPLACEMENT RESULTS OF ERCIYES UNIVERSITY PEDIATRIC CARDIOLOGY

Nazmi Narin[1], Ali Baykan[2], Özge Pamukçu[3], Aydin Tuncay[4], Suleyman Sunkak[2], Onur Tasci[2], Kazim Uzum[5]

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[5] Erciyes University; Non-Invasive; Child Cardiology

Background: Percutaneous Pulmonary valve implantation is one of the most important inventions of the last century which improves the life quality of a group of patients. Right ventricular outflow tract dysfunction is the fate of operated Tetralogy Fallot, pulmonary atresia, truncus arteriosus, some forms of transposition of the great arteries.

Objective: To share our results and experience of our institution on percutaneous pulmonary valve replacement procedure.

Methods: Between February 2015- September 2017; percutaneous Pulmonary valve replacement was performed for 10 patients. Balloon interrogation diameters were determined by 34 mm Amplatzer sizing balloons. Andrastent XXL was used for prestenting for all cases. Z-med and BIB balloons were used for stent implantation. They were chosen 1 mm larger than the indentation diameter which was measured during interrogation.

Results: Mean age and weight of patient were 12±4.6 years and 38.5±17.6 kg respectively. All the patients were operated for tetralogy of Fallot. All the patients had native, large aneursymatic right ventricular outflow tract (RVOT) dysfunction. Mean balloon interrogation diameter was 22±2.8 mm. Mean diameter of the balloon used for prestenting was 23±2.3 mm. All the cases except one were replaced with Edwards. Melody valve was used for the one with 19 mm sized balloon interrogation diameter. The procedure was performed successfully for all patients. 29 mm sized Edwards valve was implanted in 4 patients. 23 mm was implanted in 3 patients, 26 mm was implanted in 2 patients, 24 mm was implanted in one patient. Valve implantation of 2 patients was performed with stent implantation in the same session. For the rest of patients pulmonary valve implantation was performed 8-16 weeks after stent implantation. Procedure related mortality was not reported.

Conclusion: Trancatheter pulmonary valve implantation protect the patients from having right ventricle dysfunction. The patients without conduit; prestenting is mandatory to create a safe landing zone and limit the risk of stent fracture. Percutaneous pulmonary valve implantation is a safe, effective, non-invasive alternative treatment in RVOT dysfunction. Further experience in children is required therefore new studies with large number of patients should be done.

25. PERCUTANEOUS CLOSURE OF AORTA-RIGHT ATRIUM TUNNEL IN A NEWBORN

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History and Physical: 24 years old pregnant woman was referred to us because of large right fetal heart. Fifteen days ago she was given intravenous paracetamol and obstetrician suspected from ductus constriction.

Imaging: Transthoracic echocardiography after birth revealed: large right atrium,13mm Atrial Septal Defect. Tricuspid regurgitation velocity was 3.7m/s. Interestingly large ductal flow was detected. Because of her intrauterine history we have thought that pulmonary hypertension had worsened her situation. Despite anti-congestive treatment she got worse and Patent Ductus Arteriosus was occluded with 5x2 ADOII-AS. After Patent Ductus Arteriosus closure, nothing had changed her state. Then Transthoracic echocardiography was repeated: tunnel between aorta and right atrium was detected.

Indication for Intervention: Aorta-Right Atrium tunnel is a rare congenital lesion with an unknown etiology. Owing to the possible complications like risk of emboli, spontaneous rupture thrombosis, aneurysm formation, infective endocarditis, pulmonary vascular disease, coronary failure, aortic insufficiency, and calcification on the wall of the tunnel etc., it should be closed after certain diagnosis Treatment options are surgery and transcatheter closure.

Intervention: Orifice of tunnel was occluded with 5x6 ADOII-AS from retrograde side (Figure 1). After closure she got better, extubated and inotropic support was terminated.

Learning Points of the Procedure: Aorta-Right atrium tunnels should be closed even the patients are asymptomatic Our case is different because of enlarged Right Atrium and atypical location of tunnel orifice.

26. TRANSCATHETER CLOSURE WITH DEVICE IN PATIENTS WITH LARGE PATENT DUCTUS ARTERIOSUS AND MODERATE TO SEVERE PULMONARY HYPERTENSION IS EFFECTIVE AND SAFE

Radityo Prakoso

National Cardiovascular Center Harapan Kita; Cardiology and Vascular Medicine Faculty of Medicine Universitas Indonesia; Pediatric Cardiology

Background: Transcatheter closure has become a preferred procedure as compared to surgical ligation for the patent ductus arteriosus (PDA). However in large PDA with moderate to severe pulmonary hypertension, the procedure poses a challenge and the data remains scarce. This study aims to evaluate the efficacy and complications of this procedure.

Methods: Retrospective study has been conducted from January 2013 until September 2017 in National Cardiovascular Center Harapan Kita, Jakarta-Indonesia. The inclusion criteria were PDA with diameter ≥8mm with recorded moderate to severe pulmonary hypertension (mPAP ≥ 40mmHg by right heart catheterization). From 515 patients who underwent transcatheter closure during this period, 34 patients fulfilled the inclusion criteria. The results after procedure were observed clinically and by echocardiography.

Results: Median age was 19 years old (3-47 years old), median duct size was 9.8 (8.0-20)mm and mean mPAP (mean pulmonary artery pressure) was 58.5 ± 8.0 mmHg. Median flow ratio (FR) before pulmonary vasodilator test was 1.8 (0.5-21) and median pulmonary artery resistance index (PARi) was 4.8 (0.7-20). Fifteen patients with PARI ≥4 WU.m2 underwent pulmonary vasodilator test with median FR pre vasodilator test was 1.3 (0.5-3.3) increased to 4.3 (1-22), p=0.001; mean PARI before vasodilator test was 9.6 improved to 0.9 (0.1-6), p=0.001; with mean mPAP decreased from 62.2±8.7 to 40.5±17.8 (p=0.004) accordingly after device closure. There was no cardiac death. During study, there was one case of device dislodge which underwent uneventful surgical ligation afterwards. Initial residual PDA before discharge was 60.6% which all comprises of minimum centrally residual. Upon follow up from one week to four months, no residual PDA was detected. A patient developed AV fistula after the procedure and underwent uneventful surgical ligation afterwards. The median length of stay in hospital was three days.

Conclusions: Transcatheter closure with device in large PDA with moderate to severe pulmonary hypertension was effective and safe provided that the PARi after vasodilator test was less than 8 WU.m².

27. A COMPARISON OF DUCTAL STENTING AND BLALOCK TAUSSIG SHUNT IN DUCT DEPENDENT LESIONS: A SYSTEMATIC REVIEW

Radityo Prakoso[1], Prissilia Prasetyo[2]

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[2] University of Indonesia; Faculty of Medicine; General Practitioner

Background: Duct dependent cardiac lesion is a life threatening condition. Surgical Blalock-Taussig (BT) shunt is a treatment of choice in first stage palliation in such cases. Until recently, ductal stenting becomes a promising alternative treatment with less complications. The aim of this study is to compare the effectiveness and safety between ductal stenting and Blalock-Taussig shunt in duct dependent cyanotic lesions.

Method: Journal searching in PubMed, Cochrane, and MEDLINE databased from 2010 to 2017 was conducted. A total of 4 publications comprising 144 patients in ductal stenting group and 361 patients in Blalock-Taussig shunt group were included in this analysis. The primary outcome was one year survival rate and major adverse events consist of death related procedure, and restenosis that require reintervention to maintain adequate pulmonary blood flow.

Results: The pooled one year survival rate were 84% in ductal stenting group and 89% in BT shunt group. The pooled major adverse event rate were 18.8% in ductal stenting group and 28.5% in BT shunt group. Similar baseline characteristic (median age, median weight) and procedure type were adjusted. However, morphology of duct was variable among studies.

Conclusion: Ductal stenting is a promising alternative treatment for duct dependent cardiac lesion as it has comparable survival rate and less complications than BT shunt. However, patient selection, vascular access, technique, morphology of duct, type and also size (or length) of stent are critical to ensure the good results. A further large multicenter study was needed to support the practice of evidence-based medicine, especially in Indonesia and other South East Asia countries.

28. FIRST STAGE PALLIATION OF DUCT DEPENDENT LESIONS OF DUCTAL STENTING: A SYSTEMATIC REVIEW

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[2] University of Indonesia; Faculty of Medicine; General Practitioner

Background: Duct dependent cardiac lesion is a life threatening condition. Surgical Blalock-Taussig shunt is a treatment of choice for first stage palliation in such cases. Until recently, ductal stenting becomes a promising alternative

treatment with less complications. The aim of this study is to describe the effectiveness and safety of ductal stenting in duct dependent cyanotic lesions.

Method: Journal searching in PubMed and MEDLINE databased from 2010 to 2017 was conducted. Results from 12 publications comprising 532 patients were included in this analysis. The primary outcomes were successful rate of the procedure, as well as immediate and mid-to-long term major adverse events (death related to procedure, device embolization, acute thrombosis, and restenosis).

Results: All of studies in this systematic review showed a consistent result. The pooled successful rate were 94%. Immediate and mid-to-long term major adverse event rate were found in 16% of the pooled study subjects. Limitation of this study is   the high variability in patient factors, duct morphology, and techniques performed by operators.

Conclusion: Ductal stenting is relatively effective and safe as an alternative treatment for duct-dependent cardiac lesion. However, patient selection, vascular access, technique, type and size (or length) of duct and stent are critical to ensure maximal outcomes. A further large multicenter study was needed to support the practice of evidence-based medicine, especially in Indonesia and other South East Asia countries

29. PATENT DUCTUS ARTERIOSUS STENTING IN A PRETERM INFANT WITH HYPOPLASTIC RIGHT HEART SYNDROME (HRHS)

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[2] The Medical City; Department of Pediatrics; Pediatric Cardiology

History and Physical: The patient is a preterm female, delivered via emergency primary cesarean section, weighing 1.2kg. A congenital anomaly scan done at 20 weeks of gestation revealed hypoplastic right heart syndrome, tricuspid and pulmonary valve atresia with ventricular septal defect. She presented at birth with persistent severe cyanosis and desaturations as low as 50%.

Imaging: A transthoracic echocardiogram confirmed hypoplastic right heart complex with tricuspid and pulmonary valve atresia, and confluent pulmonary arteries supplied by a patent ductus arteriosus (PDA) measuring 2mm in diameter and 10mm in approximate length.

29. Figure 1. Hand Angiogram in LAO Cranial view from the right carotid showing a Vertical PDA (white arrow) supplying small sized pulmonary arteries.

Indication for Intervention: In infants with critical cyanotic heart disease, like HRHS, pulmonary blood flow is ductal dependent. The management of HRHS can be done in multiple stages of palliation and PDA stenting is the preferred method of first stage palliation compared to the Modified Blalock-Taussig Shunt (BTS) in establishing pulmonary blood flow. Due to the limited prostaglandin supply, PDA stenting was thus attempted in this very small preterm infant.

Intervention: Ductal stenting via a carotid arterial approach was done on the second day of life. The right carotid artery was accessed under direct visualization and a 4F sheath was inserted in standard technique. A BMW 0.014 inch coronary wire was guided in the pulmonary arteries through the ductus after an initial angiogram was done through the sheath side port. The ductal length was measured and an Omega bare metal coronary stent measuring 2.75mm x 12mm was inserted over the wire and was subsequently positioned across the PDA without jailing the pulmonary arteries and covering the entire ductal length. The stent was inflated to rated burst pressure giving an inner diameter of 3mm. A repeat angiogram was done in order to document adequate stent position and to visualize pulmonary blood flow. Transthoracic echocardiogram after the procedure documented adequate PDA stent flow into confluent pulmonary arteries.

Learning Points of the Procedure: In preterm infants with life threatening cyanotic congenital heart condition, a management option is through PDA stenting in order to maintain and ensure pulmonary blood flow. The procedure is limited by patient size and prematurity but with proper care and skill, it can be performed in a premature infant weighing as little as 1.2kg. Ductus arteriosus stenting is a feasible, safe, and effective procedure for premature and low birth weight infants.

29. Figure 2. AP view showing an Omega bare metal coronary stent in place *(Panel A)*; Hand injection angiogram showing adequate stent position supplying both pulmonary arteries *(Panel B)*.

30. TRANSCATHETER INTERVENTION FOR PARAVALVULAR LEAK IN MITROFLOW BIOPROSTHETIC PULMONARY VALVE

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Spectrum Health Helen Devos Children's Hospital; Congenital Heart Center; Congenital Heart Disease

History and Physical: Paravalvular leak (PVL) is a complication due to suture dehiscence between the sewing ring and native tissue resulting in regurgitation around the replaced valve. The standard treatment for pulmonary PVL is surgical repair or valve replacement. However, surgery is associated with greater morbidity and mortality. Transcatheter intervention for aortic and mitral valve PVL is effective and known to have better long-term outcomes than surgery, which has a 12-year survival of 30-40% and high rate of recurrence. In the setting of pulmonary PVL, transcatheter approach may be a useful technique with optimal outcomes.

A 22-year-old male with tetralogy of Fallot and bilateral peripheral pulmonary artery (PA) stenosis presented with multiple episodes of syncope, dyspnea on exertion (NYHA class III) and worsening lower extremity edema. He had a transannular patch repair early in life. Due to severe pulmonary regurgitation (PR), his pulmonary valve was replaced with a 27 mm Mosaic tissue valve at 8 years of age. He was noted to have free PR, and depressed systolic function at 15 years of age. Subsequently, he underwent pulmonary valve replacement with a 25mm Mitroflow bioprosthetic valve and intraoperative stenting of the branch PAs. Post-operative period required extracorporeal membrane
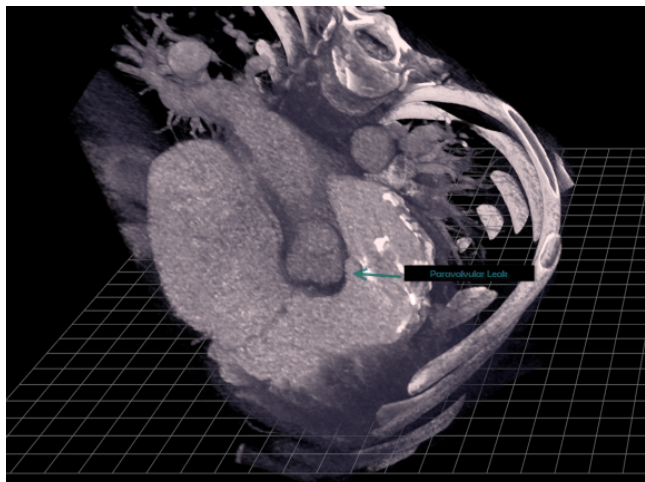

30. Figure 1. CT on True3D Viewer (Echopixel, Inc., Mountain View, CA) showing paravalvular tunnel measuring 8x6x9 mm in the posteromedial side of the pulmonary valve.

oxygenation support and prolonged tracheostomy leading to severe post-traumatic stress syndrome. On Holter monitoring, he was noted to have ventricular tachycardia.

Imaging: (See Figures 1 & 2).

Indication for Intervention: In view of worsening dyspnea, syncope, and edema, PVL closure was considered (Figure 1). Considering his complex history and associated risks with redo-sternotomy, a multi-disciplinary team recommended transcatheter PVL closure.

Intervention: Moderate stenosis was noted across the Mitroflow valve at the pulmonary position with gradient of
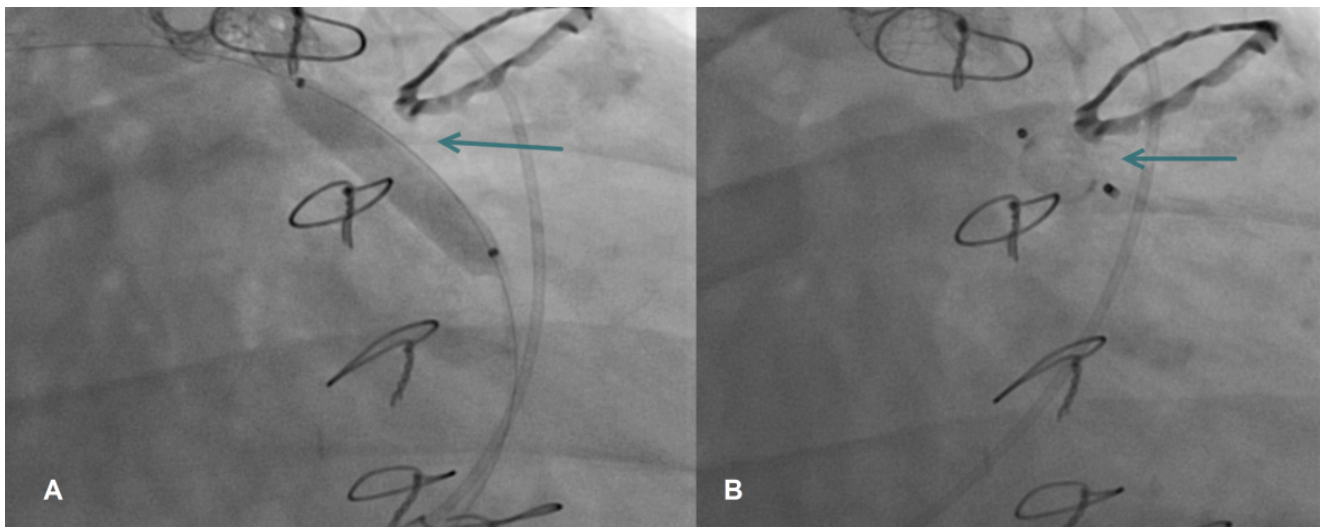
30. Figure 2. *Panel A.* PVL size confirmed using Armada balloon; *Panel B.* AVP II deployed in the PVL.

25-30 mmHg, and Qp:Qs of 1:1; PA angiography demonstrated moderate pulmonary insufficiency and PVL. The PVL was localized by balloon occlusion of the valve and simultaneous contrast injection into the PA. The defect was sized using an Armada balloon (8x4 mm; Figure 2A). After careful hemodynamic and angiographic evaluation, a 12 mm Amplatzer vascular plug II (AVP II) was deployed in the tunnel-like leak without any complications or residual leak (Figure 2B). The diastolic PA pressure improved from 6 to 20 mmHg after PVL closure. The patient recovered well and was discharged without arrhythmias on follow-up.

Learning Points: Although transcatheter closures of pulmonary PVL are reported using AVP II and ventricular septal defect occluders, successful closure is dependent on appropriate case selection and operator expertise. Transcatheter intervention is a feasible treatment option with lower complication rates than surgery and must be considered in the setting of pulmonary PVL.

31. DIFFERENT MANAGEMENT FOR THROMBOSIS COMPLICATIONS IN POST FONTAN SURGERY: REPORT OF TWO CASES

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[2] Pjnhk Jakarta; Cardiology and Vascular Fkui; Pediatric Cardiology
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History and Physical: We reported two cases of silent thrombus formation after fenestrated extra-cardiac conduit Fontan procedure which detected on routine trans-thoracic echocardiography (TTE) evaluation and its management. The first case is a 5-year-old girl with DORV, non-committed muscular VSD, severe PS, smallish LV and PDA. She underwent an uneventful fenestrated extra-cardiac Fontan procedure after bidirectional cavo-pulmonary shunt (BCPS) and atrial septectomy done a year earlier. The second case is an 11-year-old girl with dextrocardia, pulmonary atresia with the aorta arises from the RV, hypoplastic LV, large muscular VSD, PFO and MAPCAs. Fenestrated extra-cardiac Fontan procedure was also done after previous BT shunt and BCPS with atrial septectomy, and MAPCAs embolization. They were both had no clinical symptoms or abnormal hemodynamic data.

Imaging: For the first patient, multiple large thrombi of 8x6mm and 5x4mm were seen inside the extra-cardiac conduit on TTE evaluation 6 months after the operation,.

There was also a mild stenosis found at the anastomosis of IVC to extra-cardiac conduit and a good anastomosis of right SVC to RPA. TTE evaluation on second patient at 8 days post Fontan procedure revealed a long large thrombus of 10x14mm in the IVC. The anastomosis of IVC to extra-cardiac conduit and right SVC to RPA were good.

Indication for Intervention: The first patient was on achieved theurapeutic anticoagulant treatment, and the second one was still under heparin infusion, but thrombus was found on routine TTE evaluation after the operation.

Intervention: Percutaneous balloon angioplasty and stenting implantation were planned in the first case after 5 days of intravenous heparin was given. Unfortunately, due to the unavailability of the suitable stent and vena cava filter, we have to postpone the procedure. She was then on oral anticoagulation and no thrombus seen any more on TTE evaluation after 2 days and 1 months later. For the second case, a direct catheter thrombosuction and thrombolysis with TPA was performed. It was followed by intravenous TPA with 4 hourly fibrinogen level evaluation. The TPA was stopped after 10 hours since the fibrinogen level drop to 40 mg/dL. It was continued with intravenous heparin for 5 days and oral warfarin subsequently. Thrombus is not found any more on TTE evaluation after 4 hours, 5 days , and 2 months above the procedures.

Learning Points of the Procedure: Patients who have undergone the Fontan operation are at a high risk for thromboembolism.

Thromboembolism complication in Fontan surgery can occur despite of anticoagulation treatment with achieved APTT and PT level or therapeutic international normalized ratio (INR). Routine TTE evaluation can detect this complication clearly so treatment can be performed immediately. Aggressive anticoagulation infusion and catheter direct thrombosuction followed by thrombolysis reestablish the patency of Fontan circuit and save the risks of re-surgeries.

32. DUMBBELL-SHAPED CONTROLLED INFLATION OF STENT FOR FENESTRATION OF FONTAN TRACT

Kenji Suda
Kurume University School of Medicine; Pediatric Cardiology; Intervention

History and Physical: A 20-year-old male patient with lateral tunnel Fontan procedure had suffered from intractable protein losing enteropathy (PLE) for 13 years that required 14 times of hospitalization.

Indication For Intervention: Because his pulmonary arteries were already acceptably dilated with pulmonary artery stenting, we decided to create interatrial fenestration, using PALMATZ P3008E™ stent (Cordis, Switzerland) this time.

Intervention: Procedure was guided under intracardiac echocardiography. Because of slipping of the tip of Brockenbrough needle, we directed the needle by snare guide wire for tip to enface the Fontan tract wall. Once we punctured the tract, we advanced 0.035 stiff guidewire. Over the guidewire, we advanced the distal half of pre-mounted 8mm-PALMAZ stent through the inter-atrial septum. Covering proximal half of the stent with long sheath, we dilated distal half of the stent without dilating proximal part of stent. Then, we further pull back the long sheath and exposed entire stent. After pulling back the balloon until the tip of the balloon at the middle of stent, we dilated proximal part of the stent tightly holding the middle part of stent with snare guidewire to make it dumbbell shape. Finally, we further dilated the middle part of stent with 5 and 6 mm balloon and the patient SpO2 decreased from 93% to 86% resulting in increase of cardiac index.

Learning Points of the Procedure: Staged uncovering of the stent by long sheath and tight holding of stent by snare wire can make ideal dumbbell shaped stent for fenestration of Fontan tract.

33. DUCTAL STENTING IN CONGENITAL HEART DISEASE WITH DUCT DEPEDENT PULMONARY BLOOD FLOW : A FOUR YEARS EXPERIENCE FROM NATIAL REFFERAL CENTRE IN INDONESIA

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Introduction: Cyanotic congenital heart disease with duct-dependent pulmonary blood flow is a life threatening condition and often require early intervention. Blalock Taussig (BT) shunt remains the treatment of choice, but it is associated with high morbidity and mortality. Ductal stenting is becoming an alternative to maintain pulmonary blood flow as it is less invasive. However, this challenging procedure is not widely available in Indonesia.

Objective: This study aims to present our early experience with the short-term outcomes and safety of ductal stenting procedure.

Methods: We studied 14 patients who underwent ductal stenting in National Cardiovascular Centre Harapan Kita, Jakarta, Indonesia between October 2013 until Mei 2017.

Results: Indications were pulmonal atresia (n=13) and pulmonal atresia- tricuspid atresia (n=1). Median age at the procedure was 21 days (7-227 days) and median weight at the procedure was 3350 gram (2800-7200 gram). Femoral artery access was used in all procedure. Five procedure used uneventfully antegrade technique. Types of PDA were type A(n=5), C(n=5), E(n=3), and D (n=1). Stent implantation was succesful in 57% of the cases. All procedure used Bare Metal Stent as a device with vary diameter and length 2,5-4 mm x 8-15mm. A significant improvement in mean arterial oxygen saturations after stent placement was observed from previously 43.12% to 84.25% (p<0.05). There was no cardiac death during the procedure. Complications after the procedure were thrombosis (n=2), bleeding (n=3), and stent dislodged (n=2. Three deaths after the procedure were due to bleeding and stent dislodged. Due to thrombosis, only one patient underwent ballon dilatation, and done successfully. Due to stent dislodge, one patient died and other was succesfull for re-stenting. During follow up, one patient underwent radiofrequency ablation and balloon pulmonary valvuloplasty and one patient had Blalock-Taussig shunt operation. There was non significant reduction in pulse oxygen saturation six months after the procedure (7-22%;p>0.05)

Conclusion: Stent implantation of ductus arteriosus can be a good alternative for initial palliation in cyanotic congenital heart disease with duct depedent pulmonary blood flow.

## 34. A CASE OF MULTIPLE SECUNDUM ATRIAL SEPTAL DEFECT TREATED WITH TWO FIGULLA FLEX

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A case was a 75-years-old female. She was diagnosed with paroxysmal atrial fibrillation (PAF) and sinus arrest by Holter electrocardiography. Transthoracic echocardiography revealed atrial septal defect (ASD) and right heart overload (Qp/Qs 2.9). She was scheduled to ASD closure after 6 months treated catheter ablation for PAF. In transesophageal echocardiography, two ASDs were confirmed.
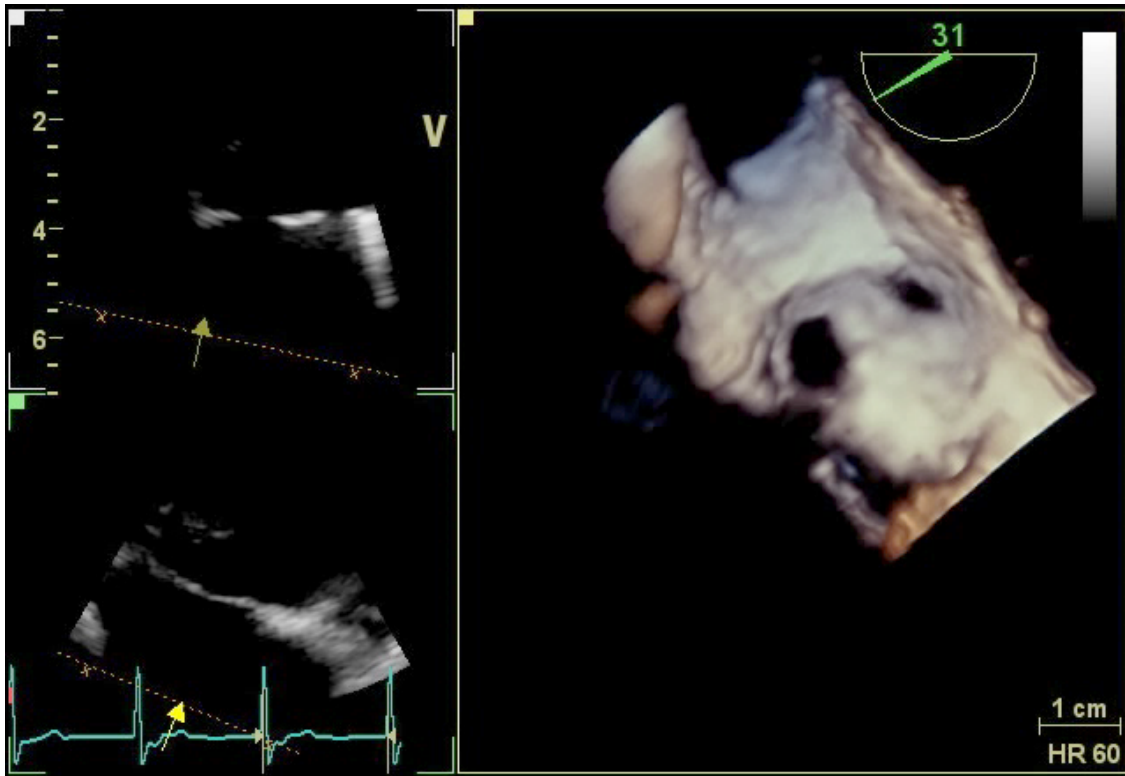
34. Figure 1.
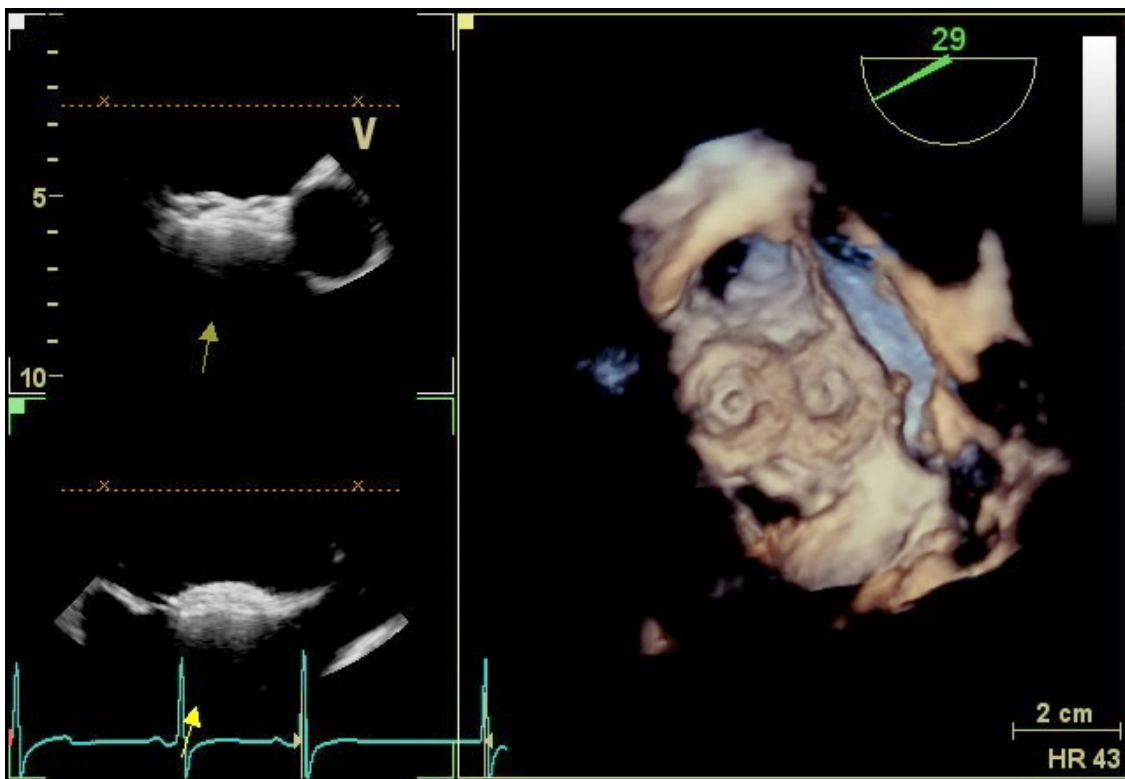
34. Figure 2.

Sizes of ASDs were 3.4×8.5 mm and 5.0×12.7 mm, and the length between both ASDs was 7.6 mm. A part of aortic rim was less than 5 mm, but the range was less than 30°, so we chose by transcatheter ASD closure. Balloon sizing was measured to be 10.5 mm for smaller ASD closer to the aortic rim (ASD1) and 12.3 mm for larger ASD in the center (ASD2). Considering short aortic rim, we chose and placed a 12 mm Figulla Flex II ASD occluder (FFO) for ASD1, then a 13.5 mm FFO placed for ASD2. After placed, a 12 mm FFO contacted with aortic vessel walls, but did not press the aortic vessel wall excessively at the contact point with FFO. Detachment was successful, and no complications have observed during follow-up period.

Erosion is a rare but serious complication of transcatheter ASD closure. In this case, FFO on the side of the aortic rim partly touched the aorta by overlapping both FFOs. FFO results in a soft contact with aortic vessel walls when placed adjacent to it. It is difficult to predict the device position after detachment in case of overlapping devices. We report a case of transcatheter ASD closure for multiple ASDs using FFOs.

35. SIMULTANEOUS TRANSCATHETER DEVICE CLOSURE OF ASD, VSD AND PDA IN AN INFANT WITH DOWN'S SYNDROME

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History and Physical Findings: An 11 month old infant with Down's syndrome weighing 7 kg was referred to our hospital with frequent respiratory tract infections and soft systolic murmur for evaluation. External features of Down's syndrome were present. Precordium was hyper dynamic with soft systolic murmur at Parasternal area with loud pulmonary component (P2).

Imaging: Chest radiograph revealed cardiomegaly with prominent vascular markings. Transthoracic echocardiogram (TTE) revealed moderate sized ostium secundum ASD (10 mm), perimembranous VSD (5 mm) and PDA (3.5 mm). There was biventricular enlargement, with severe PAH (estimated PA pressures 55 mmHg).

Indication for Intervention: After careful imaging it was found that all the defects were suitable for transcatheter closure, hence it was decided to perform simultaneous device closure of VSD, PDA and ASD.

Intervention: Hemodynamic assessment during the transcatheter procedure showed high pulmonary artery (PA) pressures (60/25 mm Hg) against systemic arterial pressures of 75/35 mmHg. First VSD device closure was performed from arterial route using 6/4 Amplatzer duct occluder II (ADO II) device by 5 French guiding catheter. Then PDA was closed using standard technique by 6/4 Amplatzer duct occluder device. Finally ASD device closure was performed using 12 mm Amplatzer Septal occluder device with 7 French delivery system. Post procedure PA pressures reduced to 45/15 mmHg against systemic pressures of 80/45 mmHg. Electrocardiogram (ECG) showed sinus rhythm with Heart rate of 110/min. Patient was discharged from hospital after 72 hours of observation.

Learning Points: Simultaneous transcatheter device closure of multiple defects is a safe alternative to surgery if suitable.

36. DEVICE SELECTION DURING TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS IN PREMATURE INFANTS WEIGHING LESS THAN 2.5 KILOGRAMS

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Background: Transcatheter closure of patent ductus arteriosus (PDA) in preterm babies remains a highly challenging procedure. There is no ideal device to fit in these clinical scenarios.

Objective: The aim of this study was to describe our experiences in device selection during transcatheter device closure of PDA in premature infants weighting less than 2.5 kilograms.

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, angiographic data, and devices were recorded.

Results: Seventeen premature infants (seven boys and ten girls) born at gestational ages ranging between 22 and 35 weeks (median, 28 weeks) were identified. All patients had

significant PDA and received pharmacological therapy as protocols. Median age and weight for procedure was 22 days (2-133 days) and 1,500 g (478-2,350 g), respectively. Six patients were associated massive pulmonary haemorrhage. The mean minimal ductal diameter was 3.5 + 1.1 mm. The mean ductal length was 7.8 + 3.6 mm. The most common PDA type was type C (n=7). There were 3 times of device migration before detachment which required to retrieve and deploy a new one. Devices used in this study were AMPLATZER™ duct occluder II additional size (ADO II AS) (n=13), AMPLATZER™ vascular plug I (VP 1) (n=1), and vascular plug II (VP 2)(n=3). Complete closure were achieved in all patients except one patient had progressive coarctation which required surgical removal 4 months later.

Conclusions: It is now currently feasible to undertake transcatheter PDA closure in premature infants body weight greater than 478 grams according to our experiences. We added at least 1.5 mm in minimal ductal diameter by echocardiogram to select the device waist. We concluded that ADO II AS could be best used in ductal diameter less than 3.5 mm, and VP 2 could be used in larger and long ductus, while VP 1 used in large and short (less than 10 mm) one.

37. TRANSCATHETER CLOSURE OF DOUBLE VENTRICULAR RUPTURE IN A PATIENT WITH NON-ST ELEVATION MYOCARDIAL INFARCTION

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History and Physical: A 68-year-old lady has history of hypertension, type 2 diabetes mellitus and uremia with regular hemodialysis, presented with sudden acute of chest pain on Jun. 1st 2015. Non-ST-elevation myocardial infarction was diagnosed, and percutaneous coronary intervention (PCI) with drug-eluting stent was performed over the proximal portion of left anterior descending (LAD) artery. Three days after PCI, apical ventricular septal rupture (VSR) was diagnosed because of grade 3 holosystolic murmur at the apical area. Three weeks after PCI, surgical repair for VSR was performed smoothly and she was discharged asymptomatically. Three months after surgical repair, she experience exertional dyspnea and effort-related chest pain. The CT angiography showed a left ventricular pseudoaneurysm over the middle portion of anteroseptum with connections to RV. The coronary angiography showed diffuse atherosclerosis over distal portion of left anterior descending artery with dynamic compression of LAD by the pseudoaneurysm. After thorough evaluation of the heart team,

percutaneous coronary intervention, transcatheter closure of VSR and pseudoaneurysm were proceeded.

Imaging: See Figures 1 and 2.

Computed tomography angiography: apical ventricular septal defect with communicated pseudoaneurysm fromation

Transthoracic echocardiogram: apical ventricular septal defect with shunt noted

Indication for Intervention:
1. Left ventricular pseudoaneurysm with ragged edge, narrow neck, and high risk of rupture
2. The pseudoaneurysm with LV and RV connections
3. Dynamic compression of left anterior descending artery by the pseudoaneurym

Intervention:
a. A 5 Fr. cutted-head pig-tail catheter and a 0.032in-*260cm Terumo guidewire crossed the ventricular septal rupture through the LV pseudoaneurysm.
b. The 0.032in*260cm guidewire was externalized by a 25mm Amplatz Goose Neck Snaire kit.
c. A 8F 80cm (45 degree) Amplatzer Torvue delivery system was crossed the VSR through the 0.032in*260cm guidewire.
d. A 16mm Amplatzer muscular VSD occluder was deployed over one of necks of LV pseudoaneurysm
e. Second transcatheter closure of pseudoaneurysm will be performed soon.
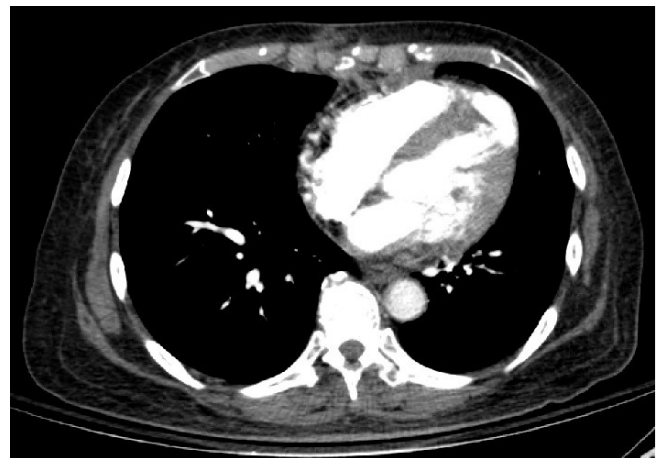
37. Figure 1.
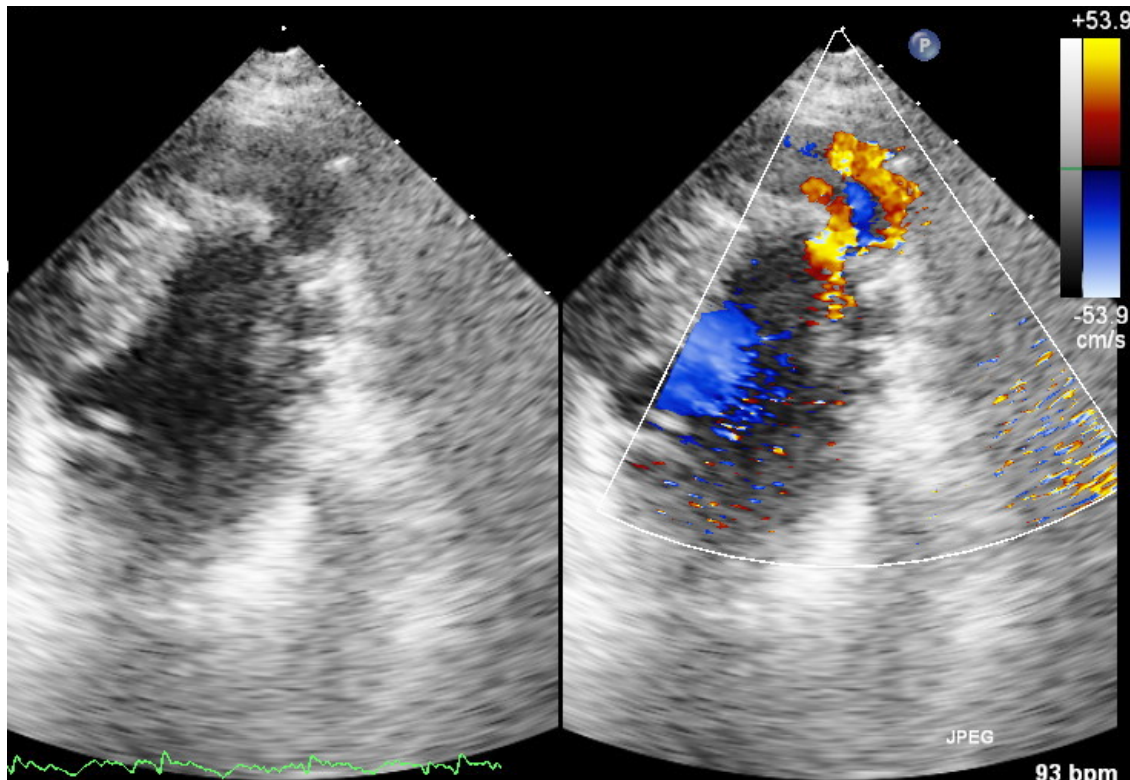
37. Figure 2.

Learning Points of the Procedure:
1. The postinfraction ventricular septal rupture (post-MI VSR) of apical septum was difficult to diagnose on transthoracic echocardiography, and new-onset holo-systolic murmur is an important clue.

2. Although there is no consensus on timing of surgical intervention of the post-MI VR, surgical intervention may be deferred as long as possible if hemodynamic stable.

3. Complete image examinations, including ECG-gated computed tomography angiography and echocardi-ography (transthoracic and transesophageal), are crucial in patients complicated ventricular septal rupture, especially in whom accompanied with pseudoaneu-rysm formation.

4. Transcatheter closure is feasible in patients with re-sidual VSR or pseudoaneurysm after surgical repair of post-MI VSR.

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