



PICS-AICS

Pediatric and Adult Interventional Cardiac Symposium

COLLABORATION TO COUNTER COMPLEXITY: THE FUTURE OF CONGENITAL AND STRUCTURAL INTERVENTIONS

SEPTEMBER 18-21, 2015
ARIA, LAS VEGAS



- A special afternoon *Joint Session with the Congenital Heart Surgeons – Building a Successful Hybrid Program – The Collaborative Approach*
- Live Case Presentations from 9 Centers Around the World
- Taped Case Presentations
- Various Sessions Focusing on Congenital and Structural Heart Interventions
- Oral and Poster Abstracts
- Nursing and Associated Professionals Breakout Session
- My Nightmare Case in the Cath Lab
- Special Session on QA/QI and Accreditation for the Cath Lab
- PreSymposium Focusing on *Innovations in Imaging for Congenital and Structural Heart Disease Intervention – Just How Far Can They Take Us?*
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MEETING ABSTRACTS

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19th Annual Meeting, Las Vegas, September 18-21, 2015

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The Pediatric & Adult Interventional Cardiac Symposium (PICS/AICS)

19th Annual Meeting, Las Vegas, September 18-21, 2015

The Pediatric and Adult Interventional Cardiac Symposium – PICS-AICS 2015 is being held at the Aria Hotel, Las Vegas from September 18-21, 2015. The focus of this years meeting is on how we can overcome greater complexity through collaboration. Hence we have focused sessions outlining opportunities for greater integration with adult structural heart disease specialists and congenital surgeons. We have endeavored to ensure the meeting continues to support open dialogue as well as visual learning, along with updates from all the relevant trials and societies, with real opportunities for networking and sharing global clinical and research experience.

This year, a record number of abstracts have been submitted and a committee of experts has chosen nearly 190 abstracts for oral and poster presentations. The abstracts cover the entire gamut of interventional cardiology for congenital and structural heart disease. Two awards will be issued this year: one for the best oral abstract presentation and the other one for the best poster abstract presentation.

I hope through this journal, which is the official journal of the PICS Foundation, you will be able to read through these interesting abstracts and learn more about the work our colleagues around the globe are doing in this exciting field. If you have any comment on any of the abstracts, feel free to communicate with the editors of the journal.

#0001

UPREGULATION OF CD40/CD40L SYSTEM IN RHEUMATIC MITRAL STENOSIS WITH OR WITHOUT ATRIAL FIBRILLATION

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Platelet activation occurs in peripheral blood of patients with rheumatic mitral stenosis (MS) and atrial fibrillation (AF) and could be related to abnormal thrombogenesis. The CD40/CD40 ligand (CD40L) which reflects platelet activation, mediate a central role in thrombotic diseases. However, the role of CD40/CD40L system in rheumatic MS with or without AF remains unclear. Expressions of CD40 on monocytes and CD40L on platelets were determined by whole blood flow cytometry and serum levels of soluble CD40L were measured by enzyme-linked immunosorbent assay in group 1 (19 patients with MS) and group 2 (20 patients with MS and AF) compared to group 3 (10 controls). Patients with groups 1 and 2 had a significant increase in expression of CD40 on monocytes (P1 and P2 = 0.000) and serum lev-

els of sCD40L (P1 = 0.014 and P2 = 0.033, respectively), but nonsignificant increase in expression of CD40L on platelets (P1 = 0.109 and P2 = 0.060, respectively) as compared to controls. There were no significant difference in all the parameters in group 1 compared to group 2. Correlation analysis demonstrated that there was a significant direct relationship between the severity of MS and serum levels of sCD40L ($r = -0.469$, $p = 0.043$). In conclusion, rheumatic MS patients with or without AF had upregulation of the CD40/CD40L system as well as elevated sCD40L levels. The levels of sCD40L had a significantly direct relationship with the severity of MS and it was the stenotic mitral valve, not AF, that had a significant impact on platelet activation.

#0002

COAGULATION FACTOR VII R353Q GENE POLYMORPHISM AND THE RISK OF ARTERIAL AND VENOUS THROMBOSIS

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Background: Elevated factor VII (FVII) level is a risk factor for thromboembolic disorders. FVII R353Q polymorphism is associated with variation in plasma FVII levels with Lower levels are associated with the 353Q genotype compared with the 353R genotype .

Aim: The aim of the study was to investigate whether factor VII R353Q gene polymorphism is associated with the risk of development of arterial and venous thrombotic disorders.

Methods: A case control study was conducted on 97 subjects; 33 patients with acute myocardial infarction (AMI), 34 patients with deep venous thrombosis(DVT) and 30 healthy controls. FVII R353Q genotypes were identified using restriction fragment length polymorphism analysis.

Results: The homozygous FVII 353QQ genotype was present only in 3% of AMI, and the heterozygous 353RQ genotype was present in 12.1% and 20.6% of AMI and DVT patients respectively in comparison to 13.3% controls (odds ratio of AMI = 1.16, 95% confidence interval =0.2-5.9, p =1.0; odds ratio of DVT = 1.6, 95% confidence interval =0.4- 6.4, P =0.4).

Conclusions: Our findings suggest that the FVII R353Q polymorphism is not associated with increased risk of arterial or venous thrombosis.

Keywords: FVII R353Q polymorphism , AMI, DVT.

#0003

TRANSCATHETER PULMONARY VALVE IMPLANTATION IN NOT TYPICAL PATIENTS.

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Introduction: Transcatheter pulmonary valve implantation become recently a modern treatment of postsurgical patients with right ventricular outflow tract (RVOT) pathology. Several standard requirements should be completed as presence of circumferential conduit/homograft, favorable right ventricle outflow tract (RVOT) morphology with clinical indication for procedure .

Aim: To present our experience with implantation of Melody valve (Medtronic Comp) in pulmonary position in not typical patients.

Material and methods: In selected 6 patient pulmonary valve implantations were performed from 08.2012 to 07.2014. All of them were after surgical correction of Tetralogy of Fallot (TOF) with increasing stenosis and/ or insufficiency of RVOT. Their age ranged from 12 to 40 (mean 24,5) years. Two of them had native RVOT with transannular patch – 3 months before procedure prestening of RVOT was performed as a landing zone creation (in one of them telescopic method in previously stented LPA). Two another patients with homograft had primary absent pulmonary valve with huge MPA (one with LPA agenesis). Another patient also with homograft had absent LPA . One 12 years old child had implanted surgically stentless biological valve in pulmonary position (Freestyle) and shortly after surgery severe pulmonary stenosis developed. Five procedures were performed from femoral access and one from jugular approach.

Results: In all cases Melody valve were implanted successfully with standard prestening before procedures. Gradient RV-PA dropped

from 1-46 (mean 25,2) to 1-25 (mean 11,3) mmHg. There was one complication- stent migration of second prestening stent to MPA in patient with TOF and absent pulmonary valve. Stent was secured and deployed in RPA with double balloon method. Fluoroscopy time ranged from 11-61 mean 32,3 minutes. During follow up good function of implanted pulmonary valves was confirmed in echo in all patients.

Conclusion: Melody valve implantation is demanding, but feasible procedure also in patients beyond classical indications.

#0004

RESULTS OF REDILATATION OF STENTS IN THE TREATMENT OF COARCTATION OF THE AORTA – SINGLE CENTER EXPERIENCE.

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Introduction: Nowadays stent implantation is the treatment of choice in selected patients (pts) with native coarctation of the aorta (CoA) or recoarctation after previous surgery (ReCoA). In certain situation (growth of the patient, neointima proliferation or planned stage stent dilatation) redilatation of previously implanted stent can be required.

Aim: To present results of stent redilatation in the patients with CoA and ReCoA.

Material and methods: Between VII 2003 and XI 2014 50 pts underwent stent redilatation: 40 with CoA and 10 with ReCoA. The procedures were performed using high pressure balloons.

Data of pts are presented in the table Stent implantation (SI)

	CoA 40 pts	ReCoA 10 pts
Age (years)	24,7 (6,5-53)	33,8 (10-65)
Gradient before SI (mmHg)	50,5 (20-94)	50,3 (30-111)
Gradient after SI (mmHg)	17,1 (0-63)	22,1 (0-36)
Stent redilatation (SR)		
Time from SI to SR (months)	13,5 (4-36)	29,7 (6-108)
Gradient before SR (mmHg)	22,2 (9-59)	39,8 (10-65)
Gradient after SR (mmHg)	8,5 (0-38)	23,5 (0-52)

Results: The procedure of SR was ineffective (residual pressure gradient > 20 mmHg) in 3 from 40 pts (7,5%) with CoA and in 4 from 10 pts (40%) with ReCoA, because of stiff lesion (p=0,023). No significant complication (stent fracture, aneurysm formation etc) were observed in any patients during follow-up.

Conclusion: Stage treatment of CoA and ReCoA with SI and than SR

usually is effective method of treatment. In our experience failure of redilatation was observed more often in pts with ReCoA.

#0005

TRANSCATHETER PFO CLOSURE IN CHILDREN AND TEENAGERS AFTER PARADOXICAL EMBOLISM EVENT.

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Introduction: In adults, studies have demonstrated a significantly higher prevalence of patent foramen ovale (PFO) in patients with unexplained, paradoxical embolism event. In contrast such data in children and teenagers are sparse.

Aim: To analyse clinical data and follow-up of youngster with PFO who underwent transcatheter PFO closure.

Methods: Between October 2001 and October 2014 seventeen patients (7 males), aged between 12 and 20 years (mean 17,1 years), had closed percutaneously PFO (from the group of 260 treated pts). All were qualified by neurologist taking in consideration presence of right-left shunt through PFO documented during Valsalva manoeuvre in transesophageal echocardiography (TEE) and contrast transcranial Doppler (c-TCD). The indication were in 8 pts transient ischemic attack (TIA), in 7 cryptogenic stroke (CS), in 1 peripheral systemic embolic event and in another 1 prevention before professional diving. Moreover before procedures in 6 pts headache were present. In all pts, but two nitinol wire mesh PFO occluders were implanted. In 2 pts double umbrella system was applied.

Results: The procedures were successfully completed in all patients and no complications were observed during hospitalization. During follow-up 1 pt have episode of recurrent TIA and in another one small residual shunt in control c-TCD was observed (without clinical consequence). In one pt treated with Amplatzer device paroxysmal atrial fibrillation occurred treated pharmacologically and 2 others patients continued to have headache.

Conclusions: Cryptogenic embolic events are rare in young patients. Transcatheter PFO closure should be considered in this group, although more investigation regarding this subject should be performed. C-TCD is sensitive, noninvasive method for PFO detection, proved in our experience particularly suitable for children.

#0006

TRANSCATHETER CLOSURE OF RUPTURED SINUS OF VALSALVA ANEURYSM WITH NEW TYPES OF NITINOL WIRE MESH PDA OCCLUDERS – SHORT AND MIDTERM RESULTS

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Introduction: Ruptured sinus of Valsalva aneurysm (RSOVA) is a rare shunt lesion frequently treated percutaneously. Lately for this purposes have been used also Chinese PDA nitinol wire mesh devices very similar to Amplatzer Duct Occluder type I (ADO). Experience with this occluders is scant.

Aim: To present results of transcatheter closure of RSOVA with Chinese PDA occluders taking in consideration short and midterm results.

Methods: From September 2010 to August 2014, 8 patients (pts) from 17 to 72 years old (mean age 40 y) have closed their RSOVA with nitinol wire mesh PDA occluders (produced by 3 different Chinese companies). All but two pts had congenital sinus of Valsalva aneurysm. Two pts had acquired RSOVA after previous cardiac surgery (one after aortic valve replacement, another after surgery of tight subaortic stenosis – LVOTO). In all pts arterio-venous loop was created and PDA devices were implanted transvenously. There were used devices 2-6 mm bigger than orifice of RSOVA. There were 7 connection between right coronary or noncoronary sinus with right atrium and 1 between noncoronary sinus and right ventricle.

Results: All PDA devices (sizes from 12/10 to 18/16) were successfully implanted in RSOVA. In one pt with iatrogenic RSOVA (after LVOT operation) device have been retrieved because of massive aortic regurgitation after implantation provoked by the device. In 72 y old woman, after aortic valve replacement, Chinese duct occluder was applied in proximal entrance to the RSOVA. Because of the presence of important residual leak on the edge of the implant the procedure had to be supplemented by closing of the distal RV orifice of RSOVA with 10 mm Muscular VSD Occluder. In one pt after embolization of ADO to pulmonary artery and its transcatheter retrieval, bigger device (Chinese one) were applied. In another pt after ADO implantation 2 y later (during pregnancy) recanalization of SOVA occurred treated successfully by Chinese PDA occluder after delivery. In follow-up (ranged from 0,5 till 4 years) no complications were observed in any pt.

#0008

OUTCOME OF PEDIATRIC PATIENTS WHO UNDERWENT TETRALOGY OF FALLOT CORRECTION IN CORRELATION WITH THE SURGICAL TECHNIQUE USED IN RELIEVING RIGHT VENTRICULAR OUTFLOW OBSTRUCTION

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Introduction and Objectives: Before the advent of surgical intervention, about 50% of patients with Tetralogy of Fallot died in the first few years of life. In the advent of surgical repair, which includes closure of the VSD and relief of right ventricular outflow tract (RVOT) obstruction has greatly improved the long-term survival of TOF patients. Potential complications have been reported in operated TOF patients if they remain asymptomatic. The objective of this study is to determine the outcome of pediatric patients who underwent tetralogy of fallot correction in relation to the surgical technique used in relieving right ventricular outflow tract obstruction (RVOT).

Methods: In this prospective study, 63 patients who underwent tetralogy of fallot correction were included. Postoperative complications of residual pulmonary stenosis, pulmonary regurgitation, and right ventricle systolic and diastolic dysfunction were determined and analyzed in correlation to the surgical technique used to relieve right ventricular outflow tract obstruction.

Results: Residual pulmonary stenosis was observed on all patients for

both groups. Right ventricular dilatation was still evident on most patients in both groups, with transannular patching group at 60.9% and pulmonary valve sparing group at 60%. RV systolic dysfunction was more common in transannular patching group, accounting for 56.5% of the group while in pulmonary valve sparing group, it was present in 19 patients, accounting for 25% of the group. RV diastolic dysfunction was present in 91.3% of transannular patching group and 85% in pulmonary valve sparing group. With regards to the distance travelled in 6 minute walk test, transannular patching group showed a mean of 297 + 71.3m while in pulmonary valve sparing group, it was 215.3 + 69.2m. 96.7% and 97.5% of transannular patching group and pulmonary valve sparing group respectively, were in functional class II, while there was 1 (4.3%) from each group who were in functional class III.

Conclusion: Both RV systolic and diastolic dysfunction are present in the early postoperative period. Diastolic dysfunction was more common among patients who had transannular patching while systolic dysfunction was more common among patients who had pulmonary valve sparing. Pulmonary incompetence was more common among the transannular patching group. Most patients in both groups were in functional class II and had sub-optimal distance travelled in six minute walk test.

#0010

A CASE OF ASCENDING AORTIC PSUDOANEURYSM REPAIR WITH AN ATRIAL SEPTAL OCCLUDER.

Bogdan Cherpak, Igor Ditkivskyy, Viatcheslav Beshlyaga, Bogdan Batsak, Natalia Iashchuk

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Ascending aortic pseudoaneurysm is a quite rare but potentially life-threatening complication. The potential sites for development of pseudoaneurysm after surgery involving the ascending aorta are valvulotomy site, clamping site, graft anastomosis, needle site and cannulation site. Despite a significant improvement in surgical, anesthetic, cardiopulmonary bypass technique management, the outcome of the surgical management of the pseudoaneurysm remains the same. Different interventional techniques including occlusion with an atrial septal occluder and endoluminal stent grafts have been used for treatment this condition. We are presenting a case of successful ascending aortic huge pseudoaneurysm repair with an atrial septal occluder in 55 year old woman following mitral valve replacement as a less expensive option as compared to transapical stent graft placement. One year of follow up showed excellent result on CT scan.

#0011

LOCAL EXPERIENCE IN BUENOS AIRES, ARGENTINA ON EFFICACY AND SAFETY OF CLOSURE OF PATENT FORAMEN OVALE: A CROSS-SECTIONAL STUDY.

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Background: The role of closure of patent foramen ovale (PFO) in patients with cryptogenic ischemic stroke is currently under review. Information on regional experience in Latin America and on local experience in Argentina is lacking. We conducted a study to describe the experience of a single interventional cardiology group from the city of Buenos Aires, Argentina regarding the efficacy and safety of

closure of PFO in patients with cryptogenic stroke or transient ischemic attack (TIA).

Methods: In this cross-sectional observational study we retrospectively collected data through a structured telephone survey applied to patients registered in a database who had undergone closure of PFO due to cryptogenic stroke or TIA performed by a single interventional cardiology group between October 2012 and April 2014. The primary efficacy end point was recurrent cerebrovascular events (stroke or TIA) after the procedure. Safety end points were classified as device-related (endocarditis, embolization or fracture) or procedure-related (palpitations, arrhythmias or dyspnea). Descriptive statistics were used.

Results: 30 patients completed the telephone survey. Median age was 54.5 years old (IQR 42-65.2). Most patients were under 65 years old (73.3%) and were female (53.3%). The main septal occluder devices used were Nit-Occlud® (43.3%) and Cardia® (36.6%). During a median follow-up of 16.7 months (IQR 9.2-24.7) there were no reports on cerebrovascular events (stroke or TIA) or device-related cardiologic complications. Procedure-related cardiovascular complications were reported in 26% of patients, being the most frequent palpitations (13%) and arrhythmias (10%).

Conclusions: This study indicates that closure of PFO due to cryptogenic stroke or TIA performed by a single interventional cardiology group in the city of Buenos Aires is relatively safe and effective.

#0013

IMPLANTABLE ATRIAL FLOW REGULATOR FOR SEVERE, IRREVERSIBLE PULMONARY ARTERIAL HYPERTENSION

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Pulmonary arterial hypertension (PAH) is a severe progressive disease leading to gradual increase in right ventricular pressure, right heart failure, and death. Despite recent advancements in treatment, many patients continue to deteriorate while on optimal medical therapy with decline in quality of life, high rate of hospitalizations and increased medical costs. Thus, there is a need for innovative therapies and interventions to improve long-term outcomes. Increasing systemic ventricular output by promoting right-to-left shunt via atrial fenestration may improve effective systemic oxygen transport and delivery despite arterial oxygen desaturation. Percutaneous stent implantation and balloon dilatation of the interatrial septum (IAS) are well-established techniques to create or enlarge atrial communication in a variety of conditions to improve cardiac output. However, complications experienced with these standard techniques include early spontaneous closure of the fenestration, excessive desaturation, stent occlusion or migration and difficulties in adjusting shunt size to achieve the desired hemodynamic effects. We describe successful emergency use of an atrial flow regulator (Mia Medical, Istanbul, TURKEY), a novel implantable device with central fenestration, in a 54-year-old female with severe PAH.

#0014**SILENT PATENT DUCTUS ARTERIOSIS: WHEN THINGS GO WRONG**

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Introduction: Infective endocarditis (IE) of the pulmonary valve is uncommon and usually occurs in conjunction with tricuspid and/or left-sided valvular endocarditis. There have been only sporadic reports of isolated pulmonary valvular infective endocarditis. Congenital heart diseases are usually associated. We report, here, a case of pulmonary IE with silent patent ductus arteriosus (PDA).

Case Report: A 22 years old female has presented 15 days ago a febrile syndrom and polyarthralgia with deterioration of general condition. She had a recent history of hemolytic anemia. . On the first physical examination, her blood pressure was 100/50 mmhg, heart rate 105 c/ min and regular, and her temperature was 38°C. Cardiac auscultation found two murmurs: a diastolic murmur heard at the pulmonic area increasing with inspiration, and a continuous systolic-diastolic murmur at the left-upper sternal border, associated to signs of right heart failure. The workup included transthoracic echocardiography which revealed many vegetations on the PV with important pulmonary regurgitation and patent ductus arteriosus (PDA). The patient was diagnosed as endocarditis. The blood cultures were negative. She was initially treated with intravenous vancomycin, quinolone and gentamicin but the evolution was fatal.

Conclusion: The incidence of PDA is rising, and it seems likely that we will continue to discover previously unrecognized cases of PDA in our adult patient populations. Asymptomatic patients may not require closure of the PDA, but this can only be determined after a thorough evaluation has been completed.

#0015**OCCCLUSION OF FENESTRATED ATRIAL SEPTUM USING MULTIPLE HELEX DEVICES**

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The Gore HELEX septal occluder has been used successfully to occlude atrial septal defects (ASDs). Several case series describe closure of fenestrated and multiple ASDs, but few have included use of the Gore HELEX device. We report our recent experience in 3 patients occluding multiple ASDs with 2 devices.

Patient 1 was a 14 year old male with a 13 mm defect by balloon stop-flow technique. A second defect, measuring 5 mm, was identified more inferiorly and posteriorly. A 30 mm HELEX device was placed in the larger defect using an over-the-wire technique. The smaller defect was occluded using a 15 mm HELEX device. Patient 2 was a 10 year old female with 3 separate defects: a small defect in the fossa ovalis, an inferior defect, and a more anterior defect. The greatest distance between defects was close to 20 mm. A 20 mm HELEX device was placed in the inferior defect. A 25 mm HELEX device was then placed in the PFO. Upon release of the devices, the device in the foramen ovale appeared to shift superiorly and there was now a residual leak from the anterior defect. The 25 mm HELEX device was

then removed using the retention suture without difficulty. A 30 mm HELEX device was deployed in the anterior defect. It appeared to be in good position and "sandwiching" the other device. Patient 3 was a 10 year old with 2 separate defects. Initially a 30 mm HELEX was used to try and occlude both defects, but the smaller defect was not occluded. Ultimately, these defects were occluded using a 20 and a 25 mm HELEX with the larger device "sandwiching" the smaller device. Our technique on these 3 cases was to leave the first device attached to the delivery system until the second device was delivered. Then, both devices were released from the delivery system. This was felt to reduce the risk of device dislodgement while deploying the second device. There were no issues with interference from the first delivery system while placing the second device. All patients had acute success and longer term occlusion on 2 year follow up on Patient 1 and 1 year follow up Patients 2 and 3.

Multiple HELEX devices can be placed safely and successfully in patients with fenestrated or multiple ASDs. The retention suture of the delivery system allows for withdrawal of a deployed HELEX without displacement of a previously placed device.

#0016**FACTORS PREDICTING BENEFIT OF AN INTERNAL JUGULAR VENOUS APPROACH FOR MELODY™ TRANSCATHETER PULMONARY VALVE IMPLANTATION**

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Background: Transcatheter pulmonary valve implantation (TPVI) is usually performed from a femoral venous (FV) approach, but this may not be the optimal method in some patients. This study aimed to determine factors associated with unsuccessful FV approach and which patients might benefit from an internal jugular (IJ) approach.

Methods: This multi-center retrospective study included all patients who underwent attempted Melody TPV (Medtronic, Inc. Minneapolis, MN) placement in either right ventricular outflow tract conduits or bioprosthetic pulmonary valves between April 2010 and June 2012 at 2 large congenital heart centers. Patients were divided into 2 groups based on the access site (FV or IJ) used to attempt TPVI. Patient characteristics, indications for TPVI, catheterization data, and procedural outcomes and complications were compared between groups. Reasons for using the IJ approach were also assessed.

Results: Of 81 patients meeting inclusion criteria (median age 16.4 years, IQR 11.7-22.8), the IJ approach was used in 14 (17%). The IJ group was younger (median age 11.9 vs. 17.3 years), had lower body surface area (mean 1.33 vs. 1.61 m²), more often had ≥ moderate tricuspid regurgitation (TR), and had a higher ratio of right ventricle to systemic systolic pressure (RVSP:Ao, mean 82.4 vs. 64.7). Seven patients in the IJ group had "technical limitations" using the FV approach as the indication for using the IJ route. Compared to the successful FV approach, the FV "technical limitations" group more often had ≥ moderate TR and higher RVSP:Ao. There were no group differences in procedural complications. However, patients requiring an

IJ approach after unsuccessful FV approach had longer fluoroscopic times and procedure duration compared to the FV group or patients in whom the IJ approach was used from procedural onset.

Conclusions: The IJ approach for TPVi is used infrequently, but is more often used in younger and smaller patients. Technical limitations to TPVi from a FV approach may be anticipated if there is \geq moderate TR or higher RVSP:Ao. In these patients, an IJ approach should be considered early, to avoid prolonged procedural times and increased radiation exposure associated with unsuccessful FV approach.

#0018

STENT ANGIOPLASTY OF PULMONARY BRANCHES AS RESCUE THERAPY OF SUDDEN SPASM OF THEM AFTER RIGHT VENTRICULAR OUTFLOW TRACT STENT IMPLANTATION IN A PATIENT WITH TETRALOGY OF FALLOT.

Roberto Mijangos Vázquez, Jose Antonio García Montes, Jorge Manuel Guevara Anaya, Aldo Luis Campos Quintero, Adrian Sánchez Flores, Carlos Zabal

National Institute Of Cardiology Ignacio Chavez, Mexico City, Mexico

Female patient 4 years 6 months of age with a history of cyanosis since birth. She was taken to left systemic pulmonary shunt at two years of age. She has a history of hypoxia crisis a month prior to admission. On admission, patient with SatO₂ 65%, rhythmic precordium, systolic murmur in pulmonary focus grade II/VI, normal second noise, normal pulses in all four limbs, clubbing.

Echocardiography was performed. Tetralogy of Fallot was diagnosed with left ventricular end-diastolic volume of 13ml (Z score -4.0). Computed tomography was done reporting significant hypoplasia of the pulmonary annulus as well as the trunk and pulmonary arteries, pulmonary systemic fistula occluded (*Figure 1a and 1b*). The case was discussed in session and decided to take cardiac catheterization for right ventricular outflow tract stenting.

Hemodynamic study was performed, where the same pressures in both ventricles and gradient of 80 mmHg between pulmonary artery and right ventricle was reported. Severe hypoplasia of the pulmonary arteries with stenosis in the proximal third was observed (*Figure 2a-c*). Right ventricular outflow tract (RVOT) stenting (3910 Palmaz Genesis Stent) was performed (*Figure 3a-c*). During control angiography, dynamic severe spasm of both pulmonary arteries with little passage of contrast to the distal pulmonary circulation was observed (*Figure 4a and 4b*). Suddenly, the patient developed significant hypotension and desaturation to 83% (PaO₂ of 46mmHg). Two doses of nitroglycerin were administered without reversing spasm, so both pulmonary artery stenting was performed (1910 Palmaz Genesis Stent in right pulmonary artery and 9x16mm LD Mega Stent in left pulmonary artery). Improved blood gas with 100% saturation and PaO₂ 235 mmHg (*Figure 5a-d*).

The patient remains under mechanical ventilation for 36 hours with adequate hemodynamic evolution without presenting evidence of re-perfusion syndrome. Hospital discharge was given four days after catheterization.

Conclusion. Right ventricular outflow tract stenting is a palliative

measure as an alternative to surgery that allows the gradual development of the pulmonary branches when they are not in adequate measures for total correction in a patient with tetralogy of Fallot.

We report a rare complication such as the sudden spasm of pulmonary branches the same as when the pulmonary infundibulum is stimulated, compromising systemic cardiac output and systemic saturation, demonstrating that pulmonary arteries stenting is an excellent choice as rescue therapy to improve hemodynamics and oxygenation status in our patient.

We are not aware of the previous description of this complication during RVOT stenting.

#0019

PERCUTANEOUS CLOSURE OF MITRAL AND TRICUSPID PROSTHETIC PARAVALVULAR LEAKS VIA FEMORAL AND RIGHT INTERNAL JUGULAR APPROACH.

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Male 69 years old with a history of inactive rheumatic heart disease. He was taken to mitral valve replacement on four occasions and tricuspid valve replacement on one occasion, the last change was to ATS prosthesis in both. Patient who a year ago started with dyspnea of small efforts, lower limb edema and orthopnea 3 pillows. Also, the patient had clinical evidence of hemolysis. Therefore he admitted to the hospital, physical examination with jugular venous distension, with mitral regurgitant murmur grade III/IV radiating to the axilla, tricuspid regurgitant murmur, first sound with varying intensity, split second sound, holosistólico click is heard, normal pulses in four limbs.

Transesophageal echocardiography was performed and reported mechanical prosthesis in tricuspid position with opening preserved as well as the presence of significant paravalvular leak in septal region. Mechanical prosthesis in the mitral position with opening preserved, prosthesis ring dehiscence in anterolateral region conditioning prosthetic valve insufficiency with significant hemodynamic repercussion.

It was decided to carry cardiac catheterization. In record pressures left atrium pressure of 36/12/20mmHg. Through femoral approach it was done right and left ventriculography observing moderate to severe regurgitation of both valve prostheses. With the help of transesophageal echocardiography (TEE) area of mitral paravalvular leakage in anterolateral region and tricuspid prosthetic leak in septal region were observed, measured by color Doppler about 5 and 3mm, respectively. The defect in mitral prosthesis was crossed from the right atrium performing transeptal puncture. Arteriovenous loop was performed to finally achieve closure of the paravalvular leak with Amplatzer vascular plug device (AVP III 14/5mm). Through right internal jugular approach, it was possible to advance the guidewire through the tricuspid paravalvular leak and closure of the leak was performed with Amplatzer vascular device device (AVP III 8/4mm). Under fluoroscopic control and using 3D transesophageal echocar-

diogram, proper position of both devices with significant decrease in regurgitant flow of both prostheses was corroborated. New registration pressures with pulmonary artery pressure of 28/12/20mmHg and left atrium pressure of 28/14/20 mmHg. The evolution of the patient after the procedure was toward improvement, without clinical evidence of hemolysis and recovery of functional class. The patient was discharged three days after the cardiac catheterization.

Paravalvular leak as a complication of surgical valve replacement is well described, being uncommon mechanical prosthesis in tricuspid position. To date, there are 3 reported cases of percutaneous closure of this type of paravalvular leak. We demonstrate the successful closure of two paravalvular leaks (mitral and tricuspid prosthesis) through the right internal jugular and femoral approach.

#0020

MODIFIED AMPLATZER SEPTAL OCCLUDER IN A PATIENT WITH OSTIUM SECUNDUM ATRIAL SEPTAL DEFECT

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A 23 year-old male with history of large ostium secundum atrial septal defect (ASD) presented to the emergency department with an inguinal hernia. He was diagnosed with pulmonary edema. Echocardiography demonstrated severe biventricular systolic dysfunction, bicuspid aortic valve with moderate aortic regurgitation, moderate to severe mitral valve regurgitation without mitral valve stenosis status-post mitral valve repair, moderately-severe tricuspid valve regurgitation and moderate residual ASD. An extracellular matrix (ECM) patch (CorMatrix[®] Cardiovascular, Inc., Roswell, Georgia, USA) was surgically placed 21 months prior to presentation. Due to patch failure two ASDs measuring 38 mm x 12 mm and 10 mm x 6 mm were visualized on three-dimensional transesophageal echocardiography (3DTEE). As the patient's left atrial pressure was 24 mmHg, balloon occlusion testing was not performed due to the risk of tissue injury. Instead a 38 mm Amplatzer septal occluder device was manually fenestrated and placed in the larger ASD with immediate hemodynamic improvements. For larger ostium secundum ASDs, closure of the defect with a fenestrated ASO should be considered without balloon occlusion test to prevent complications. Closure of ASD in a patient with severe left ventricular (LV) dysfunction may cause volume overload of the LV and pulmonary edema. However, if carefully planned allowing room for adequate left-to-right shunt, the LV can be trained to handle volume change in small increments over time. In our patient, there was a gradual increase in LV volume and decline in RV volume over 3 days of hospital stay.

#0021

RESIDUAL SHUNT AFTER OCCLUSION OF AN ATRIAL SEPTAL DEFECT WITH THE GORE HELEX SEPTAL OCCLUDER: CLOSURE WITH THE NEWER GORE SEPTAL OCCLUDER.

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Interventional closure of a secundum type atrial septal defect had been performed in a 5-year-old boy with a 25mm Gore Helex Septal Occluder (Helex). Transesophageal echo (TEE) had confirmed an oval shaped (5 x 9 mm) ASD with a partially deficient aortic rim. Balloon-sizing had shown a size of 14.5 mm. After release of the Helex, a residual shunt was noted, but assessed as not significant. The position of the device, alignment of the islets had been assessed to be good. On follow-up echocardiograms over several years the shunt did not decrease and the patient was referred for closure of the residual defect because of right heart volume overload on echocardiography.

At cardiac catheterization, TEE with 3D confirmed a residual shunt between the aortic rim and the Helex device which was crescent shaped. The hole could be passed with a guiding catheter type Judkins right and subsequently easily crossed with the Gore delivery sheath. Balloon-sizing was omitted in order not to deform the previous device. Maximal width of the defect was 7 mm, length difficult to assess for its crescent shape. To completely cover the residual hole at the side of the deficient aortic rim, exert enough radial strength and to capture especially the right atrial disc without covering the central islet of the Helex occluder, a 20 mm Gore Septal Occluder (GSO) was chosen. Closure could be achieved with the sandwich technique and good position of the GSO flat at the septum without residual shunting was documented.

Conclusion: Retrospectively, reason for the residual shunt was likely an undersizing of the initial Helex occluder. A soft device such as the GSO appears to be a good choice to close a residual shunt after the Helex device to avoid its deformation. In addition, radial strength of the new GSO appears to be sufficient for this cause.

#0022

NON INVASIVE ULTRASONIC CHORDAL CUTTING

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Objective: Basal chordae surgical section has been shown to be effective to reduce mitral regurgitation. We investigate in vitro and in vivo the feasibility of using focused ultrasound (histotripsy) for non-invasive chordal cutting to avoid cardiopulmonary bypass and invasive surgery in infarcted heart.

Methods: Experiments were performed in vitro in explanted sheep hearts (N=10) and in vivo in sheep beating hearts (N=7). In vitro, the mitral valve apparatus including basal chordae was removed, fixed on a holder in a water tank. Very high intensity ultrasound pulses were emitted from the therapeutic device (1-MHz focused transducer) placed at a distance of 64 mm under echocardiography guidance. In vivo, after sternotomy, the same therapeutic device was applied on the beating heart. We analyzed mitral valve coaptation and chordae by real time 3D echocardiography before and after basal chordal cutting. Animals were sacrificed at the end for anatomical and histological postmortem explorations to confirm the section of the chordae.

Results: In vitro, all basal chordae were completely cut after mean procedure duration of 5.5 minutes. Duration of the procedure was

found to depend linearly with the chordae diameter. In vivo, the central basal chordae of the anterior leaflet were completely cut. The mean procedure duration was 20.8 minutes (min=16; max=26). The sectioned chordae was visible on echocardiography and MV coaptation remained normal with no significant MR. Anatomical and histological postmortem explorations of hearts confirmed the section of the chordae.

Conclusions: Histotripsy succeed to cut non-invasively mitral valve chordae in vitro and in vivo in beating heart.

#0023

BALLON AND STENT FENESTRATION ANGIOPLASTY IN PATIENTS WITH IRREGULAR EVOLUTION IN THE IMMEDIATE PERIOD AFTER FONTAN SURGERY AT CARDIOLOGY NATIONAL INSTITUTE "IGNACIO CHAVEZ" FROM JANUARY 1994 TO DECEMBER 2014.

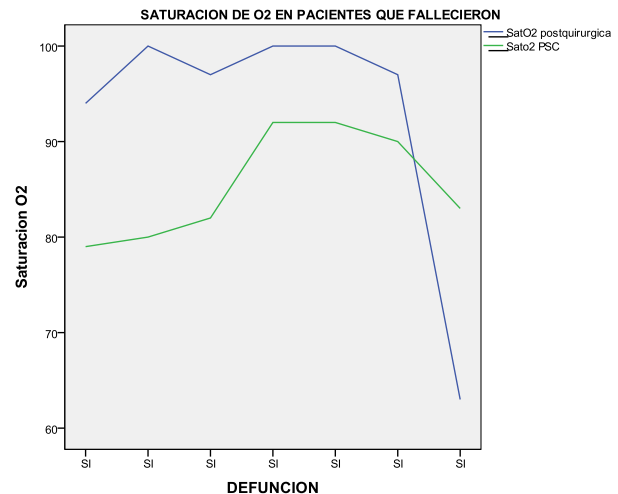
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Objectives: The experience in the balloon and stent fenestration angioplasty in patients with irregular evolution in the immediate period after the Fontan surgery at the National Institute of Cardiology "Ignacio Chávez".

Methods: We reviewed the records of patients who were operated with fenestrated Fontan circulation in our institute from January 2000 to December 2014. The variables were classified in: pre surgery (systemic ventricular ejection fraction, pulmonary artery medial pressure, systemic ventricular end diastolic pressure, McGoon index and Nakata index), trans surgery (bypass and aortic clamping), and post surgery (lactate level, pulmonary artery medial pressure, partial oxygen pressure and oxygen saturation).

Results: Of all patients, angioplasty with stent in fenestration was performed in 20 patients (80%) and angioplasty with balloon in fenestration was performed in 5 patients (20%). In these patients it was found that the saturation of oxygen after the procedure decreased with a mean value of $82.6 \pm 6.1\%$. Seven patients died, which represented 28% of all patients in the study, finding as a major cause of death cardiogenic shock in 3 patients (12%). A correlational analysis was performed, finding that patients who died had preoperative systemic ventricular ejection fraction mean value of $55\% \pm 4$, and patients who survived had a systemic ventricular ejection fraction mean value of $64 \pm 6.3\%$, a result with statistical significance ($p 0.002$). Four patients (16%) have been closed fenestration.

Conclusions: We propose that early invasive management with angioplasty with balloon and stent in fenestration can be used effectively and with acceptable risk to achieve improvement in hemodynamic conditions in the immediate or late postoperative period of these patients. This approach holds great promise in the acute management of failed Fontan circulation.



#0024

BILATERAL ABSENCE OF SUPERIOR VENA CAVA IN A PATIENT WITH ABSENT PULMONARY VALVE SYNDROME AND INFERIOR VENA CAVA MALFORMATIONS AS A CAUSE OF COMPLICATED VASCULAR ACCESS. A CASE REPORT

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Bilateral absence of Superior Vena Cava (SVC) is a very rare entity, usually reported as an incidental finding. First reported by Hussein in 1981 in a patient undergoing pacemaker placement; to the date there are eleven cases reported, only two of them with any other cardiologic malformation. We present the case of a four month old fe-

male patient admitted in our institute as an absent pulmonary valve syndrome (APVS), presenting with respiratory distress that required mechanical ventilation. A central venous access was required. During placement, easiness obtaining blood flow from elected puncture sites was noted however the wire would not advanced in any of the sites. It was decided to realized the procedure in the cath lab. Venograms were performed: neither right or left SVC were seen, both of the venous return drained in an Azygous Vein (AV), that connected to the hepatic portion of the Inferior Vena Cava (IVC). Right iliac vein was hypoplastic and stenosis was noted in the pre renal IVC. APVS diagnosed was corroborated. We present this case due to its oddity complicating a routine procedure such as a central access placement and the curious association between Bilateral absence of SVC a complex cardiac malformation such as APVS and IVC malformations.

#0025

TACKLING THE MEDUSA IN CATH LAB

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A 25 year old female started complaining of easy fatigability, breathlessness, lower limb swelling, facial puffiness and excessive sweating. On presentation she was found to be in cardiac failure with tachypnea, tachycardia and hepatomegaly. Echocardiogram showed huge right coronary artery with continuous signal in right atrium (RA) and the suspicion of coronary artery fistulae to RA. This was confirmed with CT scan at a local center and was referred to us for further management. She was taken up for the coronary artery fistula closure after initial stabilization. PDA device 20/18 was deployed under fluoroscopic guidance retrogradely after arteriovenous loop was formed. In view of residual shunt the patient was taken up for closure of the additional channel which was done using a 8 / 10 device .In follow up it was observed that the shunt was still persistent on echo, chest xray showed the devise had migrated to the lungs. CT Scan was again reviewed and finally the fistulae was plugged with additional Amplatzer Vascular plugs II (20 mm x 16mm & 22mm x 18mm) respectively. The case highlights the need for proper evaluation of the coronary artery fistulae and how multiple tracts and openings can cause difficulty in such a case.

#0026

PALLIATING AORTIC STENOSIS BY BALLOON BEYOND ADOLESCENT : IS IT WORTH IT

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Objective: To evaluate long term results of aortic valvoplasty particularly in adolescent and adults (>12 years) and compare the outcome in other age groups that is <1 year and between 1-11 years.

Patients: 165 consecutive patients treated at the median age of 9 years (0–64years). The follow up period was up to 14 years (median 3 years). The whole cohort of patients was divided into 3 age based subgroups: Group A (<1 year) n=45, Group B (1yr-11 years) n=52, Group C (> 12 years) n=68. The characteristics of each subgroup were mutually compared ,balloon to annulus ratio 0.93.

Outcome measures: Repeat BAV, grade 3 or more aortic regurgitation (AR) and surgery. **Results:** The incidence of significant AR from the whole cohort was 9.9% (8% moderate, 1.9% severe) n=16. Group

A= significant AR-9.6% (1% moderate, 2.4% severe). Group B=significant AR 11.3%(9.4 % moderate, 1.9% severe). Group C= significant AR 9% (7.6% moderate, 1.6% severe); pvalue= 0.99(C vs A)and 0.92(C vs B). Repeat BAV rate was 13.3% (n=22 out of 165 patients). Group A – n=5, (11.9%), Group B- n=10, (18.1%), Group C- n=7,(10.3%). pvalue= 0.78(C vs A) and 0.19(C vs B). Surgery in follow-up was needed in n=4(2.4%), none in group A, 2 patients in group B (3.6%) and 2 patients in group C (2.9%). Patients were followed up for a period of 14 years; Mean survival probability after the procedure was 8 years (group A = 6.5 years, group B = 8.1 years, group C = 9.9 years), pvalue= 0.49 (A vs B), 0.23(B vs C), 0.4(A vs C).

#0027

ENDOCARDIC PACEMAKER IMPLANTATION IN PATIENTS LESS THAN 10 KG. EXPERIENCE IN THE NATIONAL INSTITUTE OF CARDIOLOGY IGNACIO CHAVEZ

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Introduction: Pediatric patients represent less than 1% of the total of patients requiring pacemakers, therefore there are no specific devices for children, this makes the pacemaker implantation in toddlers difficult. The porpoise of this study is to evaluate the short and midterm follow up in the pediatric patient that undergo endocardic pacemaker implantation in our institution.

Method: Between 2006 and 2015; 25 patients weighting less than 10 Kg, were subjected to endocardic pacemaker implantation in our institution. In all of this patients the active fixation cables were introduced via a sub-clavian vein.

Results: From the 25 patients, 19 were female (76%), 6 were male (24%). The median age was 16.8±8.14 months, and the median weight 7.4±1.57 Kg. 24 patients had complete A-V block; 21 were post-chirurgical in nature (84%), 2 were congenital (8%), 1 (4%) presented after an atrial flutter ablation and 1 patient presented with a sick sinus syndrome. In 100% of post-chirurgical patients a VSD was closed. In 72% of patients the pacemaker was set in DDR mode, 20% in DDD and the rest in VVIR. During follow up 2 presented with pacemaker exteriorization and 1 cable exteriorization.

Conclusions: In our experience midterm results were satisfactory, therefore we consider trans-venous pacemaker implantation is a safe and effective method in toddlers.

#0028

INITIAL RESULTS OF A NOVEL SELF-EXPANDING VALVE FOR PERCUTANEOUS PULMONARY VALVE IMPLANTATION

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Introduction: Balloon expandable transcatheter pulmonary valve systems are not applicable to the large majority of patients with chronic severe pulmonary regurgitation (PR) following surgical right ventricular outflow tract (RVOT) rehabilitation. This report describes the clinical use and follow-up of a novel transcatheter self-expanding pulmonary valve system (Venus P Valve) for rehabilitation of the RVOT in patients with chronic severe PR.

Methods: The Venus-P valve is consisted of a self-expanding, "double trumpet" shaped nitinol support frame with a trileaflet porcine pericardial tissue valve. Patients with native RVOT and severe PR were selected and implanted with this valve. Patient demographics and pre-procedural, intra-procedural, and follow-up data were reviewed.

Results: Ten patients (seven females, 20-48 years of age) were selected for attempted valve deployment. All patients had previously underwent surgical repair with RVOT reconstruction procedure because of tetralogy of fallot (TOF, n=9) or double chamber of right ventricle (n=1). Patients were either NYHA class II (n=8) or class III (n=2) at baseline. Mean minimum "annular" diameter on transthoracic echocardiogram was 22.1 ± 2.4 mm and mean RVOT diameter was 30.4 ± 5.8 mm. All cases were successful implanted with one valve without complication, with a mean fluoroscopy time of 21.0 ± 8.2 min. Valve sizes used were 26 (n=4), 28 (n=2), 30 (n=1), and 32 (n=3). Mean pulmonary artery diastolic pressure increased from 14.6 ± 4.0 mm Hg to 22.8 ± 6.8 mm Hg ($P=0.01$). On mean follow-up of 12 ± 5.6 months, PR grade is 0 in all cases. NYHA class has improved at least one class in all cases and right ventricular end-diastolic volumes on cardiac MRI was reduced from 162.0 ± 18.8 ml/m² to 112 ± 12.5 ml/m² (n=6, $P=0.02$) at six month follow-up. One patient died 4 months after procedure because of cardiac arrhythmias. No other adverse events occurred.

Conclusions: Our Initial results demonstrates the safety and efficacy of Venus P Valve in treating native RVOT patients with surgically induced chronic severe PR.

#0029

"DEVICE-IN-DEVICE": A TRANSCATHETER ALTERNATIVE TO SURGICAL EXPLANTATION OF A FAILING INTRACARDIAC PROSTHESIS"

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Background: A failing intracardiac device is traditionally addressed by open-heart surgery. Surgical explantation of the device, although a simple procedure, carries risks that some patients are not able or willing to cope with. Thus, a non-surgical option seems desirable in selected cases.

Case-Report: A 28 year-old female patient, previously diagnosed with Takayasu Disease, underwent transcatheter closure of a secundum Atrial Septal Defect (ASD) in April 2014. At that time she presented with easy tiredness and fatigue on exertion. Transthoracic (TTE) and transesophageal echos (TEE) showed a 15 mm ASD with right heart

enlargement. The stretched ASD diameter measured 19 mm and was occluded with a 20 mm Atriasept™ Cardia ASD Device. There was no residual shunt immediately after the procedure. Three months later, the patient was asymptomatic and control TTE depicted a small shunt through the central portion of the device, with significant reduction in the right heart enlargement. At six months follow-up, the patient resumed exercise-induced fatigue. TEE showed that the device was adequately positioned but a massive left-to-right shunt was now seen through the central portion of the prosthesis by color Doppler. Three-dimensional echo (3-D) images showed the Polyvinyl Alcohol (PVA) sail was missing, despite an intact metallic structure of the device. The right atrial and ventricle enlargement had worsened. A second transcatheter procedure was performed in February 2015. We then chose to cross the defect with a hydrophilic wire as close to the center of the first device as possible. A 30-30 mm Lifetech CERA™ Multifenestrated ASD device was loaded inside a 10 F Mullins sheath and successfully implanted over the CARDIA device. TEE showed the second device nicely placed over the first one with no flow through the atrial septum.

Conclusion: The reason why the PVA sail completely disappeared in this patient is still not fully understood. One can assume that delayed endothelialization of the device and complete bioresorption of the PVA (perhaps accelerated by the baseline inflammatory disease) could play a role. We herein describe a "device-in-device" technique as an alternative to surgical explantation of a defective device. Implanting a second nitinol double disk with a connecting pin (instead of a central waist) device over the first one was technically easy, safe and effective. This device-in-device technique prevents surgical explantation of a failing device, and may become a less invasive option in selected patients.

#0030

"PERCUTANEOUS LAA CLOSURE: ALL IS WELL WHEN IT ENDS WELL"

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Background: Percutaneous Left Atrial Appendage (LAA) transcatheter closure is becoming more popular as an alternative to oral anticoagulation, showing high procedural success and few complications. Incomplete LAA closure may increase the risk of embolic stroke and, therefore, the implant of more than one device may be advisable.

Case-Report: An 80 year-old, male patient was referred for LAA closure due to a significant GI bleeding while on warfarin therapy. He had permanent atrial fibrillation and suffered two ischemic strokes. The CHA₂DS₂-VASc and HAS-BLED risks scores were 7 and 3, respectively. During the index procedure an accessory superior lobe was identified and firstly occluded with a 16 mm ACP. The body of the appendage received a 25-18 mm AGA PFO device. The immediate result was excellent, with complete exclusion of the LAA. Four days later surveillance fluoroscopy showed that the PFO device embolized to the aortic arch. The device was retrieved with a 20 mm snare. After discussion with the Heart Team a second procedure was offered. Contrast hand injections confirmed the uncovered body of the append-

age and measurements of the new landing zone were made. A 30 mm ACP device was introduced and implanted on the desired target area only to immediately pop out of the appendage. The lobe was, then, completely configured at the ostium of the appendage, while the disk was still inside the sheath and the delivery cable was found to be unscrewed from the device and loose inside the sheath. The device was ultimately retrieved with a 5 mm snare. The ACP was re-inserted but the tip of the sheath was collapsed preventing the device to come out. The sheath was removed and replaced by a new 13 F AGA 45/45° sheath and another attempt was made to implant the 30 mm ACP, only to see it pop out of the appendage again. This device was discarded and a 28 mm ACP was, at last, successfully implanted. The patient was discharged two days later on aspirin and clopidogrel and remains in excellent conditions 40 days after the procedure. Control TTE at one month revealed the devices in place and the mouth of the LAA completely occluded.

Conclusion: Complete occlusion of the trabecular portion of the LAA should be aimed and sometimes more than on device may be necessary. This case shows that a two-lobe appendage can be difficult to recognize, even by experienced operators, and measurements can be misleading. It emphasizes the need for adequately trained personnel and a fully equipped cath lab for perfect results.

#0031

THE IMPACT ON VENTRICULAR FUNCTION AFTER PERCUTANEOUS PULMONARY VALVE IMPLANTATION -ONE YEAR FOLLOW UP BY THREE-DIMENSIONAL ECHOCARDIOGRAPHY

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Objective: Percutaneous pulmonary valve implantation (PPVI) is an efficient therapy for patients with severe pulmonary valve regurgitation who underwent cardiac surgery for tetralogy of Fallot (TOF). In this study, we followed up PPVI patients for 1 year and intend to investigate the variation of left ventricular and right ventricular function in PPVI patients by means of three-dimensional echocardiography.

Methods: Eight patients who underwent cardiac surgery for TOF in youth and met severe pulmonary valve regurgitation which need PPVI were enrolled. Patients accepted two-dimensional and three-dimensional echocardiography examination before PPVI, 1 month, 3 months, 6 month, and 1 year after PPVI. The regular parameters of chambers were acquired from two-dimensional echocardiography. Other parameters such as left ventricle end diastolic/systolic volume (LVEDV/LVESV), LVEF, global longitudinal strain (GLS), global circumferential strain (GCS), global right ventricle end diastolic/systolic volume (RVEDV/RVESV), body region of right ventricle end diastolic/systolic volume, outflow region of right ventricle end diastolic/systolic volume, and inflow region of right ventricle end diastolic/systolic volume were acquired and calculated from three-dimensional echocardiography.

Results: There showed no significant difference before PPVI and 1 year after PPVI in parameters of left ventricular chamber measurements and left ventricular systolic function, such as LVEF, LVEDV, LVESV, GLS, and GCS ($p>0.05$). The right ventricular end diastolic area was significantly reduced at 1 month after PPVI, while right ventric-

ular end systolic area reduced at 3 months after PPVI ($p<0.05$). Both RVEDV and RVESV showed significantly reduced at 6months after PPVI. When right ventricle was departed into three sections, the body region of right ventricle reduced significantly at 3 months after PPVI, while similar improvements of inflow and outflow region were met at 6 months after PPVI.

Conclusions: PPVI was efficient in improving right ventricular function in patients with severe pulmonary valve regurgitation after TOF surgery. The improvement of body region of right ventricle was preceded over inflow and outflow region after PPVI. Sequent improvements of each region of right ventricle after PPVI can be detected by three-dimensional echocardiography accurately and rapidly.

#0032

ADVANTAGES OF ENDOVASCULAR PDA CLOSURE BY VENOUS APPROACH IN NEONATOLOGY

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The last 5 years, endovascular closure has began to solve this illness with fewer complications than surgery. Normally, surgeons perform the surgery in Neonatology. This was the reason why we tried to work in the same conditions. In prematures, the transportation can increase the risk of complications. Neil Wilson has promoted PDA closure in Neonatology guided by Transthoracic Echo (TTE). However, he has chosen to do it through artery puncture given the ease of access to the PDA.

Objective: To compare PDA closure in the Cath lab and in Neonatology, both procedures by venous puncture.

Material and methods: Two patients (p) were treated. **Ap:** 1045 g and the second **Bp:** 900 g. Protocol used: a) venous puncture to avoid the artery injuries b) guided by Transthoracic echo (TTE). - **PA:** in the Cath lab. The p was transported inside a transport incubator. On arrival, the patient had to be conditioned. Altogether, it took us between 30 and 40' to begin the procedure. - **PB:** in Neonatology. The p was placed in a radiant warmer. A C-arch and an ultrasound equipment were transported to Neonatology.

Results: **PA** had a PDA (type C): the transportation increased the heart insufficiency. Diam= 3.9 mm and length= 10 mm. A 4-5 ADO II device was used. Fluoroscopy time: 7'. Contrast: 6 mm. **PB** had a PDA (type C): the p stayed in Neonatology. Diam= 2.7 mm. A 4-2 Amplatzer type II AS was used. Fluoroscopy time: 3'. Contrast: 3 mm. Neither p had residual shunt in the immediate period. Two hours after procedures, the chest X ray showed the normalization of the heart's size. The TTE allowed to measure the PDA, to position the device, to control the correct position and to assess the residual shunt. **PB** suffered hemodynamic changes with TTE. Therefore, a subcostal image was done to observe the PDA and its measurements. Both procedures finished without complications. The p improved their clinical condition. Both p died of sepsis. There were no vascular injuries.

Conclusions: 1) Having used the same protocol in both p, the difference between the two was the transportation. Closing the PDA in Neonatology reduced the risks derived from the movement. 2) The

absence of vascular injuries demonstrated that the venous approach chosen was adequate and allowed to conclude the PDA closure successfully. 3) The learning curve will give more conclusions.

#0033

EXPERIENCE IN THE CLOSURE OF PATENT DUCTUS ARTERIOSUS WITH NEW OCCLUTECH DEVICE. WHAT IS THE CORRECT POSITION OF THE DEVICE?

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Patent ductus arteriosus (PDA) is one of the most frequent congenital cardiopathies associated with or without different clinical syndromes. Close the PDA using catheterization techniques with modern devices like "Occlutech" it is motive of controversy, since nowadays there isn't consent about the best way to avoid its displacement and to achieve PDA's complete occlusion. We share the following lab results.

Methods: Since July 2014 to April 2015 we have closed 10 PDA, by percutaneous approach with "Occlutech" device, in patients with clinical and echocardiography diagnosis of arterial duct. Mean age was 8 years (11 months to 21 years), and median weight was 17kg (6-40kg). In six patients with Down's Syndrome, the pulmonary border of the arterial duct ranging from 2 to 11mm (median 5). We have classified the functional class according to the NYHA. The pulmonary arterial hypertension was classified: mild, pulmonary systolic pressure was 1/3 of the systemic blood pressure; moderate, when pulmonary systolic pressure rose to 2/3 of the systemic pressure and severe, with more than 2/3. Krichenko's classification was used. The selection device size was calculated by the diameter of the ductus arteriosus pulmonary and pulmonary arterial hypertension. Patients were followed clinic, radiological and echocardiographic at 24 hours, 48 hours and a week after the procedure. The immediate residual shunt was classified as mild; if contrast get the pulmonary ductal extreme, moderate; if rise to the pulmonary artery without delineating its valve, severe, if the whole valvular was delimited. The residual shunt was moderate in 80% of patients, with complete occlusion within 1 to 7 days (median 4 days). Placement device at the PDA aortic extreme in a convex way decrease the residual shunt and it is more likely complete occlusion. Complications were embolization of a device into the abdominal aorta, a patient who had a small arterial duct, in which convexity of the retention disc could not be achieved. Statistical analysis was done with SPSS 12 software.

Conclusion: It is our experience, the Occlutech device was useful for small and large PDA closing. Residual immediate shunt were moderate. Deformation of the device retention disc, in a convex way at the PDA, it is safe, in contrast with other devices. Research with larger number of cases are required in order to more effectively answer our clinical question.

#0034

REGRESSION OF TRICUSPID REGURGITATION AFTER PERCUTANEOUS PULMONARY VALVE IMPLANTATION

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Introduction: Chronic severe pulmonary regurgitation (PR) can cause right ventricular enlargement and then functional tricuspid regurgitation (TR). However, whether correction of PR by percutaneous pulmonary valve implantation (PPVI) can reduce TR is unknown. The objective of present study was to investigate the effect of PPVI on TR in chronic PR patients.

Methods: Patients with severe PR following surgical right ventricular outflow tract (RVOT) reconstruction were selected and implanted with a Venus-P Valve, which is consisted of a self-expanding, "double trumpet" shaped nitinol support frame and a trileaflet porcine pericardial tissue valve. The patients were evaluated with echocardiography at baseline and one, three months after procedure.

Results: Ten patients (aging 35.7± 8.3 years, seven females) were successfully implanted with a Venus-P Valve. All patients had chronic severe PR because of previously surgical repair with RVOT reconstruction. Four patients had grade 2 and four had grade1 functional TR, while the other two didn't have TR. The degrees of PR were all decreased to grade 0 at one month or three month follow-up, from grade 3 (N=5) or 4(N=5) at baseline (P<0.01). The trans-pulmonary-valve gradient at baseline, one month and three month follow-up was 20.1 ±14.0, 17.0± 6.0, and 17.5± 6.3 mmHg, respectively. The right ventricular end-diastolic area (RVEDA) was decreased from 34.2± 3.2 cm² at baseline to 27.5± 6.6 cm² (P=0.03) at one month follow-up and to 26.2± 5.2 cm² (versus baseline, P=0.01) at three month follow-up. However, the right ventricular end-systolic area (RVESA) was not different among baseline (20.8 ±3.1 cm²), one month (18.3± 6.0 cm²) and three month (17.3 ±4.9 cm²) follow-up (P=0.35). The grade of functional TR was reduced from 1.2 ±0.9 at baseline to 0.8 ±0.9 (P=0.045) at one month follow-up, and to 0.5 ±0.9 (versus baseline, P<0.01) at three month follow-up.

Conclusions: PPVI could reverse right ventricular enlargement and then regress TR in severe chronic PR patients with functional TR.

#0035

CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT WITH THE AMPLATZER™ ASO: RESULTS OF A 1000 PATIENT STUDY

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Objectives: To evaluate the safety and efficacy of the St. Jude Medical™ AMPLATZER™ Septal Occluder (ASO) for percutaneous closure of secundum atrial septal defects (ASD).

Background: The ASO is a self-expanding, double-disc nitinol wire mesh occluder for percutaneous closure of ASD. Concern has been raised about the potential for cardiac injury with the ASO, although the reported incidence is rare. This prospective study was developed as the first of a two-part study to evaluate safety and efficacy.

Methods: Subjects prospectively enrolled in a 1000 patient single

arm study at 50 U.S. sites and followed for 2 years post-procedure. The primary objective of the study was to evaluate the risk of hemodynamic compromise in those receiving the ASO device. Additional safety objectives were to determine the incidence of device and delivery system-related adverse events. Efficacy was measured as the percentage of subjects for whom closure of the defect was achieved through 2 year follow-up.

Results: Between March, 2008 and May, 2012, 1000 patients (age range 0.3 - 83.6 years, mean 21 ± 22 years) underwent attempted ASD closure with the ASO. Closure was successful during the procedure in 97.9% of subjects. The percentage of subjects with complete closure was 98.5% and 97.9% at 1 month and 2 years respectively. Hemodynamic compromise related to the device occurred in 6 subjects by 2 years (0.65% of 928 evaluable subjects), due to dysrhythmia in 2, device embolization in 1, and cardiac erosion in 3. The rate of cardiac erosion was 0.3% at an average of 83 days from implant (range 12-171 days). The level of physician experience implanting the ASO device in this study showed no statistical significant difference in the rate of hemodynamic compromise ($p=0.4$ by Fisher's Exact test). An additional 31 subjects were noted to have pericardial effusions that were treated with observation or pharmacologic therapy. These events of pericardial effusion were adjudicated by an independent committee as not being caused by cardiac erosion.

Conclusions: Closure of ASD with the ASO is safe and effective regardless of physician experience. The incidence of hemodynamic compromise related to cardiac erosion is extremely rare and consistent with previous study results and reports in the literature. (Closure of Atrial Septal Defects with the AMPLATZER® Septal Occluder - Post Approval Study) ClinicalTrials.gov Identifier: NCT00650936.)

#0036 COMPARISON OF EFFICACY OF TRANSCATHETER ASD CLOSURE IN CHILDREN THAT WEIGH LESS THAN 15 KG (≤ 15) AND 15-20 ($>15 - <20$) KG

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Objectives: We investigated safety, efficacy, and follow-up results of transcatheter closure of secundum atrial septal defects (ASDs) in children weighing less than 15 kg compared with children weighing between 15-20 kg.

Methods: Over the last 7.5 years, 274 children with a weight of <20 kg underwent transcatheter closure at a single pediatric center. Patients were divided into the following two groups: Group I: weight ≤ 15 kg; and Group II: weight $>15 - <20$ kg. Data were analyzed retrospectively.

Results: There were 161 (58.8%) females. The mean diameter of the ASDs measured by echocardiography was 12.4 ± 3.7 (7-30) mm. The mean age of the children was 4.3 ± 1.3 years and the mean weight was 15.2 ± 2.4 kg. Group I included 146 (53.3%), and group II included 128 patients (46.7%). A total of 269 (98.2%) interventional operations were considered successful, and 5 (1.8%) unsuccessful. Major com-

plications occurred in 7 patients (2.5%). The stretched ASD diameter was 14.7 ± 3.9 (7-29) mm in Group I and 15.9 ± 4.7 (7.8-28) in Group II, $p=0.063$. The ASD diameter/body weight was 0.9 ± 0.2 (0.4-1.8) in Group I and 0.8 ± 0.2 (0.4-1.5) in Group II, $p=0.001$. The Amplatzer-like device diameter was 16.0 ± 4.1 (9-30) mm in Group I and 17.7 ± 5.0 (9-34) mm in Group II, $p=0.004$. The patch-like device diameter was 28.8 ± 4.6 (20-35) mm in Group I and 29.4 ± 4.1 (20-33) in Group II, $p=0.716$. The delivery sheath was measured at 8.4 ± 1.4 (6-12) F in Group I and 8.8 ± 1.5 (6-12) F in Group II, $p=0.039$. Fluoroscopy time was recorded as 9.9 ± 7.8 (3.2-48.6) min in Group I and 8.9 ± 6.7 (2.3-30.7) min in Group II, $p=0.587$. There were no statistically significant difference in the rate of unsuccessful procedures and complication rates between the patient groups ($p=0.762$ and $p=0.836$).

Conclusion: Transcatheter closure of ASDs in small children is feasible and is not associated with a greater risk of significant complications.

#0037 COMPARISON OF IN VIVO NEOENDOTHELIZATION PROCESS OF THREE ATRIAL SEPTAL DEFECT OCCLUDER DEVICES (AMPLATZER VERSUS LIFETECH VERSUS OCCLUTECH) AT CHILDHOOD

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Objectives: We investigated neoendothelization process of transcatheter closure of secundum ASD in children comprising of three different occluders in vivo way.

Methods: 44 children underwent transcatheter ASD closure. Patients were divided into the following three groups: Group I: Amplatzer, Group II: Lifetech CeraFlex, and Group III: Occlutech Figulla Flex II septal occluders were used. Data analyzed prospectively. Markers of three phase (PDGF, IL-1 α , TGF- β 1, VEGF, FGF-2, MMP-9 and FGF-1) of wound healing process were studied at the all patients before the intervention, and 1th day, 10th day and 1th month of after the intervention.

Results: The mean age of children was 7.1 ± 3.5 (2-17) and the mean weight was 26.1 ± 15.1 (11-78.6) kg. The mean diameter of the ASDs was 13.6 ± 3.9 (8-26) mm. All interventional operations were considered successfully. Group I (ASO) 15 (34.1%), Group II (CSO) 14 (31.8%), and Group III (OSO) included 15 (34.1%) patients. There was no statistically difference between Groups regarding number of patients, patient ages, defects sizes, device diameters, and total septum/device ratio ($p>0.05$). Inflammatory (PDGF, TGF β -1) and proliferative phase parameters (VEGF, FGF-2) increased after procedure ($p<0.05$). But scar formation parameters (MMP-9, FGF-1) did not changed at the end of first month. There were no statistically significant difference in the neoendothelization process between the occluders ($p>0.05$).

Conclusion: All three devices made of Nitinol with some different surface coating techniques. One possible explanation of these manufacturing features were claimed facilitate of neoendothelization. But all

of three devices, at least regarding neoendothelization are not shown a difference in children at the end of first month after the procedure.

#0038

PERVENTRICULAR PULMONARY VALVOTOMY AS A SUCCESSFUL THERAPEUTIC MEASURE IN A CASE OF PULMONARY ATRESIA WITH INTACT VENTRICULAR SEPTUM AND IATROGENIC PERFORATION OF RIGHT VENTRICULAR OUTFLOW TRACT.

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An 8 day new born is admitted to hospitalization with clinical manifestations of central cyanosis that increments while crying with a pulse oximetry of 65%. At admission a transthoracic echocardiogram is realized with a reporting diagnosis of pulmonary atresia with intact ventricular septum with confluent pulmonary arteries. The patient is taken to the catheterization laboratory finding a right intraventricular pressure 90mmHg above the systemic pressure. While trying a transcatheter mechanical valvotomy with a hydrophilic guide wire a false way is created to the pericardial cavity, posteriorly the patient suddenly deteriorates presenting hemodynamic compromise with hypotension and bradycardia. The patient required adrenaline infusion but still persisted unstable. A urgent transthoracic echocardiogram is decided to be realized in the cath lab finding an important pericardial effusion with left cavity collapse requiring urgent pericardial drainage in the catheterization laboratory. The patient still under hemodynamic compromise is transferred to the operating room, with plans of realizing a hybrid procedure. In the operating room a midline thoracotomy was performed and a purse string stitch is made on the free wall of the right ventricle, posteriorly a guided puncture towards the pulmonary valve plan achieving its perforation. After the successful perforation of the pulmonary valve, a Tyshak mini 10x20mm balloon mounted on angioplasty guide wire is passed across the valve finally realizing a pulmonary valvotomy. In the control ventricle angiography, contrast material could be seen passing to the pulmonary circulation. In the posterior pressure records, the final right ventricle pressure was of 49/2/9mmHg. The patient was transferred to the intensive care unit, with a favorable clinical progress, being discharged 2 weeks after.

The percutaneous interventional technique of pulmonary valve perforation is a therapeutic option that provides pulmonary blood flow to patients with pulmonary atresia with intact ventricular septum. Cardiac tamponade is the major complication of this type of procedure following perforation of the pericardial space. Even though it is an unusual complication, it's a serious one in these types of procedures, in which 3% of patients require urgent surgical management.

#0039

IMPACTS OF EARLY CARDIAC CATHETERIZATION FOR CHILDREN SUPPORTED BY EXTRACORPOREAL MEMBRANE OXYGENATION

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Background: Cardiac catheterization is often required for pediatric patients supported on Extracorporeal membranous oxygenation (ECMO) to identify or intervene treatable lesions. The aim of this study was to assess the characteristics of catheterization for those patients and clarify the prognostic factors for successful weaning.

Methods: Single-center retrospective cohort study from 2000 to 2013. Patients who received cardiac catheterization while on cardiac ECMO support were eligible and divided according to their primary cardiac diagnosis; congenital heart disease (CHD; n=47) and cardiac muscle disease (CMD; n=15) and compared. Subgroup analysis in CHD was conducted to determine predictors for successful weaning by univariate and multivariate logistic regression analyses. Kaplan-Meier analysis and log-rank test were performed to compare the survival to analyze the impact of catheterization performed within 2 days of ECMO support.

Results: From a total of 309 patients placed on ECMO, sixty-one (13%) cardiac catheterizations were identified in 60 patients (median age 119 days, IQR: 24, 291). Catheterization was undertaken at median of 1 day (IQR: 0, 3) after initiation of ECMO. Catheter intervention was performed in 39 (64%) cases. Procedure-related complication was noted in 8 cases (11%). There was no procedure-related mortality. The success rate of weaning was not significantly different in between CHD and CMD (70% vs 93%; p=0.15), while CMD achieved higher survival rate on discharge (53% vs 86%; p=0.03). Subgroup analysis revealed that the shorter interval between ECMO initiation and catheterization (p=0.018), no requirement of subsequent surgery (p=0.043), and no respiratory, gastrointestinal, or renal complication (p<0.01) were better prognostic factors for successful decannulation in univariate analysis. Absence of renal failure (p=0.025) and respiratory complication (p=0.0046) were significant prognostic factors in multivariate analysis. The Kaplan-Meier analysis showed significantly better survival when patients received catheterization within 48 hours after ECMO implement (p=0.047).

Conclusion: Successful ECMO weaning was achieved in patients who had early catheter intervention. Cardiac catheterization should be prompted for patients who required ECMO when an anatomical residual lesion is suspected, before end-organ complication may develop.

#0040

PERCUTANEOUS CLOSURE OF PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECTS (PM- VSDS) USING THE SECOND GENERATION AMPLAZTER DUCT OCCLUDERS (ADO II)

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Objective: The purpose of this study is to report the use of the softer second generation Amplatzer vascular occluders namely the Amplatzer Vascular Plug II (AVPII) and the Amplatzer Duct Occluder II (ADOII) for percutaneous closure of perimembranous ventricular septal defects (Pm VSDs).

Background: Previous attempts at percutaneous closure of Pm VSDs were abandoned because of incidence of heart block likely as a result of device rigidity and/or over sizing.

Methods: Retrospective review of patients who underwent closure of Pm VSDs using AVPII or ADOLII was performed.

Results: 19 patients were identified. AVPII was used in 9, ADOLII in 10. Median weight was 13.2 Kg + 19 (range 6.5 to 76); age 24 + 79 months (range 11 to 352). Post procedure, 4 were noted to have new aortic insufficiency (AI); trivial in 3 & mild in 1 (unrelated to the device). Mild tricuspid regurgitation possibly device or procedure related was seen in 4. Residual flow through the device was common post procedure and disappeared in all but 2, graded as trivial in 1. 1 patient had small residual flow above the device. Average follow-up period was 7.3 months + 7.6 (1 day – 25 months). There was no incidence of heart block, bacterial endocarditis, hemolysis, device embolization or fracture. The AI was trivial in 2, mild in 1 and resolved in 1.

Conclusions: Percutaneous closure of Pm VSDs using the softer new generation devices as the AVP II and the ADO II is feasible and safe. Longer follow up and larger series are needed.

#0041 SELECTIVE PROPENSITY OF BOVINE JUGULAR VEIN MATERIAL TO BACTERIAL ADHESIONS AND THE IMPACT OF PERCUTANEOUS PULMONARY VALVE IMPLANTATION PROCEDURAL STEPS IN THE GENESIS OF INFECTIVE ENDOCARDITIS: AN IN-VITRO STUDY

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Objective: Percutaneous pulmonary valve implantation (PPVI) using bovine jugular vein made Melody valve is safe and effective. However, infective endocarditis has been reported for unclear reasons. We sought to assess the impact of PPVI procedural steps on valvular histology, selective bacterial adhesion and leaflet mechanical behaviour.

Methods: Three valved stents (Melody valve, homemade stents with bovine and porcine pericardium) were tested *in-vitro* in 4 conditions: I) control group, II) crimping, III) crimping + inflation of low-pressure balloon and IV) condition III + post dilatation (high-pressure balloon). For each condition, valvular leaflets (and venous wall sample for Melody stents) were taken for histological analysis, bacterial adhesion using *S. aureus* and *S. sanguinis* strains and mechanical uniaxial tests of valve leaflets.

Results: Among Melody valves, incidence of transverse fractures was significantly higher in traumatized samples compared with control group ($p < 0.05$) whereas, incidence and depth of transverse fractures were not statistically different between the 4 conditions for bovine and porcine pericardial leaflets. Bacterial adhesion was higher on bovine jugular venous wall for *S. aureus* and on Melody valvular leaflets for *S. sanguinis* in control groups and significantly increased in traumatized Melody valvular leaflets with both bacteria (I vs IV: $p = 0.05$). Bacterial adhesion was lower on bovine pericardial leaflets.

Conclusion: Valved stent implantation procedural steps induce histological lesions on Melody valve leaflets. Selective adhesion of *S. aureus* and *S. sanguinis* pathogenic strains to Melody valve tissue was noted on healthy tissue and increased after implantation procedural steps.

#0042 PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE FOLLOWED BY SINGLE ANTIPLATELET THERAPY: SHORT AND MID-TERM OUTCOMES

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Introduction: Left atrial appendage closure (LAAC) is non inferior to warfarin in patients with nonvalvular atrial fibrillation (NVAF). However, postprocedural antithrombotic therapy is not clearly established. We aimed to assess the safety and efficacy of LAAC followed by single antiplatelet therapy for patients with NVAF and contraindication for anticoagulation (OAC)

Methods: Consecutive patients with a previous ischemic or hemorrhagic stroke, NVAF and contraindication for OAC underwent LAAC between July 2010 and December 2014 in 2 French centers (University Hospital of Bordeaux and Pasteur Clinic, Toulouse, France). Follow-up included clinical evaluation at 1, 3 and 6 months, and a cardiac computed tomography (CT) at 3 months to assess device position, device-related thrombus and residual leak. In case of abnormal CT, TEE was performed to confirm the suspected diagnosis. Single-antiplatelet therapy was prescribed after the procedure for at least 6 months.

Results: 81 patients (age 73 ± 8 years) were included. The mean CHA₂DS₂-VASC and HAS-BLED scores were 4 ± 1.3 and 3 ± 0.9 , respectively. Main LAAC indication was anticoagulation contraindication (71 patients, 87.6%). The procedure was successful in 100%. Periprocedural complications were serious pericardial effusion ($n=1$, 1.2%) and major bleeding ($n=2$, 2.4%). After a mean follow-up of 9.7 (3-22) months, one death occurred (following device embolization needing surgical retrieval 2 months after procedure). Four patients presented stroke/TIA/systemic embolism after a mean duration of 15 months (annualized incidence=3.2 % patient/year) that were not related with device thrombus on CT/TEE. Thrombus-related device was observed in 5 patients (4%) but without clinical related event. No bleeding was observed during follow-up.

The observed annual rates of thromboembolic and bleeding events were lower than expected by CHA₂DS₂-VASC and HAS-BLED scores ($p < 0.05$).

Conclusions: LAAC followed by a single antiplatelet therapy could be a reasonable alternative for stroke prevention. This strategy provides a significant reduction in the rate of events such as stroke or bleeding versus the score-predicted rate.

#0043 EXTENDING PERCUTANEOUS LEFT ATRIAL APPENDAGE CLOSURE INDICATIONS: THE THROMBUS

TRAPPING TECHNIQUE

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Objectives: Percutaneous LAA closure has emerged as an alternative therapeutic option for the prevention of embolic stroke in high-risk patients with non-valvular atrial fibrillation. The presence of thrombus in the LAA remains so far a contraindication of the procedure.

We aimed to describe a modified left atrial appendage (LAA) closure technique that allows a safe procedure in patients with LAA thrombus.

Methods: Between January 2011 and October 2014, LAA closure was performed in 8 patients (mean age = 75 ± 11 years old, 75 % males) with LAA thrombus and/or severe spontaneous echocardiographic contrast using a modified technique that avoids manipulations of catheters or angiography in the LAA.

Results: Two patients had a persistent thrombus despite appropriate antithrombotic therapy while all other patients had contraindication for systemic anticoagulation. The procedure was successful using the modified implantation technique in all patients. Implanted device was Amplatzer Cardiac Plug (St. Jude Medical, Minneapolis, Minnesota) in 4 patients and Amulet device in the remaining. No peri-procedural complications occurred. After a mean follow-up of 7 ± 5 months, no death or late complications were observed.

Conclusions: The thrombus trapping technique is a safe and effective procedure. This modification of the implanting technique may allow an extension of LAA closure indication to patients with LAA thrombus who were formerly considered unsuitable.

#0044

TRANSCATHETER CATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS IN SMALL PEDIATRIC PATIENTS FROM AN EXCLUSIVE TRANSVENOUS APPROACH USING ANGIOGRAPHIC AND ECHOCARDIOGRAPHIC GUIDANCE

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Introduction: Transcatheter closure is the treatment of choice for the majority of patients with a patent ductus arteriosus (PDA). However, the standard technique of this procedure may be associated with arterial complications in small pediatric patients. The aim of this study was to report experience with catheter closure of PDA in 40 consecutive small children using an exclusive venous approach.

Methods: The age of the patients ranged from 3-36 months (mean 13 ± 11 mm) and the weight from 4-14 Kg (mean 7 ± 4 Kg). The anatomy and size of PDA were defined by transvenous retrograde aortography using a Pigtail or a Berman catheter. The PDA occluder was implanted through a 7-8 F (ADO I) and 5-6 F (ADO II, ADO AS) delivery sheath

(DS) in 15 (age 22 to 36 months, mean 26 ± 5) and 25 (3 to 18 months, mean 7 ± 6) patients, respectively. The procedure was guided using hand injections of contrast media through the DS and 2D and color Doppler echocardiography from suprasternal and parasternal long and short axis, respectively.

Results: The PDA occluders were permanently implanted in all 40 patients. The mean PDA diameter (at the pulmonary end) was 3.8 ± 0.9 mm (range, 2.5 to 5.2 mm). The mean device diameter was 5 ± 1 mm (range 4 to 8 mm) and 4.2 ± 1.5 (range, 3-6 mm) for the ADO I and the ADO II occluders. Complete echocardiographic closure of the ductus at 1-month follow-up was observed in all 38 patients (100%). Immediately after the procedure there was a mild left pulmonary stenosis (peak pressure gradient of ranging from 6-8 mm Hg), in 3 patients. Five minor groin venous hematomas were the only complications of the procedure.

Conclusions: Exclusive transvenous PDA occlusion using combined angiographic and echocardiographic guidance is an effective and safe method that prevents the arterial complications of the standard approach particularly in small children. In contrast to ADO I the ADO II, AS occluders due to their low profile can be delivered through a 5-6 F delivery sheath which facilitates crossing of PDA and the injections of contrast medium for guidance of the procedure.

#0045

INTERVENCIÓNIST MANAGEMENT OF CONGENITAL CORONARY FISTULA. CASE REPORT

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Introduction and objectives: Congenital coronary fistula is a rare entity, in which there's a communication between one or two coronary arteries and a cardiac chamber, they represent 3.7% of all coronary circulation anomalies, followed by the left coronary artery in 36.3% and both coronary arteries in 18.1% (2). 90% of the cases drain in right structures of the heart. The right coronary artery is more frequently involve in 45.5% of cases. Indications for treatment are: large size fistulas, progressive left to right shunts, myocardial ischemia and heart failure. The objective of the following report is to show how the interventional management of this case can be applied in a successful manner.

Method: The case of a male 1 month and 20 days old toddler is presented, with a cardiac murmur detected at birth, showing fatigue during feeding, diaphoresis and poor weight gain. Trans-thoracic echocardiography and angiotomography were performed showing a fistula between the anterior descending coronary artery and the left ventricle was diagnosed, aneurysmatic dilation of the main left coronary artery and the anterior descending coronary was demonstrated. The septal wall of the left ventricle was showed to have aneurysmatic dilation in the relation of the fistula drainage site.

Results: Cardiac catheterization was performed showing a fistula between the proximal ostium of the left coronary artery and the left ventricle with the presence of an aneurysmatic sac in the whole length of the interventricular septum with at least 2 sites of communication with the left ventricle, these sites were closed using an Amplatzer Occluder. During placement the proximal device suffers

cobra like deformation and the second one is deployed properly. The control angiography shows a significant lowering of the contrast shunt through the aneurysmatic structure. After de procedure, the patient required management with inotropes, achieving adequate control of the heart failure.

Conclusions: Since the beginning of the percutaneous closure of coronary fistulas in the 80's this method has been recognized as a safe and effective option to treat this pathology. Chirurgic and interventionist approach show similar results in terms of efficiency, morbidity and mortality. In our case, the patient showed clinical improvement after the procedure.

#0046

DUAL-AXIS ROTATIONAL ANGIOGRAPHY IS SAFE AND FEASIBLE TO DETECT CORONARY ALLOGRAFT VASCULOPATHY IN PEDIATRIC HEART TRANSPLANT PATIENTS A SINGLE CENTER EXPERIENCE

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Introduction: Coronary allograft vasculopathy (CAV) is the leading cause of graft failure in pediatric heart transplant recipients, also adding to mortality in this patient population. Coronary angiography is routinely performed to screen for CAV, with conventional single or bi-plane angiography being utilized. Dual-axis rotational coronary angiography (RA) has been described, mostly in the adult population, and may offer reduction in radiation dose and contrast volume. Experience with this in the pediatric population is limited. This study describes a single institution experience with RA for screening for CAV in pediatric patients.

Methods: The catheterization database at our institution was used to identify pediatric heart transplant recipients having undergone RA to screen for CAV. Procedural data including radiation dose, fluoroscopy time, contrast volume, and procedure time were collected for each catheterization. The number of instances in which RA was not successful, ECG changes were present, and CAV was detected were also collected for each catheterization.

Results: A total of 97 patients underwent 345 catheterizations utilizing RA. The maximum number of catheterizations for a single patient utilizing RA was 5. Median radiation dose area product per kilogram was found to be 341.7 (mGy cm/kg), total air kerma 126.8 (mGy), procedure time was 69 minutes, fluoroscopy time was 9.9 minutes, and contrast volume was 13 ml. A total of 17 (2%) coronary artery injections out of 690 could not be successfully imaged using RA. A total of 14 patients had CAV noted at any point, 10 of whom had progressive CAV. Electrocardiographic changes occurred in a total of 10 (3%) RA catheterizations. Procedural characteristics did not differ between serial catheterizations.

Conclusions: Dual-axis rotational coronary angiography is safe and feasible for CAV screening in pediatric heart transplant recipients while offering coronary imaging in multiple planes compared to conventional angiography.

#0047

A COMPARISON OF OUTCOMES AND COSTS IN TREATMENT OF ISOLATED PDA IN SINGAPORE – SURGICAL LIGATION VS TRANSCATHETER DEVICE OCCLUSION

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Introduction: Closure of isolated patent ductus arteriosus (PDA) is indicated to reduce risk of infection, congestive heart failure and/or pulmonary hypertension. This can be achieved through surgical ligation or transcatheter device occlusion.

Aim: The objective of our study was to compare outcomes and cost of device closure through the transcatheter route using Amplatzer Ductal Occluder (ADO) vs. surgical ligation (SL).

Method: 35 patients who underwent PDA corrective procedures from February 2004 to April 2014 were included. We excluded preterm babies or those with associated other defects or co-morbidities.

Results: 10 patients had SL and 25 had PDA obliteration using the ADO. The mean age at the time of operation was 2±3.7 years and 9±7.8 years for SL and ADO respectively (p=0.01). The PDA sizes were comparable. Four patients (40%) in the SL group and 2 (8%) in the ADO group developed minor complications (p=0.02). The mean length of stay for SL and ADO were 6±2.4 and 2±0.3 days respectively (p<0.001). Eight (80%) in the SL and 5 (20%) in the ADO had a mean ICU stay of 2.6±2.6 and of 0.2±0.4 days

respectively (p<0.001). The mean cost per procedure for SL was USD 8313±4371 and USD 7388±1766 for the ADO (p=0.37).

Conclusions: The outcomes were good for both SL and ADO but the SL group had longer LOS, ICU stay and incurred greater costs. The surgery group was younger and fewer, as most PDAs are now closed through the less invasive transcatheter method. The device occlusion has advantages of improved cosmesis with less pain/faster recovery in the post-operative period. Cost savings would be even more significant when using an equally effective but cheaper device.

#0048

TECHNOLOGICAL ADVANCES IN THE PEDIATRIC CARDIAC CATHETERIZATION LABORATORY RESULT IN REDUCED RADIATION DOSE

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Objective: Reduction of ionizing radiation in pediatric/congenital cardiac catheterization is paramount. The goal should be to provide optimal imaging in line with the ALARA (As Low As Reasonably Achievable) concept. There have been many recent advances in technology in the cardiac catheterization laboratory. We sought to determine if upgraded equipment results in a lower effective radiation dose.

Methods: This is a retrospective cohort study at a single institution. We compared the effective radiation dose in pediatric patients who underwent diagnostic cardiac catheterization before and after installation of new equipment in our cardiac catheterization laboratory. The historical group underwent catheterization between July 2009

and April 2010 on a Philips Integris BH5000 biplane system. The study group underwent catheterization between April 2012 and October 2014 on either a Toshiba INFINIX-I CFI-BP or a Toshiba-I VFI-BP system. Each group contained 50 patients, who were matched by diagnosis, age, and weight. We recorded the dose area product (DAP) and fluoroscopy time (FT) for each study. The effective radiation dose (ED) was determined using previously published conversion factors.

Results: The median age for the historical and study groups was 2.5 yr and 2.6yr, respectively. The two groups were equal in respect to body surface area ($p=0.55$) and FT ($p=0.36$). The median DAP in the study group was significantly lower than the historical group ($5.8 \text{ Gy} \cdot \text{cm}^2$ vs. $12 \text{ Gy} \cdot \text{cm}^2$, $p < 0.001$). Likewise, the median ED in the study group was significantly lower than the historical group (4.13 mSv vs. 10.84 mSv , $p < 0.001$).

Conclusions: Advances in equipment technology in the cardiac catheterization laboratory can lead to significantly less radiation exposure, which is particularly important in the pediatric age group due to intrinsic properties of young tissue and stochastic effects over time. Institutions should aim, when feasible, to upgrade equipment in order to take advantage of this potential radiation dose reduction.

#0049

SUCCESSFUL PERCUTANEOUS RECANALIZATION OF A CHRONICALLY OCCLUDED IVC IN A CHILD

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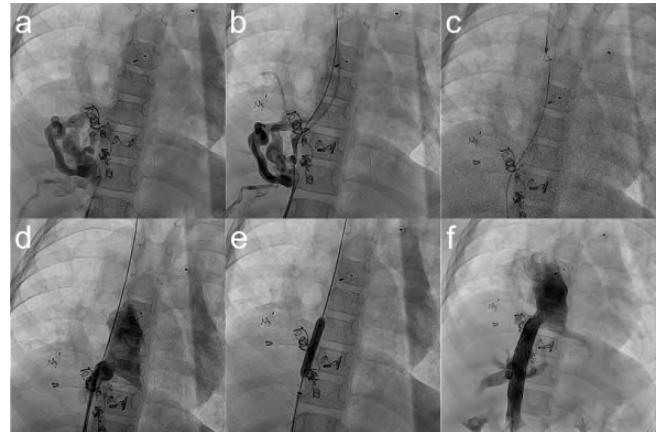
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We present the case of a 5 year-old girl with Scimitar syndrome with near-complete occlusion of her intrahepatic IVC with collateralization to hepatic veins for at least two years. She had had previous attempts at percutaneous management of her disease at another institution, which included device closure of a secundum ASD and PDA from a femoral approach. She was brought to the cath lab for potential recanalization of the IVC.

The procedure was performed under general anesthesia with access in the femoral vein and artery and right internal jugular vein. Angiography showed a hypoplastic right pulmonary artery draining to a large scimitar vein to the IVC-RA junction. The IVC appeared completely occluded with significant collateralization through hepatic veins and entered the RA near the scimitar vein (Figure a). A 6-Fr MPA guide catheter (Boston Scientific Corp, Natwick, MA) was positioned as proximal as possible in the IVC and a 0.014" Whisper wire (Abbott Vascular, Santa Clara, CA), supported by a Corsair catheter (Asahi Intecc USA, Inc, Santa Ana, CA), was carefully advanced through the true IVC lumen to the SVC (Figure b). The Whisper wire was snared and externalized from the jugular sheath (Figure c). An angled glide catheter (Terumo Medical Corp, Somerset, NJ) was advanced over the Whisper wire from the femoral vein, and a 0.035" Rosen wire (Cook Medical, Bloomington, IN) advanced through the glide catheter. This was snared and externalized and a 7-Fr Flexor sheath (Cook) was advanced to the IVC-RA junction (Figure d). A small tract was dilated with a 6 mm x 3 cm Powerflex balloon (Cordis Corp, Miami Lakes, FL) (Figure e). The Flexor sheath was exchanged for a 10-Fr Flexor sheath to accommodate stent placement, and three telescoped Palmaz XL 3110 stents (Cordis) were delivered on a 12 mm OptaPro balloon (Cordis). Final angiography showed marked improvement in the IVC

size with diminished flow through the hepatic vein collaterals (Figure f). The procedure was safe and well-tolerated. She was discharged on aspirin and clopidogrel. Follow-up echocardiography showed continued phasic flow through the stents.

This patient's successful recanalization of a chronically occluded IVC highlights the importance of recognizing venous occlusions and demonstrates the potential to treat them even after years of occlusion.



#0050

ULTRASOUND AND COMPUTED TOMOGRAPHY REGISTRATION FOR THREE-DIMENSIONAL PRINTING IN CONGENITAL HEART DISEASE

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Three-dimensional (3D) printing of patient specific cardiovascular models is an emerging experimental field for enhanced visualization of cardiac morphology. Computed tomography (CT) and magnetic resonance imaging (MRI) have been established as imaging tools to derive 3D printable models. Each imaging modality has different strengths and weaknesses which impacts 3D printing: CT enhances visualization of extracardiac anatomy; MRI is superior to other imaging modalities for quantification of ventricular volumes and myocardial architecture; and 3D transesophageal echocardiography provides the best visualization of valve anatomy. We describe registration of CT and 3D transesophageal echocardiography (TEE) datasets for 3D printing of the systemic atrioventricular (AV) valve. Image acquisition was performed using the Philips iE33 ultrasound system (Philips Medical Systems, Andover, Massachusetts, USA), and volume computed tomography (VCT) CT scanner (GE Healthcare, Waukesha, WI) in the Cartesian digital imaging and communication in medicine (DICOM) format. After completing multiplanar reformatting of the images, the DICOM datasets were imported into a dedicated post-processing software (Mimics® Innovation Suite, Materialise NV, Leuven, Belgium). Segmentation was performed followed by 3D rendering for visualization. The file was converted to stereolithography (.stl) format and printed using a 3D printer (Materialise NV). The CT dataset provided visualization of the extracardiac anatomy. The

3DTEE dataset was added for superior visualization of the systemic AV valve. The registration of the datasets resulted in an accurate model for enhanced visualization of the cardiac morphology. Our experience shows the feasibility and proof of concept of printing 3D cardiovascular models derived from multiple imaging modalities. This approach has the potential to provide detailed and anatomically accurate 3D printed models. Further research is required to evaluate the use of these 3D models in decision-making for transcatheter or surgical interventions.

#0051

PERCUTANEOUS PDA CLOSURE IN PRETERMS LESS THAN 2 KG

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Background and Aim: Preterms and low birth weights are the group that PDA is most common and intervention is most risky. Main aim of our study is to emphasize the effectiveness and safety of percutaneous PDA closure in the infants less than 2kg.

Material Method: Between the dates July 1997 to October 2014 in our center 382 PDA closures were done. 18 patients less than 2kg were included in this study. Demographic and angiographic data of the patients were reported (Table 1, Table 2 respectively).

Results: All the patients were symptomatic and PDA was decided to be contributor of this medical state. The median patient age 32days. The median weight of patients was 1603gr(910-2000gr). Mean PDA diameter was 3.2±1.3mm. Morphology of PDA: type A in 7patients, type C in 9patients, type E in 1, type B in 1 patient. Types of the devices used were: Cook coil in 2patients, ADO I in 2, ADO II in 3, ADO II-AS in 11 patients. There were no major complications reported. Left pulmonary arterial stenosis was detected in 4 patients which were all resolved in 6 months duration.

Conclusion: Preterm complications like chronic lung disease, necrotizing enterocolitis etc. increase the mortality and morbidity. In order to decrease the complications early intervention is required but surgery could be too risky. Because of the risks of surgery in the recent years interventional catheterization procedures are more commonly used.

Up to our knowledge it is the only study that discuss safety and effectiveness of percutaneous PDA closure in the infants less than 2 kg. Patient population less than 2 kg are preterms and most have additional health problems that the surgery could be dangerous but catheterisation can be used safely.

#0052

HYBRID REHABILITATION OF THE NATIVE RVOT: PULMONARY ARTERY PPLICATION FOLLOWED BY TRANSFEMORAL PULMONARY VALVE REPLACEMENT – COMPARISON WITH SURGICAL PVR.

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Background and objective: Historically the sole option for patients with a dysfunctional native RVOT requiring re-establishment of pulmonary competence has been surgical valve replacement. The objective of this study was to compare early outcomes from our initial experience with hybrid pulmonary valve replacement in which surgical plication of the main pulmonary artery is performed prior to transfemoral pulmonary valve replacement, with a contemporary cohort of surgical PVR patients.

Methods: Retrospective chart analysis of all patients with a dilated native RVOT eligible for surgical pulmonary valve replacement over the past 36 months. Pre-procedural, procedural and post-procedural data were collected. The cohorts included patients with previous tetralogy of Fallot repair (n=12), previous intervention for congenital abnormality of the pulmonary valve (n=6).

Results: Eighteen patients with a dysfunctional native RVOT met criteria for pulmonary valve replacement during the designated time period; 5 using the hybrid procedure (group 1: age, 22.8 +/-13 years) and 13 with cardiopulmonary bypass (group 2: age, 31 +/- 18.4 years). BSA was comparable between the two groups (p-value 0.843). Valve implantation was successful in all cases, with slight proximal migration of the transcatheter valve in one patient from group 1 during removal of the delivery system, requiring conversion to surgical valve replacement. Mean cardiopulmonary bypass time in group 2 was 134 minutes. There was a trend seen towards shorter hospital stay in group 1 (mean length of stay 4.6 days vs 6.5 days for group 2 (p=0.12)). There was a significantly higher requirement for blood products in group 2 respectively (p=0.007). None of those patients in group 1 required inotropic support post-operatively whereas 54% of patients in group 2 required inotropic support for at least 1 day. All patients were extubated by post-operative day 1 with the exception of 1 patient from group 2 remaining intubated for 8 days. On median follow up of 1.4 months for group 1 and 9.2 months for group 2, the average peak gradient across the RVOT was 22 and 14.2 mmHg for groups 1 and 2 respectively (p=0.131) and the PI grade was no greater than mild for all patients in both groups.

Conclusions: Transfemoral hybrid pulmonary valve implantation following RVOT plication provides a reasonable alternative to surgical pulmonary valve replacement, reducing morbidity and possibility of longer-term consequences of repeated cardiomy. Care must be taken when performing simultaneous pulmonary artery interventions as this may impact upon transcatheter valve stability.

#0053

NOVEL USE OF A DRUG-ELUTING BIOABSORBABLE VASCULAR SCAFFOLD IN CONGENITAL HEART DISEASE: EARLY EXPERIENCE

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Background: The aim of catheter intervention for vascular stenosis is the restoration of lumen area and optimization of distal blood flow. Bare metal stent (BMS) insertion, particularly in infants, limits the vessel diameter potential. Design modifications to bioresorbable stents, resulting in polymer-based, drug eluting, bioabsorbable vascular scaffolds (BVS) have reportedly overcome some of these faults. We

describe the first reported use of a drug eluting BVS in three patients.

Methods: Retrospective review of consecutive patients undergoing insertion of BVS. Outcome measures included procedural success, need for re-intervention and complications.

Results: Three patients were eligible for inclusion: (1) A newborn (3.0kg) with severe RPA stenosis, due to compression from an aneurysmal RV-PA conduit, post repair of type two common arterial trunk, (2) An 8 year old boy with pulmonary atresia/VSD and MAPCAs, and (3) An infant (4.1kg) with severe LPA stenosis in the setting of an LPA sling. In all three cases the procedure was technically successful with excellent relief of stenosis and no procedural complications. In Case 1 there was early restenosis due to either external pressure or early reabsorption of the stent. This responded to further BMS insertion. In Cases 2 and 3 the BVS has continued to perform well.

Discussion: BVS offers short-term relief of stenosis, radial support of the healing lesion and crucially, in children, the potential for long-term growth. This small case series suggest some variation in performance of BVS and greater experience is required to judge clinical utility.

#0054

FONTAN FENESTRATION CLOSURE WITH AMPLATZER DUCT OCCLUDER II DEVICE

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Background: Device closure of the Fontan fenestration is a well established catheter intervention. Most of the devices commonly used, and especially the Amplatzer Septal Occluder, are relatively bulky. The ADO2 is a low profile, flexible, and inexpensive device that seems well suited to the Fontan fenestration. We report our experience of this novel technique.

Methods: A retrospective review of patients undergoing Fontan fenestration closure with an ADO2 device. Outcome measures included procedural success, pre- and post- procedural differences in oxygen saturation and mean pulmonary artery pressure and complications.

Results: Over 34 month study period, 13 patients were eligible for inclusion. All procedures were technically successful. There was a significant increase in oxygen saturations (Mean= +12%, P<0.01) after fenestration closure but no significant change in mean pulmonary artery pressure (Mean= +0.5 mm Hg, p = 0.08). There were no procedural complications.

Conclusion: Fontan fenestration closure with the ADO2 device is a simple, short, and cost-effective procedure. Although there are no commercially available devices specifically designed for fenestration closure, the ADO2 characteristics recommend it to occlusion of varying sizes and morphologies of Fontan fenestration.

#0055

MIDTERM RESULTS OF TRANS CATHETER CORONARY ARTERY FISTULA CLOSURE, IMPROVEMENT OF DILATED CORONARY ARTERY ORIGIN AFTER COMPLETE CLOSURE OF FISTULA

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Background: The coronary artery fistula identifies a bypass pathway that connect the coronary artery to a chamber of the heart so called coronary-cameral fistula or any segment of the systemic or pulmonary circulation that called coronary arterio-venous fistula. Fistula enlarges over time, and induces complications such as steal from the adjacent myocardium, thrombosis and embolism, congestive heart failure, myocardial infarction, arrhythmias, and infective endocarditis, aneurysm formation, rupture, and sudden death, especially in older patients. The therapeutic goal is complete closure of the fistula without compromising the normal coronary blood flow and regression of dilated coronary artery origin to normal size.

Methods: 25 patients with age range of 2 months to 15 years old underwent percutaneous trans catheter closure between October 2007 and April 2015. Exclusion criteria were: fistulae with multiple connections, and acute angulations that make catheter positioning difficult or impossible. Sites of origin of these fistulas were: RCA in 9 patients, LCA in 16 patients. Drainage sites of these fistulas were: right atrium in 6 patients, coronary sinus in 2 patient, right ventricle in 17 patients.

Results: Performed coils were included: cook coils in 6 patients, pfm coils in 14 patients, ev3 coils in 2 patients, ADO II in 3 patients. All patients were considered to have successful procedure. Just in 1 patient procedure failed due to complete heart block so that, procedure was done in another time successfully. Follow-up studies by ECG, TTE and CT angiography and selective angiography showed complete occlusion in all patients with no evidence of recanalization and residual shunt and improvement of dilated coronary artery origin, regression of dilated coronary artery origin to normal size. We administered low dose aspirin (3 to 5 mg/kg/day) at least 6 months with clopidogrel (0.5-1 mg/kg/day) for at least 1 month. In patients with persistent coronary artery dilatation (>8 mm) we continued low dose aspirin therapy until coronary artery diameter decreased to near normal size, although there is little available information concerning the risk of coronary thrombosis in this group.

Conclusions: In recent years increasing numbers of devices for therapy of CAVF are available. Selection of device and technique for every patient varies based on many factors especially the anatomic characteristics of the fistula. We present our experience in occlusion of CAF in small pediatric patients with different and difficult anatomy of fistula and usage of different devices with both antegrade and retrograde approaches. The midterm follow up of patients indicates that Trans catheter therapy is a safe and effective method of occlusion CAVF. Coronary CT angiography and selective coronary angiography are helpful in the assessment of complete fistula occlusion and improvement of dilated coronary artery origin.

#0056

ADO II IN PERCUTANEOUS VSD CLOSURE IN PEDIATRIC PATIENTS

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Background: It is hard to find an ideal device to use for every VSD successfully. If inappropriate device was chosen; complication rate increases, procedure time gets longer that prolongs exposure to ionizing radiation. Therefore interventionalists are in the search for new ideal devices. Main aim of our study to show that ADO-II device can be used for small ventricular septal defects successfully, safely with low complication rates.

Material and Methods: Between the dates April 2011- October 2014, 17 VSD closures with ADO-II device. Actually there were 16 patients but one of the patient had 2 perimembranous defects which were closed separately. Patients having muscular and perimembranous VSD with hemodynamically significant left to right shunt detected by clinical examination and echocardiography were included in the study.

Results: Age of patients ranged between 3-18 years. Weight of the patients was between 14-76 kg. VSD diameter ranges between 2-6.7 mm (3.75 ± 1.25). One of them was muscular, eighteen of them were perimembranous type. Fourteen of the perimembranous defects were aneurysmatic, tunnel shaped. We have used mostly venous route (12 patients) for closure. One of the patients had two separate VSDs. The distance between two defects were 7 mm. Therefore we have used two separate devices to occlude them. One of the defect was 3.2 mm, occluded with ADO II sized 5x4 from arterial side. The other one was 3.4 mm width and closed with 5x6 mm ADO II from venous side. All cases were successfully closed, no major complications were reported. There was no incidence of left bundle branch block, P-R prolongation, or complete heart block.

Conclusion: Perimembranous aneurysmatic ventricular septal defects are difficult, risky for percutaneous closure because of its proximity to aortic, atrioventricular valves, conduction tissue. We have showed that ADO-II devices (in fact they are off-label use) can be used safely, effectively in such defects. Up to our knowledge this is the only study includes largest number of pediatric patients whose VSD were closed by ADO-II.

#0057 PERCUTANEOUS ASD AND VSD CLOSURE IN 4 MONTHS OLD INFANT IN THE SAME SESSION

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Transcatheter VSD and ASD closure have been done successfully for a long period of time. We report percutaneous VSD and ASD closure at the same session in a malnourished infant with a significant left to right shunt. As far as we know; this case is the youngest one that percutaneous VSD closure done when hybrid procedures are excluded.

Case: A four months old male infant weighing 4.6 kg; was referred to pediatric cardiology for a systolic murmur heard during newborn period. Perimembranous inlet typed VSD sized 4 mm and 8 mm sized secundum ASD were detected by echocardiographic examination. During the follow-up period weight gain of the patient was insufficient and tachypnea was seen therefore decongestive treatment was given. Despite the medical treatment his symptoms persisted and got worse. Surgical treatment was planned but it was found too risky. Therefore we planned to close the defects percutaneously. Qp/Qs ratio was calculated as 4, pulmonary arterial pressure measured as 37/10 mean 29 mmHg. VSD was closed by 4x4 ADO II, ASD was closed

by 9 mm sized ASO successfully. In the first control visit (6 months after percutaneous closure) his weight was 6.2 kg. No residual shunt was seen in the echocardiography and the frequency of having lower respiratory infections were decreased.

Discussion: Ventricular septal defects with significant shunt cause dilatation in the left chambers of the heart, cardiac dysfunction and arrhythmia. It also increases the risk of infective endocarditis. For selected patients; percutaneous VSD closure is an alternative to surgery. Transcatheter VSD closure was performed successfully in older children. As far as we know it is the first time that percutaneous VSD, ASD closure were done in such a small infant. We think this case will be promising for the other cases in future.

#0058 TRANSCATHETER PATENT DUCTUS ARTERIOSUS OCCLUSION IN PREMATURE NEONATES: A SINGLE CENTER EXPERIENCE

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Background: Transcatheter patent ductus arteriosus (PDA) occlusion is feasible in premature neonates and may improve lung function. Reports documenting the success and safety of PDA occlusion in this patient group are lacking.

Methods: All patients in the Neonatal Intensive Care Unit at our center who were referred for transcatheter PDA occlusion between 1/2010 and 11/2014 were retrospectively identified. Relevant clinical and procedural details were extracted. A modification of the respiratory severity score (RSS) (FiO₂ x mean airway pressure) was used to characterize degree of pulmonary support before and at intervals after catheterization.

Results: 20 patients were identified with median age of 96 days (13-247) and weight of 3.1 kg (1.7-4.7). Prior to intervention, 4 (20%) patients were on no pulmonary support, 7 (35%) on nasal cannula, 3 (15%) on non-invasive continuous positive airway pressure, and 6 (30%) mechanically ventilated. The PDA was type C tubular morphology in 19 (95%) patients with median minimum diameter of 2.4 mm (1-5) and length of 10 mm (3-14). Exclusive echocardiographic imaging was used in 2 (10%) patients. The PDA was successfully occluded in 16 (80%) patients and deemed too short for occlusion in 4. Ratio of minimum PDA diameter/PDA length was > 0.5 in all unsuccessful attempts and < 0.5 in all successful cases. Of the 16 cases of occlusion, Amplatzer Vascular Plug II was used in 15 (94%) and angiographic occlusion demonstrable in all. No deaths or vascular complications occurred and no pulmonary artery or aortic obstruction was seen. 4 (20%) patients required blood transfusion of < 15 cc/kg due to hypotension and another required transfusion > 15 cc/kg due to unexpected bleeding around the vascular sheath. Excluding 1 patient with significant comorbid congenital heart disease, the RSS improved at 3 days in 9 (60%) patients and at 7 days in 11 (73%) compared to pre-intervention value.

Conclusions: Transcatheter PDA occlusion was safe and feasible in this population. A ratio of minimum PDA diameter/PDA length of < 0.5 was predictive of technical success. Using a surrogate marker for

degree of respiratory support, at 7 days nearly 75% of patients required less support than prior to the procedure. There was no mortality, but blood transfusions were more frequent than expected.

#0059

U.S. MULTI-CENTERED PIVOTAL TRIAL OF THE NOVEL GORE® CARDIOFORM SEPTAL OCCLUDER FOR PERCUTANEOUS CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECTS

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Objectives: We evaluated the safety and efficacy of the Gore Septal Occluder to percutaneous close secundum atrial septal defects.

Background: The Gore® CARDIOFORM Septal Occluder (GSO) is low profile, double-disc occluder composed of a nitinol 5-wire frame and covered with expanded polytetrafluoroethylene, designed for percutaneous closure of defects in the atrial septum.

Methods: Patients were enrolled prospectively in a single arm trial from 10 U.S. sites and followed up for the 6 month post-procedure protocol endpoint (and up to 3 years longitudinal follow-up). Core lab measured outcomes were evaluated, with the primary endpoint for a composite clinical success (successful device implant, clinical closure at 6 months, no serious adverse events at 30 days, no device events at 6 months).

Results: Between October, 2012 and June, 2013, 50 patients (age range 3.4 to 68.3 years) with static sized atrial septal defects between 4 and 17mm (mean 10+/-3mm) underwent attempts to implant a single GSO. Multiple defects were present in 20%, and 26% had a deficient retro-aortic rim. Implantation with GSO was successful in 47/50 (94%), with 30 day serious adverse event rate of 0%. The primary endpoint was met in 93.0%, with clinical closure success of 100% at 6 months. There were no device embolizations or need for reinterventions at time of last follow-up.

The most common minor adverse events were anesthesia-related in 14%.

Conclusions: Closure of defects in the atrial septum with the novel Gore® CARDIOFORM Septal Occluder is safe and effective. (U.S. Multicenter Pivotal Study of the Gore Septal Occluder for Percutaneous Closure of Secundum Atrial Septal Defects; [ClinicalTrials.gov Identifier: NCT01711983](https://clinicaltrials.gov/ct2/show/study/NCT01711983)).

#0060

THE USE AND OUTCOMES OF SMALL, MEDIUM AND LARGE PREMOUNTED STENTS IN PEDIATRIC AND CONGENITAL HEART DISEASE

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Background: Premounted stents (PS) have a lower profile than traditional stents, allowing for delivery through smaller sheaths and placement within small patients. These PS require future dilation, given the somatic growth of the patients. Our aim was to evaluate the use and outcomes of small, medium and large PS in pediatric and congenital heart disease patients.

Methods: All small, medium and large PS placed in our catheterization laboratory from 2006 to 2014 were retrospectively reviewed. Patient, vessel and PS characteristics were collected at the time of implantation and at each subsequent catheterization or surgical intervention.

Results: PS were placed in 69 vessels within 58 patients in our study cohort with a 97% success rate. The median age at implant was 1.9 years (interquartile range [IQR] 0.7-8.3) with a median weight of 11.5 kg (IQR 8.1-27.4). PS were placed in 52 pulmonary arteries, 12 major veins and 5 aortas resulting in significant improvements in vessel size and pressure gradient ($p < 0.0001$). Over a median follow-up duration of 3.1 years (IQR 1.3-5.2), 25 patients (43%) required re-intervention (18 catheter-based, 3 surgical and 4 both) at a median time of 1.4 years (IQR 0.9-3.0) from implant. Factors associated with earlier re-intervention included age ≤ 1.9 years (HR 2.42, $p = 0.03$) and weight ≤ 11.5 kg (HR 2.48, $p = 0.03$) at the time of stent implant, and bare-metal PS compared to covered PS (HR 4.16, $p = 0.001$). Patients receiving bare-metal PS were younger and smaller than those receiving covered PS ($p = 0.0002$). In-stent stenosis (ISS) was seen in 12 patients on follow up catheterization with an incidence of ISS was 46% in the 26 patients who received follow-up angiographic evaluation. No identified characteristics were associated with ISS development, including "oversizing" the PS. ISS was seen in 25% of covered PS compared to 52% of bare-metal PS, but this difference was not statistically significant ($p = 0.13$).

Conclusions: Small, medium and large PS are effective in treating lesions in the congenital catheterization laboratory. Younger patients, smaller patients and bare-metal PS are at risk for requiring earlier re-intervention. ISS is seen frequently within PS, and larger studies are needed to identify risk factors. Frequent follow-up is required in this patient population.

#0061

SURGICAL ACCESS TO THE HEART FOR TRANSCATHETER INTERVENTIONS IN CONGENITAL HEART DISEASE: A SINGLE CENTER REVIEW

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Introduction: Surgical access to the heart or great vessels may allow for diagnostic or interventional catheterization procedures that would otherwise be less safe, extremely challenging or simply not feasible due to either poor vascular access or unfavorable anatomy and/or physiology. We hypothesized that hybrid surgical access to the heart, aorta or pulmonary arteries may, in certain clinical scenarios, allow for improved outcomes with low morbidity. We review our single center 8-year experience with surgical hybrid access in congenital heart disease.

Methods: Single center descriptive, retrospective review of all cases from 9/06 – 11/14 in which a surgeon provided direct access either to the heart, aorta or pulmonary artery for diagnostic or interventional purposes. Hypoplastic left heart hybrid stage 1 procedures were excluded. Categorical data are presented as median with range.

Results: 12 patients (6 male) underwent surgical hybrid access procedures; median age 4.1 years (range 0 days – 14 years), median weight 17.6 kg (range 3.3-126), median BSA 0.72 m² (range 0.20-2.3). Diagnoses included aortic coarctation (3), tetralogy of Fallot (3), hypoplastic left heart syndrome with intact/restrictive atrial septum (2), single ventricle s/p BT shunt with possible shunt narrowing/occlusion (2), single ventricle with restrictive atrial septum after BDG (1) and Swiss cheese ventricular septum (1). 8/12 patients underwent interventions. Interventions included coarctation stenting from direct cut down on femoral or carotid arteries (3), per-atrial septoplasty (3), per-ventricular VSD closure (1) and LPA stent dilation in-situ (1). All interventions were successful. Diagnostic usages included assessment of BTS in the setting of cyanosis (2) and "exit" pulmonary artery angiography (2). Complications included aortic coarctation stent embolization (1; retrieved and stabilized in aorta), blood loss requiring transfusion (1) and SVT requiring IV adenosine. No deaths.

Conclusions: Surgical hybrid access to the heart and great vessels allowed for effective intervention and also provided important diagnostic information in multiple varied complex congenital heart abnormalities with low morbidity and no mortality in this single center experience.

#0062

A LOGICAL METHOD OF SELECTING AN APPROACH FOR AMPLATZER SEPTAL OCCLUDER IMPLANTATION USING TRANSESOPHAGEAL ECHOCARDIOGRAPHY

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Percutaneous closure of atrial septal defects (ASDs) using an Amplatzer Septal Occluder (ASO) has become the first choice procedure recently. However, when ASO deployment using the ordinary (left upper pulmonary vein [LUPV]) approach is difficult, the procedure may be prolonged and complications may occur. We have previously reported a method for identifying cases in which ASO deployment would be difficult using the LUPV approach. Our findings revealed that ASO deployment is predicted to be difficult in patients with an ASO size exceeding the $\{(\text{angle between Superstiff Guidewire and intra-atrial septum}) \times 1.44 + 48.1\} \times \text{left atrium diameter (mm)}$ on transesophageal echocardiography, and we recommend that an alternative approach to deploy ASO should be introduced from the beginning in such cases. In this study, we examined the validity of this method for determining the appropriate approach.

Between January 2009 and May 2015, in 127 cases (age, 2.5 – 86.6 [median 12.5] years; weight, 12.1 – 78.9 [median 41.3] kg), the approach used for ASO deployment was decided based on this method.

In 103 patients, it was predicted to be able to deploy the ASO using the LUPV approach, while in 24 were predicted to be difficult. 98 of the 103 patients (94%) were successfully treated with the LUPV approach; however in the remaining 5 patients, the deployment ASO

was unsuccessful using the LUPV approach and was subsequently successfully performed using another approach (right pulmonary vein approach). 2 of these 5 patients had fenestrated ASDs and 1 had a floppy rim, however the other 2 patients had no specific characteristics. In the 24 patients in whom the LUPV approach was predicted to be difficult, the ASO was successfully deployed using the right upper pulmonary vein approach at the first attempt.

This study showed that this method has a very high accuracy. We can avoid the risk of complications by using this method, as alternative procedure can be introduced from the beginning for indicated cases. Although this method is not perfect for predicting difficulty, especially in patients with fenestrated ASDs or floppy rims, we consider this method of selecting the ASO deployment approach to be extremely useful for avoiding various risks.

#0063

SUCCESSFUL PATENT DUCTUS ARTERIOSUS STENTING IN A 1.8 KG PRETERM NEWBORN WITH EXCELLENT OUTCOME - A CASE REPORT

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Stenting of patent ductus arteriosus (PDA) is a palliative technique that is evolving as an alternative to shunt surgery. Patients with duct dependant pulmonary circulation are often palliated by shunt surgery. Performing shunt surgery below 2 kg weight in a preterm baby is associated with increased risk of complications and has variable outcomes in terms of morbidity and mortality. We present here a two days old 1.8 kg preterm male baby with duct dependant pulmonary circulation who was palliated successfully by transcatheter means. He successfully underwent bidirectional Glenn surgery 8 months after the procedure and currently doing very well. Ductal stenting in such a small preterm baby has rarely been described in the literature.

#0064

TRANSCATHETER CLOSURE OF SINUS VENOSUS ATRIAL SEPTAL DEFECT WITH ANOMALOUS DRAINAGE OF RIGHT UPPER PULMONARY VEIN INTO SUPERIOR VENA CAVA- AN INNOVATIVE TECHNIQUE

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Sinus venosus atrial septal defect (SVASD) is located high in the atrial septum where the right superior vena cava (RSVC) enters the right atrium, and is commonly associated with partial anomalous pulmonary venous return of right upper pulmonary vein (RUPV) into RSVC. Transcatheter closure of such defects has not been described in the literature. We have developed an innovative technique to close this defect by transcatheter means. We present here a 35 year old patient with SVASD and anomalous drainage of RUPV in RSVC in whom we closed the defect along with rerouting of RUPV to left atrium (LA) using a 12mm x 61 mm adventa V12 covered stent in the RSVC with good outcome.

#0065**AMPLATZER SEPTAL OCCLUDER VERSUS FIGULLA ASD OCCLUDER: A COMPARATIVE STUDY FOR PERCUTANEOUS CLOSURE OF ATRIAL SEPTAL DEFECTS. SINGLE CENTER EXPERIENCE**

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Objectives: Occlutech Figulla ASD Occluder (FSO), a later-generation double-disk device, is an alternative device to Amplatzer Septal Occluder (ASO) with some structural innovations including increased flexibility, minimizing the amount of material implanted, and absence of the left atrial clamp. We report our experiences with FSO and compare the outcomes of this device versus ASO.

Interventions: Between December 2002 and February 2015, 161 patients diagnosed with secundum atrial septal defects underwent transcatheter closure. The FSO device was used in 32 patients, and the ASO was used in 129. A mean age of 23.4 ± 16.1 years (median age 17 years, range 4–74 years) underwent percutaneous closure of moderate-to-large secundum ASD. Implanted ASO devices were in range from 10 mm to 38mm; implanted FSO devices were in range from 10.5 mm to 36mm; The ASO devices were delivered through a 7 Fr to 13 Fr sheath; the FSO devices were delivered through a 7 Fr to 12 Fr sheath.

Results: Patient characteristics, stretch size of the defect, device left disc size, procedure, and fluoroscopy time were similar between the groups. However, the difference between device waist size and stretched diameter of the defect was significantly larger, and device delivery sheath was significantly larger in FSO group and device left disc size was significantly lower in the FSO group. In all patients, the residual shunt was small to trivial during follow-up and the reduction in prevalence of residual shunt with time was similar in both groups. We found no differences in complication rate between the two devices. The success rate using either device was excellent (ASO 97.8% and OFSO 98.4%). There were no significant differences between the major and minor complications when comparing the two devices. There were no significant differences of a fluoroscopic time. Both devices were safe and effective for percutaneous ASD closures.

Conclusions: Both devices are clinically safe and effective in ASD closure. ASO device has similar outcomes when compared to FSO device.

#0066**VASCULAR ACCESS RELATED ADVERSE EVENTS IN A MULTICENTER COHORT: A REPORT FROM THE CONGENITAL CARDIAC CATHETERIZATION PROJECT ON OUTCOMES (C3PO)**

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Objectives: To describe the prevalence of and identify risk factors for vascular access related adverse events (ARAE) in patients undergoing pediatric cardiac catheterization in a large multicenter cohort.

Background: ARAE are a known complication following pediatric cardiac catheterization. Prevalence and predictors of ARAE in a large multicenter cohort have not previously been described.

Methods: Patient and procedural characteristics during cardiac catheterization were collected prospectively from 8 centers using the Congenital Cardiac Catheterization Project on Outcomes (C3PO) web-based registry. All ARAE were independently reviewed and classified by a 5 level severity scale.

Results: 14,461 cardiac catheterization procedures were performed, which included 33,058 access events. 351 ARAE were identified in 341 cases, with a procedural prevalence of 2.4%. High severity (level 3, 4 or 5) ARAE were reported in 57 (16.2%) cases, of which 6 (1.8%) were severity level 4. There were no access-related deaths. The most common ARAE included pulse loss (140, 39.9%), groin hematoma (63, 18%), and rebleed after bandages applied (70, 19.9%). Associated univariate patient risk factors included: younger age ($p=0.002$), lower weight ($p<0.001$), and single ventricle physiology ($p<0.001$). Additionally, low mixed venous and low systemic oxygen saturations were associated with higher rates of ARAE in both the single ventricle and non-single ventricle subgroups. Procedural variables including need for an intervention, length of the procedure, and largest venous or arterial sheath/weight ratio were all associated with higher rate of ARAE (all $P<0.001$). Cardiac index, history of prior catheterization, and access site used were not statistically significant.

Conclusions: ARAE occurred in 2.4% of pediatric cardiac catheterizations and were more likely in smaller children, SV physiology, and lower mixed venous and systemic saturations. Procedural risks included need for intervention, length of procedure, and use of larger venous or arterial sheaths. These data provide a valuable baseline for the development of future ARAE prevention and treatment strategies.

#0067**RESULTS OF COIL CLOSURE OF PATENT DUCTUS ARTERIOSUS USING A TAPERED TIP CATHETER FOR ENHANCED CONTROL**

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Background: Transcatheter coil occlusion has traditionally been used for small patent ductus arteriosus (PDA) closure. Various techniques have been devised to enhance coil control and prevent embolization. Since 1995, we have delivered coils via 5 Fr modified vertebral catheters (MVC) tapered to a 0.033" distal tip for enhanced control during delivery and retrieval. We report embolization rates and efficacy with this technique.

Methods: Catheterization reports, angiograms, and echocardiograms were retrospectively reviewed for patients with PDA occlusion using the MVC from 2001 to 2014. Residual shunting was determined by angiography and echocardiogram within 24 hours post-procedure. Procedural success was defined as \leq trivial angiographic and color Doppler echocardiographic shunt, no aortic or LPA obstruction, and absence of embolization.

Results: 125 coil occlusions were attempted in 103 patients. Patients were mostly female (82%) with median age 4.4 (range 0.6-74) years. Most PDAs were Krichenko class A (45%) or E (17%). Minimal diameter was 2 (0.6-6) mm. 15 patients (15%) required > 1 coil. 4 coils were removed with a snare/biopsy due to aortic/LPA obstruction after release. 7 coils were malpositioned while still held by the MVC of which 3 embolized while attempting withdrawal. 5 embolized after full release. Total embolization rate was 8/125 (6.4%). 3 patients underwent eventual PDA closure with the MVC and a larger coil, 2 were closed with an Amplatzer Duct Occluder, 2 with 0.052" coils and 1 ligated surgically. Embolizations were more likely in PDAs \geq 2.5 mm (OR 14.6, 95% CI 2.6-83, $p < 0.01$).

11/98 (11%) patients had trivial shunt by the final angiogram. 6/88 (6.8%) patients with echocardiograms had trivial shunt within 24 hours post-procedure by echocardiogram. No patient had > trivial residual shunt for an overall success rate of 92%. For PDAs < 2.5 mm the success rate was 97%.

Conclusions: Coil delivery using the MVC is safe and effective for small PDAs. While fully controlled release & retrieval devices are now available for PDA closure, coil occlusion with the MVC should still be considered for small PDAs, especially in resource limited regions.

#0068 PERCUTANEOUS CLOSURE OF PDA IN PATIENTS LESS THAN 4000 G

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Introduction: PDA, a common condition in newborns has 1:2000 incidences in newborns over 38 weeks, and augments to 50-80% in low weight born preterms. PDA is associated with high mortality, morbidity, cardiac failure, necrotizing enterocolitis, and bronchopulmonary dysplasia. Percutaneous closure of PDA is a more promising alternative to surgical closure in low weight patients. **Materials and Methods:** Patients lower than 4000 g with hemodynamically significant PDA (cardiac failure, cardiomegaly, pulmonary hyperflow, left sided heart dilation, left atrial aortic ratio - (LA/AO) > 1.4) and/or pharmacological closure failure. Procedure: General anaesthesia, percutaneous closure of PDA with ADO II AS dispositive (choice of the dispositive 2mm greater than pulmonary diameter), femoral vein with 4 F sheath < 2000 g or femoral vein and artery > 2000 g, non-ionic contrast medium 0.5 - 2 cc/kg, angiographic PDA measurements (pulmonary and aortic diameters and length). Liberation of the dispositive in patients < 2000 g by use of echocardiography, and in patients > 2000g using aortography. Median variables with interquartile range variables are presented with frequency percentages. **Results:** 21 patients were enrolled with median age, 46 days (range 22-89), 51.1% male, 52.4% < 2000 g, weight, 1900 g (1236 - 4000), 66.7% preterms, LA/AO, 1.55 (1.5 - 1.6), 52.4% with pharmacological closure failure, 42.9% requiring mechanical ventilation and inotropic support, PDA classification, 8% A1, 13% C, Pulmonary diameter, 2.5 mm (2-3), Aortic diameter, 5 mm (4.7 - 6), PDA length, 7 mm (7-8), 42.9% with ADO II AS 4/4 dispositive used and 42.9% ADO II AS 5/4. After closure 90.5% extubation < 48 hr, 23.8% inotropics, 28.6% transfusions, and no complications or vascular lesions occurred. Analyzing the pre and post variables: days hospitalized pre closure, 8 (1-29), post closure, 3 (1-23). Heart Rate, pre close, 155 bpm (145 - 168.5), post close, 135 (121 - 155), Systolic blood pressure, pre close, 77 mmHg (67 - 84), post close, 82 (74-86),

Diastolic blood pressure, pre close 38 mmHg (31.5 - 42.5), post close, 55 (50-61.5), Pulse Oximetry, pre close, 92% (90-96), post close, 98(94-99.5). A significant difference occurred between differential pressure pre close and post close; 38 mmHg, (33 - 42) versus 27 (20.5 - 30) $p < 0.001$. **Conclusion:** Percutaneous closure of PDA with ADO II AS is a secure alternative for patients less than 4000 g.

#0069 ACUTE MANAGEMENT OF HYPOXIC CRISIS WITH PERCUTANEOUS RIGHT VENTRICULAR OUTLET TRACT STENT

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Introduction: TOF and other critical right ventricular outlet tract (RVOT) obstructions with ventricular septal defects (VSD) can cause hypoxic crisis. Percutaneous right ventricular outlet tract STENT is a saving measure in critically ill patients.

Material and Methods: Paediatric patients (0-18 years old) with TOF or RVOT obstruction with VSD and hypoxic crisis since the year 2010 until 2014. Procedure: General anaesthesia, right catheterization to implant STENT in RVOT (The STENT was chosen in relation to lower infundibular diameter). Median variables with interquartile range variables are presented with frequency percentages.

Results: 6 patients were enrolled, 5 of them with TOF and 1 with with Atrioventricular Septal Defect with infundibular stenosis. The median age was 7 months (range 4.75-26.75), 50% males, RVOT gradient pre STENT 66.5 mmHg (58 - 72), pulse oximetry 69% (48.5 - 80.5), lower infundibular diameter 4.5 mm (3.7 - 5.6), cardiac structures Z - SCORE were, pulmonary annulus -3.7 (-4.1 - -2.2), right pulmonary artery -3 (-3.4 - -2.7), left pulmonary artery -2.7(-2.8 - -2.1), STENT size 5 x 18 mm until 8 x 29 mm, 86% 1 STENT and 3 patients with 2 STENT. During the procedure the patients were unstable, requiring high pharmacological and ventilatory assistance. Post procedure, pulse oximetry was 94% (88.5-95), post STENT implantation days 16 (9 - 47), definitive surgery 83.3% valvulotomy and RVOT repair, preserving the native valve and 16.6% prosthetic valve. 1 patient died from non cardiac complications (sepsis). The surgeon had no difficulties in the removal of STENT. 5 living patients had a satisfactory health in its following.

Conclusions: Percutaneous STENT in RVOT is a safe and effective alternative treatment in patients with hypoxic crisis. Unstable patients before and during the procedure changed favourably after STENT implantation allowing a more stable condition for surgery. Corrective surgery performed in less than 1 month after the stent provides retirement and keeps the native valve. Prospective studies are needed to clarify the indications for this procedure in critical and non-critical patients with TOF and other critical RVOT obstructions with ventricular VSD.

#0070 TRANSTHORACIC ECHOCARDIOGRAPHIC AND FLUOROSCOPIC INTEGRATION FOR RIGHT VENTRICULAR OUTFLOW TRACT STENT IMPLANTATION IN INFANTS WITH CYANOTIC FORMS OF TETRALOGY OF FALLOT

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Background: Both systemic to pulmonary artery shunts and complete neonatal repair are associated with relatively high mortality rates in patients with cyanotic forms of Tetralogy of Fallot (TOF). The development of right ventricular outflow tract (RVOT) stenting has provided a less invasive means to improve pulmonary artery blood flow and delay definitive surgical repair. While typically performed solely under fluoroscopic guidance, the aim of this study was to assess the utility of fluoroscopic and transthoracic echocardiographic integration to improve RVOT characterization, and in turn efficacy of stent selection and deployment.

Methods: Retrospective data analysis of patients undergoing RVOT stenting with fluoroscopic and echocardiographic integration from January 2012 through May 2015 at three institutions. Pre-procedural investigation, patient demographics, and clinical follow-up data were included. Data is presented as mean \pm standard deviation.

Results: Sixteen patients underwent RVOT stent placement of twenty total stents, utilizing a combination of fluoroscopy and echocardiography for RVOT characterization, stent selection, and deployment. Patients ranged in age from 9 to 63 days, with a mean age of 39.38 days (\pm 19.18), and mean weight at time of procedure of 3.53 kg (\pm 0.76). Mean pre-procedural annulus size was 4.49 mm (\pm 1.23), with a mean oxygen saturation of 70.88 % (\pm 5.58). Mean fluoroscopy time was 19.8 min (\pm 15.3). Mean balloon deployment size was 5.43 mm (\pm 0.85). Three patients required deployment of multiple stents to achieve adequate relief of obstruction across the RVOT. Stent deployment was successful in all cases. Following successful stent deployment, mean improvement in oxygen saturation was 21.13 % (\pm 4.43). Three patients experienced complications including transient hypotension requiring vasopressors, development of pericardial effusion, and balloon rupture with stent deployment. There were no procedural deaths. At a mean follow up of 16.13 months (\pm 10.58), no patients required reintervention prior to surgical repair, and to date 14 of 16 patients have completed definitive surgical repair at an average of 186.97 days (\pm 140.05).

#0071

PROSPECTIVE STUDY ON PATENT DUCTUS ARTERIOSUS STENTING IN CYANOTIC CONGENITAL HEART DISEASE WITH DUCTUS RELATED BRANCH PULMONARY ARTERY STENOSIS- A PRELIMINARY RESULT

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Ductus related branch pulmonary artery (PA) stenosis is common in cyanotic congenital heart disease (CHD). Patent ductus arteriosus (PDA) stenting is not recommended for concerns of jeopardizing further the affected branch. This however has not been based on extensive evidence.

Objective: To study PA growth in duct-dependent cyanotic CHD with branch PA stenosis following PDA stenting.

Methods: Prospective, non randomized study. Inclusion criteria : weight \geq 2.75kg, age < 3 months. Presence of unilateral or bilateral branch PA stenosis. CT Scan was performed for morphologic evaluation and case selection. Patient with severity tortuous PDA were excluded. Vascular access and PDA stenting techniques were according to ductus morphology. CT thorax was repeated 3 months post procedure for early evaluation and cardiac catheterization repeated at 9 months post stenting prior to surgical repair. P1 was labelled for distal diameter of an affected branch PA (mm) and distal diameter of a unaffected branch PA was labelled as P2 (mm). P1 to P2 ratio was then calculated. The measurement was then repeated at 3 month and 9 months post procedure respectively.

Results: Between February 2014 to May 2015, 34 patients who full filled the inclusion criteria underwent PDA stenting. Vascular access was by femoral artery in 17 patients (50.0 %), axillary artery in 12 (35.3 %), transvenous in 4 (11.8 %) and carotid artery in 1 (2.9 %). 21 patients had early evaluation by CT scan at 3 months post and 15 patients had repeat catheterization at 9 months. About 26 patients (75.5 %) had LPA stenosis, 5 (14.7 %) had RPA stenosis and 3 (8.8 %) had bilateral stenosis. At presentation P1 was 4.32 + 1.39 mm and P2 was 4.83 + 1.60 mm respectively, with P1/P2 ratio of 0.9. At 3 months post procedure, the ratio was 1.24. At 9 months post stenting, the ratio was 1.1. 3 patient required rescue Blalock Taussig shunt at day 4 of post stenting due to compressed stents. There was no deaths and no stent migration. The immediate complications were bleeding from puncture site in 11 (32.4%), hypotension in 12 (35%) and over shunting in 5 (14.7 %). 1 patient need balloon dilatation of stents at 9 months post stenting due to in-stent stenosis. 9 underwent surgery 1 to 6 months after repeat cardiac catheterization. 6 underwent corrective surgeries and 3 underwent palliative Glenn shunt. All patients had uncomplicated surgeries.

Conclusions: Patent ductus arteriosus stenting is ductus related branch pulmonary artery stenosis results in satisfactory growth of PA despite jailing of an affected branch. This is a viable alternative to surgery for the early palliation of duct dependent cyanotic CHD. However close monitoring is required and further studies are warranted.

#0072

SEVERE CONTRALATERAL PULMONARY HYPERTENSION FOLLOWING TRANSCATHETER RESUSCITATION OF ISOLATED DUCTAL ORIGIN OF A PULMONARY ARTERY

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Background: In the rare situation where there is isolated ductal origin of a pulmonary artery (DOPA), intervention to establish re-perfusion of the affected lung without direct re-anastomosis may lead to pulmonary hypertension in the contralateral lung.

Methods: Multi-center review of patients with DOPA, who underwent palliation with a ductal stent and developed pulmonary hyperten-

sion in the contralateral lung. Centers that participated included Texas Children's Hospital, St Justine Hospital, and Rush University Medical Center.

Results: Three infants with right-sided DOPA who underwent uncomplicated palliative ductal stenting were noted to develop severe pulmonary hypertension in the contralateral lung. None of these patients had aortopulmonary collaterals. Case A received two 3x12mm Integrity stents (Medtronic, Minneapolis, MN) at birth; Case B received two 3.5x13mm Zeta coronary stent (Abbott Vascular, Santa Clara, CA) at 10 days and Case C received a 4x19mm Jostent covered coronary stent (Abbott Vascular, Abbott Park, IL) at 6 months.

After developing severe pulmonary hypertension in the left lung, case A demonstrated clinical improvement only after prostaglandin infusion to open up the left ductus. This was subsequently stented with a 3x12mm Integrity stent and eventually the infant underwent surgical anastomosis of right pulmonary artery to the main pulmonary artery at 4 months. Case B underwent repeat catheterization demonstrating normal pressures in the RPA and LA, and was managed with pulmonary vasodilators for 1.5 months prior to surgical re-anastomosis. Case C required surgical banding of the ductal stent that lasted for a year before undergoing surgical re-anastomosis. Pulmonary artery pressures returned to normal in all patients following surgical re-anastomosis.

Conclusions: In these three cases we demonstrate the development of severe contralateral pulmonary hypertension following ductal stenting of a right sided isolated DOPA. Normalization of pulmonary artery pressures resolved in all cases following surgical re-anastomosis. With initial ductal stenting, the normally connected lung continues to receive the entirety of systemic cardiac output, and thus is unlikely to have developed pulmonary hypertension due to excess pulmonary blood flow. The cause of pulmonary hypertension in the normally connected lung in these cases is unclear but we surmise the presence of a neuro-endocrine response to abrupt increase in flow to the lung with DOPA as a possible mechanism.

#0073

FIRST-IN-MAN 2016: NOVEL SELF-EXPANDING ELASTOMERIC BIORESORBABLE SCAFFOLD TO TREAT PEDIATRIC PULMONARY ARTERY STENOSIS

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Background: No commercially available stents exist to treat small children without limiting vessel growth and requiring future surgical removal. Bioresorbable stents would revolutionize congenital heart disease by providing neonates and infants the therapeutic option of stent angioplasty.

Methods: A novel self-expanding bioresorbable scaffold (480 *Biomedical, Inc*) was designed to provide acute radial strength comparable to balloon-expandable metal stents commonly used in larger children (Palmaz Genesis, *Cordis*), to sustain radial strength up to 6 months,

and to complete active resorption by 12 months. Bench evaluations of scaffold radial resistive force (RRF) and chronic outward force (COF) were conducted after simulated use in physiological conditions. In vivo scaffold tests were conducted in pulmonary arteries of rapid growing Micro Yucatan swine [median 8.5 (4.0-13.6) kg].

Results: The self-expanding scaffold is a composite of braided, bioresorbable poly (L-lactide-co-glycolide) monofilaments coated with a cross-linked poly (lactide-co-caprolactone) elastomer. Radiopaque edge markers are incorporated into the device for fluoroscopic visualization. Radial resistive force is greater than a Genesis stent comparator (984 ± 39 mmHg vs 830 mmHg). The chronic outward force is 293 ± 13 mmHg, whereas conventional balloon-expandable stents have no outward force and therefore no ability to self-expand with vessel growth. In simulated 6 month in vitro testing, radial resistive and chronic outward forces declined 10-20% per month. Scaffolds were tested in vivo up to one year in rapid growing micro Yucatan swine. There was no acute or follow-up (3, 6, and 12 months) thrombosis, constrictive remodeling, or branch-loss and minimal neointimal proliferation. Scanning electron microscopy showed endothelialization at 1 month. Angiography confirmed 13 – 39% vessel diameter growth over the 12-month in-life duration. Micro CT and histology show sufficient resorption at one year.

Conclusions: Demonstrated performance features of this pediatric-specific bioresorbable scaffold include self-expansion, elastomer-strengthening, 6F-profile, and programmed degradation without need for drug elution. First-in-man clinical testing is planned for 2016.

#0074

COARCTATION OF THE AORTA: FUTURE RISK DESPITE ADEQUATE REPAIR

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Purpose: Patients (pts) with repaired coarctation of the aorta (CoA) have a shorter life expectancy than their peers. Coronary artery disease/myocardial infarction is the most common cause of late death, likely due to abnormalities of the arterial endothelium. There is limited long-term data for pediatric pts. We hypothesized that pts with CoA would show arterial endothelial dysfunction despite successful repair.

Methods: Pts >5 years of age with successful repair of CoA (defined as residual gradient <20 mmHg by echo or upper/lower extremity BP) without associated significant congenital heart disease (CHD) were included. Twenty-five pts were identified from August 1, 2011 until April 28, 2014, with successful enrolment of 11 pts. One pt was later excluded due to previously unidentified associated CHD. The average (avg) age was 15.3 ± 3.6 yrs. The avg corrected echo gradient post-repair was 11.3 mmHg ± 8.5 . Evaluation included carotid intima media thickness (cIMT) measurement, flow mediated vasodilation (FMV) testing, exercise stress testing (EST), and 24 hour ambulatory blood pressure monitoring (ABPM).

Results: Not all pts enrolled were able to complete all components of the evaluation; some had unsatisfactory data for interpretation. Nine pts underwent EST, of which 3 (33%) met criteria for exercise-induced hypertension. One pt had SBP in the 90-95th percentile. Seven pts un-

derwent cIMT measurement, of which 5 (71%) were abnormal. Eight pts underwent FMV, only 7 with interpretable data, of which 3 (42%) were abnormal. Eight patients underwent ABPM, only 4 with adequate data for interpretation. Three pts (75%) met criteria for ambulatory hypertension, with 2 pts (50%) meeting criteria for severe ambulatory hypertension. There was no significant association among CoA type or repair type with abnormal EST, cIMT, ABPM or FMV.

Conclusion: Pts with CoA demonstrate persistent arterial abnormalities despite adequate repair. CIMT is a validated predictor of future cardiovascular events in adults and was abnormal in 67% of pts. This is consistent with our hypothesis that these pts have abnormalities in their arterial endothelium which will place them at increased risk for future cardiac events at an early age. Further study is warranted in a larger population to better define this risk profile and reduce late morbidity and mortality.

#0075 RIGHT HEART FUNCTIONS IN ADULTS AFTER PERCUTANEOUS PULMONARY VALVE IMPLANTATION

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Objective: Percutaneous pulmonary valve implantation (PPVI) is an efficient therapy for patients with severe pulmonary valve regurgitation who underwent cardiac surgery for Tetralogy of Fallot (TOF). In this study, we aimed to investigate the variation of right heart function in PPVI patients in order to reveal the impact of PPVI on right heart.

Methods: Eight patients who underwent cardiac surgery for TOF in youth and had severe pulmonary valve regurgitation were enrolled. Patients accepted two-dimensional and three-dimensional echocardiography examination before PPVI, 1 month, 3 months, 6 month, and 1 year after PPVI. Global right ventricle end diastolic/systolic volume (RVEDV/RVESV), body compartment of right ventricle end diastolic/systolic volume, outflow compartment of right ventricle end diastolic/systolic volume, and inflow compartment of right ventricle end diastolic/systolic volumewere analyzed by three-dimensional echocardiography. The diameters of right atrium, and degree of tricuspid regurgitation were analyzed by two-dimensional echocardiography and color flow imaging.

Results:The right ventricle end diastolic area was significantly reduced at 1 month after PPVI, while right ventricle end systolic area reduced at 3 months after PPVI ($p<0.05$). Both RVEDV and RVESV showed significantly reduced at 6months after PPVI. The body compartment of right ventricle reduced significantly at 3 months after PPVI, while similar improvements of inflow and outflow compartment were found at 6 months after PPVI. The degree of tricuspid regurgitation was consecutively reduced for 6 month after PPVI. Meanwhile, the diameters of right atrium showed consecutively improvement as well.

Conclusions: PPVI was efficient in improving right heart function in patients with severe pulmonary valve regurgitation after TOF surgery. The improvement of body compartment of right ventricle was earlier than that of inflow and outflow compartment after PPVI. The degree of tricuspid regurgitation and the diameters of right atrium were consecutively improved after PPVI.

#0076 NOVEL HYBRID LARGE STENT IMPLANTATION THROUGH THE ASCENDING AORTA VIA RIGHT AXILLARY THORACOTOMY IN AN INFANT WITH AORTIC COARCTATION

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Objectives: To report a novel hybrid procedure for aortic recoarctation in a low-weight infant performed via right axillary thoracotomy.

Case report: A 9 kg 6-month-old infant with aortic coarctation had had surgery at the age of 15-days and 45-days but he remained with 60mmHg transaortic gradient postoperatively. He has had a balloon aortoplasty but had not achieved a sufficient decrease in the transaortic pressure gradient (60 to 35mmHg). He was brought to the cardiac catheterization laboratory where a novel hybrid procedure was performed under general anesthesia.

The right axillary thoracotomy was performed and a 7F sheath was placed into the ascending aorta. He received 100UI per kilogram of heparin.

Stent implantation was performed using a Palmaz Genesis 1910 stent mounted on a 7x20mm powerflex balloon. During high-pressure-dilatation the stenosis-waist in the stent resolved at 6 atm and the pressure-gradient dropped from 60 to 0 mm Hg. Good immediate angiographic, clinical, and hemodynamic results were obtained. The final transaortic gradient was 0 mm Hg. There were no procedural complications. The patient was doing well at the 30-day and 6-month follow-up. The transaortic pressure gradient remained low (15 mmHg by echo). Reintervention has not been required so far.

Conclusion: Hybrid large stent implantation through the ascending aorta via right axillary thoracotomy is a safe and effective procedure as its performing in this 9 Kg infant has exemplified.

#0077 TRANSCATHETER NATIVE PULMONARY VALVE AND TRICUSPID VALVE REPLACEMENT WITH THE SAPIEN XT: INITIAL EXPERIENCE AND DEVELOPMENT OF A NEW DELIVERY PLATFORM

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Background: While the Melody valve is unable to be used for replacement of large pulmonary outflow tracts, the 29mm Sapien XT transcatheter valve, designed specifically for aortic valve replacement, can potentially be used in these large native outflow tracts. Techniques to enable off-label use of the Sapien XT valve for large diameter pulmonary and tricuspid valve replacement are described.

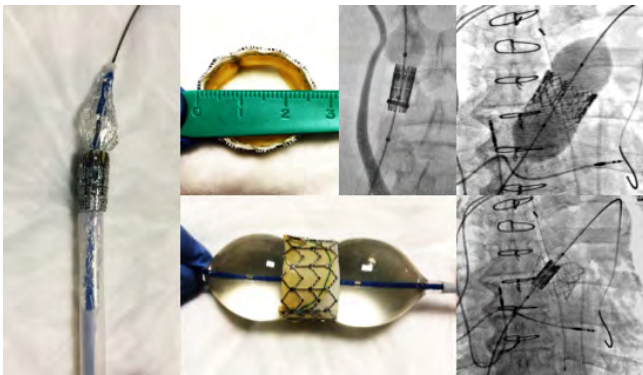
Methods: Use of the Sapien valve for transcatheter pulmonary and tricuspid valve replacement using both the commercially available Novaflex+ system and using a novel flexible delivery system (Fig 1) was reviewed. This customized flexible delivery platform was con-

structured using the Ensemble sheath and a 30 mm Nucleus balloon. This system was bench tested prior to its clinical use.

Results: Ten patients had successful implantation of Sapien valves into native right ventricular outflow tracts (n=7) or tricuspid valves (n=3). There was no stenosis or regurgitation after Sapien valve implantation. Several of the pulmonary valve replacement cases were extremely challenging due to the limited flexibility of the Novaflex system (fig 2). The Sapien valve was crimped onto a 30mm Nucleus balloon preloaded through an Ensemble sheath. This system was able to consistently deliver the Sapien valve safely in a bench model as well as in native right ventricular outflow tracts in two patients (Fig 3).

Conclusion: The 29 mm Sapien XT valve allows for large diameter transcatheter valve replacement in both the pulmonary and tricuspid positions. Initial results of new techniques to utilize a more flexible delivery platform are described that could obviate the need for the Novaflex system.

Figure 1.



#0078 FULLY PERCUTANEOUS TRANSTHORACIC LEFT ATRIAL ENTRY AND CLOSURE TO DELIVER LARGE CALIBER TRANSCATHETER MITRAL VALVE IMPLANTS

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Background: To overcome limitations of transapical and transeptal access to deliver large caliber transcatheter implants to the mitral valve, we hypothesized that the left atrium could be accessed through the posterior chest wall by displacing the lung with CO₂ under imaging guidance.

Methods: We tested fully percutaneous transthoracic left atrial access in 12 animals (10 pigs and 2 sheep) and 3 human cadavers under real-time magnetic resonance imaging (n=10) or x-ray fluoroscopy plus C-arm computed tomographic (n=2) guidance. We also simulated transthoracic trajectories to the left atrium on human contrast-enhanced cardiac computed tomographic angiograms.

Results: Animals were survived for median 7.5 days (Q1-Q3, 7–8.5

days). The pleural space was insufflated with CO₂ to displace the lung, an 18-26F sheath was delivered to the left atrium, and the left atrial port was closed using an off-the-shelf nitinol cardiac occluder (*Amplatz Atrial Septal Occluder*) successfully in 12/12 animals. There was no procedural mortality and no important change in hemodynamics (heart rate, mean arterial pressure and expired CO₂). Median bleeding into the pericardium and pleura were 55mL (40–73mL) and 10mL (10–75mL) respectively, which were immediately auto-transfused. 1 hemodynamically insignificant pericardial effusion was observed at follow-up. We also successfully accessed and closed the left atrium in 3 human cadavers under realtime magnetic resonance (n=1) or X-ray fluoroscopic guidance (n=2). A theoretical trajectory to the left atrium, assuming the right lung was displaced, was present in all of 10 human cardiac computed tomographic angiograms analyzed.

Conclusions: Percutaneous transthoracic left atrial access is feasible in large mammals and in human cadavers under realtime magnetic resonance or x-ray fluoroscopic guidance. The presence of potential transthoracic trajectories to the left atrium on human cardiac computed tomographic analysis suggests clinical translation is realistic. This technique could provide fully percutaneous access to deliver large caliber transcatheter mitral valve implants.

#0079 CHALLENGES AND OUTCOME OF BALLOON AORTIC VALVULOPLASTY IN CHILDREN AT VARIOUS AGE GROUPS

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Objectives: This study was aimed to determine the success, complications, trouble shooting, and survival of patients after balloon aortic valvuloplasty (BAV).

Background: The introduction of transcatheter aortic valve ballooning in infants and children with severe aortic stenosis has greatly improved symptomatology and quality of life. Even certain neonates with critical aortic stenosis and poor left ventricular function have benefitted tremendously following aortic valve ballooning.

Methods: A cohort of 81 patients with severe aortic valve stenosis underwent aortic valve ballooning from august 2010 to April 2015 . All patients had single procedure . Clinical, hemodynamic, and follow-up morbidity and mortality data were collected.

Results: The cohort mean age was 90.5 ± 9.8 months. male to female ratio was 3:1. BAV was performed for symptomatic relief and to gain time for surgical aortic valve replacement. The mean pressure gradient decreased from 80 ± 6 mm of Hg to 25 ± 7 mm of Hg. The mean aortic valve annulus increased from 12 ± 2 mm to 15 ± 3 mm. Serious adverse events occurred in 5 patients (6.17%), Death in one child (1.2 %) during procedure ,ventricular premature contractions in 3 (3.7 %), bradycardia in 1 (1.2 %), mortality rate 1 (1.2%)

Conclusions: Balloon aortic valvotomy is quite rewarding in paediatric age group with good results. This procedure relieves symptoms as well as preserves left ventricular function for future aortic valve replacement.

#0080**AORTO-RIGHT VENTRICULAR SHUNT AFTER AORTIC VALVE REPLACEMENT: INTERVENTIONAL OCCLUSION WITH AN AMPLATZER DUCT OCCLUDER II**

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Aortocardiac fistulas are rare, especially if they develop after surgical aortic valve replacement. We present the case of a 62-year-old woman who sought care for dyspnea and heart failure symptoms 3 months after bioprosthetic aortic valve replacement. Her postoperative course was complicated by third degree AV block, and a DDD pacemaker had already been implanted. Echocardiography revealed an aorto-right ventricular (Ao-RV) shunt with preserved left ventricular function and mild stenosis of the bioprosthesis without a true paravalvular leak. Treatment of aorto-right ventricular fistulas can be accomplished interventionaly or may otherwise require a surgical approach.

Cardiac catheterization confirmed the diagnosis and showed a left-to-right shunt from the right coronary cusp to the cavity of the right ventricle with a Qp:Qs of 1.4:1 and mild pulmonary hypertension. The fistulous connection could not be well delineated by transesophageal echocardiogram (TEE) and angiography alone. Therefore, balloon-sizing was performed using a Tyshak II balloon of 8 × 20 mm, until achieving a complete interruption of flow assessed by TEE. Minimal diameter of the defect was 4.2 mm, the distance to the right coronary artery measured 8 mm and the distance to the prosthetic valve ring 6.6 mm. It was decided to attempt closure retrogradely avoiding a arteriovenous loop by choosing an Amplatzer™ Duct Occluder (ADO) II device 06-04 (9-PDA2-06-04). An additional advantage of this device is the small sheath size required. ADO II implantation could be performed easily and the final angiogram documented good position of the device and showed near complete closure while still under heparin. There was no interference with the prosthetic aortic valve or development of valve insufficiency and no compromise of flow to the right coronary artery. Echocardiography repeated the following day documented no residual shunt through the AO-RV fistula. **Conclusion:** Percutaneous closure of an aorto-right ventricular shunt can be performed avoiding an arteriovenous loop using an ADO II via the retrograde approach if anatomical details including a sufficient distance from the coronary arteries and aortic valve are documented.

#0081**CREATION OF A NOVEL PERCUTANEOUS ANIMAL MODEL OF PULMONARY VEIN STENOSIS**

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Objective: To create and validate a percutaneous animal model of pulmonary vein stenosis applicable to congenital heart disease and/or acquired pulmonary vein stenosis by using thermal injury within the pulmonary veins.

Background: Congenital and acquired pulmonary vein stenosis is rare, with a high mortality. Surgical and transcatheter (balloon angioplasty, stent implantation) interventions have similar challenges

with occurrence of restenosis being common. The optimal device for pulmonary vein stenosis has not yet been identified.

Methods: Yorkshire Swine piglets (4 animals, 2 weeks old, 5kg each) placed under GA, right and prograde left heart catheterization performed through the PFO. Thermal injury balloons (LesionGen) were heated using RF energy once fully inflated within the pulmonary vein to create a local injury/tissue response to approximate cellular changes. Each piglet received thermal injury in 2-3 vessels. Piglets were recovered and housed prior to follow-up diagnostic catheterization at either 30 or 60 days and were sacrificed and histopathology performed on all intervened vessels.

Results: All animals survived the initial procedure and underwent follow-up catheterization.

Hemodynamics: 30 day animals demonstrated increased mean PA pressure of 4-5mmHg. 60-day animals demonstrated no change in mean PA pressure.

Angiography: Pulmonary vein stenosis measured by percent diameter stenosis relative to the normal vessel: 30-day animals 52.29 ± 24.67%, 60-day animals 12.52 ± 4.95% (mean ± SD). One vessel was 100% occluded acutely after thermal balloon injury and remained occluded at 30-day follow-up.

Histopathology: Thermal injury noted in one pulmonary vein in both 30-day animals (slight non-stenosing intimal hyperplasia) and in one 60-day animal (minimal non-stenosing intimal hyperplasia, slight perivenous fibrosis).

Conclusion: Thermal injury was able to successfully induce neointimal hyperplasia in neonatal swine pulmonary veins. Greater tissue proliferation was noted at 30 days compared with 60 days and may represent healing. Thermal injury is a feasible modality for percutaneous induction of pulmonary vein stenosis. Additional investigation to determine the optimal balloon design and optimal thermal injury delivery is needed.

#0082**ANGIOPLASTY PROCEDURE IN AORTIC COARCTATION**

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Hypothesis: follow up of patients (p) with Aortic Coarctation (Ao Co) post angioplasty (BCA) procedure.

Material and Methods: retrospective analysis of 84p post angioplasty procedure. 76p Ao Co native

Grouped by severity: mild <20mmHg, moderate 20 a 40 mmHg, severe >40mmHg. Topics reviewed: age at diagnosis, clinical manifestations (cardiac insufficiency (CI), arterial hypertension (AH)), defect extension (localized, extensive, isthmus hypoplasia), associations, initial treatment (catheterization or surgery), and long term evolution. Multivariable statistical analysis T test p<.05.

Results: 84p with Ao Co post BCA; Age at diagnosis: 20% <1month, 50% 1-2 years, 30% >2 years;

Age at BCA: median 8±8 month. Clinical exam: 95% no pulse, 33% CI and 21% AH; 1p AH without IC.

EKG: right ventricular hypertrophy in 53p, left in 31p. Associations: ventricular septal defect 23p (15p perimembranous, 7p muscular, 1p sub-aortic), 8p ductus, 1p mitral stenosis, 6p mitral insufficiency, 6p aortic insufficiency, 2p right aberrant subclavian artery.

Anatomic types: 83.1% localized: 9.9% membranous, the others fibromuscular; 1p extensive; 14/84p hypoplasia of transverse aortic arch. Severity: 30% moderate, 60% severe. BCA: 52p procedures over 84p; 44p one BCA, 4p two BCA (2p native Ao Co), 1p: four BCA, 1p needed stent. Efficiency: efficient in 38/ 47p (80.8%); not efficient in 8p, 1p died of cardiogenic shock during the procedure. Gradient post procedure: dropped from 50±18mmHg to 14±10mmHg (p: 0.00), and increase the size of the isthmus X: 14±2.43cm versus X: 18±3 (p: 0.07). Re-coarctation (RC): 17/30p with native Ao Co, all <1 year old with CI, early RC X: 12±10month; 2p had small sacular aneurysms.

RC 57% native Ao Co, versus 13.3% after surgery. 4/84 small sacular aneurysm (4.2% in Ao Co native, 1.2% in after surgery). Stent: 33 p; X: 9.5±5 a, 25/33p Ao Co was severe, 8 p moderate. 2p aortic arch hypoplastic.

#0083

SHOULD PULMONARY LOOP TECHNIQUE BE A ROUTINE ON PERCUTANEUS PDA CLOSURE IN ADULTS? TWO NATIONAL CENTERS EXPERIENCE.

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PDA is a congenital heart disease usually diagnosed and treated in childhood however a small amount of patients reach to adulthood unoperated. This heart condition varies from asymptomatic heart murmur, disturbed functional class to lv systolic dysfunction and pulmonary hypertension.

Percutaneous PDA closure is a worldwide well accepted technique for treat children with this disease however experience in adults is still on development.

Method: this is a retrospective study of two national university cath labs in Venezuela. Our study describes the population, devices, procedure and follow-up in adults with PDA treated percutaneously from April 2001 to April 2015.

Results: a total of 45 patients were included in the study and for epidemiological reasons older than 12 years were considered as adults. There were 37 females and 8 male patients. The medium age was 28.1 years. The more used device was the Amplatzer PDA occluder with 40 cases followed by Amplatzer septal occluder and coil with 2 cases each respectively. Duct occluder was used in one single case.

Aorto-pulmonary loop was performed in cases in which operators were unable to access descending aorta from pulmonary arteries despite multiples attempts. Pulmonary loop technique was used on 42 cases.

All cases but one were done with less than 15 minutes flouroscopy time. There were no residual shunts 24 hours after the procedure. No major complications were reported. Short after the procedure one of the patients developed AF with no embolic events after 4 years follow-up. Two patients required medication for IV systolic dysfunction

Conclusions: percutaneous PDA closure is a feasible and safe procedure in adults with high success rate without major complications. In most cases aorto-pulmonary loop would shorten the procedure in adults. Amplatzer PDA occluder is the more used device for this condition, however off label use of septal occluder and muscular VSD occluder should be considered in selected cases.

#0084

TECHNIQUES FOR TRANS-CATHETER RETRIEVAL OF EMBOLIZED NIT-OCCLUD® PDA-R AND ASD-R DEVICES

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Background: Nit-Occlud® (Atrial Septal Defect) ASD-R and (Patent Ductus Arteriosus) PDA-R devices are used outside the USA for closure of the patent ductus arteriosus and atrial septal defects. When embolization occurs, these devices have been difficult to retrieve. **Methods:** Bench simulations of retrieval of PDA-R and ASD-R devices were performed in a vascular model (Fig 1). Retrieval of each device was attempted using snares or biptome forceps. A range of devices were embolized in an animal model. Retrieval methods were systematically tested in a range of sheath sizes, and graded in by difficulty and retrieval time.

Results: Devices grasped by the biptome in the center of the proximal part of the devices were easily retrieved in both models. Bench studies determined the minimum sheath sizes needed to retrieve each device. Sheathes two french sizes greater than the delivery sheath were successful with this technique. Five of the six PDA-R devices were successfully retrieved in vivo (Fig 2). Four were retrieved by grasping the middle of the right atrial ASD-R disc or PA end of the PDA-R device with a biptome, and one small PDA-R device was retrieved using a 10mm snare. Nine ASD-R devices were retrieved successfully. For ASD-R 28 mm and 30 mm devices, a double biptome technique was needed (Fig 3).

Conclusion: ASD-R and PDA-R devices can be successfully retrieved in the catheterization lab. It is critical to grab the center portion of the right atrial disc of the ASD-R device or pulmonary portion of the PDA-R device and to use adequately sized sheathes.

Figure 1.

Device	Minimal Sheath Beveled	Snare middle	Snared Disc	Forceps Right Atrial Disc		Forceps Left Atrial Disc		Forceps Middle of Right Disc
				Grip1	Grip2	Grip1	Grip2	
ASD-R 8mm	14F	0 / 3	0 / 3	0 / 3	0 / 3	0 / 3	0 / 3	3 / 3
ASD-R 18mm	14F	0 / 3	0 / 3	0 / 3	0 / 3	0 / 3	0 / 3	3 / 3
ASD-R 30mm	16F	0 / 3	0 / 3	0 / 3	0 / 3	0 / 3	0 / 3	3 / 3
				Pulmonary Disc Wire		Aortic Disc		Middle Pulmonary
PDA-R 8,5	16F	1* / 3	1* / 3	1* / 3	1* / 3	1* / 3	1* / 3	3 / 3

Figure 2.

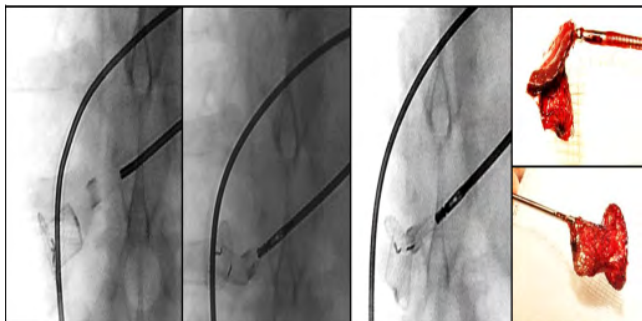
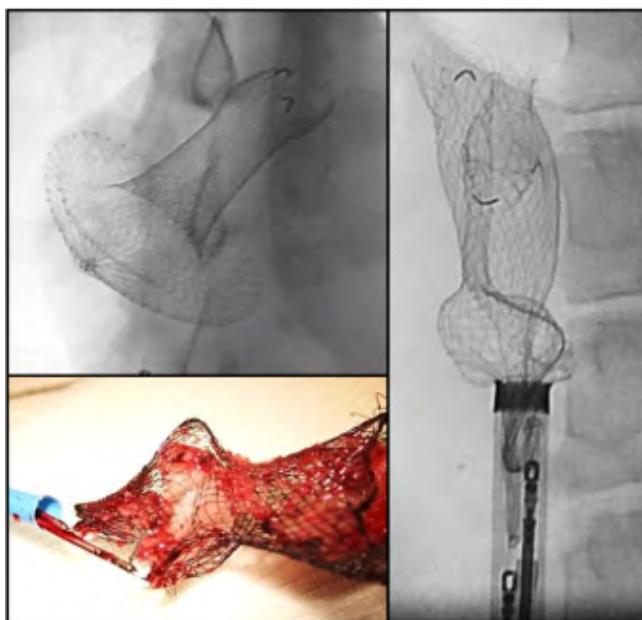


Figure 3.



#0085

BIGGER ISN'T ALWAYS BETTER: INITIAL EXPERIENCE WITH THE 3.3 FR MONGOOSE® PIGTAIL CATHETER FOR AORTIC ANGIOGRAPHY DURING PDA CLOSURE IN SMALL PATIENTS.

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Introduction: Use of a smaller vascular sheath in the femoral artery may be associated with lower vascular complication rates. The 3.3 Fr Mongoose® Pediavascular pigtail catheter is a new angiographic catheter designed to allow higher flow rates and maximal burst pressures, potentially resulting in improved angiographic quality in a small catheter. We reviewed our initial experience with this catheter during PDA closure procedures and compared it to prior experience with 4 Fr pigtail catheters

Methods: Retrospective review of all patients in whom the Mongoose® catheter was used for aortic angiography during PDA closure from 12/13-4/15. Inclusion criteria were weight \leq 20 kg and presence of a PDA. Angiographic efficacy, procedural details and complications were reviewed and compared to the prior 10 cases in which a more standard 4Fr angiographic catheter was used from 9/12-12/13. Variables are reported as median with range. Comparisons were performed using the Mann-Whitney U test; p value < 0.05 was considered significant.

Results: Twelve patients (9 female) met inclusion criteria for this study and were catheterized with a 3.3 Fr Mongoose®. Median wt 10.5 kg (range 6.4-18.2), ht 81 cm (range 37-111) and BSA 0.47 m² (range 0.33-0.75) were not different from the 10 pts (3 female) in the 4Fr group (p= NS): median wt 9.9 kg (range 6-16.8), ht 80 cm (range 64-102) and BSA 0.46 m² (range 0.31-0.74). Angiographic quality was subjectively adequate with both catheters in all cases with no objective difference in average pixel density between the 2 techniques [3Fr: 76.7 (range 33.5-90); 4Fr: 70 (range 38-102); p=NS]. Total contrast used was similar between the 2 groups (3Fr: 4.2 ml/kg; 4Fr: 4.9 ml/kg; p= NS). Radiation dose (air Kerma) was similar in the 2 groups [3Fr: 28.1 mGy (range 17.2-38); 4Fr: 38 mGy (range 20.4-58.5); p = NS]. Echocardiography on POD# 1 demonstrated PDA closure in 10/12 3Fr pts and 10/10 4Fr pts (p=NS); at latest f/u, all are closed. No complications were encountered in either group with good pulses and perfusion on POD#1.

Conclusions: The 3.3 Fr Mongoose® allowed for adequate and similar angiography to the more standard 4Fr pigtail catheter, allowing safe and effective transcatheter PDA closure in small children.

#0086

SIMPLE TECHNIQUE TO CREATE DIABOLO STENT CONFIGURATION – AMPLATZ GOOSENECK SNARE

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Introduction: The use of diablo stents greatly aids in stent stability and creates an accurate predetermined waist. This is best described for creating transcatheter Fontan fenestrations. A number of techniques to create the diablo configuration have been previously described.

Objective: To describe a simple reliable technique to aid in creating diabolos configuration using a gooseneck snare without increasing the size of the delivery sheath.

Methods: The diabolos configuration was created using a standard 5-mm Amplatz GooseNeck true 90° coaxial snare loop centered on an intentionally oversized angioplasty catheter. The stent chosen for deployment was then mounted on the balloon and snare. The lowest profile of the snare loop was maintained with the snare catheter as the stent is crimped onto the angioplasty catheter. Fluoroscopy was used to confirm a proper snare position at the middle of the stent prior to deployment. An introducer size 2 Fr larger than that recommended for the angioplasty catheter was chosen. Once the stent is centered across the desired location the distal portion of the stent to the snare is unsheathed and deployed. The entire system is then withdrawn against the wall and the proximal stent is unsheathed and deployed. The diabolos configuration is created with an accurate 5 mm waist and the stent stability is assured. The snare and balloon are then removed and if necessary the waist can be enlarged to the desired diameter. Data expressed as median and IQR.

Results: A total of 6 diabolos stents were successfully implanted in 4 patients; 5 to create a transcatheter fenestration and 1 across restrictive atrial septum. Their weight was 24.8 kg (19.6-46.95) and age was 9.2 years (6.28-13.23). The sheath size was 9 (9.5-10.75) Fr and the balloon size was 12 (10.5-13.5) mm. There were no complications and a consistent diabolos configuration with a central waist of 5 mm was created. In two patients the waist was easily dilated to a desired size.

Conclusion: The snare serves as a readily available tool, available in adequate length, sterile, has sufficient tensile strength, preconfigured with a true 90° coaxial loop, radiopaque to aid in positioning, and does not increase the size of the delivery sheath yet creates a consistent and reproducible diabolos configuration. Further there is no suture that limits potential for future dilation. This technique is a simple, reproducible, easy to learn, and addresses limitations of other techniques.

#0087

CARDIAC CATHETERIZATION IN THE IMMEDIATE POSTOPERATIVE PERIOD: DO RESULTS FROM HIGH VOLUME CENTERS APPLY TO THE REAL WORLD

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Background: Cardiac catheterization performed in the immediate postoperative period (< 6 weeks) is a high risk procedure. The published data is limited and exclusively from high volume centers.

Objective: The goal of this study was to compare the real world outcomes for early postoperative catheterization with published data from larger centers.

Methods: In this retrospective study previously published definitions, outcome measures, inclusion and exclusion criteria were chosen. All patients undergoing unplanned postoperative cardiac catheterization excluding central line placement, pericardiocentesis, post-transplant surveillance biopsies, and fluoroscopy only procedures between November 2007 and May 2015 were analyzed. The primary outcome measured was whether there was a change in management; transcatheter intervention, unplanned reoperation, or change in medical

treatment. The secondary outcomes measured were death, cerebrovascular accident, major adverse event, need for emergent surgical bailout or mechanical support, worsening or new onset acute kidney injury. All decisions were made after multidisciplinary discussion. The data is expressed as median with IQR.

Results: Eighty-eight patients, median age 117 days (36 to 209.5 days), weight 4.5 kg (3.52 to 6.63 kg), underwent 134 catheterizations on median postoperative day 21.5 (8 to 41 days). Sixty (45%) procedures were performed in patients with single ventricle physiology. In 107 (80%) procedures there was a change in clinical management. Fifty-two (39%) procedures were interventional and 82 (61%) were diagnostic. Fourteen (10%) procedures were performed on ECMO. Success rates by procedure were: angioplasty 55 %, stent implantation 100 %, and occlusion 100 %. SAE during cardiac catheterization included thrombosis in the Fontan circuit (one procedure), and access site bleeding (one procedure). Twenty-three interventions involved stent implantation and 22 interventions were balloon angioplasty. Intervention (balloon angioplasty or stent implantation) across a fresh suture line (<42 days) was performed during 27 (52%) procedures. Suture disruption or trans-mural vascular tears were not observed. There was no procedural mortality. Twelve patients (14%) died within 30 days post catheterization and 22 (25%) patients died before hospital discharge.

Conclusions: Similar to data published from high volume centers our data shows that postoperative diagnostic and interventional catheterizations can be safely performed and yield critically important information. The outcomes reported by high volume centers can be reproduced in the real world setting.

#0088

TRANSCATHETER CLOSURE OF CONGENITAL VENTRICULAR SEPTAL DEFECTS

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Purpose: Report the experience of 34 cases of transcatheter closure of congenital ventricular septal defects (VSD).

Material and Methods: Transcatheter device implantation was attempted in 34 patients (p) with congenital VSD until November 2014. The median age was 9.7±7 years.

Anatomic VSD types: 21 perimembranous (2 case post surgery both with light prolapse), 1 multiple (needed 3 devices). 13 muscular (7 middle ventricular- 2 after surgery-, 4 muscular-membranous, 2 multiple),

Devices used: 21 Amplatzer (14 muscular, 7 membranous devices and 1p PDA device) type device VSD; 2:9/6 ductus, 10/6, 2:12/6, 2:12/8, 14/8, 2:16/8, y VSD 18, 12,10 y Amplatzer ductus occluder2; 1 AGA ADO II

2 devices N°6: 2 Type II, T III, TI; N° 7 Type II, N°8 Type II, N°10 Type II, N°12 Type III.

8 Nit Occlud VSD device. (12/6, 2p 12/8, 5p 10/6, 2p 14/8)

Results: Procedure was successful in 28 cases (96.5%). Median VSD size was 7 mm (range 3–22). Fluoroscopy time was 24±15' (range 3–146).

Complications: with *AMPLATZER device*: 1p tricuspid regurgitation (no surgery was necessary), minor rhythm disturbances in 3p, complete atrioventricular block (CAVB) in 3 p (perimembranous, 2 transitory, 1 required pacemaker); left anterior hemiblock (transitory), 2 muscular VSD. 1p stenotic tricuspid valve.

Multivariable analysis: the only variables associated with risk of complications were age (P: 0.012) and weight (P: 0.0035).

Univariable analysis: risk factors for CAVB were the device type (P: 0.03) and VSD location (P: 0.05). With *NIT OCCLUD device*: embolization in 1 case, 1p minimal aortic regurgitation, 3p haemolysis (2 main, 1 severe that required Nit Occlud ductus 9/6).

In both type of device residual shunt was immediate in 11/34, 6 month later 2/34 minimal shunt, 2/34 light aortic regurgitation (1 minimal, 1 light)

Multivariable Cox proportional hazards analysis: no others risk factors were found.

Conclusion: Transcatheter closure of congenital VSD offers encouraging results. Complications are limited; the most relevant one is complete atrioventricular block in perimembranous VSD. More experience and long-term follow-up are mandatory to assess its safety and effectiveness

#0089

CARDIAC CATHETERIZATION OF PEDIATRIC PATIENTS SUPPORTED BY EXTRACORPOREAL MEMBRANE OXYGENATION

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Objective: Heart catheterization (HC) is commonly performed in pts being supported by extracorporeal membrane oxygenation (ECMO). We aimed to evaluate the safety and utility of HC in pediatric pts on ECMO.

Methods: Retrospective analysis of HC performed between 1/2000 and 5/2015 in pts <18 years of age while on ECMO. Pts placed on ECMO at the time of HC were excluded. Pt and procedural data obtained included indications for HC, interventions, procedural complications and outcome.

Results: A total of 365pts received ECMO support during the study period. Of those, 51pts underwent 53 ECMO runs and 55 HC. Nineteen pts had congenital heart disease (two-ventricle physiology in 13 and single-ventricle in 6), 12 acute myocarditis, 9 chronic cardiomyopathy, 8 heart transplant, 2 pulmonary hypertension and 1 ischemia. Indications for ECMO included ventricular dysfunction in 22, cardiac arrest in 20, unable to wean from surgical bypass in 7 and cyanosis in 4. An intervention was performed in 42/55 HC (79%), including septostomy for LA decompression in 34, stent placement in 6

(pulmonary artery 2, BT shunt 2, Fontan fenestration 1 and coronary artery 1), collateral embolization in 1 and adjustment of Fontan fenestration size in 1. Diagnostic HC was performed to image coronary arteries in 4pts, pulmonary veins and arteries in 3 and 2 respectively and aorta and central shunt in 1 each. Biopsy was performed in 1pt and in 1pt septostomy was deferred due to an atrial thrombus. Diagnostic HC was followed by surgery in 4pts (30%): 2pts required pulmonary artery plasty and shunt revision, 1pt had compression of circumflex artery by external pacemaker lead and 1pt had repair of anomalous LCA. Major complications occurred in 3pts (5.6%): 1pt died due to hemothorax after pulmonary stent placement, 1 suffered perforation of the right femoral vein requiring a covered stent and 1 developed a pericardial effusion due to perforation of the atrial wall but needed no further intervention. Median follow-up time after HC was 141 days (IQR 13.5-1493). Outcome of the 53 ECMO runs included decannulation in 27 (53%), heart transplantation in 9 (17%) and transition to ventricular assist device in 3 (4%). ECMO was withdrawn in 14 pts (26%).

Conclusion: HC can be safely performed in pts on ECMO for diagnosis or therapeutic interventions. Early HC is recommended in pts with circulatory collapse of unclear etiology.

#0090

INACCURACY OF A CONTINUOUS ARTERIAL PRESSURE WAVEFORM MONITOR WHEN USED FOR CONGENITAL CARDIAC CATHETERIZATION

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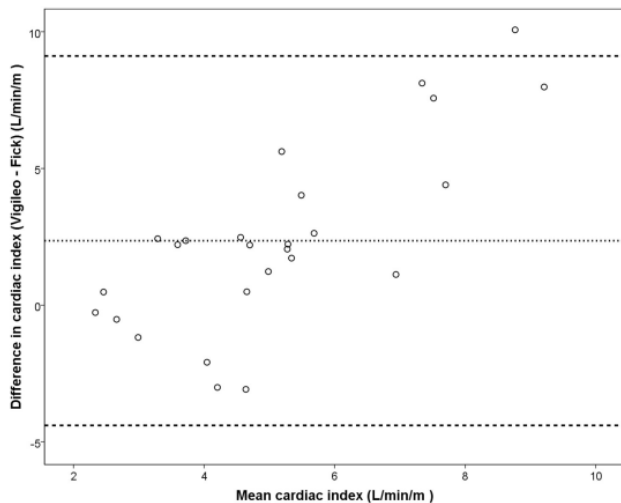
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Background: Cardiac index (CI) is vital for hemodynamic calculations in cardiac catheterizations for congenital heart disease (CHD). Oxygen consumption (VO_2), used in the Fick equation to calculate CI in patients with intracardiac shunts, is cumbersome to measure. Many catheterization labs rely on published predictive equations for VO_2 which are known to be suboptimal. The FloTrac sensor (Edwards Lifesciences Corp., Irvine, CA) uses real-time arterial waveform tracings to calculate CI but has not been used in children with CHD undergoing cardiac catheterization (cath).

Methods: Patients undergoing clinically indicated cath were prospectively enrolled from 9/2014 to 5/2015. All cath were performed with general endotracheal anesthesia. VO_2 was measured using the Vmax[®] Encore 229 monitor attached to the ventilator circuit. While in a steady hemodynamic state, the FloTrac transducer was connected to a 4 or 5-Fr pigtail catheter in the descending aorta and CI was obtained. CI by the Fick equation using measured VO_2 was compared to CI from the FloTrac sensor using paired t-test and Bland-Altman analysis.



Results: 26 patients (median age 5.2 years, 1.5 – 18.3) were studied. Indications for cath included: ASD (n = 6), PDA (n = 6), coarctation (n = 3), pre-Fontan hemodynamics (n = 2), pulmonary artery/RV-PA conduit intervention (n = 2), pulmonary hypertension (n = 2), shunt quantification (n = 2), IVC obstruction (n = 1), post-Fontan evaluation (n = 1) and post-transplant evaluation (n = 1). CI by FloTrac was higher than CI by Fick (6.28 vs. 3.92 L/min/m², $p = 0.002$). Bland-Altman analysis (Figure) showed a consistent overestimation of CI by FloTrac which worsened as CI increased (mean bias 2.36 L/min/m², 95% limits of agreement -4.4, 9.1).

Conclusion: The results of this study show that the FloTrac sensor can be used to measure CI in children with CHD undergoing catheterization. However, for children with higher CI, the sensor is too inaccurate for routine clinical use. Further studies may allow for modifications of the algorithms to obtain more accurate CI in this population.

#0092

INITIAL EXPERIENCE WITH THE NEW PUL-STENT IN TREATING POST-OPERATIVE BRANCH PULMONARY ARTERY STENOSIS

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Objective: The Pul-Stent (MED-zenith medical scientific co. Ltd, Beijing, China) is a new cobalt alloys stent with hybrid cell design (a combination of closed and open cells), specially licensed for pulmonary artery stenosis. The aim of this study was to evaluate its effectiveness, safety and maneuverability.

Methods: 21 patients were enrolled in this study. Among them 8 cases were post surgical repair of tetralogy of Fallot, 7 patients were post surgical repair of pulmonary atresia with ventricular septal defect, 2 cases were after Fontan procedures, and 1 patient has stenosis at Glenn pathway, and 3 cases were isolated pulmonary branch stenosis. The median age was 7.2 years (range 2.0 -13.7 years). The median weight was 21.1kg (range 13-32 kg). And there were 20 cases of transcatheter stent implantation and 1 case of hybrid procedure.

Results: Totally 23 Pul-stents have been implanted in successfully 21

patients (14 males and 7 females) through 7-12 F delivery sheaths, among them 17 stents in left pulmonary artery and 6 stents in the right side. The catheter-measured pressure gradient at the stenosis decreased from 32.7 ± 13.2 mmHg to 12.0 ± 12.7 mmHg ($p < 0.001$) and the diameter of the narrowest segment increased from 4.5 ± 1.4 mm to 9.5 ± 2.1 mm ($p < 0.001$). The right ventricle pressure to aortic pressure ratio decreased from 0.55 ± 0.12 to 0.36 ± 0.08 ($p < 0.003$). The total procedure time ranged from 30 to 220min median 109min, and the fluoroscopy time ranged from 9 to 67min (median 26 min). There were 3 cases of stent micro-migration, further stent implantation were performed in 2 cases, and there were 2 cases of post-stenting pneumorrhagia. No balloon rupture, no stent fracture and other severe complications were observed. No significant restenosis was detected by following cardiac ultrasound studies and selected cardiac catheterization in 6-months Follow-up.

Conclusion: Pul-Stent tracking and delivery was excellent, the initial experience has shown that Pul-Stent implantation was effective and safe in treating post-operative branch pulmonary artery stenosis. Further follow-up study should be investigated to make sure whether those good results will be permanent or not.

Key words: Branch pulmonary • Stenosis • Stent implantation • Children

#0093

HYBRID MITRAL VALVE REPLACEMENT USING TRANSCATHETER HEART VALVES: A NOVEL APPROACH FOR INFANTS AND SMALL CHILDREN WITH MITRAL VALVE DISEASE

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Objective: Treatment of mitral valve (MV) disease in small pts is a challenging issue as there are few options available for MV replacement (MVR). We present our experience using current transcatheter heart valve (THV) technologies for the treatment of MV disease in infants and small children.

Methods: Review of surgical database and hospital records for all pts who underwent hybrid MVR with THV's.

Results: From 02/2013 - 06/2015, 5 pts (4 males) underwent hybrid MVR using a THV; 3/5 had previous MV repair. Main indication for MVR included symptoms associated with stenosis (3) and insufficiency (2). In all cases intrinsic MV tissue and chordae were removed surgically before THV was placed. Three pts (age 22, 34, 37 months, 10-13kg) received a Melody valve (Medtronic, Minneapolis, MN) implanted on a 16mm balloon (1pt) and 18mm in 2. Two infants (5, 9 months; 4, 5kg) had an Edwards Sapien 3 valve (Edwards, Irvine CA) implanted under compassionate use criteria on 16 and 18mm balloons. Melody valves were secured to the MV annulus with sutures to the stent in 2 pts and to a surgically created cuff in 1 or to the fabric "skirt" of the Sapien3. Two Melody pts required concurrent procedures to accommodate the valve. Post-op TTE showed mean MV gradients <5mmHg in all but 1 pt (9mmHg, Sapien). One pt had a small perivalvular leak (Melody). All pts had < mild MV insufficiency. New LVOT obstruction (20mmHg) was noted in 1 pt (Sapien). One pt (Melody) with history of pulmonary hypertension (PHTN) suffered PHTN crises in the early

post-op period. Median follow up time was 7 months (range 1-28). Two pts required reintervention: 1 pt (Melody) underwent surgery for a subaortic membrane unrelated to the MVR and mild MV stenosis. The Melody THV leaflets had 2 holes and a few more appeared post redilation thus a 2nd Melody THV was placed within the previous. A second pt (Sapien3) developed progressive MV stenosis due to poor opening of valve leaflets underwent successful dilation at cath. On last follow-up, mean MV gradient tended to be higher among Sapien pts than Melody pts (16,22mmHg vs 4,8,11 respectively).

Conclusion: Hybrid MVR with THV's is feasible in small children. LVOT tract obstruction or perivalvular leak at implantation may be avoided using different techniques. Transcatheter redilation of the Sapien valve is possible. Further follow up to assess long-term function and durability of THV's in the MV position is needed.

#0094

OUTCOMES OF STENT IMPLANTATION IN PULMONARY VEIN STENOSIS FOLLOWING REPAIR OF TOTAL ANOMALOUS PULMONARY VENOUS CONNECTION

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Introduction: Pulmonary vein stenosis (PVS) following repair of total anomalous pulmonary venous connection (TAPVC) is often acutely progressive and lethal. Neither surgery nor transcatheter interventions have yielded satisfactory long-term results.

Methods: Consecutive patients who underwent stent implantation (SI) for PVS following repair of TAPVC between January, 2008 and May, 2015 were identified retrospectively. In principle, sutureless repairs for PVS and atrial septum defect creation were performed initially, and if possible, 7mm stents were implanted percutaneously or intraoperatively for recurrent PVS. Aggressive reinterventions for in-stent stenosis (ISS) were performed at intervals of a few months. The ISS was graded based on the ratio of lumen-to-stent : <0.5=severe, 0.5-0.7=moderate, 0.7-0.9=mild, >0.9=no stenosis.

Results: A total of 15 pulmonary veins (PV) were stented in 5 patients. Bare metal stents (BMS) were used in 15 PVs, including a 7mm Express Vascular LD (n=13) and 4mm Liberte (n=2). Handmade covered stents (CS) were used in 2 PVs in 1 patient to overlap prior implanted stents in order to control relentless ISS (n=2). The age at the time of the SI was 8(4-38) months. During a cross-sectional follow-up of 30(6-81) months, occlusion was documented in 2 stents and severe ISS in 4 stents, moderate ISS in 2 stents, mild ISS in 6 stents, and no stenosis in 3 stents. Reinterventions were performed a median of 6(2-14) times over an interval of 1-7 months. There was a statistically significant improvement after SI in the lumen diameter (2.4mm to 6.3mm, p<0.001) and systolic right ventricle pressure to aortic pressure ratio (1.0 to 0.5, p=0.041) and a statistically significant difference between no/mild/moderate ISS and severe/occlusive ISS in the minimum di-

ameter (2.5mm versus 1.7mm, p=0.037) and reference diameter (6.5mm versus 3.5mm, p<0.001). The number of 7mm stents with no/mild/moderate ISS was 2 in all 3 surviving patients, 1 in 1 deceased patient (due to pertussis), and 0 in the remaining decedent (due to chylothorax).

Conclusions: SI for PVS was acutely effective in relieving stenosis and pulmonary hypertension. ISS was common and more severe especially in PVs with a smaller minimum diameter and reference diameter. Although aggressive reinterventions were needed, patients with more than two 7mm stents were able to survive over the long term.

#0095

COIL EMBOLIZATION AS TREATMENT FOR CONDUIT RUPTURE DURING MELODY TRANSCATHETER PULMONARY VALVE IMPLANTATION

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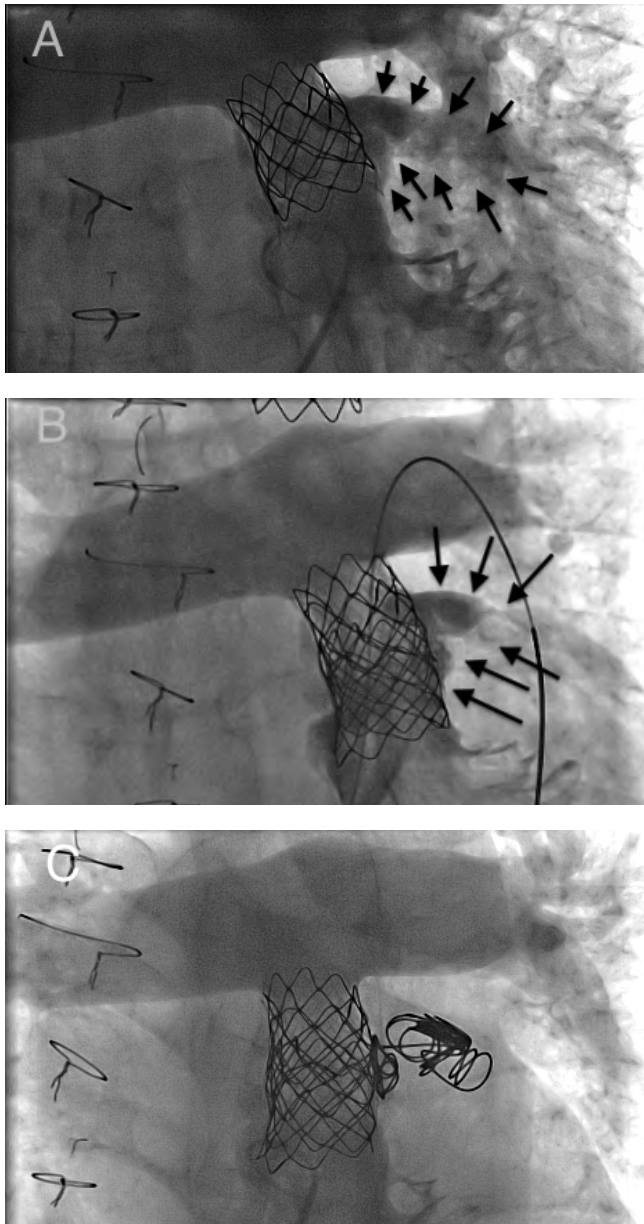
Objective: To describe the use of coil embolization for the successful treatment of right ventricular (RV) to pulmonary artery (PA) conduit rupture during Melody™ transcatheter pulmonary valve implantation.

Background: Conduit rupture is a known and serious complication of percutaneous pulmonary valve implantation. Coil embolization as treatment of conduit rupture has not been previously reported.

Case: The patient is a 29 year old male with a history of congenital aortic valve stenosis and tortuous aortic isthmus status-post surgical aortic valvotomy in infancy followed by Ross procedure at 12 years of age with placement of a 24 mm pulmonary homograft in the RV to PA position. He developed coarctation and severe homograft stenosis with moderate insufficiency (regurgitant fraction of 28%). Cath lab hemodynamics revealed RV pressure 75% of systemic with a 39 mmHg gradient from RV to PA. The homograft was heavily calcified and measured 16.4 mm at its narrowest. After stenting of the coarctation, the homograft was pre-stented with a 4010 Palmaz XL stent and post-dilated using a 16 mm followed by an 18 mm Vida balloon. This resulted in a small contained conduit tear. Placement of two 18 mm Melody™ valves was unsuccessful in covering the tear, which only expanded (Figure 1). The tear was then embolized using one MReye 35-14-12 and four Nester 35-14-10 embolization coils with complete resolution. Follow up CT scan showed no further extravasation or aneurysm formation.

Conclusion: Coil embolization should be considered as a therapeutic option to treat conduit rupture, particularly when other modalities fail or are unavailable.

Figure 1. Conduit rupture post Melody implantation (A & B) and after coil embolization (C).



**#0096
TRANSCATHETER AORTIC VALVE REPLACEMENT IN YOUNG PATIENTS WITH CONGENITAL HEART DISEASE**

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Background: Patients with congenital heart disease (CHD) often require multiple operations early in life, increasing their risk with each additional surgery. TAVR can be an attractive alternative to surgical

aortic valve replacement.

Methods: Retrospective review of patients with CHD who underwent TAVR at our institutions.

Results: A total of 6 pts underwent TAVR between 5/2013–5/2015 (Table 1). Each had a different form of CHD. Indications included AS in 1, AI in 2, and mixed AS/AI in 3. All were high risk for surgery: poor LV function (3/6 pts) ± multiple previous sternotomies (mean 3.5, range 1-5). Mean sheath time was 125 mins (63-234), mean fluoro use was 23 mins (11-51). Percutaneous approach was utilized in all (femoral in 5 and jugular vein in 1). AS gradients fell from 44mmHg to 6mmHg (p<0.05). Average length of stay was 2 days (1-4). Mean follow-up was 6 months (1-23). All had ≤ mild AI, 5/6 had ≤ mild AS, and all had sustained resolution of prior symptoms. Complications included a femoral arterial dissection requiring surgery in 1.

Pt	Diagnosis	Age	Wt (kg)	Indication	Valve Type
1	HLHS s/p Fontan, neo-AI	8.7	23.5	AI	22mm Melody
2	DORV, d-TGA s/p ASO, AVR	11.5	38.9	AS, LV dysfxn	23mm Sapien 3
3	Shone's, s/p arch repair, MVR, AoV balloon	14	36.3	AS/AI, LV dysfxn	22mm Sapien XT
4	AVSD s/p repair, sub-AS repair, AoV/MV plasty	17.8	69.1	AS/AI	23mm Core valve
5	d-TGA s/p ASO	25.7	59	AI, LV dysfxn	29mm Core valve
6	Bicuspid AoV	25.2	70	AS/AI	29mm Sapien XT

Conclusion: To our knowledge this is the largest series to date reporting the use of TAVR in young patients with CHD. AS and AI were successfully treated in all patients regardless of underlying diagnosis. TAVR can be performed safely in carefully selected patients with CHD and may reduce the need for repeat surgical valve replacements. Collaboration with surgeons and interventionalists with TAVR experience is key. Longitudinal follow-up studies are needed to determine long-term outcomes.

**#0097
TRANSCATHETER FONTAN FENESTRATION CLOSURE WITH THE GORE HELEX SEPTAL OCCLUDER IN 21 PATIENTS**

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Background: Persistent fenestrations in the Fontan pathway can result in hypoxemia and/or paradoxical embolization. The Gore Helix Septal Occluder can be used for transcatheter fenestration closure, but its use has not been extensively reported.

Methods: We retrospectively reviewed all patients who underwent attempted transcatheter Fontan fenestration closure using the Gore Helix Septal Occluder at our center from 2007 to 2011.

Results: 21 patients underwent attempted Fontan fenestration closure with the Gore Helex Septal Occluder with a median age of 5.5 yrs (3.7-33.1) and weight of 17.2 kg (14.3-79). 17 (81%) patients had undergone extracardiac Fontan operation, while 4 (91%) had a lateral tunnel Fontan. 19 (90%) patients underwent fenestration closure for hypoxemia and 2 (10%) for cerebral paradoxical embolic event. A 15mm device was successfully placed in all 21 patients. A femoral venous approach was used 20 (95%) patients and an internal jugular approach in 1 patient. 7 (33%) had additional transcatheter interventions performed during the procedure. The median fluoroscopy time was 31.1 min (9.4-70.5). After closure, the median aortic saturation increased from 86% (76-91) to 96% (89-99), median Fontan pressure increased from 11 mmHg (8-16) to 13 mmHg (9-17), and median mixed venous saturation was unchanged (pre=67% (52-74), post=67% (56-80)). No major complications occurred and obstruction of Fontan pathway was not observed in any patient. Complete occlusion of the fenestration was noted in all patients either at time of catheterization or by follow-up echocardiogram or clinical saturation.

Conclusions: Transcatheter Fontan fenestration closure with the Gore Helex Septal Occluder is safe and effective. The 15mm device is very low-profile and unlikely to lead to Fontan pathway obstruction.

#0098

COOPERATIVE APPROACH TO ASD CLOSURE AT A SINGLE INSTITUTION

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Background: Patients with a secundum atrial septal defect (ASD) and volume loading need closure of their defect. With current technology, patients and physicians have a choice between surgical closure or device closure. The exact criteria for determining which approach to take is still being defined. We present our experience utilizing a cooperative approach to optimize decision-making when planning closure of an ASD.

Methods: This is a 10-year single center retrospective review of all the secundum ASD closures from October 2003 through December 2014. The IRB of the participating center approved this study. Once it was decided that the patient required closure of the secundum ASD, the patient was evaluated by The Heart Center physicians (including pediatric and adult congenital cardiologists and congenital heart surgeons) for device closure or surgical closure. Transthoracic echocardiograms (TEE) were performed by the primary cardiologist before discussion. The group bias is for device occlusion if possible. If device occlusion was questionable by surface echocardiogram then evaluation in the cath lab with TEE was planned. Patients were scheduled for possible device closure with the surgical team on backup. The categories which were evaluated to determine the closure method were ASD size and adequacy of the rim tissue, and ASD size relative to the atrial size. An ASD > 32-34mm was expected to have a balloon size too large to close with a device. If there were adequate margins on the superior, inferior and posterior sides then the patient was considered be eligible for device closure.

Results: A total of 225 patients had secundum ASD closure with 141 patients in the device closure group, 65 patients in the surgical group and 19 patients who went to the cath lab for further ASD evaluation and were determined to be surgical candidates. Of the 19 patients

taken to the cath lab under the dual approach; there were 6 attempted device occlusions. The mean age (SD) for the device group was 22.3years(20.8), 5.4years(5.6) for the surgical group and 8.9years(7.3) for the third cohort (p<0.001). The mean length of hospital stay was 0.98 days(0.15) for the device group, 3.56 days (6.3) for the surgical group, and 2.53(0.7) days for the third cohort (p<0.001). The mean size of the primary ASD was 11.7mm(5) for the device group, 15.81mm(7.4) for the surgical group and 16.11mm (5.5) for the third cohort (p<0.001). The procedural attempt success rate was 95.9% for the device group and 100% for the surgical group. The immediate and follow-up success rates were 96.4%, 98.5% respectively for the device group, 98.4%, 100% for the surgical groups and 94.7%, 100% for the third cohort (all p>0.05). Major complication rate was 1.4% for the device group and no major complications in the surgical group. The minor complication rate was 2.1% for the device group and 16.7% for the surgical group. There were no deaths with any of the groups.

Conclusions: Appropriate patient selection is an important factor for successful secundum ASD closure. We determined our cooperative approach has benefits to the patient including avoiding multiple anesthesia inductions as well as improved patient and family experience as the patient will have their ASD closure during that single visit.

#0100

EXTENSIVE EXPERIENCE WITH TRANSHEPATIC CARDIAC CATHETERIZATIONS FOR CONGENITAL CARDIOVASCULAR DISEASES IN CHILDREN

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Objective: To describe our extensive experience with transhepatic cardiac catheterizations for congenital heart disease in a large cohort of patients.

Background: The feasibility, repeatability, and short term safety of transhepatic cardiac catheterizations have been previously described. To our knowledge there are no reports of results of transhepatic cardiac catheterizations in a large cohort of patients.

Methods: Demographic, catheterization and clinical data and success and repeatability rate were obtained from a retrospective chart review of all patients who underwent transhepatic cardiac catheterizations at St. Christopher's Hospital for Children between June 1, 2005 and May 31, 2015.

Results: 1281 diagnostic or therapeutic cardiac catheterizations were performed at our institution in that period. 52 (4%) procedures were performed via transhepatic approach. 34 (65%) procedures were performed in 23 patients with biventricular circulation and 18 (35%) procedures were performed in 10 patients with single ventricle. The median weight was 6.7 kg (3.2 to 34 kg). The indication for the transhepatic approach was no alternative venous access in 43 (83%) or preferred route despite presence of alternative venous access in 9 (17%). Multiple (2-5) transhepatic catheterizations were performed in 10 (30%) patients. Two (4%) patients had significant complications, which resolved without sequela. Two (4%) patients had transient AV block. Six (18%) patients died of unrelated causes. All other patients are clinically stable without sequela at the last follow up.

Conclusions: Transhepatic approach for cardiac catheterizations is reliable and relatively safe alternative for patients without alternative

venous access with complex congenital cardiac diseases or when this approach provides some advantage for the procedure. Transhepatic approach can be performed repeatedly and safely in small children sometimes requiring large venous access.

#0101

INTERMEDIATE FOLLOW-UP RESULTS OF AMPLATZER DEVICE OCCLUSION OF SECUNDUM ATRIAL SEPTAL DEFECTS

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Background: The purposes of this study is to document the results of Amplatzer Septal Occluder (ASO) closures of atrial septal defects (ASD) in a large number of patients with particular emphasis on intermediate-term follow-up in an attempt to provide evidence for feasibility, safety, and effectiveness of this method of ASD closure. Immediate and short-term results of ASO occlusion of ASD in children have been well documented, but intermediate and long-term follow-up data are limited.

Methods: During a seven-year period ending June 2011, 65 patients with secundum ASDs were taken to cath lab with intent to occlude the ASDs. Transcatheter closure of ASDs was performed in 61 (93.8%) with an Amplatzer Atrial Septal Occluder. The device size selection was based on the balloon diameter by using the stop-flow technique. In 3 patients, no attempt was made to occlude the PDA either because of inadequate posterior rims (n=1), inadequate length of atrial septum (n=1), or lack of surgical back-up (n=1). In 1 patient the device was unstable due to thin flail superior rim and was uneventfully retrieved out of the patient. The follow-up data review protocol is approved by the IRB.

Results: The ASDs measured 5.6-29.5 mm (mean 14) by TEE and 8.7-30 mm (mean 17.7) by using the balloon stop-flow technique. The ASDs were occluded with ASO devices measuring from 8 to 36 mm and were delivered via 7 Fr to 12 Fr sheaths. The Qp:Qs was 0.9-4.5 (mean 1.8). One patient developed 3° A-V block requiring implantation of a pacemaker. There were no other major complications reported (no device dislodgment, no aortic perforation and no thrombus/vegetation formation during follow-ups. Minor complications included arrhythmias (first and second degree atrioventricular blocks (n=7) and mild mitral (n=2) insufficiency detected by color Doppler echocardiography were transient and resolved after 15 months of follow-up. There was also transient trivalvular (n=13), or small (n=9) residual ASD shunt. There was a reduction of small shunts to trivial and trivial to no shunts after 15 months of follow-up. No recurrence of paradoxical embolism was observed in the 2 patients in whom the atrial defect was closed to prevent further episodes of cerebrovascular accidents and headaches.

Conclusions: This large, single-institution experience with long-term follow-up confirms the feasibility, safety, and effectiveness of Amplatzer device closure of the ASDs. Most of the ASDs, irrespective of type, shape, length, and diameter can be effectively closed with no major long-term complications.

#0102

ANTEROGRADE AND RETROGRADE CATHETERIZATION WITH THE MINIATURE PRESSURE-WIRE MANOMETRIC SYSTEM: AN EXCELLENT ALTERNATIVE FOR DIAGNOSIS IN CYANOTIC CHILDREN

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Introduction: Measuring intravascular pressures is crucial when studying congenital heart diseases. However, in children, conventional catheterization might be difficult due to tortuosity and size of the vessels. In cyanotic patients, the passing of a catheter through a shunt might lead to further cyanosis. We present our experience with the PressureWire Certus (St Jude Medical Inc) manometric system for diagnostic catheterization.

Methods: We studied 8 patients (pts) with cyanotic heart disease (mean age: 18 months and mean weight: 13kg). All procedures were performed under general anesthesia. All pts had univentricular physiology with a variety of associated conditions. 4 pts had Blalock-Taussig shunts. All pts were supposed to undergo a Glenn procedure in the near future but, even with 4 French catheters, it wasn't possible to access the pulmonary arteries. The miniaturized Pressure Wire system was the only way to get pulmonary pressure waves.

Results: We were able to acquire pulmonary pressures in all pts. The miniaturized system allowed easy passage through stenotic areas and aortopulmonary shunts without worsening of the cyanosis. There were no complications related to the procedure or the anesthesia.

Conclusion: The miniature Pressure-Wire manometric system presented itself as a good method for studying pts with complex cyanotic diseases in cases where access to pulmonary arteries was not possible by conventional means.

#0103

PERCUTANEOUS CLOSURE OF A PATENT DUCTUS ARTERIOSUS THROUGH THE JUGULAR VEIN IN A PATIENT WITH LEFT ISOMERISM

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Introduction: Pediatric catheter intervention has evolved with new devices, new delivery systems and mainly with the experience of operators. Therefore, patent ductus arteriosus (PDA) is almost always closed percutaneously. We report a case in which we bypassed an anatomic pitfall safely and effectively.

Case report: 14 months old girl presenting with tachypnea and low weight. Echocardiogram revealed a large PDA with left atrium and left ventricle overload. The inferior vena cava was not seen on subxyphoid view. In the cath lab, we confirmed absence of the inferior vena cava and venous drainage of lower body through the azygous vein to the superior vena cava. Aortographies were performed to show and measure the ductus. Through the right jugular vein we easily accessed the right ventricle, pulmonary artery, ductus and descending aorta. Over a stiff wire we introduced the Steer Ease 7 French sheath. We then delivered the Nit-Occlud PDA-R 7mm device. After the pro-

cedure, compression of the puncture site in the neck for 15 minutes was enough to stop the bleeding. No hematoma was formed. The whole procedure lasted 50 minutes and the fluoroscopy time was 10 minutes.

Conclusion: We routinely use the femoral vein for closure of PDA. However, in the event of venous thrombosis or anatomical variations, we showed that the jugular vein can be safely used.

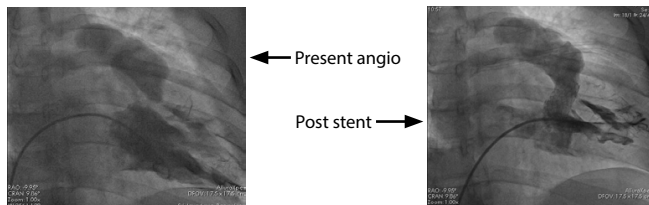
#0104

BAIL OUT RVOT STENTING IN A PREGNANT PATIENT WITH SEVERE ISOLATED INFUNDIBULAR STENOSIS

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A twenty one year old lady with seven months of amenorrhea was diagnosed first time to have heart disease and referred to our hospital. She had complaints of dyspnea on exertion on walking short distance. She had cyanosis with room air saturation of 86%. She had harsh ejection systolic murmur of grade 3/6 left second and third space. ECG showed RVH with RV strain. Echocardiogram showed dilated right atrium and ventricle with right ventricular dysfunction. There was a moderate size OS ASD with right to left shunt. There was severe infundibular stenosis with gradient of nearly 170 mmHg. Fetal echocardiogram was normal and fetal growth was adequate. She was planned for RVOT stenting keeping in my mind the hypoxemic effects on fetus and possibility of worsening RV failure in further weeks of pregnancy. Her abdomen was covered with a lead shield during the procedure. Right ventricle angiogram showed hypertrophied RV with severe infundibular stenosis. The lesion was crossed with 5 F Judkins right catheter with terumo 0.035 wire. A 2910 palmaz stent was mounted over a 14X40 atlas balloon and deployed across the RVOT. The right ventricle pressure fell down from 150 mmHg to 45 mmHg. The saturation after 24 hours was 92% and on follow up after 2 weeks was 95%. The fetal growth is satisfactory and she is symptom free. She has been continued on aspirin. She is due for delivery in first week of July.



#0105

SUCCESSFUL DEVICE CLOSURE OF PATENT DUCTUS ARTERIOSUS WITH TRANS-PULMONARY ECHOCARDIOGRAPHIC GUIDANCE WITHOUT CONTRAST ANGIOGRAPHY

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Background: Though contrast angiography is the standard guidance

of device closure of patent ductus arteriosus (DC-PDA), it is contra-indicated in patients with severe renal disease that often seen in senile patients. We have developed trans-pulmonary echocardiography (TPE) using ICE catheter placed in pulmonary arteries, main pulmonary artery (MPA) and left pulmonary artery (LPA), to guide DC-PDA (Cathet Cardiovasc Intervent 2015). We report 2 cases that successfully underwent DC-PDA without contrast angiography.

Materials and Methods: Subjects were 2 patients with PDA aged 48.5 and 71.2 years old. The sizes of PDA were 3.6 and 6.4 mm with Qp/Qs of 1.7 and 1.9, respectively. The older patient suffered from renal dysfunction. Prior to the DC-PDA, both patients underwent contrast X-ray computed tomography to clarify the anatomy. TPE was obtained by the ICE catheter at MPA and LPA that was inserted through 2nd sheath at femoral vein. During the DC-PDA, we primarily used TPE to guide the procedure and also decided to minimize contrast angiography as long as we could comfortably perform the procedure. In the second case, we additionally used CARTO system to help understand the orientation of cutting plane of TPE.

Results: We could successfully close both PDA without any contrast angiography. TPE at MPA view and LPA view worked very well to determine the diameter and length of PDA, to monitor the device placement, and to determine the residual shunts. TPE did not increase the risk of complication except for transient arrhythmia, though new operator needs some learning time to understand orientation of TPE.

Conclusion: TPE using ICE catheter can be the standard guide for DC-PDA, especially adult patients with renal dysfunction.

#0106

PERCUTANEOUS TRANSCATHETER CLOSURE OF VENTRICULAR SEPTAL DEFECT USING AMPLATZER DUCT OCCLUDER

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Objectives: Transcatheter closure of ventricular septal defect (VSD) has become a good alternative treatment option to surgery. However, complete atrioventricular block (CAVB) after device closure still remains a controversial issue. In our institute, Amplatzer Ductal Occluder (ADO; St. Jude Medical Corporation, MN) is used to close the defect, since the shape of ADO is suitable for perimembranous VSD with aneurysm, due to the anatomical resemblance, and the device has no right ventricular disc, which is presumed to be the contribution of development of CAVB. In this study, we show our results of transcatheter closure of VSD and the complications.

Methods: From Aug 2009 to Apr 2105, 39 patients underwent percutaneous closure of perimembranous and muscular VSD with ADO. We reviewed the medical records of the patients retrospectively.

Results: 15 male and 24 female patients underwent transcatheter closure of VSD. Of them, 24 patients had perimembranous VSDs and 15 patients had muscular VSDs. The median age was 6.6 years old (range 2.1-48.9 years old) and median body weight was 23 kg (range 8.0-75.7 kg). The mean shunt diameter was 4.6±1.7 mm and the mean shunt amount (Qp/Qs) was 1.6±0.3. The median fluoroscopy time was 23

minutes (range 4.6-133 minutes). The mean follow up duration was 21 months (range 1-69 months). The early and mid-term success rate was 92.3% (36/39). In addition, there was no CAVB except 1 transient atrioventricular block which disappeared in the lab, within 5 minutes. There were 3 cases with major complications: in 1 patient, immediate result was good but next day the device was embolized into descending aorta, which was retrieved through femoral artery; in 1 patient there was moderate residual leak and hemolysis through the device; in 1 patient the device was entangled in chordae of tricuspid valve during procedure. All 3 patients underwent surgical closure with no significant sequelae. There was no significant difference between types of VSD.

Conclusion: In selected case, transcatheter closure of VSD using ADO is safe and effective alternative treatment option for surgical closure. Especially we have no case of CAVB. However, long-term result may be needed.

#0107 INTERATRIAL SEPTUM THICKNESS IN PEDIATRIC PATIENTS AND ITS IMPACT ON CLOSURE OF INTERATRIAL SEPTUM DEFECTS WITH SELF-CENTERING DEVICES

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Aim: Some difficult ASD cases with deficient rims or large defects may require specific maneuvers to facilitate transcatheter occlusion of these defects with self centering devices. In our center we developed a modification of balloon assisted technique (BAT) for difficult ASDs to assist proper positioning of the device. Our aim was to demonstrate the efficiency of ASD closure with self-centering devices in children and its relation to the interatrial septal thickness.

Methods and results: Over 2 years, 65 patients with ASD secundum were referred for closure; from which 50 cases were suitable for transcatheter closure by transthoracic echocardiography during precatheter evaluation. In this study the IAS thickness of different rims were lesser than previously published ranges. Ten difficult defects required assisted techniques, where 6 of them were successfully closed using the pediatric version of BAT using a small sized valvuloplasty balloon.

Conclusion: This is the first paper to consider the delicacy and the easier giving in of the IAS in pediatric interventions that involve the IAS in the form of stretchability due to high elasticity or tearing of the thin IAS. Though the results showed weak relation to IAS thickness yet studying a larger number of patients might help prove the concept of weaker IAS in childhood. Modifying present techniques for closure of IAS defects and adopting newer techniques has to be considered. In this study the IAS thickness of different rims were lesser than previously published ranges (32). This difference can be explained by the fact that those patients had ASDs and were young in age. Agmon Y et.al.(14) found that age and body surface area (BSA) were significantly associated with IAS thickness (median: 6 mm; range: 2-17 mm). IAS thickness increased by 12.6% per 10 years of age (95% confidence interval: 9.0-16.4%) adjusting for sex and BSA, and increased by 7.0% per 0.1 m² BSA (confidence interval: 5.0-9.2%) adjusting for age and sex. They reported that age, sex, and BSA are responsible for 22.5% of the variability in IAS thickness. They concluded that IAS thickening is an age-associated process. Similarly, Galzerano D. et al., (1995) (18) re-

sults demonstrate that IAS thickness increases by age; no correlation exists between IAS thinning and age. They noted that at the time of ventricular end-systolic phase, the IAS thickness ranged from 4 to 13 mm (mean 6.7 ± 1.9 mm). On the other hand Schwinger ME et.al (32) reviewed results of 119 transesophageal studies to study the effect of age. They found that the thickness correlated weakly with the age of the patient. In the present work we could not reach any significant difference between the patients who needed assisting techniques and those who did not. To our Knowledge, this is also the first paper to consider the delicacy and the easier giving in of the IAS in pediatric interventions that involve the IAS in the form of stretchability due to high elasticity or tearing of the thin IAS. Though the results showed weak relation to IAS thickness yet studying a larger number of patients might help prove the concept of weaker IAS in childhood

#0108 PATHWAY TO INDEPENDENT INTERVENTIONAL PRACTICE: UGANDA HEART INSTITUTE PEDIATRIC CARDIAC CATHETERIZATION

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Background: Population statistics estimate 10,000 children are born each year with congenital heart disease in Uganda. Over the past decade, Uganda Heart Institute has developed a cardiovascular surgical program. A complementary cardiac catheterization program was started in February 2012 with the aim of developing independent operation after five years of mentorship.

Methods: A biplane X-ray cardiac catheterization lab was built adjacent to a new cardiovascular operating room. Uganda Heart Institute physicians, nurses, and technologists began training with government and non-governmental organization support toward independent operation. Innovative prospective five-year independence plan includes visiting in-country clinical service and training trips, encouraging autonomy through targeted case selection (diagnostic, balloon pulmonary valvuloplasty, patent ductus arteriosus device closure), out-of-country training fellowships, and weekly telemedicine case discussion/mentorship sessions.

Results: Since inception, Uganda Heart Institute has performed 139 congenital heart disease catheterization procedures [diagnostic (57); balloon pulmonary valvuloplasty (28); patent ductus arteriosus device closure (41); other (13)]. 24% are independent Uganda Heart Institute procedures (no international provider presence) with the goal of increasing each year [2013 (3); 2014 (17); 2015 (5months: 13)]. In-country clinical service and training trips have been conducted by five organizations [total n = 10; World Children's Initiative (4), Gift of Life/Chain of Hope (4)] traveling with physicians, nurses, and technologists. Uganda Heart Institute catheterization operators have trained at Amrita Institute of Medical Science and Research for 4 months observing and participating in 192 procedures. Weekly telemedicine

conferences (n = 39 months) have facilitated dialogue and education covering clinical case selection, planning, and review. Challenges impeding more rapid progress include streamlined inventory procurement, timely domestic hardware support, and expert support staff (anesthesia, intensive care) shortage.

Conclusions: Through mentoring, Uganda Heart Institute is progressing toward the goal of 100 annual independent cases.

#0109

PERVENTRICULAR MELODY VALVE PLACEMENT: RESULTS AND RECOMMENDATIONS BASED UPON INITIAL EXPERIENCE

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Objective: Perventricular Melody valve placement has usually been used as a bail-out approach in patients (pts.) who had failed attempted percutaneous placement. We used perventricular technique electively in a small group of patients who were not candidates for percutaneous approach. The objective of this study is to assess the feasibility, results and to offer recommendations for optimal outcomes.

Methods: The procedure was attempted in 5 patients. Pt. size precluded percutaneous approach in 4 and one patient had limited venous access that would not allow placement of large sheath. Tetralogy of Fallot was present in 3 and truncus arteriosus in 2. Weight ranged from 4.7- 28.1 kg. All pts. had at least 2 median sternotomies. Four pts. had RVOT conduits and one pt. had trans-annular patch. Conduit size ranged from 14 to 21 mm. All pts. had severe conduit regurgitation and 4 had moderate to severe stenosis. All pts. met criteria to undergo surgical valve placement. Procedures were performed in the hybrid cardiac suite. Transesophageal echocardiography (TEE) was used in 2 pts. in addition to fluoroscopy. The steps of the procedure were similar to the perventricular procedure for VSD closure except that this procedure was performed using sub-costal approach without sternotomy with the sheath introduced through the diaphragmatic surface of the right ventricle.

Results: Technical success was 100%. All pts. were pre-stented before Melody valve placement. In two pts. With absent pulmonary valve, the pre-stent migrated into the branch pulmonary artery during advancement of the delivery sheath for Melody valve. These stents were anchored in the branch pulmonary artery without any sequelae. Tricuspid valve chordal injury occurred in 1 pt. which resulted in moderate tricuspid regurgitation. This is one of the three pts. where TEE was not utilized. No pt. required conversion to cardio-pulmonary bypass. Follow up was available in all and ranges from 1 month to 3 years. All pts. were doing well at the last follow up.

Conclusions: Our initial experience demonstrates that perventricular pulmonary valve can be placed safely in small sized pts. Care needs to be utilized in pre-stented pts. to prevent stent migration. TEE should be utilized to ensure that tricuspid valve chordae are not being compromised. We conclude that the technique is feasible in small sized pts. and has steep learning curve.

#0110

WORLDWIDE EXPERIENCE WITH THE USE OF COCOON SEPTAL OCCLUDER FOR CATHETER CLOSURE OF ATRIAL SEPTAL DEFECTS. PROCEDURAL AND FOLLOW-UP RESULTS

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Introduction: Transcatheter closure of atrial septal defects (ASDs) is an established treatment modality but no current device provides an ideal solution. The Cocoon septal occluder (CSO) is a new device with certain design features that make it potentially attractive for closure of ASDs.

Methods: In this non-randomized worldwide multicenter study we investigated the safety and efficacy of the CSO for closure of atrial septal defects (ASDs) in 3254 patients (1575 children and 1679 adults). Median age of the patients was 13.5 years (range 2-68 years) and median weight was 28 kg (range 11-65 kg). The device is an improved new generation double disc design made of Nitinol wire mesh that is coated with platinum using NanoFusion technology. The discs are connected by a waist with diameter ranging from 6 mm to 40 mm with 2 mm increments. Mean echocardiographic ASD diameter was 21±7mm (range 14-35 mm), while the mean device diameter was 24±8 mm (range 17-40 mm).

Results: The CSO was permanently implanted in 3243 patients (99.6%). Two devices were implanted in 75 patients (2.3%). Complete echocardiographic closure of the defect immediately after the procedure or at the 3 month follow-up, was observed in 3232 patients (99.4%). 11 patients had a trivial residual shunt. Device embolization occurred in 9 (0.27%) patients with insufficient septal rims. No device-related erosions or allergic reactions were observed during a follow-up period that ranged from 6 – 70 months.

Conclusions: The CSO is a safe and effective device that adds to our

armamentarium for catheter closure of atrial septal defects in children and adults. Further studies are required document its long-term safety in a larger patient population.

#0111

NOVEL ACCESS TO THE NATIVE ATRIA FOLLOWING TOTAL CAVOPULMONARY ANASTOMOSIS

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Accessing the atria following total cavopulmonary anastomosis (Fontan) with the extra-cardiac conduit or intra-cardiac baffle can be a challenging task. Rare reports describing both per-thoracic access and conduit trans-septal puncture for a limited scope have been published. We present the use of these approaches for various therapeutic aims. Between 2009 and 2014, 5 patients ages 7 to 28 underwent one of these techniques; three per-thoracic and 2 trans-septal Fontan puncture (one lateral baffle and one extra-cardiac Fontan): 1. A 28 year old with lateral baffle Fontan and sick sinus syndrome underwent trans-septal puncture of the lateral tunnel via the superior vena cava for successful left atrial lead placement and pacing. This patient previously had a failed attempt at surgical placement of a pacing wire on pace receptive tissue. 2. Two patients ages 7 and 14 years with extra cardiac Fontan underwent per-thoracic access of the right atrium for device occlusion of a re-canalized left superior vena cava to the coronary sinus. This resulted in significant improvement of their saturations. 3. An 8 year old with an extra-cardiac Fontan and history of embolic stroke underwent per-thoracic access of the left atrium, thus providing a route for device closure of a patent native pulmonary artery. This was performed to reduce the risk of future embolic events. 4. A 27 year old with revised classic Fontan to an extra-cardiac Fontan, underwent trans-septal puncture of the conduit. This provided access to the native atria for ablation of incessant atrial flutter. All 5 cases were technically successful. Complications occurred in only one patient who had blood loss through a fractured sheath and required a blood transfusion. This patient also had temporary heart block, likely due to device placement, which self-resolved. Removal of the sheath following per-thoracic approach in all 3 patients was uncomplicated, with no difficulty achieving hemostasis with direct pressure.

Conclusions: Per-thoracic and trans-septal techniques are alternative approaches to provide access to the left and right native atria following total cavopulmonary anastomosis. These techniques may allow for therapeutic procedures which mitigate the need for further open heart surgery.

#0112

RIGHT VENTRICLE TO PULMONARY ARTERY (RV-PA) CONDUIT DISRUPTION DURING TRANSCATHETER PULMONARY VALVE REPLACEMENT (TPVR) AND THE PARCS* TRIAL. *PULMONARY ARTERY REPAIR WITH COVERED STENTS

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Introduction: On 1/25/2010 the Melody TPV was approved for replacement of the pulmonary valve for patients with CHD who have dysfunctional right ventricle to pulmonary artery conduits. RV-PA homograft conduits are frequently calcified and rigid. Dilatation of these conduits prior to TPVR, poses a significant risk of conduit tearing or rupture. The NuMED Covered Cheatham-Platinum Stent (CCPS) has been used in the prevention or treatment of aortic wall injury in coarctation of the aorta stent trial (COAST II) and during TPVR procedures into RV-PA conduits under Emergency Use (EU) or Compassionate Use (CU) conditions.

Aims: The aim of this study is to prospectively assess the effectiveness and safety of the NuMED Covered Cheatham-Platinum Stent (CCPS) for the treatment of RV-PA conduit disruption, occurring during cardiac catheterizations aimed at enlarging the conduit or making the conduit competent by the implantation of a transcatheter pulmonary valve.

Methods: PARCS has collected CCPS implant information on 50 prospectively enrolled patients with conduit disruptions from multiple institutions around the country between 1/1/2013 and 9/11/2014. Catheterization records and 6 months follow up visit data were collected. Outcomes of the valve implant associated with CCPS use were compared to the effectiveness and safety of the TPV implants without CCPS use.

Results: From January 2013 (1/1/2013) to September 2014 (9/11/2014), 50 patients received CCPS during TPV implant procedures. Patient age ranged from 6 to 44 years (median 17 years). 27 (54%) patients had TOF/PA and PA/IVS spectrums. 45 (90%) patients had pulmonary or aortic homografts, 2 had Contegra conduits, 2 had dacron conduits and the conduit was not specified in the remaining one patient. Conduit size ranged from 7 to 28 mm (Median 19 mm). 31 patients had pulmonary stenosis, 9 had pulmonary regurgitation and the remaining 10 had mixed disease. The mean preintervention minimum angiographic conduit diameter ranged from 5.1 to 20.5 mm (10.6 ± 3.2). 4 patients had pre-existing tears, and 46 patients developed tears during balloon dilations. Median largest balloon size used for dilation prior to tear recognition was 18 mm. The average ratio of the largest balloon prior to conduit tear to minimum conduit diameter ranged from 1.1 to 2.8 (1.8 ± 0.5). The average ratio of the largest balloon to initial conduit diameter ranged from 0.8 to 1.5 (1.0 ± 0.2). 42 patient had contained tears, 4 had partially contained tears and the remaining 4 had non-contained tears. Conduit tears were repaired by covered stents in 48 out of 50 patients. A total of 63 covered stents were used (single CPSS for 40 patients, two each for 7 patients and three each for the remaining three). After CCPS therapy, 4 patients developed new, small, contained peri-vascular leaks. 3 were left untreated without any sequelae and 1 leak was closed with Melody implantation. The mean pre-implant peak-to-peak RVOT gradient ranged from 5 to 96 mmHg (39.3 ± 17.1 mmHg) compared to 1 to 28 mmHg (10.85 ± 6.1) postimplant. One patient had somewhat serious CCPS related complication. On echo at 6 months, peak Doppler RVOT gradient ranged from 2-49 mmHg (21.88 ± 11.2) and mean gradient 4.5-23 mmHg (12.6 ± 5.4). Valve competence was maintained during follow-up, with no patients having more than no/trivial PR.

Conclusions: In this prospective multicenter study the CCPS was successful in treating RV-PA conduit disruption occurring during TPV im-

plant procedures without negatively impacting the function of the transcatheter valve. Small, constricted, and homograft conduits were found to be more prone to rupture.

#0113

TRANSCATHETER CLOSURE OF RUPTURED SINUS VALSALVA WITH LIFETECH SYMMETRICAL PERIMEMBRANOS VSD DEVICE

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13-year old female presented emergency room with chest pain when echocardiography performed sinus valsalva ruptured and moderated aortic insufficiency detected. When she was 4 years old operated from perimembranos VSD. 7 days ago she presented emergency room with chest pain. Echocardiography was shown 7 mm sinus valsalva rupture to Right ventricular and moderated aortic insufficiency. Ruptured valsalva was transcatheter closed with 10 mm Lifetech symmetrical perimembranos device. After the procedure sinus valsalva rupture closed completely and aortic insufficiency decreased. In conclusion ruptured sinus valsalva can be treatment transcatheter symmetrical perimembranos VSD device is an alternative to surgical treatment.

#0114

INITIAL EXPERIENCE OF CARDIAC CATHETERIZATION ON ECMO SUPPORT

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Background: Extracorporeal membrane oxygenation is an important support for the failing circulation. There are diagnostic and therapeutic indications for cardiac catheterization in children on ECMO.

Objective: To report our experience in patients who underwent cardiac catheterization on ECMO.

Case Reports: Four catheterizations were performed in 3 patients on ECMO. The main indication for cardiac catheterization was evaluation for possible pathology amenable to transcatheter or surgical therapy (n = 3) and planned transcatheter intervention for known pathology (n = 1). Patient 1 had interrupted aortic arch, aortic arch hypoplasia and aortic valvar and subvalvar stenosis. He underwent a Damus-Kay-Stencel (DKS) procedure. He developed severe biventricular dysfunction and was subject to ECMO. Patient had not improved, which led to the takedown of the DKS, performing enlargement of the ascending aorta and PT banding. He failed several attempts of weaning from ECMO and was referred to a diagnostic catheterization that showed stenosis of the origin of the pulmonary arteries. The team decided to correct it in surgery but he had gotten worse and was sent to cath lab again after 4 days. Balloon angioplasty of the right and left pulmonary arteries were successfully performed. Patient 2 was a 3-year-old patient who had Hypoplastic Left Heart Syndrome and just had a Fontan completion with poor outcome. He had the Fontan takedown. Because of the deterioration of his hemodynamics and oxygenation status, ECMO support had begun. Patient was referred to the cath lab where collateral systemic-pulmonary

fistulae from the internal thoracic arteries and mediastinal vessels of moderate intensity were embolized, resulting in a significant reduction of these flows. Patient 3 was a 2-months-old male who had had biventricular failure after corrective surgery for tetralogy of Fallot and AVC. Left pulmonary artery hypoplasia was demonstrated.

Conclusions: Cardiac catheterization requires careful consideration of procedural location, transport, and vascular access. It can be performed safely on patients with ECMO support. Catheterization during ECMO enables the diagnosis and treatment of residual lesions, helping the improvement of the patient condition.

#0115

TRANSCATHETER THERAPY FOR ACUTE OCCLUSION OR CRITICAL STENOSIS OF EXTRACARDIAC CONDUITS AFTER FONTAN COMPLETION

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Introduction: The extracardiac conduit has been largely used for completion of the Fontan operation in children with univentricular hearts. Acute occlusions of this pathway are life threatening and need to be promptly recognized and treated to provide better chances of survival in this population.

Method: We report the percutaneous therapy in three critically ill patients with evidence of acute obstruction of extracardiac conduits. Patient 1 was a 3-year-old male with pulmonary atresia with intact ventricular septum. Patient 2 was a 5-year-old male with hypoplastic left heart syndrome. Patient 3 was a 3-year-old female with double-outlet right ventricle and non-committed VSD. They had all undergone Fontan palliation and had all presented with abdominal pain, vomiting and low output syndrome symptoms at the ER. Thrombolytic therapy was attempted without success in one of them. Total occlusion of the fontan pathway beginning at the suprahepatic veins level was seen at the Cath Lab in all three cases. A 0.014 guide-wire was advanced through the occlusion in all cases and thrombus aspiration was performed in 2 of them. Stent placement into the conduit was performed in all cases. Unobstructed flow into the conduit was achieved in all 3 cases. Patient 1 had a Palmaz Genesis 2910 stent placed into the conduit and balloon angioplasty of the upper side of the conduit with the same 15x40mm Maxi-LD balloon. Balloon dilation of the left pulmonary artery was performed with a 10x20mm powerflex balloon. He died after 5 days from hepatic failure and brain hemorrhage. Patient 2 had undergone stent implantation into the left pulmonary artery and the fontan pathway a couple of months before. There was total occlusion of the fontan pathway where the stent was placed. Balloon angioplasty of the conduit stent was performed with a 12x20mm powerflex balloon and a Palmaz Genesis 1910 stent was placed in the junction of the conduit with the pulmonary artery. Patient 3 had a Palmaz Blue 7 x 18mm stent implantation into the left pulmonary artery and two Palmaz Genesis 2910 stents were placed into the conduit. Both patients demonstrated rapid improvement in their clinical status after the procedure, were extubated at the same day and are doing well, asymptomatic, 18 months after the procedure.

#0116

UNZIPPING OF SMALL DIAMETER STENTS AS A MANAGEMENT STRATEGY FOR NEONATAL COARCTATION OF THE AORTA IN A GROWING SWINE MODEL

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Background: Surgical repair for critical coarctation of the aorta (COA) in the neonate is favoured over trans-catheter therapies. Small diameter stent (SDS) implantation may be effective in relieving the stenosis acutely in this situation. However, the circumferential size of SDS implanted in a neonate does not adapt to the growth of the vessel leading to refractory stenosis in the future. If stents can be longitudinally fractured – unzipped, using angioplasty balloons, it can be re-dilated to the eventual adult vessel diameter as the child grows. The VeriFLEX and the Express stents were found to be most feasible and safe to unzip in a previously conducted in vivo experiment. The objective of this study was to determine the long term effects of using SDS to treat coarctation of the aorta in new-born piglets that would eventually be unzipped as the pig grows to adulthood.

Methods and Results: COA was surgically created in 10 new born piglets (Median weight 2.4 Kg). A poly-ethylene terephthalate band was applied in 5. Excision of half the aortic wall followed by application of a constricting suture was used in the other 5. A cardiac catheterization performed 4 weeks later (median weight 5.8 Kg), in 8 of the surviving piglets demonstrated significant angiographic stenosis and a peak systolic gradient of 34 ± 8 mmHg in both models. The stenosis measured 4 ± 1.5 mm. The COA was treated with implantation of a 4mm VeriFLEX stent in 5 piglets and a 6mm Express stent in 3 piglets. Repeat catheterization was performed when the piglets were 26 ± 6 Kg. Re-stenosis with a peak systolic gradient of 18 ± 12 mmHg was treated by dilation of the stents till they unzipped with no residual gradient. All stents unzipped without any complications. Four piglets were euthanized to determine the acute effects of stent unzipping. Re-catheterization was performed on the rest at 54 ± 8 Kg with further angioplasty or implantation of a large stent (Palma XL) to treat any residual stenosis. The medial dissection score on HP microscopy was 1 ± 0.8 acutely and 0.5 ± 0.5 in the chronic model.

Conclusions: It is feasible to implant a small diameter stent to treat coarctation of the aorta in new-born piglets. It is feasible and may be safe to unzip these stents without significant vessel wall injury. Unzipping of stents allows for future re-dilation or re-stenting with a large diameter stent preventing residual stenosis.

#0117

X-RAY FUSED WITH MRI (XFM) GUIDANCE OF TRANSCATHETER INTERVENTIONS IN CONGENITAL HEART DISEASE: PRELIMINARY RESULTS

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Background: Interventional cardiologists are pursuing increasingly complex catheter based intervention. Fusion imaging provides soft tissue context that may simplify interventional procedures, reduce radiation exposure, and decrease contrast burden.

Methods: We prospectively recruited patients referred for transcatheter device implantation. Radiation and contrast exposure for X-Ray Fused with MRI (XFM) cases was compared to intervention matched cases from our preceding 10 year institutional experience and Likert scale operator assessments of value were recorded.

Results: From 11/2013 to 5/2015, 20 patients were enrolled. Cardiac MRI data indicated intervention should be deferred in 5 patients, and XFM guidance was performed in 15 patients [median age 10.6 years (2.5–62 years); median weight 47 kg (13–104 kg)] with the following indications: pulmonary artery (PA) stenosis (n = 7), conduit stenosis/insufficiency (n = 3), aortic coarctation (n = 3), and ventricular septal defect (n = 2). Diagnostic cardiac catheterization data showed intervention was not indicated in 4 cases. Interventional XFM cases (n = 11) had shorter mean fluoroscopy times, and lower mean contrast dose than controls. Operators reported XFM was never misleading, "strongly agreed" or "agreed" that XFM soft tissue data was additive in all cases and may have allowed for omission of traditional angiography in 6 cases.

Conclusions: XFM can reduce radiation exposure and contrast dose by providing operators with useful soft tissue data in selected congenital heart disease interventions.

Case Type Results: mean value (range)	PA balloon or stent angioplasty		Coarctation balloon or stent angioplasty		Ventricular septal defect device closure	
	XFM n = 6	Control n = 142	XFM n = 3	Control n = 74	XFM n = 2	Control n = 26
Fluoroscopy time (min)	24 (13-44)	42 (9-154)	11 (8-14)	22 (7-100)	40 (21-59)	43 (17-170)
Contrast (ml/kg)	4.2 (2.6-5.6)	5.9 (0.2-22)	2.6 (0.9-5.7)	3.8 (0.8-11)	2.2 (1.0-3.3)	7.0 (1.2-13)

#0118

CLINICAL EVALUATION OF A RADIO-PROTECTIVE CREAM FOR THE HANDS OF THE PEDIATRIC INTERVENTIONAL CARDIOLOGIST

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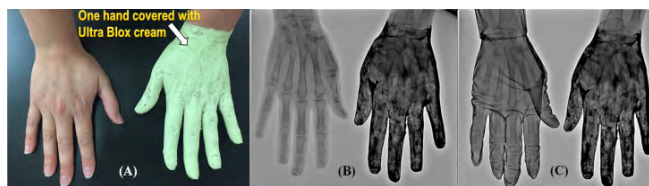
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Background: The hands of interventional cardiologists receive high doses of scatter radiation due to their proximity to the X-Ray beam. Radiation attenuating gloves have about a 26% attenuation rate, but may reduce dexterity and tactile sensation. The UltraBLOX™ is a new FDA approved X-Ray attenuating cream that can be applied to the operator's hands for radio-protection (Figure). The aim of this study was to evaluate the effectiveness of this cream during lengthy cardiac catheterization procedures in children.

Methods and results: Two nanoDot™ dosimeters were secured side by side on the dorsum of the operator's (n=2) left hand close to the wrist. One dosimeter and the rest of the hand were covered with 0.2 mm layer of the cream. The other dosimeter was unshielded. Procedures were performed using 110 kVp fluoroscopy at 15 pulses/sec. Four time categories were analysed for differences in attenuation. The patients in all 4 groups were well matched for age and size. Procedural and cumulative hand radiation doses were higher with longer procedural duration. The overall % attenuation by the cream was 39.7% (28.6 - 51.5) and was not affected by the length of the procedure (median: 40.9% at 30 min and 41.4% at 180 min; p=0.66) or the dose of radiation. The kappa statistic for inter observer agreement for good tactile sensitivity was 0.82.

Conclusions: The UltraBLOX™ provides a new option for radio-protection for the hands of interventional cardiologists without impairing tactile sensitivity. The attenuation afforded did not reduce up to 180 min.

Figure (A) UltraBLOX™ cream shielding the left hand. (B) Fluoroscopy of the operator's hands: the left hand is shielded by the cream while the right hand is unshielded (C) The left hand is shielded by the cream; the right hand is shielded by a radiation attenuating glove.



#0119

ULTRASOUND-GUIDED FEMORAL ARTERIAL ACCESS IN PEDIATRIC CARDIAC CATHETERIZATIONS: PREVALENCE AND RISK FACTORS FOR ACUTE LOSS OF ARTERIAL PULSE - A PROSPECTIVE SINGLE CENTER COHORT STUDY

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Objective: The objectives of this study was to describe the prevalence of and identify risk factors for acute loss of arterial pulse (LOP) in children who had ultrasound guided femoral arterial access (UGFAA) during cardiac catheterization procedures.

Background: LOP is a known complication in children following arte-

rial access for cardiac catheterizations. The prevalence of LOP requiring treatment when UGFAA is not employed in ranges between 4% and 8% in most studies. Younger age has been the most consistent risk factor identified for LOP in most studies.

Methods: A prospective study was performed including 486 cardiac catheterizations using UGFAA in children (≤ 18 years) over a 20 months period. Ultrasound and Doppler evaluation were performed prior to and at the end of the procedure. Treatment was initiated for the presence of thrombus or with absence of Doppler pulsations an hour post-procedure. Multivariate analysis was performed to identify independent risk factors for LOP.

Results: LOP was identified in 33 cases (6.8%) with 23 (4.7%) requiring treatment. Femoral artery thrombus was diagnosed in 9 patients (1.8%). For children ≤ 6 months the incidence of LOP was 22% with 13.6% requiring treatment. Though Age ≤ 6 months and weight ≤ 5 Kg were strong predictors for LOP, a femoral artery diameter of ≤ 2.2 mm was the only significant independent predictor for LOP (OR = 3.8, 95% CI: 1.8 - 8.8, P = 0.002). Number of access attempts, time required for access, operator experience, sheath size, sheath exchanges, activated clotting time, hemoglobin, cardiac output, procedure length, etc., were not found to be significant factors.

Conclusions: The overall incidence of LOP requiring treatment of 4.7% is similar to reports where UGFAA is not used. A femoral artery diameter of ≤ 2.2 mm was the only significant independent predictor for LOP in this carefully designed prospective study.

#0120

GROWTH CURVES FOR FEMORAL VEIN AND ARTERY IN CHILDREN UNDER FIVE YEARS OF AGE

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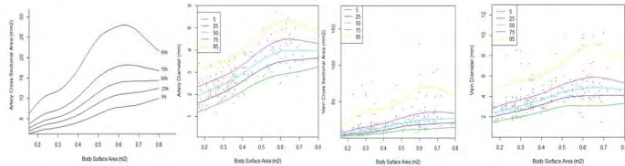
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Background: The femoral vein (FV) and artery (FA) are the most common vessels used for catheter access in children. However, nomograms based on the sex, race, age or size of children are not available at present. This knowledge, however, may be of fundamental importance for pediatric interventional cardiologists who use these vessels to perform complex interventions, requiring large catheter and sheath sizes. The objective of this study was to construct growth curves for FV and FA in children ≤ 5 years of age.

Methods: A prospective study was performed on 400 children with congenital heart diseases ≤ 5 years of age undergoing cardiac catheterization procedures over a 20 months' period. Patients who had previous cannulation of these vessels were not included in this study. Ultrasound evaluation was performed under anesthesia just prior to obtaining access on both the right and left femoral vein and artery. The diameter and the cross sectional area of these vessels were measured at a level just proximal to the bifurcation of the common FA. Regression modeling was applied to derive the growth curves based on quantile polynomial regression, which yielded good fit to the data judged by R-squared and the LMS transformation method was used to determine the smoothed percentile.

Results: Growth curves were constructed for the diameter and CSA of the FA and FV against patient age and body surface area (BSA). Distinction for sex and race was not made secondary to the small sample size. Only the right femoral vein and artery was used for analysis. The Figure below illustrates the findings.



Conclusions: It is now possible to predict the normal diameter of the femoral vein and artery, and these nomograms may help with planning an interventional procedure. Future studies with larger sample size may be useful.

#0121

9 YEARS SINGLE-CENTER EXPERIENCE IN HYPOPLASTIC LEFT HEART SYNDROME CARDIAC CATHETERIZATION

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Introduction: Hypoplastic left heart syndrome (HLHS) patients are more likely to have catheter interventions as the prognosis of this condition has improved over the years. Various transcatheter procedures can be performed in order to access the hemodynamic and morphological status and to ameliorate the patient condition. We reviewed our institutional experience of transcatheter cardiac catheterization in HLHS patients.

Methods: Retrospective review of all HLHS patients who underwent cardiac catheterization since 2006 in our institution.

Results: A total of 273 operations were performed in 162 patients with HLHS. Forty percent of those patients (66 patients) had a total of 209 transcatheter procedures (diagnostic or therapeutic). Twenty procedures were performed after the first stage of palliation (post-norwood) (9.5%), at the mean age of 7.4 ± 3.6 months, 139 were after second-stage (post-Glenn) (66.5%) at the mean age of 2.2 ± 1.6 years and 50 procedures were after third-stage (post-Fontan) (24%) at the mean age of 6.3 ± 3.2 years. Procedures were more commonly performed in patients after second-stage (66.5%) compared to patients after other stages ($P = 0.016$). Similarly, interventions were more commonly required in patients after second-stage (65.3%) ($P = 0.042$). Fifty-two patients (78.9%) needed 78 therapeutic interventions. Interventions performed included collaterals arteries embolization= 64%, pulmonary arteries stents = 18%, venovenous channels embolization= 4%, balloon PA angioplasty = 4%, aortoplasty using balloon or stent = 4%, stent or balloon fenestration opening = 2%, occlusion of fenestration = 2%, venous system stent placement = 2%. Median number of procedures/patient was 3.16 ± 1.88 (range 1-10). Median number of intervention/patient was 1.5 ± 1.3 (range 1-5). Most of the procedures (72%) were performed after 2010.

Conclusion: The optimal treatment of patients with HLHS is a process

in evolution. Transcatheter procedures are commonly required and contribute for the success of the palliation. Most commonly we have performed diagnostic catheterizations and interventions after the second-stage of the treatment, preparing the patient for the Fontan procedure.

#0122

CONTINUOUS DIALYSIS DURING INTERVENTIONAL CARDIAC CATHETERIZATION IN PEDIATRIC PATIENTS WITH SEVERE RENAL FAILURE

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Introduction: Interventional catheterization (cath) may be needed for pts with severe renal failure requiring dialysis. In these pts, long complex caths pose a challenge due to high contrast load and risk of electrolyte disturbances and fluid overload. There are no reports of continuous renal replacement therapy (CRRT) or peritoneal dialysis (PD) during caths.

Methods: retrospective review of intra-procedural CRRT or PD during caths from 2013-15.

Results: 4 pts in severe renal failure (3 in chronic renal failure; 1 in acute renal failure with concomitant chronic liver failure) were dependent on CRRT (n=3) and PD (1). 3 had systemic vein thromboses referred for recanalization & stenting, of which 2 were being denied renal transplantation due to severe and widespread venous thromboses. 1 had aortopulmonary collaterals referred for embolization, which were precluding listing for liver transplant. CRRT (3) and PD (1) were performed with dialysis team present in cath lab throughout the entire cases. Median (range) weights and ages were 36 (11.4-62.6) kg and 8.5 (8 months-17 years) yrs. Procedure time was 474 (220-651) min, and fluoroscopy time was 111 (65-142) min. Total contrast dose was 4.7 (3.5-7.9) cc/kg. Intended cath interventions were successful in all 4. 1 pt had cath complications (vena cava tear and liver hematoma, both successfully treated). There were no complications related to CRRT or PD, and no contrast or fluid-related complications. All 3 pts needing transplants were listed after interventional cath, and all 3 received organs, of which 1 died after renal transplant.

Conclusion: Pts with severe renal failure and significant cardiovascular morbidities need not be denied complex interventional caths due to concerns regarding fluid-overload or contrast-related complications. In some pts, listing for organ transplantation may be dependent on ability to perform a cath intervention. Radiographic contrast is freely dialyzable using CRRT or PD, and both modalities can be instrumental in removing excess fluid administered at cath, especially in anuric patients. We demonstrate safety and feasibility of performing long and complex cath procedures while providing intra-procedural CRRT or PD, even in young children. Close collaboration between nephrology, cardiology, and the dialysis team is necessary for management of this challenging patient population.

#0123

DISCREPANCY BETWEEN TRANSTHORACIC AND

TRANSESOPHAGEAL ECHOCARDIOGRAPHY EVALUATION OF ATRIAL SEPTAL DEFECTS IMPACTS THE CATHETERIZATION PROCEDURE

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Introduction: Percutaneous closure of atrial septal defects (ASDs) is reliant on appropriate anatomy, traditionally evaluated by both transthoracic and transesophageal echocardiography (TTE and TEE respectively). The inherent discrepancy between TEE and TTE has been incompletely described.

Methods: The primary objective of this study was to examine instances in which more than one ASD device was attempted prior to procedural completion to determine discrepancies between TTE and TEE assessment. In addition to overall ASD dimension, the following ASD rims were measured: inferior, posterior, anterior-inferior, anterior-superior (ie retroaortic), superior, and right upper pulmonary vein. The ratio of the device left atrial (LA) disc diameter to overall defect diameter (by TEE) was noted for each case.

Results: 116 patients underwent a pre-procedure echocardiogram. A total of 18 patients had >1 ASD device attempted prior to procedural completion, with 4 patients having different device type (Hexel to ASO, eg) and 14 patients having similar device type, but different size. All patients had only a single ASD and therefore no patient had more than one ASD device implanted at procedural completion. In comparing TTE to TEE rim measurements for the entire cohort, the right upper pulmonary vein rim ($p=0.02$) and posterior rims ($p=0.02$) were larger on TEE by 25.7% and 10% respectively. On the other hand, the anterior inferior ($p=0.01$) and inferior ($p<0.01$) rims were smaller by 13.4% and 17.2% on TEE. However, the overall defect size was comparable between TTE and TEE ($p=0.79$). Interestingly, there were no significant differences in individual ASD rim assessment between TTE and TEE in those cases where >1 ASD device was attempted. In cases with >1 ASD device attempt, the ratio of the initial LA disc to defect size was smaller at 1.91, compared with 2.27 for the cohort with only a single ASD device attempt. Ultimately, the cohort with >1 ASD device had a final ratio of 2.24.

Conclusion: Careful pre-assessment should be undertaken with the understanding that TEE provides a more reliable evaluation of atrial septal anatomy. Importantly, pre-procedural counselling should take into account an expected discrepancy between the two imaging modes and the potential procedural impact on ASD device occlusion.

#0124 IDENTIFYING GAPS IN TECHNOLOGY FOR CONGENITAL INTERVENTIONS: ANALYSIS OF A NEEDS SURVEY FROM CONGENITAL INTERVENTIONAL CARDIOLOGISTS

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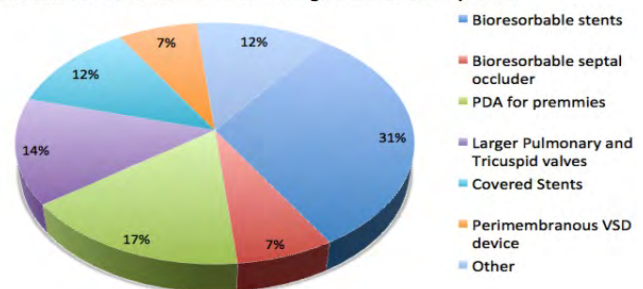
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There is an evolving need for modification and development of devices and equipment dealing with congenital heart lesions. We carried out a device-needs survey to evaluate gaps in device and equipment availability inside and outside the US. The survey was sent out via e-mail to members of the CCISC and the SCAI with a reach of over 350 congenital interventionalists. The survey consisted of 16 questions. Responses were received from 68 cardiologists in 8 countries, 90% from inside the US. In terms of the most desired devices, 25 respondents (37%) ranked bioresorbable stents as their first choice from a list of 12 possible devices. Similarly, 14 participants (21%) ranked large covered stents as their first choice. Respondents predicted that annual bioresorbable stent usage for pulmonary artery stenosis and aortic coarctation is expected to average at 27 and 20 stents per year respectively and 82% of participants indicated the most commonly required bioresorbable stent diameter to be between 6-10mm. Bioresorbable stents for coarctation were expected to be larger, with 40% of participants suggesting the most commonly used bioresorbable diameter to be 10mm. For PDA stenting, 71% participants indicated a required stent diameter between 4 and 6mm, and 32% of respondents identified a preferable stent length of 20mm. Bioresorbable materials, nitinol and stainless steel were equally identified by interventional cardiologists. 64% of all participants reported that a 4 Fr sheath size as the maximum size desired for PDA stenting. As for covered stents, 33% of all respondents indicated the maximum diameter for a large covered stent as 30mm with the most requested length being 40mm (36%). The number of large covered stents needed annually at different institutes varied from 0-40 with the highest numbers being 10 stents per year (26%) followed by 20 and 40 stents per year (11% each). Participants were also asked which new or modified device would affect the greatest number of their patients with results outlined in Fig1. These data clearly point towards a need for the development/approval of pediatric bioresorbable stents, and the need to approve the use of large covered stents in the pediatric age group in the USA.

New or Modified device that would affect greatest number of patients



#0125 PERCUTANEOUS ANGIOPLASTY AND STENT INSERTION ON RCA IN ASYMPTOMATIC 11 YEAR-OLD CHILD WITH 3 CORONARY VESSELS STENOSIS AFTER KAWASAKI DISEASE

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Kawasaki disease is an acute vasculitis of childhood that affects the coronary arteries and has rare long-term complication of coronary aneurysm stenosis. We report a case of patient, who had giant coronary aneurysms and stenosis of 3 coronary arteries and undergone PTCA and stent insertion on RCA. This 4 years-old boy transferred to our hospital for aggravating coronary aneurysms with diagnosis of Kawasaki disease. He did not show any clinical symptoms such as fever and chest pain. Normal sinus rhythm and no ST segment change were presented on electrocardiography (ECG) and also no significant finding on Tc-99m myocardial SPECT (MIBI) study was showed. On the initial coronary angiography, multiple fusiform aneurysms in RCA and proximal giant aneurysm (diameter 12mm) in proximal LAD were found (Figure 1). He has taken anticoagulant medications (Warfarin, Clopidogrel) and regular ECG, echocardiography, chest radiograph were followed up from diagnosis of Kawasaki disease. Subtotal occlusion of proximal LAD were detected on the heart computed tomography (CT) 4 years after diagnosis. Close observation was decided, because he had no coronary symptoms, normal ECG finding, uneventful result in the tread-mill test and well-developed collateral vessels of the coronary arteries were seen in the coronary angiography. When he was 12 year-old 8 years after diagnosis, scheduled heart CT revealed total occlusion in the proximal giant aneurysm of the LAD, and aggravated stenosis and calcification in the middle portion of RCA, LCX and massive collaterals inter-coronary arteries. Similar finding were also found in the coronary angiography (Figure 2). Coronary bypass surgery was excluded because of high possibility of re-stenosis in the bypass graft by suggestion of cardiac surgeons. Finally he underwent percutaneous coronary ballooning and stent implantation (3.5mm *15mm) on stenotic part of RCA (Figure 2). After intervention, ECG showed normal sinus rhythm and echocardiography showed no regional wall motion and heart CT revealed relief of intraluminal stenosis in the middle RCA with pseudoaneurysm formation (Figure 3). In patient with multiple coronary aneurysms after Kawasaki disease, progressive coronary stenosis is a challenge to pediatric cardiologist. Cardiac intervention can be an optimal choice in such patient but Multidisciplinary approach should be considered in the management of multiple coronary stenosis in children.

#0126

INITIAL AND MEDIUM-TERM RESULTS OF BALLOON VALVULOPLASTY OF CRITICAL PULMONARY STENOSIS: A SINGLE CENTER EXPERIENCE

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Background: Critical pulmonary valve stenosis (CPS) represents an emergency, and immediate treatment is mandatory. CPS is a ductus-dependent CHD because the open ductus arteriosus supplies pulmonary circulation. Balloon valvuloplasty (BVP) is now the first therapeutic option.

Objective: Here, we present our mid-term results in Pediatric Cardiology Unit, Children Hospital, Mansoura University in percutaneous balloon pulmonary valve valvuloplasty (PBV) in cases of critical pulmonary stenosis (CPS) in the period from 2005 to 2013 to assess the safety and efficacy of transcatheter intervention for critical pulmonary stenosis.

Method: Between April 2005 to June 2013, all consecutive patients

with CPS treated with balloon valvuloplasty in our hospital were analyzed retrospectively. Patients were followed up from 18 months to 8years (mean 64.8 months [5.4years]) by clinical examination and echocardiography.

Result: Sixty four consecutive patients were analyzed. Their gestational age was 38.63 ± 1.48 weeks. Eight patients (12.5%) were preterm newborn. Postnatal age 15.5 ± 7.6 days, range 4-35 days). Weight 3.06 ± 0.3 Kg. 58.5 % was male and 41.5 % was female. Fifty-two of patient (81.2%) received PGE1 infusion before the procedure to maintain the ductal patency in a dose of 0.05 to 0.1 $\mu\text{g}/\text{kg}/\text{min}$. Balloon valvuloplasty was accomplished in 61 (95.3%) of 64 interventions. The procedural success, early outcome, complication rates, midterm results and pulmonary regurgitation were retrospectively studied. Pre-dilatation by Brio coronary balloon was used in 18 patients (28.1%) followed by TAYSHAK® mini balloon. TAYSHAK® mini balloon was used from the start in 46 patients (67.1%) with balloon annulus ratio 1.3. Arterial oxygen saturation elevated from ($67.5 \pm 8.5\%$) to ($91.4 \pm 4\%$). Peak-to-peak pressure gradient across the valve fell from (94.5 ± 15.0) to (27.6 ± 12.0) ($P < 0.001$). Right ventricular pressure fell from (111.5 ± 18.0) mmHg to (46.5 ± 12.5) mmHg ($P < 0.001$). The ratio of right ventricular pressure and aortic pressure fell from 1.87 ± 0.21 to 0.45 ± 0.4 ($P < 0.001$). Prostaglandin E was continued because the right ventricle showed a dynamic infundibular pulmonary stenosis in 4 patients, Prostaglandin was discontinued 3-4 days later and the PDA closed spontaneously in all. Propranolol was started to treat secondary infundibular obstruction in 15 patients for 3-4 months. Two patients had very difficult pulmonary valve cannulation with the wire due to severe TR severe RVH so, PDA stent was inserted in each to maintain pulmonary circulation. Six months later, both patients underwent successful balloon pulmonary valvuloplasty. Two patients lost follow up. Echocardiography on follow up revealed a mean trans-pulmonary systolic gradient of < 30 mmHg, trivial to grade I pulmonary valve regurgitation, and in the short axis the ventricular septum was convex, confirming infra-systemic RV pressure in 55 patients (85%). On follow-up five children (7.8%) required a second balloon dilatation with good results.

Conclusion: Balloon pulmonary valvuloplasty is relatively safe and effective in neonatal CPS. It may be associated with a lower morbidity and mortality than surgical treatment.

#0127

THE ROLE OF CATHETER INTERVENTION FOR ADULT PATIENTS WITH SINGLE VENTRICLE PHYSIOLOGY

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Background: Little data is available on efficacy of catheter intervention for adult patients with single ventricle physiology.

Methods: We retrospectively reviewed all patients over 20 years old who underwent catheter intervention (CI) for single ventricle physiology at our institution between January 2005 and December 2014.

Results: Twenty-one catheter interventions were performed in 10 patients. The median age was 30.9 years (range 20.1-63.0 years) and median weight 46.1kg (range 37.2-73.1kg). Only one patient, who had undergone lateral tunnel Fontan, was followed up from infant at our hospital. The remaining 9 patients were referred beyond adolescence. Stage of palliation at referral time was natural course in 2 patients, Blalock-Taussig (BT) shunt in 4, bidirectional Glenn (BDG) in 1, original Fontan in 1 and Atrio-Pulmonary Connection Fontan in 1. Anatomical diagnosis was SRV in 4 patients, Tricuspid atresia in 3, DILV in 2 and DORV in 1. The CI prior BDG was one balloon angioplasty for shunt (5%), the CI between BDG and Fontan consisted of thirteen aortopulmonary collateral coil embolizations (61%) and one veno-venous collateral coil embolization (5%), the CI after Fontan included two balloon angioplasty and one stent implantation for Fontan route (14%), two aortopulmonary collateral coil embolizations (10%), one veno-venous collateral coil embolization (5%). There were no major complications regarding catheter intervention in this study. One patient who was natural course and two patients who had BT shunt at referral time had reached BDG, the remaining 7 patients had completed extracardiac TCPC (including extracardiac TCPC conversion).

Conclusion: Catheter intervention plays an important role in the management of adult patients with single ventricle physiology.

#0128

A NOVEL TECHNIQUE USING TRANSJUGULAR APPROACH STEERABLE GUIDE CATHETER FOR A PATIENT WITH ATRIAL SEPTAL DEFECT AND IVC OCCLUSION

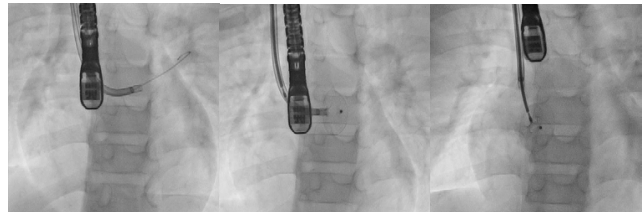
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A 11-year-old man was referred to our hospital for transcatheter closure of atrial septal defect (ASD). Transesophageal echocardiography revealed an 11-mm secundum ASD with aortic rim deficiency. Because he had a congenital occlusion of inferior vena cava,

To deliver a device via transjugular approach, we selected an Agilis steerable guide catheter (St. Jude Medical, St. Paul, MN), which was able to create an acute curve by the handle and to insert another 8 Fr sheath to load the device. Under fluoroscopy and transesophageal echocardiography guidance, the Agilis catheter was positioned across the defect into the left atrium, and then a 0.035 inch Amplatzer extrastiff guidewire (Cook, Indianapolis, IN) was advanced into the upper left pulmonary vein. A 13-mm Amplatzer Septal Occluder (St. Jude Medical, St. Paul, MN) was loaded into the sheath and advanced into the left atrium using the Agilis catheter. The position of the device was confirmed by transesophageal echocardiography, and the device was released.

Because transjugular approach is difficult to maintain a pulmonary venous guidewire position and deploy the device stability, the procedure is very challenging.

The Agilis catheter is a steerable and adjustable curved guide catheter and has an insertion valve accommodating an 8.5 Fr catheter at the most proximal end to insert the device. This technique is useful in patients with IVC occlusion.



#0129

THE USE OF DIGITAL SUBTRACTION 3-D ROTATIONAL ANGIOGRAPHY DURING CARDIAC CATHETERIZATION IN CHILDREN LESS THAN TWO YEARS OF AGE

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Background: Advantages of rotational angiography during cardiac catheterization include tomographic imaging, 3D road-mapping etc. Concerns over potentially higher contrast and radiation doses have limited its routine use in infants. We instituted a digital subtraction 3D rotational angiography (DS-3DRA) protocol for use in infants. The objective of this study was to compare radiation and contrast doses required for obtaining DS-3DRA with conventional digital 3DRA (DA-3DRA) in children ≤ 2 years of age.

Methods: Radiation and contrast doses required for DS-3DRA was compared with age-, size- and diagnosis-matched historical controls that had DA-3DRA. Only children ≤ 2 years of age were included in the study. A 1:1 control matching was performed. Those patients that did not have matching controls were excluded from the study. The diagnostic quality and utility of these two modalities were scored by 4 qualified independent observers.

Results: The study (n=7) and control (n=7) groups were well matched for age (mean 14 vs. 15 months; p=0.239) and size (mean BSA 0.42 vs. 0.44 m²; p=0.103). The mean dose area product (DAP) to acquire DS-3DRA was 34% higher than DA-3DRA (128 vs. 188 cGy·cm²; p=0.014). Similarly, the DS-3DRA air-Kerma, albeit small, was 47% higher than the DA-3DRA air-kerma (mean = 21.7 vs. 11.4 mGy; p<0.01). However, the contrast volume to acquire the best diagnostic quality DS-3DRA was 44% less than what was required for DA-3DRA (mean 1.02 vs. 1.81 mL/kg; p<0.001). The diagnostic quality and utility scores for the rotational angiography (86% vs. 84%; p=0.32), multi-planar reformation (84% vs. 88%; p=0.12), 3D reconstruction (79% vs. 86%; p=0.14), and 3D road-mapping (88% vs. 89%; p=0.36) were similar for both modalities.

Conclusions: Digital subtraction rotational angiography can help reduce contrast volumes required to perform 3DRA in children ≤ 2 years of age. The radiation dose for DS-3DRA, albeit small, is a little over a third higher than for DA-3DRA. The diagnostic quality and utility of DS-3DRA for infants with congenital heart diseases is equivalent to conventional 3DRA.

#0130

SUCCESSFUL CLOSURE OF AN APICAL MUSCULAR VSD USING AMPLATZER DUCT OCCLUDER II DEVICE ON POSTOPERATIVE PATIENT ON ECMO*Levent Saltik², Reyhan Dedeoglu¹*¹Department of Pediatric Cardiology, Istanbul University, Cerrahpasa Medical Faculty, Istanbul, Turkey²Anadolu Medical Center, Istanbul, Turkey

Residual ventricular septal defects (VSDs) following cardiac surgery are not uncommon and were defined as haemodynamically significant and surgically remediable lesions present after surgery. Venoarterial extracorporeal membrane oxygenation (ECMO) is the most potent form of acute cardiorespiratory support available and enables complete relief of cardiac workload.

We describe the successful closure of an apical muscular VSD using Amplatzer Duct Occluder II (ADO II) device on postoperative patient on ECMO

A 5-year-old patient, weighing 12 kg, had presented with having difficulties in weaning from cardiopulmonary by-pass after surgery for VSD closure and pulmonary conduit attached to the systemic ventricle. Preoperative Echocardiography revealed mesocardia, corrected transposition, multiple VSDs, mitral valve insufficiency, pulmonary valve stenosis. At operation VSDs were closed and conduit placed between pulmonary artery and the left ventricle (LV). After surgery child could not be weaned off bypass and ECMO was initiated for cardiac support. Echocardiogram revealed one moderate apical VSD. There was a significant systemic ventricular volume overload. Because of the apical location of the VSD, the patient was taken up for a device closure on ECMO. Cardiac catheterization was performed from left femoral artery and vein. A left ventricular angiogram and transesophageal echocardiogram were done. We chose to use the 6/6 ADO II device for VSD closure. Echocardiography showed the device optimally placed with minimal residual flow. The child could be extubated in 36 hours and was discharged in a stable condition at 1 week. The aim of cardiac ECMO is to profoundly unload the heart and decrease its work. Significant residual leaks may occur after repair of any type of VSD. Postoperative patients with residual VSD will not recover until these defects are addressed surgically or percutaneously. Percutaneous closure is less invasive and may be preferable. Hence, we thought of ADO II because of its better profile.

#0131

CARDIOVASCULAR COMPLICATIONS OF HISTOPLASMOSIS IN CHILDREN: REPORT FROM A SINGLE CENTER IN AN ENDEMIC REGION*Michael Perez¹, Mario Briceno-Medina¹, Rush Waller¹, Emily Hayes¹, David Zurkowski², Shyam Sathanandam¹*¹University of Tennessee, LeBonheur Children's Hospital, Memphis, TN, USA²Harvard Medical School, Boston, MA, USA

Background: Histoplasmosis is endemic to the Mississippi river valley. Fibrosing mediastinitis is a rare complication that may lead to thoracic vascular stenosis, compression of the airways and pericarditis. It is an indolent process leading to sequelae that usually present in adulthood. Rarely, it manifests in children. The aim of this study was to

describe cardiovascular complications of Histoplasmosis in children.

Methods: We performed a retrospective review over a 5 year period between 2009 and 2014. Patients who had a diagnosis of Histoplasmosis during childhood and developed cardiovascular sequelae were included in the study.

Results: We identified 15 children (12 female and 3 male) with cardiovascular manifestations. The median age at presentation was 15 years (IQR: 13-16 years). The chief presenting symptom included chest pain in 5, shortness of breath in 5, fatigue in 4 and upper respiratory tract symptoms in 1. The diagnosis of histoplasmosis was confirmed either by antigen, IgM antibody testing or through biopsy. Six children had a hemorrhagic pericardial effusion at presentation requiring pericardiocentesis, 2 of whom progressed to develop bilateral pulmonary artery stenosis requiring stent implantations. The remaining had calcified granulomas that caused a mass effect leading to stenosis in the right pulmonary artery (RPA) in 5, left pulmonary artery in 2, superior vena cava in 1, descending thoracic aorta in 1 and the pulmonary veins in 3. The interventions included angioplasty in 5 children, 10 stents implanted in 6 patients and 3 patients required resection of a mediastinal mass. In one patient who was left untreated till adulthood, a stenosis in the RPA could not be resolved by angioplasty or stent implantation. Two children have mild vascular stenosis that have not yet required intervention.

Conclusions: Fibrosing mediastinitis secondary to Histoplasmosis in children is a rare finding. Complications may require aggressive interventions. It may be feasible to perform balloon angioplasty and/or stent implantation to treat vascular stenosis. Refractory stenosis or airway compression may require surgery. Hemorrhagic effusions of an unknown etiology require close follow-up as fibrosing mediastinitis may present at a later date.

#0132

EXPERIENCES OF COMBINED TREATMENTS OF SELECTIVE PULMONARY VASODILATORS AFTER THE TRANS-CATHETER CLOSURE IN ATRIAL SEPTAL DEFECT WITH PULMONARY ARTERIAL HYPERTENSION*Lucy Eun, Nam Kyun Kim, Jae Young Choi*

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Background: The clinical course of patient with transcatheter closure of atrial septal defect (ASD) with pulmonary arterial hypertension (PAH) has not been completely understood. Variable pattern of the disease progression and the severity of disease in similar underlying defects may be the important factors to predict the clinical outcome.

Methods and Results: From May 2006 to June 2012, 457 patients underwent transcatheter closure of ASD. Among them, 68 patients had PAH at the time of procedure. PAH was classified as mild (40-49mmHg), moderate (50-59mmHg), severe (above 60mmHg) according to pulmonary artery systolic pressure (PASP). We reviewed the course of the PAH and complications in these subjects. In mild PAH group (n=37), thirty two patients had normalization after the transcatheter closure of ASD, and the remained patients had normalization within 1 month. In moderate PAH group (n=17), thirteen patients showed normal PA pressure after closure of ASD, and 4 patients normalized within during follow-up. In severe PAH group (n=14), there was no patient who showed immediate normalization after tran-

scatheter closure. During follow-up period, normal PA pressure was shown in 12 patients who had remaining PAH after the procedure. No significant complications related to ASD occlusion and PAH were demonstrated.

Conclusions: Patients with Atrial septal defect with pulmonary hypertension have more complex clinical and pathophysiologic characteristics. Therefore, treatment strategy in congenital heart disease patients with pulmonary hypertension should be tailored to individual details of disease as well as general measures targeting the pulmonary arterial hypertension.

#0133

ACUTE AND MID-TERM OUTCOMES OF STENT IMPLANTATION FOR RECURRENT COARCTATION OF THE AORTA IN YOUNG SINGLE VENTRICLE PATIENTS FOLLOWING THE NORWOOD PROCEDURE: A MULTI-CENTER PICES INVESTIGATION

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Objective: To evaluate acute and mid-term outcomes of stent implantation (SI) for recurrent coarctation of the aorta (RC) in single ventricle (SV) patients following the Norwood operation.

Background: RC is common following the Norwood operation and is a risk factor for morbidity and mortality. Balloon angioplasty (BA) is usually the first line treatment but occasionally results in unsatisfactory outcomes that may warrant SI. There are limited data on acute and mid-term outcomes following SI for treatment of RC in the young SV population.

Methods: Multi-center retrospective study, including 7 participating US centers from 2007 to 2015. SV patients who underwent SI for RC between Norwood operation and Fontan completion were included. Acute and mid-term outcomes were examined, including serious adverse events (SAE). A core laboratory was used for angiography assessment. Coarctation index (CI), defined as the ratio of narrowest arch dimension to the diameter of descending aorta at the diaphragm was calculated. Paired t-test and Wilcoxon signed-rank test were used to compare pre- and post-SI variables.

Results: Twenty-four SV patients were included with a median age of 4.6 (IQR 3.5, 10.0) months and weight of 5.6 (4.9, 8.0) kg. Nine (37.5%) patients underwent SI prior to stage II palliation and 15 (62.5%) underwent SI between stage II and Fontan completion. BA was performed prior to SI in 21 (88%) patients. The approach to SI was prograde in 17 (71%), "hybrid" in 5 (21%), retrograde in 1 (4%) and via carotid artery cut-down in 1 (4%). The median CI before and after SI was 0.52 (0.39, 0.62) and 0.96 (0.89, 1.06) respectively ($p < 0.0001$). The peak systolic gradient across the RC site improved from 20 (15, 23.5)

to 0 (0,0) mmHg following SI ($p < 0.0001$). There were no procedural deaths but SAEs occurred in 9 (37.5%) patients, including significant hypotension/bradycardia requiring treatment (29%), stent embolization (4%) and blood loss requiring transfusion (4%). During a median follow-up duration of 28.3 (12, 57.3) months, freedom from death or heart transplant was 79%, and freedom from re-intervention was 50% with median time to re-intervention of 15.9 (5.7, 24.7) months.

Conclusions: SI for treatment of RC in SV patients after the Norwood operation provides excellent acute relief of obstruction. Intra-procedural hemodynamic instability is common and re-intervention is frequent at mid-term follow-up.

#0134

SAFETY, FEASIBILITY, RESULTS, AND ECONOMIC IMPACT OF COMMON INTERVENTIONAL PROCEDURES IN A LOW VOLUME REGION OF THE UNITED STATES

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Background: Rural areas of the U.S. may not have a full-time pediatric interventional cardiologist (IC); this requires patients to travel out of state even for minor interventions. Travel may put increased financial burden on both the patient's family and their state's Medicaid program. Since 2005, we have adopted a policy of performing cardiac catheterizations and common interventional procedures with a visiting IC. The purpose of this study is to evaluate the safety, feasibility, and economic benefit of this arrangement.

Methods: We reviewed data of all patients who underwent cardiac catheterizations from May 2005 through September 2014 at our center. Variables analyzed were type of procedure, results, and follow-up six months after procedure.

Results: A total of 180 catheterizations were performed, of which 98 were for atrial septal defects (ASD), 46 for patent ductus arteriosus (PDA), 16 for diagnostic procedures, 12 for balloon pulmonary valvuloplasty, 4 for balloon aortic valvuloplasty, 2 for Fontan fenestration dilations, 1 for aortic pseudoaneurysm occlusion, and 1 for right ventricular outflow tract stenting. Amongst 98 ASD cases, 95 devices were placed successfully, 2 defects were not able to be closed due to concomitant pathology and 1 patient was referred for surgical closure because of high risk anatomy. 1 patient developed 1st degree AV block and 1 patient developed intra- and post-procedural SVT. Follow-up data was available for 78 of the 95 patients who had a device placed. All but 2 patients had no cardiac symptoms at 6 months. No device embolization, erosion, or residual shunt was seen. PDA closure was successfully performed in 43 of 46 procedures. A device was not implanted in 3 cases due to hemodynamically insignificant PDA ($n=2$) and unavailability of appropriate device ($n=1$). Residual shunt was present in 1 patient who had coil embolization; this patient required a repeat procedure. Follow-up data was available for 33 of the 43 patients and showed that all patients were asymptomatic with complete closure.

Conclusion: With a technical success rate of 100% and results comparable to those of high volume centers, cardiac catheterization and

interventions can be performed safely with excellent results. We believe that performing procedures in such an arrangement is safe, feasible, and has a positive economic impact on the patients' families and their state.

#0135

TECHNICAL FACTORS DURING BALLOON ANGIOPLASTY OF COARCTATION OF THE AORTA AND THE RISK OF RECURRENCE

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Background: Balloon angioplasty (BA) is a common treatment for coarctation of the aorta (CoA), but is associated with recurrence (reCoA). Technical factors during initial BA of CoA may play a role in incidence of reCoA. We sought to identify procedural and patient features associated with freedom from re-intervention following BA.

Methods: All BAs for CoA from 2003 to 2014 were reviewed to obtain the minimum CoA diameter (MinCD), reference aortic diameter (RefAD), length of CoA, pressure gradient, balloon inflation pressure (BIP), maximal balloon diameter, balloon waist diameter, and presence of intimal disruption. The primary endpoint was reCoA. Variables were examined for association with re-intervention using Cox regression.

Results: We identified 175 pts who underwent BA (14 native, 161 post-surgical CoA) performed at a median age of 4.4 months (IQR 3.2, 8.3). Interventions were performed using median BIP of 10 atm (6, 12), balloon max: MinCD ratio of 2.1 (1.7, 2.5), balloon max: RefAD ratio of 1.1 (0.9, 1.2), and balloon waist: RefAD ratio (BWR) of 1.0 (0.9, 1.1). Following BA, 57 (32.6%) cases required re-intervention. Patient age \leq 3 months was strongly associated with re-intervention ($p < 0.001$). Prior surgical repair, length of CoA, % stenosis, pressure gradient, and severe intimal disruption were not significantly associated with reCoA. $BWR > 1$ [HR =0.58 (95% CI 0.34, 0.99)] was also associated with higher likelihood of re-intervention, independent of prior surgery, or length of CoA. Interestingly, native CoA and surgical CoA had equivalent rates of reCoA ($p=0.52$).

Conclusion: The diameter of the balloon waist at maximal inflation pressure is associated with risk of reCoA. In addition, infants \leq 3 months of age at BA are at higher risk of reCoA. Native and post-surgical CoA seem to respond similarly to BA.

#0136

MULTI-MATERIAL 3D PRINTING FOR PRE-INTERVENTIONAL TAVR PLANNING

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Transcatheter Aortic Valve Replacement (TAVR) is widely becoming an accepted therapy for aortic stenosis. In the last 10 years, estimates

place the deployment of TAVRs as high as 50,000 worldwide. Differences in size and morphology of the aortic root and surrounding anatomy are important considerations in determining which TAVR to deploy. 3D printing based off of patient images can be leveraged to create models for patient-specific surgical planning purposes.

An 82 year old female was diagnosed with severe aortic stenosis. Traditional measurements based on CT were inconclusive on size of TAVR for deployment. The decision was made to print an aortic model in a compliant medium with calcifications in a non-compliant medium. TAVR devices were deployed in the model to assist with device determination.

The multi-material, 3D print of the patient's diseased aortic anatomy allowed physicians to perform two mock interventions on the patient-specific model with different TAVR specifications. From the results of the patient-specific, simulated TAVR deployment and information traditionally available through conventional imaging, the clinicians selected the larger available TAVR device for future deployment in the patient.

This case study and modelling process yield compelling results for pre-interventional planning in regards to TAVR deployment. Specifically, representing the two tissue types, lumen and sclerosis, was an achievement through new 3D printing techniques. Integration of this rapidly developing technology within cardiovascular centers is recommended for further study and validation

#0137

INITIAL EXPERIENCE WITH NEW VIEWFLEX XTRA ICE CATHETER FOR MANAGEMENT OF STRUCTURAL CARDIAC LESIONS

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Objective: ICE catheter has proven to be a valuable tool to close atrial septal defects (ASD) and patent foramen ovale (PFO), left atrial appendage and valvular lesions. We have started using Viewflex Xtra ICE (VICE) catheter to close ASD/PFO and placement of Melody valve. The objective of this study was to review our experience with this catheter, its advantages and drawbacks compared to the Acunav ICE (AICE) catheter.

Methods: VICE) catheter can be introduced through an 11 F sheath. It has Agilis Sheath handle and large curvature radius that provides control over viewing angles and positioning. It has a single-handed, no lock control for full maneuverability, with excellent torsional and tip response. We reviewed our experience with this catheter for ASD/PFO closure and its feasibility during Melody valve placement in the pulmonary position.

Results: There was learning curve in VICE maneuverability and optimal image acquisition. The imaging and color quality were excellent. Its large curvature radius hindered image acquisition during initial experience but overall was an excellent feature. Twelve patients underwent successful percutaneous ASD/PFO closure and two pts. had Melody valve placement. One patient had two devices placed. All cases were successful; there were no acute or late device related complications. Mean age ranged 1.5 years to 64 years (mean, 34.03 \pm 25.02 and median, 30). Weight ranged from 11.96 kg to 152.1 kg (mean,

71.75 ± 44.17 and median, 71.83). The procedure time was compared to historic data obtained from patients who underwent similar procedures with AICE catheter. There was no statistical difference in time of procedure, despite initial learning curve with VICE.

Conclusion: The VICE catheter can be used safely in ASD/PFO closure in children and adult. It increases maneuverability by a self-locking capability allowing quick positioning and repositioning. The image quality appeared similar and the color quality was superior to AICE. The procedure time was similar despite initial learning curve. The VICE catheter can be an alternative option for imaging guidance in intracardiac interventions.

#0138

CLINICAL EVALUATION OF THE TOSHIBA 3D MULTI-MODALITY FUSION SOFTWARE APPLICATION IN CONGENITAL CARDIAC INTERVENTIONAL CATHETERIZATIONS

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Background: The Toshiba, 3-D Multi-Modality Fusion Roadmap (3D-MMF) is a software application that enables overlay of previously acquired 3D-DICOM image data sets (vendor neutral) with live 2-D fluoroscopy images, to enhance 3-D anatomical reference. C-arm and table positioning is integrated with the 3-D reference image for automated tracking that aids procedure planning and catheter guidance. The objectives of this study was to determine the feasibility of performing multi-vendor 3D-MMF using 3-D datasets obtained from a either a Siemens CT, GE MR scanner or LCI or 3D-rotational angiography (3DRA) using the Toshiba Infinix system and to determine the differences in procedural radiation and contrast doses between 3DRA-Fusion, MR-Fusion and CT-Fusion during cardiac catheterizations.

Methods: Catheterization data from matched patient groups undergoing 3DRA-Fusion, MR-Fusion and CT-Fusion were reviewed. The radiation, contrast dose, anesthesia time, fluoroscopic time were compared including what was needed to obtain the CT or MR. Scores for the quality and utility of the 3D-fusion roadmap during the procedure and clinician satisfaction were obtained from the operators and 4 qualified independent observers. **Results:** The 3DRA-Fusion (n=15), MR-Fusion (n=15) and the CY-Fusion (n=10) groups were well matched for age (mean 9.8, 10.2 and 11.1 years; p=0.39) and size (mean BSA 1.02, 1.08 and 1.2 m²; p=0.11). Patients in the MR-Fusion group compared to the CT-Fusion and 3DRA-Fusion groups had lower indices of radiation exposure measured by fluoroscopy time (18 vs. 19.4 vs. 21.8 Minutes; p=0.04), total dose-area product (2454 vs. 5607 vs. 4101 cGy-cm², p=0.01), and total air kerma dose (499 vs. 806 vs. 654; p=0.01). There was also a significant reduction in contrast dose (2.7 vs. 5.9 vs. 4.9 mL/kg, p <0.001). Procedural time tended to be shorter in the MR-Fusion group (163 vs. 167 vs. 214 minutes; p <0.03) but anesthesia time was significantly longer (384 vs. 213 vs. 258 minutes; p <0.001). For clinical utility, 3DRA-Fusion had highest satisfaction scores (90%) among operators and independent observers compared to MR-Fusion (82%) and CT fusion (84%).

Conclusions: It is feasible to perform multi-vendor, 3D MMF using the new Toshiba software with good clinician satisfaction scores. MR-Fusion helps reduce procedural radiation and contrast doses during congenital, cardiac, interventional catheterizations.

#0139

EXTRACARDIAC FONTAN FENESTRATION DEVICE CLOSURE: ACUTE RESULTS AND MID-TERM FOLLOW UP

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Objectives: To evaluate the acute results and mid-term follow up of patients who have undergone device closure of an Extracardiac Fontan fenestration.

Background: A fenestrated Fontan is commonly performed as the final palliative surgery in single ventricle patients. In most cases these fenestrations are closed in the interventional catheterization laboratory with various device types, allowing for improvement in oxygen saturations and eliminating the risk of paradoxical embolus. However, there is concern for long-term outcomes in these patients. Although there are several publications relating to device closure of Fontan fenestrations, we provide the experience of a single institution with comparatively longer term follow up in a larger number of patients.

Methods: A retrospective review of all patients who underwent attempt at device closure of a Fontan Fenestration at Cardinal Glennon Children's Medical Center/Saint Louis University was performed. Demographics, Fontan fenestration type, and procedural data were recorded, and medical records were reviewed for follow up data. O₂ saturation and Fontan pressure pre and post fenestration closure were compared using a paired t-test.

Results: Forty-one patients were identified, one of which was not felt to be a candidate for fenestration closure, and of the remaining 40 patients, 31 (78.9%) had their fenestration closed with an Amplatzer Vascular Plug II and 9 (21.1%) were closed with the Amplatzer Septal Occluder. After device closure, the aortic saturation increased significantly by 8.8% (p<0.0001) and the conduit pressure did not significantly change (13.6 to 14.5 mmHg; p=0.061). The patients were followed for an average of 3 years (range 1 month to 6.4 years) after device closure. Mean transcutaneous oxygen saturation at follow-up was 96.1%. There was one procedural complication in which an AVPII embolized, was retrieved percutaneously, and then the fenestration was successfully closed. There was one patient who developed plastic bronchitis following device closure, but that was felt to be secondary to atrial septal restriction present prior to device closure, and symptoms improved following surgical revision of the Fontan with atrial septectomy.

Conclusion: Device closure of Fontan fenestrations is a safe and effective procedure resulting in increased aortic saturations with no significant change in conduit pressure, with reassuring mid-term follow up.

#0140

TRANSCATHETER CLOSURE OF A MITRAL VALVE PARAVALVULAR LEAK IN A 7 MONTH OLD CHILD

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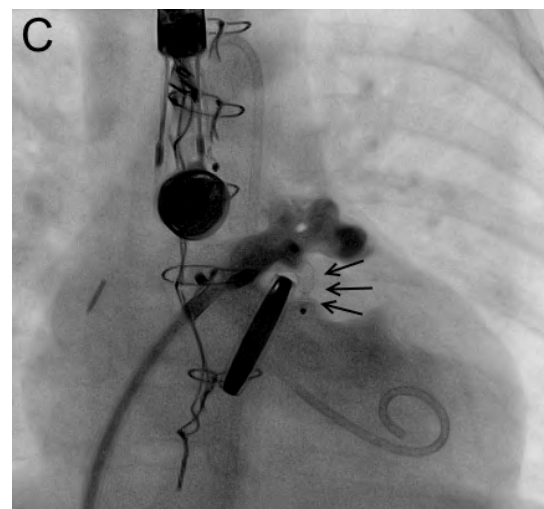
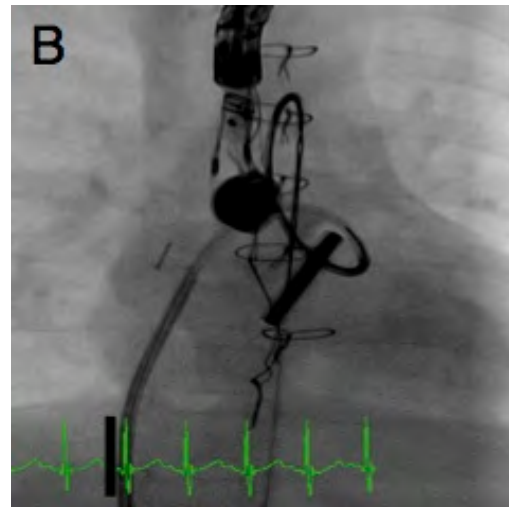
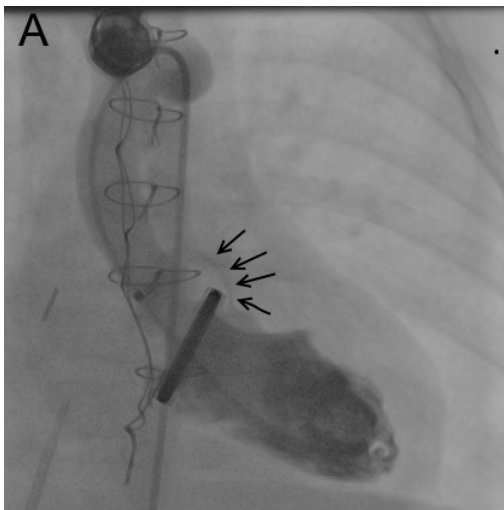
Objective: To describe successful percutaneous treatment of a paravalvular leak (PVL) in an infant with Shone's complex and a supra-annular mechanical mitral valve (MV).

Background: Mitral valve replacement is a relatively rare procedure in young children. PVLs are a known complication of mitral valve replacement. To our knowledge, this is the first report of a PVL treated percutaneously in a child this age.

Case: The patient is a 7 m old, 6 kg, male with a history of Shone's complex status post aortic arch reconstruction and balloon valvuloplasty of the MV. Due to severe mitral insufficiency, he underwent MV replacement with a 16 mm Medtronic open pivot AP 360 mechanical aortic valve in the supra-annular mitral position at 5 months. He developed a posterior PVL post-operatively with persistent hemolysis requiring repeated transfusions. Medical therapy with pentoxifylline failed. Thus, 2 m post-operatively, he was referred for percutaneous cardiac catheterization for PVL closure. Transesophageal echocardiography (TEE) identified a small-sized PVL between the mouth of the left atrial appendage and the left upper pulmonary vein. A trans-septal approach was utilized. Using a Cobra catheter, a 0.018" floppy wire was advanced from the venous sheath through the leak and into the ascending aorta, where it was snared by a multisnare introduced from the arterial sheath. A 4mm Amplatzer vascular plug II was then positioned anterogradely and was successfully deployed in the tract. No significant leak was visualized on angiography or TEE and the child's hemolysis subsided.

Conclusion: Device closure of mitral valve paravalvular leaks in a very small child is technically feasible, and may obviate repeat surgery.

Figure 1: Paravalvular leak (A), wire course (B), vascular plug after deployment (C).



#0141

A CASE REPORT: PERCUTANEOUS, TRANS-CATHETER CLOSURE OF THE CIRCUMFLEX TO LEFT VENTRICLE, CORONARY-CAMERAL FISTULA

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Introduction: A 4 - year old male child presented with chest pain and failure to thrive. Clinically he had mild cardiomegaly, a loud P2 and a grade II/VI systolic murmur at left sternal border and apex. Radiologically , he had unusual but mild localised protrusion at left heart border (Figure-1). Echocardiography was done on the IE33 Philips 3D Ultrasound System, which revealed a large coronary cameral fistula (CCF), arising from circumflex coronary artery just after its origin and terminating into LV. A Coronary cameral fistula (CCF) or coronary arterio-venous fistula(CAVF) is an uncommon type of shunt lesion due to presence of an abnormal fistulous tract between one of the branches of coronary artery and the cardiac chamber (CCF) or vascular structure (CAVF).^{1,2} A large fistula may present with chest pain, growth failure, congestive heart failure , arrhythmias or with life threatening

events due to rupture of aneurysmal vessel.¹ About one third of total cases of the CAVF are from the left coronary system. The left ventricle is uncommon site of termination of CCF.²

Methods: To analyse the course, dimensions of CCF and detailed coronary anatomy, CT angiogram was obtained on a 128 multi-slice computerized tomography scanner by Siemens. The fistulous tract was 11.3 mm in diameter through-out and narrowed to 9mm size just before its termination. The CCF had two elbows. The mouth of fistula was situated into the vicinity of posterior mitral valve leaflet and its tensor apparatus. A per-cutaneous tran-catheter closure with Amplatzer Vascular Plug II (St Jude Medical) was planned after analysis of findings and the review of literature. The location of mouth of CCF actually ruled out feasibility of an arterio-venous loop and deployment of a device from the LV side. Therefore, an embolization device was thought to be more appropriate. AVPII has advantage of cross sectional coverage of fistula by controlled single device release due to its special design which includes multiple lobes and non-tapering ends. Coronary anatomy revealed, a right dominant coronary system hence the theoretical risk of compromising coronary circulation to inferior wall, was not an issue. The procedure was done under general anesthesia, in cath lab (Philips FD 10 System), under the guidance of fluoroscopy and trans-thoracic echo. The appropriate angled views (RAO 3-20° and Caudal angulation 15-34°) were used for the visualization of transverse length CCF and its opening into LV. The left coronary artery (LCA) selective angiogram was taken with the help of a Judkin left coronary artery catheter (LCAC). Subsequently, LCAC was exchanged over the wire (0.035" x 260 cm Terumo exchange guide-wire, 'J' tip) with another 8 french Multipurpose braided guide catheter. The wire was further secured by looping it into LV cavity. The wire was advanced into ascending aorta, arch and finally it was stationed into descending aorta, below the diaphragm. An AVP II (AVP2-016, 16 X 12 mm) was introduced with the help of the cable, under fluoroscopy and ECG monitoring. After ascertaining the position and dye injection, the plug was embolized between two elbows of fistula (Figure-2). Post procedure angiogram showed insignificant whip of contrast. The AVP was released successfully. Post procedure coronary angiogram was normal.

Result: The Patient had chest discomfort transiently, in early post-procedure period. On 6 months, follow-up, patient improved clinically and echocardiographically. There was no residual flow. Post procedure CT angiography revealed AVP in an appropriate position (Figure-3).

Conclusion: We report a case where a CCF was detected on echocardiography and CT angiography. The CCF was closed successfully with Amplatzer Vascular plug II. In best of our knowledge, this is the first case of AVPII embolization used for percutaneous trans-catheter closure of circumflex to left ventricle coronary-cameral fistula.

#0142 FIRST EXPERIENCE WITH THE ABSORB BIORESORBABLE VASCULAR SCAFFOLD (BVS) IN CONGENITAL HEART DISEASE

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Introduction: Children outgrow metal stents, obligating them to future transcatheter dilations and eventual surgical removal. A bioabsorbable stent, or a stent that goes away with time, would solve this problem. The aim of our study is to describe our experience with BVS in the setting of different vascular lesions in children.

Methods: Clinical records, catheterization data, and operation notes of ten consecutive patients undergoing BVS implantation since July-2013 were studied retrospectively.

Results: The patient's median age was 11.2 months (14 days-11,6 years) and the median weight was 6.5 kg (2.3-48). The underlying vascular lesion was: Postoperative pulmonary vein stenosis in two patients; an anomalous infradiaphragmatic right pulmonary venous stenosis collector in a preterm infant; two hypoplastic left pulmonary arteries after Norwood procedure, one right coronary artery spasm in a William's syndrome after percutaneous aortic valvuloplasty; one right lobar pulmonary artery in a Pulmonary Atresia after unifocalization; one aortic arch coarctation; and two renal arteries in the setting of mid aortic syndrome. Vascular stenting was achieved in all patients. Mean fluoroscopy time was 29 minutes. Based on the type of the lesion, vascular access was gained from the femoral vein (n=5), femoral artery (n=4) and one hybrid procedure through the dissection of the right ventricular cavity. In 6 patients predilation of the vessel was performed. Stent's size (mm) used were 3.5x12 (n=7), 2.5x12, 3x12 (n=2). In 7 patients, subsequent stent overdilation with coronary balloons, was necessary to achieve the maximum diameter of the vessel. The angiographic result was satisfactory in all cases. No related complications and non acute obstruction were observed. Relief of the symptomatology was achieved in all cases in the acute follow-up: hypoxemia, ventricular dysfunction. A redilatation of stent was performed in one case, 71 days after implantation. Three patients underwent cardiac surgery (two on pulmonary veins, and one Glenn): 37, 76 and 94 days after stent implantation. At the time of surgery, stent structure was not found by the surgeon, and procedure was carried out without any difficulty.

Conclusion: Considering advances in percutaneous treatment of CHD, the biodegradable stents are already a reality, and BVS stenting is a reliable and safe alternative to angioplasty, metal stents, or surgical approach in selected patients.

#0143 EARLY EXPERIENCE OF CERAFLEX SEPTAL OCCLUDER: A MULTI-CENTRE STUDY

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Background: Concerns regarding cardiac erosion have spurred the development of more compliant atrial septal occluder devices, which theoretically may reduce the risk. We describe our early experience of the Ceraflex septal occluder (CSO).

Methods: Retrospective review of CSO device use at two tertiary units in Ireland over 12 month period.

Results: During the study 43 patients underwent cardiac catheterization in which CSO was deployed. Table 1 describes demographics and lesions occluded. The procedure was technically successful in 42 cases (98%) with excellent rates of residual flow. One CSO was recap-

tured due to instability of device. There was one instance of device embolization (2%) and none of erosion.

Conclusion: This is the second largest study of the CSO to date. These results indicate that the CSO is suitable for a wide range of inter-atrial communications, has excellent closure rates, is safe and is less expensive than alternative devices. Longer-term follow-up is required to evaluate risk of erosion.

Table 1: Demographics and lesion characteristics

Mean Age (s.d.)	6.95yrs (4.8)	2°ASD (n)	35
% Male	35%	Mean 2°ASD size (s.d.)	11.2mm (6.0)
Mean weight (s.d.)	25.3kg (16.3)	Mean Stop flow size (s.d.)	12.3mm (5.7)
Mean Follow-up (s.d.)	4.2months (2.5)	% Deficient aortic rim (<5mm)	42%
Total Follow-up	180 months	PFO (n)	2
		Fontan Fenestration (n)	6
% Residual flow: Immediate	None 81	Trivial 14	Small 5
% Residual flow: 6 weeks	None 91	Trivial 7	Small 2

#0144

USE OF THE AMPLATZER VASCULAR PLUG II FOR OCCLUSION OF THE NATIVE RIGHT VENTRICULAR OUTFLOW TRACT IN SINGLE VENTRICLE PALLIATION

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Background: Pulsatile antegrade flow in the pulmonary circulation in patients with a bidirectional cavopulmonary connection (BCPC) has been suggested to improve long term outcome, but may cause volume loading and prolonged pleural drainage, necessitating occlusion of the residual connection between the ventricle and the pulmonary artery.

Objectives and methods: To describe the utility of the Amplatzer Vascular Plug II in closing a residual ventriculopulmonary connection after BCPC and provide a review of the available literature on device closure of such connections in single ventricle patients.

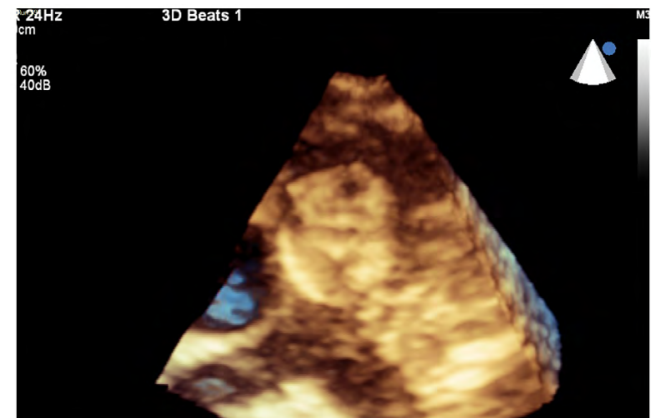
Results: We used an Amplatzer Vascular Plug II (AVPII) for percutaneous closure of the right ventricular outflow tract via retrograde approach in an 18 month old child with double inlet left ventricle, normally related great arteries, and pulmonary stenosis, presenting with prolonged chylothorax following pulsatile BCPC. The narrowest RVOT diameter was 5.5mm, occluded with a 10mm AVPII device with stable result and successful decrease in pleural drainage. Review of the

literature revealed fourteen reported cases of effective transcatheter closure of ventriculopulmonary connections, 11 with an Amplatzer duct occluder, 3 Amplatzer septal occluders, and 1 Rushkind umbrella (one case required 2 devices). Twelve children were in good condition on follow up with clinical improvement, two had died non-procedure related deaths.

Conclusions: Residual ventriculopulmonary connections after a BCPC can be safely closed percutaneously using various devices. The multi-lobed, flexible quality of the Amplatzer Vascular Plug II makes it a particularly suitable device for this procedure.



Angiography image (lateral view) following device release, demonstrating stable device position and good flow in the branch pulmonary arteries.



3-dimensional echocardiogram demonstrating the device in good position one month following implantation and unobstructed pulmonary arteries.

#0145**LEAVE NOTHING BEHIND: INITIAL EXPERIENCE WITH THE ARSTASIS AXERA ARTERIAL CLOSURE DEVICE IN PEDIATRICS**

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Background: Arterial closure devices in children may be undesirable due to foreign material (collagen, suture) left behind in a vessel expected to undergo future somatic growth. The Arstasis AXERA arterial closure device (AXERA) creates an ultra-low angle arteriotomy to deliver tissue-on-tissue overlap for secure vascular closure without patient implant. We report on the first pediatric use of this device.

Methods: A retrospective, random, single-center study was performed pulling pediatric patient encounters (ages 5-18 yrs) undergoing heart catheterization with arterial sheath placement from April 2010 to November 2014. Demographics, periprocedural details, and time to hemostasis/discharge were compared among patients who received AXERA (N=34) and those who did not (N=44). The decision to use AXERA was at the discretion of the primary operator. Two sample t-test analysis was used to compare the two groups, with significance set at $p < 0.05$.

Results: Demographic characteristics, type of procedure, and heparin dosing were similar between groups. Median sheath size was significantly larger in the AXERA group (6 Fr vs 4 Fr, $p < 0.001$). AXERA was successfully deployed 33/34 times (97%) with no reported hematomas or loss of pulse post procedure. Angled wires were utilized in >95% of cases. Time to arterial hemostasis was significantly shorter in the AXERA group 8.4 ± 5.3 min compared to the manual compression group 13.4 ± 3.1 min ($p < 0.001$) and remained significant after adjustment for heparin and protamine dosing, ACT levels, and systemic blood pressure. Time to discharge after procedure also trended towards shorter times in those patients being discharged same day.

Conclusions: AXERA appears to be safe and effective in larger pediatric patients. Time to arterial hemostasis was significantly reduced compared to manual pressure. Time to discharge can also be potentially decreased, potentially representing cost savings. Long term follow-up and larger studies are necessary to completely evaluate safety and economic implications.

#0146**ECHOCARDIOGRAPHY IS THE MORE PRUDENT METHOD TO MEASURE AORTIC VALVE ANNULUS DIAMETER WHEN PERFORMING BALLOON AORTIC VALVULOPLASTY**

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Background: During balloon aortic valvuloplasty (BAV) for congenital aortic stenosis, operators minimize the balloon-to-aortic annulus ratio (BAR), as $\text{BAR} > 1.1$ is associated with increase in AI. Yet, the method

of measurement of the aortic valve annulus has not been standardized or evaluated as an important factor in outcomes of BAV.

Methods: BAV patients at two large pediatric centers between 2007-2014 with complete echocardiogram (echo) and catheterization (cath) data were included. The aortic valve annulus diameter was determined by echo as the distance between the valve hinge points in the long axis view. Largest balloon diameter used, and reported valve annulus as measured by angiography was reported for each patient. The BAR based upon the cath measurement (BARc) was compared with the BAR based upon the echo (BARe). BAV outcomes were compared. Primary endpoint was increased aortic insufficiency (AI) by at least 1 degree (none, mild, moderate, severe) by echo.

Results: 98 patients undergoing BAV had available echocardiogram and catheterization data. The median age at valvuloplasty was 2.1 months IQR(0.2- 105.5), BSA 0.3 m^2 IQR(0.2-1.0), pre-balloon gradient 58.0 mmHg IQR(48.0-70.0), and median reduction in gradient 35.5 mmHg IQR(26.0-43.0). The median cath-derived aortic valve annulus diameter was 8.2 mm IQR(6.8 - 16.0), larger than the echo-based annulus of 7.5 mm IQR(6.1-14.8) ($p < 0.001$). This corresponded to a significantly lower median BARc of 0.9 IQR(0.9-1.0), compared to the median BARe of 1.1 IQR(1.0-1.1) ($p < 0.001$). The amount of discrepancy in measured diameter increases with smaller valve diameters ($p = 0.041$) and neonate status ($p = 0.044$). Using catheterization, only 3 (3.1%) patients had an "excessive" BARc of > 1.2 , while 12 (12.2%) had an excessive BARe ($p = 0.029$). Of the patients with increased AI, only 3 (5.5%) had $\text{BARc} > 1.1$, while 21 (38%) had $\text{BARe} > 1.1$ ($p < 0.001$). There was no trend towards improved gradient reduction using either BARe or BARc.

Conclusions: Angiography has been traditionally used for measurement of aortic annulus for cases of BAV. Angiographic calibration methods are problematic. Angiographic measurement is associated in a higher BAR, and increased AI. Operators should use caution when relying on cath measurements of the aortic valve when performing BAV.

#0147**CATHETERIZATION IN EARLY POSTOPERATIVE PERIOD FOLLOWING PEDIATRIC CARDIAC SURGERY: SECURITY AND EFFICACY**

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Introduction: Cardiac catheterization in postoperative critical care unit period after cardiac surgery is generally perceived as high risk and often debated; to date there is little published data regarding this setting.

The aim of this study is to examine the indications, safety and efficacy of catheterization performed early after congenital heart surgery.

Methods: All catheterizations performed within six weeks after surgery between January 2011 and December 2014 were retrospectively reviewed. Morphological, surgical and catheterization data, including mortality and reintervention were analyzed.

Results: 75 patients, median age 5 months (0-169), median weight 6 kg (1.5-65) underwent 83 catheterizations on median postoperative

day 8. Procedures were either interventional (n=63) or non-interventional (n=20). Primary diagnoses were heterogeneous, but the majority had complex intracardiac anomalies, and 43,4% had functional univentricular physiology.

Main indications for cardiac catheterization included: low cardiac output (51%), residual lesions by echo (25%) and persistent hypoxemia (13%). Twenty-seven children required extracorporeal cardiopulmonary support. Intervention procedures included: stent implantation (n=41), angioplasty (n=13) and vascular/shunt occlusion (n=11). Most of these interventions (67%) involved a recently created suture line. Ten catheterizations were associated with complications (acute renal failure, two stent migration, four arrhythmias and two superior cava vein perforations). There were no complications related to patient transport, and there was no procedural mortality. 31% of patients died during ICU postoperative period with an hospital discharge survival of 60%. Non-interventional catheterization (p=0,012), and extracorporeal cardiopulmonary support (p=0,025) were risk factors for death.

Conclusions: In our experience, transcatheter interventions can be successfully performed in the early postoperative period. Catheterism also allows undiagnosed residual lesions to be found which may have a positive impact on patient outcome. These procedures must be supported by a multidisciplinary team.

#0148 LONG-TERM OUTCOME OF COIL OCCLUSION IN PATIENTS WITH PATENT DUCTUS ARTERIOSUS

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Objective: We aimed to evaluate the long term results of patients who underwent transcatheter closure of patent ductus arteriosus (PDA) using Cook detachable coils.

Methods: The records of 234 patients who underwent transcatheter closure of PDA using the detachable coils between 1996 and 2015 were reviewed. All patients underwent coil only occlusion until 2005. After 2005 when duct occluders became available, detachable coils were used only in elongated, some complex and small ducts. PDA was categorized according to the classification described by Kricheenko et al. All patients were followed up by color Doppler echocardiography at 24-48 hours, 1 month, 3 months, 6 months, 12 months and every 1-2 year after the procedure.

Results: Coil occlusion was attempted in 234 patients. Median patient age was 2.5 years (range, 10 months-39 years), median weight was 12 kg (range, 7-55 kg), and median PDA diameter was 2 mm (range, 1-4.3mm). The angiographic appearance of the ductus was type A in 124 (53%), type B in 16 (6.8%), type C in 18 (7.7%), type D in 98 (3.8%), type E in 54 (23.1%) and others in 13 (5.6%) patients (postoperative residual PDA in 9, residual shunt after umbrella occlusion in 3 and residual shunt after coil occlusion in 1). The catheter approach was

arterial in 176 (75.2%), venous in 36 (15.4%), a combination of arterial and venous in 22 (9.4%) procedures. The number of coils implanted in each procedure was 1 in 215 (91.9%), 2 in 15 (6.4%), 3 in 1 (0.4%) patients. Transcatheter coil occlusion procedure was successful in 229 patients (97.8%). In 5 (2.2%) patients, the coil occlusion was unsuccessful: detachable coil embolized in 2 patients (0.8%) and in 3 patients (1.2%) coil occlusion was abandoned after first attempt, as ducts were considered unsuitable for coil closure. In 1 patient hemolysis was observed after the procedure and resolved with additional detectable coil next day. Five infants had femoral artery occlusion, in 3 of them embolectomy was performed and 2 infants were treated by heparinization and thrombolysis. Overall occlusion rate were 94.7% (217/229) on echocardiography at a median follow-up of 23 months (range, 1 day-17 years): 179/229 (76.5%) at the end of the procedure, and 183/229 (78.2%) at 24-48 hours post procedure. In most cases with residual shunt (23/29), spontaneous occlusion was observed in the first year, but not observed after 4 years. The latest documented time for residual shunt was 8.5 years.

Conclusions: Our results indicate that coil occlusion is an effective and safe procedure for patients with PDA. Small residual shunts tends to close spontaneously in first year, but may persist long time.

#0149 TRANSCATHETER RIGHT VENTRICULAR DECOMPRESSION (RVD) IN INFANTS WITH PULMONARY ATRESIA (PA) + INTACT VENTRICULAR SEPTUM (IVS) WITH SIGNIFICANT CORONARY SINUSOIDS (CS): IS IT SAFE?

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Introduction: Safety and outcome of transcatheter RVD procedure in infants with PA+ IVS with significant CS is not well described in the literature.

Aim: Evaluation of the transcatheter RVD procedure in patients with PA+ IVS with significant CS with emphasis on the safety and long term outcome.

Methods: Retrospective review of the database from February 2003 to February 2015.

Results: 11 patients with PA+IVS and significant CS had transcatheter RVD procedure. 7/11 patients had significant fistulous connection from right ventricle (RV) to both the right coronary (RCA) and left anterior descending (LAD) arteries, 2/11 patients had fistulous connections to only LAD and 2/11 patients had fistulous connection to only RCA. In 10/11 patients there was a good filling of left coronary artery (LCA) and RCA branches in aortogram and in one patient the LAD was extremely small distal to the fistula. Transcatheter RVD was achieved in all the 11 patients with the RV pressure decreasing from the median of 146 (range: 118-212)% to a median of 66 (range: 44-81) % of systemic blood pressure. Following the RVD, RV angiogram was done in 8/11 patients and none of them had any significant CS.

4/11 patients had procedure related complications. One patient with large CS to RCA and LAD with extremely small LAD distal to the fistu-

la died immediately after the procedure with myocardial ischaemia. Other complications in remaining 3 patients include transient hypotension, bradycardia and contrast induced acute renal failure.

7/ 9 live patients were followed at a median duration of 15 (13-123) months following the RVD. All seven patients had good left ventricular function at the time of recent follow up. Two patients with recurrent sub pulmonary stenosis had CS seen in the follow up angiograms, which disappeared following the surgical RVOT reconstruction.

Conclusion: Transcatheter RVD in patients with PA+ IVS with significant CS is relatively safe procedure with good long term outcome. It is essential to exclude any stenosis or atresia of coronary arteries before embarking on RVD procedure.

#0150 INVOLVEMENT OF SUBCLAVIAN ARTERY INTO A SEVERE COARCTATION, IS IT A CONTRAINDICATION FOR STENTING?

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We describe a case of severe coarctation with subclavian artery involvement of a 22 years old symptomatic female referred to our center for endovascular resolution. She was under losartan, amlodipine, diuretics and beta blockers with mild response to medical treatment.

For admittance her BP was 180/100 mmHg and a soft pan systolic murmur was heard on left sternal border and between the spine and left scapula. Absence of pulses on inferior limbs was markedly noted.

Prior to angiography a CT contrast scan with 3d reconstruction was performed and details of anatomy and collaterals were discussed with the cath lab crew. After review of all data an endovascular procedure was planned.

The case was done under general anaesthesia without pacing. Adequate stent deployment under balanced general anaesthesia, with remifentanyl and sevoflurane was given. The main purpose was to induce a relative decrease of 20-25% of baseline BP values with hemodynamic stability, until the release of the stent. Controlled hypotension was carried out, increasing the dose infusion of remifentanyl and propofol bolus of 50 to 75 mg .

Non significant residual gradient was detected and flow to left subclavian artery was normal .

Involment of left subclavian artery into a severe coarctation is infrequent but it is an issue of concern.

These techniques helped to leave the non covered part of stent's struts at the edge of coarctation, and where the clue for safe coarctation relief and keep adequate flow to LSA.

Control CT scan one month after the procedure confirmed postop findings.

LSA involvement not should be considered an absolute contraindication for coarctation stenting. Team work is essential for adequate stent deployment on these cases.

#0151 USE OF 3D ROTATIONAL ANGIOGRAPHY (3DRA) IN HYPOPLASTIC LEFT HEART SYNDROME (HLHS) AFTER NORWOOD I OPERATION: UNMASKING AND TREATING COMPLEX STENOSIS NOT DETECTED BY BIPLANE ANGIOGRAPHY

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Background: In patients with hypoplastic left heart syndrome (HLHS) severe deterioration can occur after Norwood I operation (NWI) based on AP shunt underperfusion or aortic arch stenosis. Best visualization of the substrate is crucial. 3DRA at start-up can unmask complex substrates not visible by biplane angiography and guide the interventional approach.

Methods: We retrospectively studied our patients with HLHS and severe deterioration who underwent heart catheterization (Cath) between May 2013 and May 2015 and analysed procedural and epidemiological data. 3DRA was used when the hemodynamic problem could not be identified with biplane angiography.

Results: (numbers represent median (min-max)). 6 patients were included with a weight of 4,1 kg (3,5-4,7) and age 43 days (8-92) at Cath which was performed 33 days (2-85) after NWI. Procedure time was 121 min (97-232). 3DRA required rapid pacing of the ventricle between 200 to 250/min. The entire morphology was visualized in one run using 16 ml (11-26) of contrast (Iohexal 300mg/ml). 3DRA dose area product (DAP) was 29 uGum2 (19-60) compared to a total procedural DAP of 444 (80-544) corresponding to 8,2% (3,6-40,3). In all 6 patients the substrate was not or not sufficiently visible on the initial biplane angiographies. After 3D reconstruction virtual angulations and segmentation technique delineated the complex substrate. In 3 patients the AP-shunt was stented. 1 patient underwent stenting of the neo-aortic-arch. In 1 patient the AP-shunt and in another the aortic arch were balloonedilated. No 3DRA related complications occurred.

Conclusion: 3DRA can be performed safely in critical ill patients after NWI. A single 3DRA run does visualize the entire topography and delineate shunt related stenosis and neo-aortic-arch substrates. 3D reconstruction enables virtual angulations not achievable by biplane angiography. Substrates would have been missed or misunderstood by the use of biplane angiography only. 3DRA radiation dose and contrast amount are low. Multiple angulated biplane angiographies with high amount of contrast and radiation can be avoided. 3DRA road mapping shortens procedure time and adds safeness.

#0152 SHORT TERM OUTCOMES OF PATENT DUCTUS ARTERIOSUS CLOSURE WITH NEW OCCLUTECH DUCT OCCLUDER: A MULTICENTER STUDY

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Background: The Occlutech duct occluder (ODO) is a new self-expanding nitinol device with a shape that is reminiscent of a "champagne cork". Its body is wider at the pulmonary artery end than the aortic end and has no distal protruding hub. It is available in longer lengths than the Amplatzer duct occluder.

Objective: We aimed to evaluate the characteristics and short term results of patients who underwent transcatheter closure of patent ductus arteriosus (PDA) using the ODO.

Methods: We reviewed the clinical records of 59 patients from different centers in Turkey, who underwent percutaneous closure of a PDA with an ODO between December 2013 and May 2015. PDA was classified according to the classification described by Kricheenko et al.

Results: Median patient age was 2.5 years (range, 6 months-17 years), median weight was 15 kg (range, 5-60 kg), and median PDA diameter was 2.5 mm (range, 1.2-7 mm). The angiographic appearance of the ductus was type A in 49 (83%) patients, type B in 1 (1.6%) patient, type C in 3 (5%) patients, type E in 5 (8.4%) patients. Median fluoroscopy time was 14 minutes (range, 4.2-30 minutes). Fifty-seven out of 59 patients (96.6%) had successful ODO implantation. Occlusion rates were 36/57 (63.1%) at the end of the procedure, 50/57 (87.7%) at 24-48 hours post procedure, and 56/57 (98.2%) on echocardiography at a median follow-up of 2.2 months (range, 1 day-17 months). In only one patient device-related complication was observed (embolization to aorta). In another patient, the device was withdrawn before release.

Conclusion: Our results indicate that transcatheter closure of PDA using the ODO is safe and effective. While early residual shunt ratio was higher than the other duct occluders, the residual shunt ratio was equivalent to other devices during the follow up. Larger studies and longer follow up are required to assess whether its shape and longer length make it superior to other duct occluders.

#0153

CASE REPORT: USE OF TRANSTHORACIC ECHOCARDIOGRAM ALONE, WITHOUT

TRANSESOPHAGEAL ECHOCARDIOGRAM AND LEFT VENTRICULAR ANGIOGRAM FOR POSITIONING AND RELEASE OF VENTRICULAR SEPTAL DEFECT DEVICE.

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Device closure for muscular ventricular septal defect (VSD) is a well established mode of treatment. Routinely it is done with the help of transesophageal echocardiography (TEE), fluoroscopic guidance and left ventricular angiogram in the catheterization laboratory. I describe a case, where the procedure was done using transthoracic echocardiography (TTE) and fluoroscopic guidance and the device was released with TTE guidance alone without angiogram.

6 year old male child presented with a history of recurrent respiratory tract infections. Clinically had signs of left ventricular dilatation and 4/6 pansystolic murmur was heard best at the apex. TTE revealed single moderate sized (8mm on the left ventricular side and 6mm on the right ventricular side) posterior upper muscular VSD left to right shunt. The decision was made to close the VSD with device. Anatomy of VSD was delineated by doing left ventricular injection of contrast in atleast two views and the device size was marked as 12mm muscular Amplatzer VSD device. VSD was crossed retrogradely and arterio-venous loop was made through which Mullin's sheath introduced anterogradely through the right femoral vein. Once the Sheath tip was positioned in the left ventricle facing the apex, the device was introduced through the sheath and pushed till the tip of the device came out of the sheath. TTE was done to confirm the tip position. Then left ventricular disc was released and positioned along the septum. Then an unexpected incident happened, the injector stopped working. Left ventricular angiogram could not be done to confirm the device position (The most important step in the procedure). I decided to go ahead with TTE (at least 3 views) for confirmation of the position of the device. The right ventricular disc was released with the TTE guidance. The final positioning of the device was confirmed with TTE. The device was unscrewed and released from the cable. Post procedure TTE showed device in good position and no residual shunting.

TTE could be used as a potential alternative for TEE during VSD device procedure and risks of endotracheal intubation can be avoided. I learnt the hard way that TTE could potentially be used even if angiogram could not be done (due to unexpected event) to confirm the positioning and releasing the device.

#0154

STENT IMPLANTATION IN CRITICAL COARCTATION AS A BRIDGING THERAPY IN VERY-LOW-BIRTH-WEIGHT INFANTS

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Background: Surgical treatment is the therapy of choice for aortic coarctation (CoA) in term newborns. In very low birth weight newborns (VLBW) therapy is challenging due to weight, vulnerability for side effects of Prostaglandin and unbalanced systemic versus pulmonary perfusion. Coronary-stent implantation can be used in critically ill VLBW newborns as a bridging-therapy to surgery.

Objective: We report on our experience with coronary stent implantation in 4 VLBW infants with critical CoA.

Methods: Clinical, echocardiographic and angiographic data were reviewed for the 4 patients who underwent CoA stenting between 2011 and 2014 including follow until surgery.

Results: At intervention median age was 12 days (7-15), weight 950 gr. (680-1500). Invasive gradient at cath was 42,5 mmHg (40-55) with residual gradient of 0 (0-10) after stentimplantation. Stentdiameter ranged from 3-5mm. Median procedural time was 85 min.

There were no complications during the procedures. At follow up the femoral artery used for intervention was occluded in all infants without clinical compromise. All but one infant showed unremarkable follow-up until surgery which was performed at a median age of 6,25 months (3,5-8) with a weight of 5,35kg (5,0-5,8). In one infant re-cath was necessary to further postpone surgery because of early re-stenosis which was associated with a severe aortic aneurysm 2 months after stentimplantation. With still a low weight of 2,2kg a coronary graft stent was implanted and the aneurysm completely covered. All children received surgical correction with longitudinal incision of the coronary stent and patchplasty. During the postoperative follow up with a median of 1,6 years (0,1-3) no re-intervention was indicated.

Conclusions: Stentimplantation is an option to treat CoA in critical ill VLBW newborns in whom Prostaglandin had to be stopped or was ineffective. Our experience is limited to 4 patients below 1500gr of weight. The procedure is technically challenging and demands a special workflow. Bridging-to-operation was successful and all 4 newborns underwent surgical correction months after stentimplantation.

#0155

SEVERELY REGURGITANT LV-AAO CONDUIT IN A FAILING FONTAN PATIENT TREATED WITH A VASCULAR ENDOGRAFT AND MELODY TRANSCATHETER VALVE VIA A NOVEL HYBRID APPROACH

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A 28 year-old male with d-transposition of the great arteries, hypoplastic right ventricle (RV), ventricular septal defect (VSD) and straddling tricuspid valve status post Fontan palliation presents with increasing abdominal ascites and lower extremity edema. Four years following his Fontan operation, the patient underwent placement of a 20 mm homograft conduit from the left ventricular (LV) to ascending aorta (LV-AAo) due to progressive severe restriction of the VSD. Given his new and progressive symptoms, the patient was referred to the catheterization laboratory where hemodynamic evaluation revealed Fontan pressures of 25 mmHg secondary to elevated RV and LV end diastolic pressures (EDP) of 22 and 21 mmHg, respectively. There was severe regurgitation of the LV-AAo conduit. As the patient was an extremely high-risk surgical candidate secondary to his numerous prior sternotomies, high Fontan pressures, and severe diastolic dysfunction, he was referred back to the catheterization laboratory 2 months later for transcatheter valve placement within the LV-AAo conduit. The LV-AAo conduit inserted on the leftward aspect of the ascending aorta following the lesser curve of the transverse arch. This created an almost 180 degree tight turn from the transverse arch to the distal LV-AAo conduit and precluded transcatheter valve

delivery from a femoral arterial approach. The proximal LV-AAo conduit takeoff was from the LV apex with an oblique orientation to the ventricle, precluding a transapical approach. A vascular surgery team sutured an 8 mm Dacron tube graft directly to the right axillary artery, which provided direct approach to the LV-AAo conduit via the right innominate artery. Once the conduit was accessed, an 82 mm Endurant II stent graft (Medtronic, Minneapolis, MN) was placed within the heavily calcified LV-AAo conduit prior to conduit stenting to protect from possible catastrophic rupture. A Melody® Transcatheter Pulmonary Valve (Medtronic, Minneapolis, MN) was implanted within the LV-AAo conduit entirely within the distal end of the stent graft. Post-procedural LV EDP dropped considerably to 10 mmHg and the LV-AAo conduit peak systolic ejection gradient was unchanged at 11 mmHg. Angiography demonstrated no residual LV-AAo conduit insufficiency. The patient tolerated the procedure well without complication and was discharged to home the following day.

#0156

OUTCOMES OF TRANSCATHETER ATRIAL SEPTAL INTERVENTIONS IN CONGENITAL HEART DEFECTS

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Background: The atrial septum (AS) is an anatomic structure of paramount physiological importance in critical congenital heart defects such as right and left heart obstruction, compromised Fontan circulation or LV failure. In this setting, an intervention to create or enlarge an atrial communication may improve the hemodynamics and be lifesaving.

Objective: The purpose of this study is to determine the frequency, type, complications and outcomes of transcatheter atrial septal interventions (ASI) in a pediatric population with congenital heart defects.

Methods: Using our cardiac catheterization database and electronic medical record, we retrospectively reviewed all patients that had an intervention in the atrial septum in our catheterization laboratory between June 1996 and July 2013. We collected demographic, procedural and follow up data. The interventions were divided: 1) left heart obstruction, 2) right heart obstruction and 3) left atrial (LA) decompression during left ventricular mechanical support and 4) miscellaneous. We used parametric statistics to compute and analyze the means, standard deviation and differences.

Results: A total of 52 patients (mean age 1.2 ±3.2 years; 30 (58%) males, underwent ASI during the study period. The ASI included: stent placement (n=9, 17.3%), septostomy using static (n=32, 61.5%) and cutting (n=12, 23%) balloon techniques, and radiofrequency perforation (n=2, 3.8%). For the patients with available follow up data (n=39), mean follow up was 3.3±2.7 years; and all had stable hemodynamics and achieved complete surgical palliation. There were 3 non-procedural deaths. For group 1 (n= 30), mean LA decreased (13±6 to 9±4 mmHg, p <0.01) and there was acute success in 26 (86%). The remaining 4 patients required subsequent interventions. There were minor complications in 3(10%). In group 2 (n=9), all achieved right atrial (RA) decompression (n=6) or improved filling of left ventricle (n=3). There were no major complications. In group 3(n=2) the LA was decompressed (18 to 12 mmHg, p=0.03) in both and there were no

major complications. In group 4 (n=11) improved oxygen saturation or RA decompression was achieved in all and there were no major complications.

Conclusions: Transcatheter atrial septal interventions to create or enlarge an atrial communication is an effective procedure and can be performed safely.

#0157

PERCUTANEOUS CLOSURE OF ATRIAL SEPTAL DEFECTS (ASD/PFO) GUIDED BY INTRACARDIAC ECHOCARDIOGRAPHY (ICE)

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Background: The transesophageal echocardiography (TEE), has been the most used method to guide percutaneous closure of ASD/PFO. The necessity of a professional other than the one performing the intervention, who is not always available; the intolerance of the endoesophageal probe in longer procedures and the necessity of sedation or general anesthesia and disadvantages of using ECTE. On the other hand, ICE makes possible both procedures been done by only one professional, under mild sedation or local anesthesia.

Objective: Showing the experience of the service with occlusion of ASD/PFO guided by ICE.

Method: Between 04/2011 and 1/2015 201 procedures were done under ICE control. The probe was introduced through the femoral vein until right atrium, followed by delicate maneuver to get the wanted images. After that, the procedures followed the same steps used when they were guided by TEE. Finally, the sheaths were removed and manual compression was done for 5 to 20 minutes.

Results: The procedures were done with success in 201 (100%) patients: 129 (64%) female, age of 7 to 78 years old (mean=36,6+19,3); weight 28 to 92 kg (mean+62,5+13); fluoroscopy time (mean=5.7+2,4 mi), procedure time (mean=21,5+6,4mi). Complications: Four patients (2,0%) had transient arrhythmias and two (1,0%) had small arterio-venous fistula in the local of the puncture, with spontaneous resolution in one month.

Conclusion: The images' quality is fundamental to getting good results and making the procedure safe. ICE provides this quality, associated with freedom of schedule. It has been an excellent option to guide these procedures.

#0158

PERCUTANEOUS CLOSURE OF OSTIUM SECUNDUM ATRIAL SEPTAL DEFECT USING AN AMPLATZER DEVICE IN CHILDREN WEIGHING LESS THAN 20 KILOGRAMS

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Percutaneous closure is the method of choice for the treatment of

ostium secundum atrial septal defects (ASD) because it is highly successful and has low morbidity and mortality rates. However, this method is challenging to perform in young children (<20kg) due to a higher risk of complication.

Aim: To present our unit's experience in ostium secundum atrial septal defect closure in children.

Method: Between March 2010 and October 2013, 36 children weighing up to 20kg each underwent percutaneous closures of atrial septal defects. In each case, the reason for performing ASD closure was significant hemodynamic repercussion. All patients underwent general anesthesia and were administered 3-5 mg/kg/day acetylsalicylic acid starting one week before the intervention and continuing for 6 months after the procedure. A single dose of cefazolin was given as prophylaxis against endocarditis. The recommended prophylaxis for endocarditis was maintained for 6 months. A transesophageal echocardiogram using a pediatric probe was performed in all patients.

Result: The procedure was successful in 100% of the patients. The smallest and the largest devices were sizes 14 and 28, respectively (mean=18). The device/weight ratio was less than in 15 of the patients (13.9%) and over 1 in 31 of the patients (86.1%). Supraventricular tachycardia developed in two of the patients (9.6%); conversion with adenosine was used in one patient, and venous amiodarone was administered over a course of 24 hours in the other patient. Headaches presented in four of the patients (11%), lasting from 7 to 25 days. No residual shunt was observed in 34 of the patients (94.4%), and there was a trivial residual shunt in two of the patients (5.6%). Following the procedure, the right heart chambers of all of the patients became normal, and all patients clinically improved without further complications.

Discussion/Conclusions: Percutaneous closure of ostium secundum atrial septal defect in children weighing less than 20kg is indicated in cases where there are significant hemodynamic repercussions or when a septal defect gradually becomes enlarged. Generally, in such circumstances, the atrial septal defect is considered to be large relative to the child's weight; therefore, the risk of complication is higher. In our series, the procedure was successful in 100% of cases and produced no major complications. Percutaneous closure of ostium secundum atrial septal defects may be performed safely in children weighing less than 20kg. In our opinion, it is the method of choice for the treatment of this condition.

#0159

CLOSURE OF MULTIPLE ATRIAL SEPTAL DEFECT WITH MORE THAN ONE AMPLATZER SEPTAL OCCLUDER DEVICES, EXPERIENCE IN A SOUTH AMERICAN HOSPITAL

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Background: The closure of multiple atrial septal defect (ASD) with more than one Amplatzer Septal Occluder (ASO) devices have been described, but there is a few publications relating the experience of this procedure in a South American Hospital. **Objectives:** Describe the

experience of closing multiple ASD with more than one ASO devices, effectiveness and follow up in a South American Hospital (Guayaquil-Ecuador).

Methods: From June 2013 to May 2015, four patients (median age 47,6 years, median weight 48,5 Kg) went to closure of multiple ASD with more than one ASO devices under transesophageal echography (TEE) guidance.

Results: The chosen devices were 1 to 2 mm more than the diameter of the balloon sizing using the "stop flow" technique. In four patients were used 8 devices. The mean diameter of the large and small defects were 19,75 mm and 12,75 mm. The device mean diameters used were 20,5 mm and 14 mm. After the procedure all 4 patients had no residual shunt, there were no complications. One patient had mild mitral regurgitation, described previously in a transthoracic echography, with no modification after the procedure. The mean follow up were 9,75 months (5 to 18 months).

Conclusions: The closure of multiple ASD with more than one ASO devices is an effective procedure with no complication described in this experience. Follow up is very important to guarantee the successful long-term outcome of the procedure.

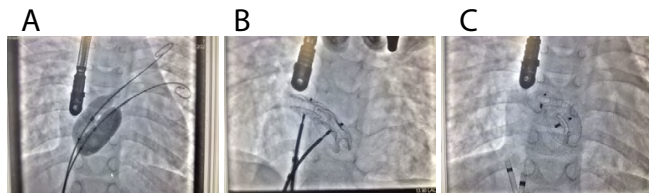


Figure 1. Fluoroscopy of the procedure in one patient. A. Defects crossed with two size balloons. B. The large and de small device were deployed. C. Devices released.

#0160

PERCUTANEOUS OCCLUSION OF PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECT: MID- AND LATE-TERM FOLLOW-UP

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Background: Percutaneous occlusion of perimembranous ventricular septal defect (pmVSD) has been an option to handle it, with good and safe early results. In other hand there is little data on long-term follow up (FU)

Objectives: To determine safe and effectiveness of pmVSD percutaneous closure and its complications in mid- and late-term follow up.

Methods: Prospective, nonrandomized study including 60 patients (62,7% female) submitted to percutaneous occlusion of pmVSD from

June/09 to May/15. Mean age $9.9 \pm 6,6$ years and mean weight $32,4 \pm 18,7$ Kg. Most procedures were performed under sedation, guided by transthoracic echocardiography (TTE). PmVSD was retrograde crossed. Electrocardiography was performed during the first two days, and then 1, 3, 6 and 12 months and every year thereafter. Echocardiography was performed looking for residual shunt and aortic insufficiency annually.

Results: Mean pmVSD diameter was $6.1 \pm 2,2$ mm, which 40% was multi fenestrated VSD, Four different devices were used - Cera Lifetch (n=48), Shsma Lepu (n=9), Flipper (n=2) and Nit Occlud (n=1). 40% had residual shunt immediately after procedure, however during follow up there was only 13% of minimal or mild shunt (90% of multi fenestrated VSD). Coil devices showed high frequency of residual shunt (67%). There were 14 cases of FU loss (23%). Median FU time is 2,4 years (1 month - 5 years). Although 14% had some arrhythmia, only one pt was submitted to pacemaker implantation, and half of them were back to sinus rhythmus before 6 months of FU. Three pts had aortic insufficiency, two mild insufficiency without worsening during follow up and one underwent to aortic valvuloplasty due to noncoronary leaflet perforation.

Conclusions: Double disk device occluders showed to be safe and effective, with low incidence of significant arrhythmia or aortic insufficiencies in mid and long term follow up.

#0161

STENTING DUCTUS ARTERIOSUS AS INITIAL PALLIATION FOR DUCT-DEPENDENT CONGENITAL HEART DISEASE: EARLY OUTCOME AND FOLLOW-UP

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Stenting the ductus arteriosus for congenital heart disease with duct-dependent pulmonary circulation is an alternative to surgical palliation due to its lower morbidity and risk of complications. This study aims to analyse the safety of stenting the ductus arteriosus, determine risk factors influencing its complications and the mid term follow-up until a surgical approach if necessary.

Method: Retrospective analysis of medical records in 80 (58,7% males) children in whom stenting of the ductus arteriosus (DA) as initial palliation were performed from April 2007 to May 2015.

Results: The mean age was 91.4 days (SD 194.2) with a median of 19 days at the time of the procedure. 53.8% were neonates. The average weight was 3.5 kg (SD 1.73). 20% of patients have some other underlying disease; prematurity being the most frequent (7.1%) and 74.6% were in ICU support. The following diagnoses were identified: transposition of the great arteries (6.4%), pulmonary atresia or critical pulmonary stenosis (34.6%), pulmonary atresia with ventricular septal defect (VSD) (32,1%), univentricular heart (26.9%). Success was achieved in 92.4% of procedures with two (2,5%) deaths related

to procedure. There was an increase in DA average diameter of 1.93 mm to 3.68mm ($p < 0.001$) and in the O₂ saturation of 65% to 82% ($p < 0.001$). 51% of patients had hypoplasia of the pulmonary arteries. Stent-related complications occurred in 26,6% and they have been: acute occlusion (6,3%), stent migration (5,1%) and obstruction of one of the pulmonary arteries (10%). Univentricular hearts were more associated with stent-related complications (52%; $p=0,01$). There was a higher incidence of complications and deaths with hypoplastic pulmonary arteries (37%; $p=0,08$ and 39,5%, $p=0,02$, respectively) The mean ICU stay and hospital stay were 7,3 and 20 days respectively. The mortality rate at follow up were 8,8% before hospital discharge and 13,8% after. 7,6% related to stent or hypoxia. The mean follow up was 15,3 months (SD 21,5) and the mean time among procedure and surgery was 10 months (median 4,2). 22,6% of patients underwent other percutaneous intervention and 23,8% surgical approach. **CONCLUSION** Stenting in ductus arteriosus is an alternative to the initial surgical palliation in most patients, but attention should be paid to the degree of hypoplasia of the pulmonary arteries and close monitoring before the definitive approach.

#0162

COLLABORATION OF PEDIATRIC AND ADULT INTERVENTIONAL PROGRAMS FOR MELODY VALVE IMPLANTATION: BUILDING PROCEDURAL EXPERTISE AND A CONGENITAL CARDIAC TEAM

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Objective: Interventional cardiologists and cardiac surgeons from two institutions sought to capitalize on individual program strengths to build a single, high-quality Melody Valve program.

Background: Interventionalists from a free-standing children's hospital and an adult academic medical center possess separate expertise in congenital cardiac, coronary artery disease and transcatheter techniques. Combining the knowledge and procedural experience of each team could provide distinct advantages for children and adults undergoing Melody Valve implantation.

Methods: The two institutions formed a single interventional team to provide Melody Valve treatment at both centers. The team, consisting of adult and pediatric interventional cardiologists, an adult cardiovascular surgeon and a congenital cardiovascular surgeon, collaborated on peer-to-peer training, shared clinical privileges, proctoring, patient selection and case scheduling. Generally, patients <18 years were treated at the children's hospital and patients >18 years at the adult center.

Results: From July 2012 to May 2015, the team treated 31 patients meeting criteria for Melody Valve in right ventricle to pulmonary artery conduits. Successful implantation was performed in 26 patients (14 at the children's hospital, 12 at the adult center). Concern over potential coronary compression (3 patients) and inadequate landing zone (2 patients) prevented implantation in 5 patients. The successful team dynamic allowed further collaboration at the children's hospital. In 2014, two children (age 16 months and 4 years) with severe coronary ostial stenosis underwent successful coronary stent angioplasty.

Conclusion: The collaborative approach led to more rapid procedural volume and expertise for the team. Collaboration of adult and pediatric interventionalists provided further clinical benefits, including successful complex coronary interventions in children.

#0163

USE OF ISOPROTERENOL TO ASSESS GRADIENTS IN COARCTATION OF THE AORTA FOR INTERVENTIONS IN THE CATHETERIZATION LABORATORY: UNMASKING THE BORDERLINE COARCTATION

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Introduction: One of the indications for intervention in coarctation of the aorta (CoA) is a peak-to-peak gradient >20 mmHg. However, gradients are dependent in part on the pt's physiologic state. Those with borderline CoA may develop increased gradients during exercise, and those under general anesthesia may display falsely lower gradients. Some data demonstrate that isoproterenol (ISO) may simulate a more active physiologic state under anesthesia resulting in larger and more accurate gradients at catheterization; however, the utility of ISO to assess gradients before and after CoA interventions has not been well studied. The objective of this study was to describe the use of ISO to assess borderline CoA gradients before and after an intervention.

Methods: A retrospective review was performed on 2-ventricle pts who underwent intervention for CoA with ISO testing from 10/2012 to 3/2015 at a single institution. Demographic, hemodynamic, and angiographic data were evaluated.

Results: Twenty-six pts were included (mean age 8.6±6.5 yrs). CoA was the underlying diagnosis in 22 pts. The remaining had hypoplastic (3) or interrupted (1) arch. Eight pts had prior surgery, 6 had prior catheter intervention, 4 had both, and 8 had no prior intervention. ISO increased the heart rate by 49±18%. The mean gradient doubled from 18.4±13.6 mmHg at rest to 39.3±19.5 mmHg with ISO challenge ($p < 0.001$). Among the 24 pts given ISO post-intervention, the gradient decreased from 40.6±19.7 to 16.9±16.7 mmHg ($p < 0.001$). Seventeen pts had initial borderline resting gradients (≤ 20 mmHg). Within this sub-group, the gradient almost tripled from 10.1±5.7 mmHg at rest to 28.3±10.1 mmHg with ISO ($p < 0.001$). Fourteen of these pts (82%) developed significant gradients (>20 mmHg). Following intervention, the CoA minimum diameter improved from 8.4±3.9 to 11.1±4.4 mm ($p < 0.001$). In the 13 pts who received the same ISO challenge post-intervention, the gradient decreased from 31.6±8.2 to 9.7±7.8 mmHg ($p < 0.001$).

Conclusion: ISO can be used to increase cardiac output to unmask a significant CoA gradient and to assess the effectiveness of an intervention for CoA. This is particularly useful in pts with a borderline gradient under general anesthesia. Stent implantation and balloon angioplasty can effectively reduce the gradient elicited by ISO and improve the vessel caliber.

#0164

PRE-MOUNTED STENTS IN BRANCH PULMONARY ARTERIES: A SHORT TERM SOLUTION

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Background: Transcatheter stenting of branch pulmonary artery stenosis (BPAS) has been shown to be effective, however if placed in a young child will require serial re-dilation with growth. Use of small pre-mounted stents in growing children raises concern of long term viability with limited expandability.

Methods: 61 children underwent 83 pre-mounted stenting for BPAS from 1/1/2003 to 10/1/2013. Cardiac defects included 33% tetralogy of Fallot / double outlet right ventricle, 5% transposition, 20% pulmonary atresia (PA) with major aorto-pulmonary collateral arteries (MAPCAs), 7% PA without MAPCAs, 13% truncus, and 20% single ventricle. 28% of patients had genetic syndromes, including DiGeorge, Down and Alagille. 72% of patients had native BPAS, and the rest were post-op. Median age at procedure was 7.5 months and median weight was 6.3 kg. Stent sizes ranged from 4 mm to 9 mm; with a median of 6 mm. Average duration of follow up was 3.2 years. 14% of stents were placed within 30 days of a cardiac surgery.

Results: Short term outcomes were good, with mean improvement of stenotic vessel caliber by 153%, mean reduction of stenosis degree by 58%, and mean improvement of pressure gradient by 63%. There were 8 procedural complications (9.6%), including 5 embolizations, 1 ventricular tachycardia requiring electrical cardioversion, and 2 cardiopulmonary arrests. Long term outcomes were poor, with freedom from re-intervention at 1 year of 51% and 5 years of 14%. Post balloon dilations were not very effective, increasing mean stent diameter from 5.0 mm to 5.8 mm. Only 1 stent was able to be fractured longitudinally. Freedom from surgical stent removal (SSR) was 81% at 1 year 35% at 5 years. Predictors of poor outcome include Blalock-Taussig shunt surgery (79% requiring SSR, p 0.009) and smaller stent size (p 0.005). Predictors of good outcome include peripheral BPAS (0% requiring SSR vs 54% for central BPAS, p 0.049) and greater improvement of pressure gradient (72% improvement in the non-surgical group vs 56% in the SSR, p 0.045).

Conclusions: Pre-mounted stent is a short term solution for BPAS with very poor long term outcomes. Every effort should be made to avoid it as much as possible and use larger stents that can be dilated to adult size if able.

#0165

SUCCESSFUL PERCUTANEOUS CLOSURE OF BILATERAL PULMONARY ARTERY MYCOTIC ANEURYSMS IN AN INFANT

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Introduction: Mycotic aneurysms are rare in pediatrics compared to the adult population. Mycotic aneurysms are known to carry a high risk of spontaneous rupture and death. Surgical intervention also carries a high risk of rupture, significant bleeding and mortality. There are reports of percutaneous closure with coils or detachable balloons in adults. We describe the first reported case of successful percutaneous closure of mycotic pulmonary aneurysms in an infant.

Procedure: The patient is a 5.2 kg 2 month old former premature infant transferred from an outside hospital with MRSA sepsis, meningitis and septic emboli to the lungs. On CTA, she was noted to have bilateral lower lobe pulmonary artery aneurysms measuring 2cm X 1.5 cm. She was treated with multiple IV antibiotics and clinically improved. Pediatric surgery and Interventional Radiology turned her down for exclusion of the aneurysms as the risk of rupture and death was felt to be too high.

After review of the CTA, she was taken to the cath lab and a 5 Fr. Sheath was placed in the RFV and a 2.5 Fr. monitoring cath was placed in the RFA. Multiple selective hand injections were performed in both lower pulmonary arteries. Both aneurysms measured approx 2 cm with swirling flow. The aneurysmal branches both measured 2.5-3 mm and were accessed with a Pilot wire, Contada microcatheter and angled glide combination under fluoro road mapping being careful not to advance the catheters into the aneurysm. 4mm Amplatzer Vascular Plugs II were advanced and deployed at the neck of the aneurysm on both sides. Repeat angiograms demonstrated complete occlusion of the aneurysm and no obstruction to flow to normal branches. There were no complications. She was discharged to home 4 days later. She had a repeat CTA 2 months later which demonstrated complete resolution of the aneurysms.

Conclusion: Percutaneous occlusion of mycotic pulmonary aneurysms can be successfully performed in pediatric patients. Careful review of CTA for the location, size and feeding branch is very helpful in planning the cath. Significant care needs to be taken not to advance the catheters into these very thin walled aneurysms

#0166

UTILIZING MOBILE TECHNOLOGY TO IMPROVE COMMUNICATION-THE EASE APP

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Introduction: Parents of children are naturally very anxious during any operative procedure. We sought to utilize current smartphone technology to explore how this could be improved utilizing an application called EASE (Electronic Access to Surgical Events). This application updates families of patients undergoing cardiac interventions utilizing text, photo and video.

Methods: All parents of children undergoing cardiac catheterization were offered use of an application on their smart phone, or one provided to them during their child's procedure to receive one way communication with the staff in the laboratory on the condition of their child via text message, video or photographs at a minimum of every 30 minutes. All parents who utilized the EASE Application during their child's cardiac catheterization were surveyed after utilizing the application.

Results: The study cohort includes 118 patients that underwent cardiovascular interventions and utilized the EASE application. 99% of the parents reported they would use this application if they themselves or their loved one required future medical procedures. 97% said the texts, photos and videos were appropriate, and 74% reported that the availability of EASE would influence their choice of hospital should they themselves, or a loved one require future surgery or

intervention. 97% of all families surveyed felt they were more at EASE with the use of this application and found it superior to traditional ways of updating them during invasive procedures. Overall, the app was rated 9.9/10 for overall experience with the EASE application.

Conclusion: Families found that use of the EASE application during cardiac interventions is an effective and superior supplement to the use of traditional methods of communicating with families during invasive cardiac catheterizations.

#0167

PREVENTING ARTERIAL OCCLUSION AFTER CARDIAC CATHETERIZATION

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Background: Arterial occlusion is a relatively common complication seen in smaller patients. Arterial spasm and local injury can predispose to thrombosis and loss of arterial patency. Reported occurrence ranges from 4.3-5.4%, with low weight considered as a risk factor. Intra-arterial nitroglycerin reduces risk of radial arterial occlusion in adults. We reviewed the incidence of arterial occlusion after administration of femoral arterial nitroglycerin (FAN) in patients weighing < 10 kg after cardiac catheterization.

Objective: Outcomes of patients weighing <10 kg who received FAN were reviewed. A retrospective review of the demographic, procedural data and outcomes was performed.

Results: Five patients underwent 6 procedures where they received FAN from November 2014-May 2015. Weight ranged from 2.3 kg – 9.1 kg, age ranges 20 days – 16 months. Procedures performed were patent ductus arteriosus occlusion in 3 and hemodynamics in 2 patients, with 3 or 4 Fr arterial sheaths. All patients received FAN before removal of arterial sheaths. Angiogram showed improvement in arterial spasm after FAN. Clinical follow-up revealed equal pedal pulses in the immediate post-procedural and follow-up period.

Outcomes: Administration of FAN reduced clinical loss of pulse in our cohort of patients < 10 kg. Although our population size was limited, FAN may be considered in patients at risk for arterial occlusion. A larger study is needed.

#0168

BALLOON-EXPANDABLE COVERED STENT IMPLANTATION FOR TREATMENT OF TRAUMATIC AORTIC PSEUDOANEURYSM IN A PEDIATRIC PATIENT

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Traumatic aortic injuries occur rarely in the pediatric population. Adult vascular interventionalists more frequently encounter aortic injury, and endovascular graft placement is a commonly used management approach. The standard of care in pediatric traumatic aortic injury is an open surgical repair, although it is not always the optimal approach. Endovascular graft placement has been trialed in pediatric patients, but its use has technical limitations. We describe the case of an 8-year-old female passenger in a motor vehicle collision, resulting in formation of a traumatic aortic pseudoaneurysm. Due to her comorbidities, she was a high-risk surgical candidate, and therefore, un-

derwent successful percutaneous implantation of an investigational balloon-expandable covered Cheatham platinum (CP) stent (NuMed, Inc., Hopkinton, New York). This case demonstrates the utility of balloon-expandable covered stents for treatment of pediatric traumatic aortic injury (TIA) as an alternative to open surgical repair or percutaneous endograft implantation.

#0169

ANDRASTENTS IN CONGENITAL HEART DISEASE: EXPERIENCE IN 36 PATIENTS

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Introduction: AndraStents are cobalt-chromium balloon expandable and hand mounted stents recently developed for large vessels. XL Andrastents can be expanded from 8 to 25 mm and XXL up to 32 mm. Our experience on AndraStents implantation for congenital and postoperative cardiovascular lesions will be presented.

Methods: Between 2012 and 2015, AndraStent XL and XXL were used in 36 patients for large vessel stenosis and preenting of native RVOT before transcatheter pulmonary valve (TPV) by hand crimping on BIB or ZMed balloons.

Results: The mean patient age was 14.9 years (5–50 years), and the mean weight was 44 kg (15–84 kg). 40 stents were used in 36 patients; For aortic coarctation (AC) in 19, right ventricular outflow tract (RVOT) dysfunction in 19 and branch pulmonary artery stenosis in two. XXL was usually used for large RVOT and XL for AC. Of the 18 patients with RVOT dysfunction 14 of them were native, others were conduits. In coarctation patients two of them weighed less than 20 kg (15 kg and 17 kg). The mean diameter of the balloons used for implantation was 19.2 mm (8-30), and 10 of them were larger than 24 mm. The foreshortening percentages were found to be similar to those claimed by the manufacturer on fluoroscopic images. The vessel diameter was increased from a median 4.5 mm to a median of 12.5 mm, and the pressure gradient was decreased from a mean 40 mmHg to a mean of 3 mmHg in patients with coarctation. Stent slipping on the balloon has occurred in one and fracture in one. A bare and a covered Cheatham-Platinum (CP) stent were implanted on the fractured stent, and then PPVI was performed.

Conclusion: AndraStents have several advantages over Cheatham platinum stents: Its material and design allow better tissue penetration and better curve, and a lower crimping profile. Furthermore, XXL can be used with large aneurysmatic RVOTs since dilation up to 32 mm is possible. Sometimes can be used one Fr larger than the balloon shaft in lesions straight ways to reach such as AC, so it can be used in AC patients less than 20 kg in weight. A relatively low radial force, tendency to slipping of the balloon during the advancing in tortuous way and absence of a covered form are disadvantages when compared with CP stents.

#0170

TRANSCATHETER CLOSURE OF SECUNDUM ASD WITH COCCOON SEPTAL OCCLUDER IN CHILDREN; EARLY AND INTERMEDIATE TERM RESULTS

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Introduction: The aim of this study is to investigate the efficacy and safety of Cocoon septal occluder (CoSO) in ASD closure, which has similar characteristics with Amplatzer septal occluders (ASO) but low cost than it.

Methods: From January 2004 to December 2014, 724 patients underwent transcatheter ASD closure with various devices. Initially we used ASO in 144 patients. The other devices used were 434 Cardiofix septal occluders, 29 Ceraflex, 13 Cardia, 9 Figulla Occlutech, 7 Gore Helix, 2 Hyperion, 2 PFM septal occluders later. Nowadays, we have been using predominantly CoSO in ASD closure. We evaluated the efficacy and safety of CoSO in ASD closure in patients whose ages <18 years and compared with the patients' that ASO was used in regarding to procedural success, complications, procedure and fluoroscopy times, complete occlusion rate in one month. Only transthoracic echocardiography (TTE) was performed before the procedure in all, but TTE or transesophageal echocardiographic guidance was preferred according to complexity of the defect or echogenicity of the patient during the procedure.

Results: We have used CoSO in 76 and ASO in 87 children. Age and weight of the patient in CoSO and ASO groups were comparable as 8.5 ± 3.9 vs 8.2 ± 3.3 years, 29.8 ± 15.5 vs 27.1 ± 11.2 kg, respectively. Mean size of defects and devices were not statistically different between the groups; 15.1 ± 5 vs 15.2 ± 3.8 , $p: 0.85$ and 19 ± 5.5 vs 20 ± 4.8 , $p: 0.95$; respectively. The number of TTE guidance was 35 in CoSO and 45 in ASO. The complex defect rate and deployment technique was similar in both groups. Procedural success rate was %100 in both groups. Procedure and fluoroscopy time were significantly lower in CoSO group (48.6 ± 21.6 vs 66 ± 28.1 ; $p: 0.008$ and 8.8 ± 5.7 vs 16.6 ± 11.6 ; $p<0.001$, respectively). Complications were minimal and 2 in CoSO and 2 in ASO. Complete occlusion rate was similar as %97 in CoSO and %99 in ASO in one month. No complication has occurred during the intermediate term follow-up in both.

Conclusions: Our early and intermediate term results showed that CoSO is efficient and safe alternative in transcatheter ASD closure. It can be preferred because of low-cost.

#0171

TRANSCATHETER INTERVENTIONS IN NEONATES WITH CRITICAL PULMONARY STENOSIS IN THE ERA OF DUCT STENTING

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Introduction: Critical pulmonary stenosis (CPS) is defined as severe PS in a newborn with cyanosis or signs of low cardiac output at presentation. Pulmonary blood flow is mostly duct dependent. We present our experience with CPS between 2005 and 2014.

Method: 56 patients aged between 2-28 days (median 7 days) underwent pulmonary balloon valvuloplasty (PBV). Duct stenting was per-

formed immediate after in patients that hypoxemia persists (<75%) and had smaller RV and RVOT. In good RV morphology or non-constricted PDA, we waited for one week on prostaglandin (PGE) infusion. If hypoxemia persists longer, stent was implanted.

Results: In 56 patients, 46 of them were duct dependent, 10 of them have significant hypoxemia but duct had been occluded. The procedure was successful in 55 of 56 (98%). In one patient we couldn't crossed the valve and underwent to surgery. Predilation with coronary balloons in 10 and snare assisted technique was needed in two for crossing the valve with the final balloon. 20 newborn needed duct stenting; 14 in the same and 6 in subsequent session. Duct spontaneously occluded in two when waiting on PGE, recanalized and stented in one and surgical shunt was performed in another. Stent implantations were done antegrade fashion in 16, retrograde in four. There was no procedure-related mortality. The mean Z scores and valve diameters in duct stent group were significantly lower for both tricuspid and pulmonary valve than the others'. In one patient in whom pericardial effusion was developed, effusion was drained and the procedure was completed. During the follow up (median 58 months), transcatheter reintervention was performed in 10; PBV due to recurrent PS in 6, stent redilation in 3, transcatheter shunt occlusion in one. Surgical interventions were needed in 4; RVOT reconstruction in two, Glenn anastomosis in two. Severe pulmonary regurgitation was seen in two but no need valve replacement yet.

Conclusion: Although additional interventions are not uncommon in early and intermediate time after the procedure, PBV should be the first choice in newborn with CPS.

#0172

PERCUTANEOUS PULMONARY VALVE IMPLANTATION WITH EDWARDS-SAPIEN XT IN PATIENTS WITH NATIVE AND LARGE RIGHT VENTRICULAR OUTFLOW TRACT; EARLY PRELIMINARY RESULTS

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Introduction: Percutaneous pulmonary valve implantation (PPVI) has been used mainly for conduit dysfunction in right ventricular outflow tract (RVOT). Until recently, native RVOT without stenosis used to be considered a relative contraindication to transcatheter valvulation. We present early results of PPVI with Edwards-Sapien XT (ES-XT) in repaired tetralogy of Fallot (TOF) patients with native-large RVOTs.

Method: 12 s/p repaired TOF patients who had native RVOT with free pulmonary regurgitation and right ventricular dilatation without significant stenosis. Balloon sizing was performed in all patients with semi-compliant (\pm compliant) balloons for secure pre-stenting. The size of the Z-Med balloons and BIB catheters that the Andra Stents XXL would be mounted on was decided up to the indentation diameter occurred on the balloon during interrogation; as at least 2 mm larger than the indentation diameter.

Results: Median age and weight of the patients were 16 (8-50) years and 46 (27-84) kg, respectively. Indentation diameters with balloon interrogation were between 21.3 and 27.5; a median of 24.2 mm, and balloon sizes used for pre-stenting were 24 to 30 mm; a median of 27

mm. Successful valve implantation was achieved in all patients; 26 mm in four, 29 mm in others in the same or subsequent sessions, 20 – 47 days later. Valve function was good in all immediate after and at the last follow-up; a median of 2,5 months ranging 7days - 9 months.

Conclusion: PPVI with ES-XT valve, which has larger sizes as 23, 26 and 29 mm, is feasible and safe in patients larger native RVOT without stenosis in adolescents and adults. Newer delivery system (Novaflex), which is used through 14-20 Fr smaller sheaths, gives us also an opportunity of early transcatheter valvulation in smaller patients with native RVOT or early conduit dysfunction.

#0173

TRANSCATHETER TREATMENT OF MIDDLE AORTIC SYNDROME (MAS) WITH BARE AND COVERED STENT IMPLANTATIONS

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Introduction: Middle aortic syndrome (MAS) is an uncommon cause of arterial hypertension in children and young adults characterized by long segment narrowing of the distal thoracic and/or abdominal aorta. Stenosis of the abdominal aorta may be associated with stenoses of renal and visceral arteries.

Method: Between 2012 and 2015, five patients underwent stent implantation for the treatment of with MAS. In patients with severe sub-atretic stenosis, predilation with smaller sized balloons was required before stent implantations. Balloon size that stents will mount was selected according the diameter of distal aorta (1-2 mm smaller). When first stent does not cover the lesion completely additional stents were implanted by telescopic method. If the lesion is close to the critical vessels bare stents if not covered stents were implanted. After implantation further dilation was performed to optimum size in the same session or subsequent session after 6 months.

Results: Median age was 17 years (14–22 years). None had inflammatory signs of Takayasu arteritis but one had neurofibromatosis. Length of the stenosis varied between 19 mm and 105 mm (median 64 cm) and median diameter of the lesion was 3.3 mm (1.5-5.4 mm). Aortic narrowing was isolated in 4 patients and coexisted with left renal artery stenosis in one. 5 covered stents implantation was required for long segment sub-atretic lesion in one, two stents in three and single in one. Covered stents were used in two patients, both bare and covered stents in one and only bare stents in the last in two stages; cutting balloon suboptimal dilation in the first session than bare stents in the second. Balloon angioplasty for unilateral renal artery stenosis was performed in patient with neurofibromatosis. There was no procedural related complication. Redilation was needed due to suboptimal dilation in the first session in one and antihypertensive medication was continued in all.

Conclusion: Transcatheter treatment of long segment middle aortic syndrome is an effective and safe treatment option with excellent results. It improves both vessel diameter and pressure gradient by using multiple stents with telescopic method. Staged dilation may be preferred in some situations.

#0174

TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS WITH OCCLUTECH DUCT OCCLUDER: PRELIMINARY RESULTS

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Introduction: Occlutech PDA occluder is a new device for PDA closure and limited data available on it. It is fundamentally different as the shank the device is 2 mm larger at the pulmonic end than the aortic end, contrary to Amplatzer duct occluder. The aim of this study was to evaluate the feasibility, safety, and efficacy of this new device.

Method: 10 selected patients with conical shape PDA underwent transcatheter closure with Occlutech PDA occluder from November 2014 to May 2015. Decision for device size selection was based on the narrowest diameter of the PDA according to the manufacturer recommendation as the aortic end of the occluder shank to be at least 1.5-2.0 mm larger than the narrowest diameter of the duct. Angiogram was performed to confirm the device position and evaluate residual shunt just before and after the releasing the device. Patients were followed up by clinical examination and echocardiography at 24 hours, one month, 3 months and 6 months.

Results: The median age of the 10 patients was 2.5 years (6 months to 28 years) and median weight was 12.1 kg (7.5 to 50 kg). Narrowest PDA diameter was median 2.55 mm (2.0-5.8 mm). All patients had continuous cardiac murmur on examination and all PDAs were type A. Intervention was successful in all. Final angiogram after ten minutes showed complete closure in 9 of them. A moderate residual shunt was seen in only one who has the largest PDA diameter among all. This patient had also hemolysis confirmed by hemoglobinuria. It resolved in five days with medical treatment. Complete closure was observed at one month after the intervention in this patient. None of the patients showed evidence of stenosis at branch pulmonary artery and descending aorta by echocardiography during the 4 months of median follow-up (3- 6)

Conclusion: Our immediate and early-term results showed that Occlutech PDA occluder is a safe and effective device in transcatheter PDA closure. We have not observed any significant left pulmonary artery stenosis event though it might have been expected due to improper shape of the device for the conical type ducts which is most frequently observed and have larger aortic side in all. Limitations of the preliminary study were nonrandomized and unperformed lung perfusion scintigraphy. Further studies are required in larger groups with long-term follow-up and lung perfusion studies.

#0175

PERCUTANEOUS PULMONARY VALVE IMPLANTATION: EARLY AND INTERMEDIATE TERM RESULTS IN 36 PATIENTS

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Introduction: We report our initial experience in percutaneous pulmonary valve implantation (PPVI) in 30 patients with conduit and native right ventricular outflow tract (RVOT).

Method: Between 2012 and 2014, 36 patients with RVOT dysfunction underwent to catheterization for PPVI. Pre-stenting was performed in all in the same or the previous session.

Results: Mean age and weight of the patients were 16.5 years (6.0–50) and 49 kg (19–90), respectively. The diagnoses were s/p repaired tetralogy of Fallot (TOF) in 21 patients, s/p surgical correction of pulmonary atresia with VSD in six, Ross procedure for aortic valve in four, common arterial trunk in three, and s/p repaired transposition of the great arteries with VSD and pulmonary stenosis in two. 21 patients was repaired with a conduit whereas 15 patients with native RVOT. 13 patients were s/p repaired TOF with transannular patch, 12 of them had free pulmonary regurgitation without significant stenosis (<25 mmHg). Implantation was successful in all attempted (19 Melody, 17 Edwards-Sapien). Valve implantation was performed in the same session after pre-stenting in 13 and in subsequent session in 23 patients. The valve sizes for Melody; were 20 mm in 5 patients, 22 mm in 14, for Edwards-Sapien; 20 mm in one, 23 mm in 4, 26 mm in 4, and 29 mm in 8. The pressure gradient between the right ventricle and the pulmonary artery decreased significantly from 50 ± 14 mmHg to 11 ± 6 mmHg. No more than trivial regurgitation was observed immediate after the implantation. No procedure-related mortality occurred. After Melody valve implantation, three patients experienced infective endocarditis. Medical therapy was sufficient in two, while one needed surgery due to severe valve dysfunction. No significant restenosis has occurred yet (median 8 months follow-up). One patient who had severe left ventricular dysfunction with implanted pacemaker after Ross surgery suddenly died at home three months after the procedure, probably due to ventricular arrhythmia.

Conclusion: PPVI is a safe and effective option that can delay the need for redo surgery. We observed infective endocarditis in only Melody valves but no in Edwards-Sapien. PPVI is feasible not only in patients with a conduit but also in patients with large native RVOT with free pulmonary regurgitation using Edwards-Sapien valves.

#0176

OUTCOMES AND PREDICTORS OF REINTERVENTION IN PERCUTANEOUS TREATMENT OF AORTIC COARCTATION WITH AND WITHOUT STENT IMPLANTATION

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Balloning and/or stenting Aortic Coarctation (CoA) had become the treatment of choice in late childhood and adolescents patients with native and recurrent CoA, the complex anatomy of the aortic arch may be determinant in the medium and long term outcomes.

Objective: To show immediate and late results of percutaneous treatment of CoA and identify predictors of early and late reintervention.

Material and Methods: Since January 2002 to July 2014, 71 procedures of Balloning and/or endovascular stent placement were performed in

51 patients(pts). Mean age and weight :13 +- 5 years and 41+-11 kg respectively. Balloon angioplasty was performed in patients under 18 kg and stent placement over it. Transverse aortic arch, aortic isthmus and aortic descendent diameter were measured and gradients pressure modifications registered.

Results: Aortic Coarctation angioplasty and stent placement was effective in all patients. Initial mean systolic pressure gradient of 33,7+-17 mmHg decreased to 5 +-3 mmHg post stenting. Thirty eight patients underwent a single succesful procedure, 13 patients required more than one intervention. The mean transverse aortic arch diameter, isthmus and aortic arch Zvalue expresing hypoplasia were 10,3+-3,8mm,7,5+-3,7 mm and Z -1,2. CPbare stent was implanted in 10pts with normal transverse aortic arch, CP covered stent in 24pts and Advanta V12 in 7 pts, all with critical isthmus diameter and Palmatz 4014 in 3. There were 4 fracture, all in CP stent of first generation that required Stent reimplantation. Only one patient who had underwent bare stenting of native CoA developed aneurysm wich was succesfully treated with a covered CP stent. When the transverse aortic arch and aortic isthmus diameter correlations were made by logistic regression analysis, there were significant association between the isthmus and the need of reintervention with p0,43. There were no significant tendence between the transverse aortic arch diameter and Z value p0,8.

Conclusions: Percutaneous treatment of native and recurrent CoA is safe and effective with technical success of 100% at immediately. At medium and long follow up there were a strong correlation of complex anatomy and the need of reintervention .

#0177

SUCCESSFUL TRANSCATHETER CLOSURE OF AN AORTICO-LEFT VENTRICULAR TUNNEL WITH AMPLATZER VASCULAR PLUG II

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Introduction: Aortico-left ventricular tunnel (ALVT) is an abnormal communication between the aortic root and the left ventricle bypassing the aortic valve. Reports on device closure of aortico-left ventricular tunnel are. We present a successful ALVT closure with an Amplatzer vascular plug II (AVP II) not reported before.

Case: 14-year-old male referred for grade 3/6 diastolic murmur. Echocardiography revealed a tunnel-like communication between the aortic root and left ventricle (LV) causing diastolic regurgitant flow and LV enlargement and systolic dysfunction (LVEDd was 7.2 cm and EF: 45 %, FS: 22%). Narrowest point of the tunnel was 7.7 mm in diameter and 27 mm in length by echocardiography. On angiography, narrowest point was measured 5.8 mm in the middle part and 11 mm at the left ventricular opening side. After crossing the defect, balloon sizing with was performed to delineate size and course of the defect and showed a loose indentation on the 8 mm Tyshak balloon. Firstly, a 12 mm AVP II was used for closure but could not be released due to significant residual flow. Then a 14x12 mm Amplatzer duct occluder was tried. It closed the defect satisfactorily but caused significant aortic regurgitation (AR). Finally, it could only be possible to close the defect with 16 mm AVP II completely without significant AR. Echocardi-

ography on the next day showed complete occlusion with significant reduction in LV dimension and trivial-mild AR. At 4 months after the device closure, echocardiogram showed the device positioned well with no residual shunt and trivial-mild aortic regurgitation.

Conclusion: AVP II can be preferred in transcatheter closure of ALVT because of the soft and good occlusive characteristics. Another advantage of plug is not to protrude into the left ventricular outflow tract as duct occludes. However, measurements of ALVT dimensions on echo and angiography may be misleading due to complex morphology and larger devices than predicted may be required.

#0178

STENTING OF THE ARTERIAL DUCT FOR PULMONARY CIRCULATION IN INFANTS WITH FUNCTIONAL UNIVENTRICULAR HEART: SINGLE CENTER EXPERIENCE IN 68 PATIENTS

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Introduction: Ductal stenting has emerged as a non-surgical alternative to surgical aorto-pulmonary shunt in patients with duct-dependent or decreased pulmonary blood flow. This study reports our experience with duct stenting in 68 patients with functional univentricular heart (FUH).

Method: We retrospectively analyzed 68 infants who had FUH in 136 patients underwent cardiac catheterization for duct stenting in our institute between 2004 and 2014. Ductus was classified as Type A; Short, straight, originating from descending aorta (DAO), Type B; Longer, somewhat tortuous, originating from DAO, Type C; Long, vertical, more tortuous, originating from distal arch, Type D; Originating from subclavian artery and Type E; Bilateral.

Results: Median age was 20 days (3 days–8 months) and median weight was 3.4 (2.7 – 6.8) kg in 68 patients. 26 had pulmonary atresia with intact ventricular septum, 15 had tricuspid atresia or severe hypoplasia, 10 had unbalanced complete AVSD, 10 had double/single inlet ventricle and 7 had miscellaneous type of FUH. Ductus was Type A in 24, Type B in 26, Type C in 9, Type D in 6, Type E in 3. Implantation was successful in 65 of 68 (95%), unsuccessful due to acute ductal constriction in two and migration to descending aorta in one. Implantation was performed retrograde in 53, antegrade in 11 and both (bilateral duct stenting) in two. Oxygen saturation increased from $70\pm 7.6\%$ to $87\pm 4.6\%$, immediate after the procedure. One patient died after successful stent implantation probably due to pulmonary overflow. The follow-up period ranged from 6 months to 10 years (median 66 months). 48 infants reached to Glenn anastomosis without surgical intervention. Fontan completion was achieved in 19 of them. However, aorto-pulmonary shunt was required in 11 infants after 3 days to 7 months of the procedure, 2 were lost to follow up. Three patients died without intervention 4 days-6 months later during follow-up. The deaths were not related to the procedure. Stent redilation was performed in 14 patients due to decreasing of oxygen saturation in 3 to 10 months.

Conclusion: Stenting of the duct in infants with FUH is effective and safe alternative option as a bridge to second stage palliation. Mortal-

ity rate is comparable even better to conventional surgical shunt in FUH. Additional advantages of duct stenting to surgery are shortening hospital stay, eliminating problems of thoracotomy and reducing the number of operations.

#0179

USING A STEERABLE DELIVERY CATHETER TO SUCCESSFULLY DELIVER A CERAFLEX SEPTAL OCCLUDER TO CLOSE AN ATRIAL SEPTAL DEFECT IN A CHILD WITH INTERRUPTED INFERIOR VENA CAVA-AZYGOS CONTINUATION

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Introduction: Transcatheter secundum atrial septal defect (ASD) closure through the femoral vein is not always feasible in children with interrupted inferior vena cava (IVC), especially with large delivery sheaths. This paper reports on the jugular approach using a steerable delivery catheter to facilitate orientation of the device to the atrial septum in a child with interrupted IVC.

Case: A 12-year-old boy was referred to our hospital for percutaneous closure of a secundum ASD. On echocardiography, enlarged right heart cavities, left atrial isomerism, secundum ASD, interrupted IVC with azygos continuation and atrial septal aneurysm was observed. Transesophageal echocardiography revealed with a 19,2 mm secundum ASD with sufficient rims except aortic rim (3,5 mm). Coloured flow diameter was measured 22,9 mm and total atrial septum size was 40 mm. Cardiac catheterization was performed with the aim of closing the defect through azygos continuation. Using this route, the sizing balloon catheter couldn't be advanced through the femoral vein with azygos continuation. Therefore, through the jugular vein and an extra-stiff guidewire was placed into inferior pulmonary vein. Sizing balloon was glided across the defect. The stop flow and stretched sizes were 22.7 mm and 25.6 mm, respectively. A 24-mm Ceraflex Septal Occluder (CSO) was chosen and attempts at deployment of the device failed due to prolapse of the retention disks. Therefore, an Fustar steerable guiding catheter, which can be bent by a handle located on the sheath to create a better angle was used in order to easily anchor and deploy the device. A 24-mm CSO was loaded and delivered to the left-sided atrium through a 12F curved long sheath and easily implanted due to perfect alignment of the device with the interatrial septum. The patient was discharged the next day and did not experience any problems during the six-month follow up period.

Conclusion: To our knowledge, this is the largest atrial septal defect that was closed percutaneously through jugular vein in children. In our case, we observed that transjugular use of a steerable guide catheter for percutaneous closure in a pediatric patient with large ASD and interrupted IVC is feasible and convenient.

#0180

PERCUTANEOUS STENT IMPLANTATION FOR THE TREATMENT OF COMPLEX COARCTATION OF AORTA (COA) AND AORTIC ARCH OBSTRUCTIONS

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Background: Stent implantation (SI) has become an accepted modality for treatment of COA in older children, adolescents and adults. However, it may be challenging and technically demanding procedure in complex anatomic variations; i.e. subatresia, aortic/isthmus atresia, transverse arch hypoplasia or stenoses, short segment COAs very close to the left subclavian artery, long segment middle aortic syndromes, thoraco-abdominal or abdominal COAs, COAs associated with aneurysm or PDA, COA in Turner syndrome, COA associated with abnormally origin right subclavian artery from the coarcted segment.

Method: 136 patients with COA underwent to SI in our institute between 2007 and 2015. 45 of them had different properties and needed different techniques than standard SI. Antegrade approaches with radial artery puncture, perforation of the membrane or ligament between the proximal and distal parts, rapid pacing, multiple stent with telescopic method, double balloon-double wire technique, immediate asymmetric redilation with semi-compliant balloons were required in these complex COAs.

Results: Mean age was 17.7 ± 8.9 years (4.0- 49 years) and weight was 52.3 ± 20.3 kg (19-90). COA was subatretic in 8, was associated with PDA in nine and aneurysm in nine. Guidewire perforation of aortic atresia was performed in 4. Five patients had long middle aortic syndrome and abdominal COA very close to the vital branches or side branches from the coarcted segment. Transverse aortic arch hypoplasia or stenosis was treated by SI in 3. COA was very close to the left subclavian artery in seven. SI was successful in all. 53 stents (41 Covered CP, 7 Bare CP, 5 Andrastent) were used in 45 patients. Mean pressure gradient decreased from 49.5 ± 23 to 4.3 ± 5.6 mmHg. One patient with Turner syndrome died 10 days after the procedure due coronary artery thrombosis and myocardial infarction during the SI in spite of percutaneous thrombus aspiration and revascularization. During the median 50 months of the follow up, 5 re-interventions were required for restenosis in 4 and for stent fracture in one.

Conclusion: By the time, SI for the treatment of complex COAs have become safe and more effective alternative than the surgery with implementing new and different techniques as gaining more experience using bare or covered stents up to specific situations.

#0181

SINGLE CENTER EXPERIENCE ON CUTTING BALLOON ANGIOPLASTY IN THE TREATMENT OF BRANCH PULMONARY ARTERY STENOSIS AFTER SURGERY IN SMALL CHILDREN

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Introduction: Cutting balloon angioplasty (CBA) is a promising technique for the treatment of highly challenging vascular stenosis especially in peripheral pulmonary artery stenosis. We will present our experience on CBA for the treatment of branch pulmonary artery stenosis (BPS) in childhood.

Methods: Seventeen children <5 years old, median age of 18 (4.5-54) months, median weight of 9,5 kg (5.5-16), with BPS after surgical re-

pair of congenital heart diseases treated with CBA were prospectively analyzed. We used staged approach for dilation of stenotic vessel to avoid rupture. After CBA, further dilation was performed with optimal size low pressure balloon (LPB), and if it was not effective, dilated 1-2mm<optimal size high-pressure balloon (HPB) was used. If result was insufficient, optimal size LPB was used again.

Results: Diagnosis of children was s/p Jatene for TGA in 11, s/p repaired TOF- PA 2, s/p repaired TA /interruption in 2, s/p Taussig-Bing and coarctation in 1, s/p Glenn in 1. 28 vessels were dilated with CBA. Stenotic vessels were RPA in 5, LPA in 1, bilateral pulmonary artery in 11. Two vessels underwent subsequent LPBA and 26 vessels underwent HPBA. The diameter of the vessels increased from 3.2 ± 0.85 to 5.5 ± 1.4 mm ($p < 0.001$). The RV/LV pressure ratio decreased from 0.9 ± 0.17 to 0.57 ± 0.14 ($p = 0.001$). Vessel diameter increased by >%50 in 15 patients; procedural success rate was 88%. Increase in vessel diameter <%50 was observed in 2 patients both associated with supra-valvar stenosis that became prominent after balloon dilations. The procedure and fluoroscopy times were 213 ± 57 and 59 ± 21 minutes, respectively. In one s/p Jatene patient, ascending aorta to the RPA fistula was developed and underwent to surgery due to significant residual shunt after device closure. No procedure related mortality was observed. At a median follow-up of 18 months, 4 patients underwent to successful surgery for recurrent supra-valvar stenosis, and additional moderate TR in one. The remaining children are well, last echocardiographic gradient, median 45 mmHg, range 25-55 mmHg.

Conclusions: CBA is a feasible technique for treatment of BPS. CBA can be useful to delay the intervention up to appropriate age for pulmonary stent implantation.

#0182

OUTCOMES OF RECANALIZATION IN CHILDREN WITH VENOUS OBSTRUCTION WHO UNDERWENT VENOPLASTY OR STENT PLACEMENT

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Objective: To determine the outcome of venous recanalization via venoplasty or stent placement in children.

Methods: We reviewed all available charts between 2007 and 2015. Patients were included if they had obstruction of the SVC, IVC or Innominate vein requiring venoplasty or stent placement. Patients were excluded if age greater than 5 years or weight greater than 10kg at the time of catheterization.

Results: Twenty-three procedures were performed on 17 identified patients. Five of 17 patients required re-intervention (group 1) at an average time of 3.2 months, while 12 patients remained free from re-intervention for an average of 21 months (group 2). Age (7.0 vs 6.8 months) and weight (5.8 vs 6.0 kg) were similar between groups. Two patients in each group died, and 3 patients were lost to follow-up (1 vs. 2). Patients in Group 1 were treated with venoplasty alone (n=6) or both venoplasty and stenting (n=5). Only one patient required a third intervention. The average reduction in pressure gradient was 9.6 mmHg. Sixty percent of patients were anticoagulated prior to catheterization, and 60% were anticoagulated post-catheterization. Three of the patients in Group 1 had undergone orthotopic heart transplant. Patients in Group 2 were treated with venoplasty alone (n=5), stent placement alone (n=3), or both (n=4). The average reduction in

pressure gradient was 3.6 mmHg. Fifty percent of patients were anticoagulated prior to catheterization, while 66% were anticoagulated post-catheterization. 1 patient in Group 2 had undergone orthotopic heart transplant.

Discussion: The majority of pediatric patients undergoing venous recanalization will only require a single procedure. Re-intervention does not seem to be related to patient age, weight, affected vessel, anticoagulation regimen, or method of intervention.

#0183

PEDIATRIC HEART CENTER EXPERIENCE WITH IMPELLA PERCUTANEOUS MECHANICAL SUPPORT FOR DECOMPENSATED CARDIOGENIC SHOCK

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Background: Decompensated cardiogenic shock (DCS) remains a serious complication with high mortality and morbidity rates in children. Aggressive therapy with inotropic support and intubation may be insufficient requiring mechanical support. Pediatric experience with Impella is limited. We present the largest case series to date of patients treated with Impella at a single free standing children's hospital.

Methods: Retrospective chart review of Impella devices in the setting of DCS.

Results: 6 patients (2 female) were supported with (7) devices including Impella 2.5 (n=1), CP (n=4), and 5.0 (n=2). Median age was 16 years (r=6.5-25), wt 60 kg (22-74), and BSA 1.71 m² (0.91-1.97). Median duration of support was 10 days (r=5-18). Baseline PCW/EDP improved from 21.5 mmHg (r=15-28) to 15.2 mmHg (r=8-19). All patients survived 30 days post explant. 2 pts were placed while on ECMO in lieu of atrial septostomy for left heart decompression. 4 pts with femoral access with 2 required graft placement for 5.0 device. 3 pts explanted without additional mechanical circ support. 2 pts (33%) had increased level of mechanical support after a period of initial stabilization to ECMO and BiVAD. 2 pts device placed under conscious sedation including 1 pt via percutaneous axillary insertion who developed a non limb threatening arterial occlusion. 2 pts had site bleeding due to underlying DIC or anticoagulation.

Conclusion: Use of Impella device should be considered in pts with DCS or as a means of left heart decompression on ECMO.

#0184

USE OF THE EKOS SYSTEM IN VENOUS OCCLUSION IN PEDIATRIC POPULATION

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Background: Treatment of acute venous thrombosis can be challenging in the pediatric population. We present the use of EKOS (EkoSonic Ultrasound Endovascular System) in 2 patients with acute massive venous thrombosis.

Case #1: A 9 month old (6.8 kg) infant post repair of atrioventricular

septal defect 4 months ago. He had a protracted course with progressive heart failure, severe AV valve regurgitation and pulmonary vein stenosis. During cardiac catheterization, he was noted to have extensive thrombosis of the left internal jugular vein and L-SVC, draining to the coronary sinus. Thrombectomy was performed using the Angiojet followed by local administration of t-PA overnight. Follow-up angiography the next day showed significant residual thrombus. The Angiojet system was therefore placed for overnight therapy. Follow-up angiogram revealed improved flow in the SVC with diminished clot burden. Further manual aspiration was performed with the Pronto catheter and patient switched to heparin with no further thrombosis noted on follow-up catheterization and Doppler studies. There was unobstructed flow in the femoral vein used for placement of the EKOS system.

Case #2: A 15 month old (8.1 kg) infant post heart transplant 4 days ago with donor-recipient size mismatch, after failed palliation of congenital heart disease. Post transplant he has required inotropic support with progressively worsening head and upper body edema. Echocardiogram was concerning for SVC obstruction. Angiography showed complete occlusion of the SVC, right and left innominate veins, with inadequate response to balloon angioplasty. The EKOS system was placed overnight. However, the patient developed progressive hypotension, anuria, and low cardiac output due to severely depressed right ventricular function. He was therefore taken for urgent surgical thrombectomy. There was no evidence of pulmonary embolism noted during surgery.

Conclusion: We report the use of EKOS system for treatment of venous occlusion in small children. There were no procedure-related adverse events with complete resolution of the thrombus in one case.

#0185

PERCUTANEOUS VENTRICULAR SEPTAL DEFECT CLOSURE: A SINGLE CENTER EXPERIENCE

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Transcatheter VSD closure is an effective, safe and challenging technique depending of the anathomy situation. We show the initial experience in transcatheter congenital VSD closure with device's choice in relation to the VSD anathomy

Material and Methods: Between 2005 and 2013 were performed 39 procedures in 38 patients(pts). Mean age was 12 years (3-27). All patients had clinical or echocardiography left ventricle overload evidence secondary to QP/QS >1,5:1, one patient with refractory cardiac left fealured. Low to moderate RV or PA elevation. All procedures were performed monitored by TEE.

Results: VSD Closure was effective in 37 of 39 procedures. Mean VSD diameter was 7,23 +- 3,7mm (from 4 to 14 mm). Amplatzer mVSD was implanted in 12 mVSD(mean diameter 8mm). ADOS II 6/4mm was used by retrograde approach in 3 hmVSD and in the last a NOPDA 7x6. 15 of 19 pmVSD were closed with NO LeVSD (8-12 mm). In the other 4 pmVSD: Amplatzer pmVSD, CERA pmVSD device in 2 pts and 2 Memopart excentric pmVSD in the last pt. Inmediate effective closure was achieved in all mVSD, hmVSD and in 35 pmVSD. In a patient with NO LeVSD and in 1 of CERA device, trivial residual shunt with complete closure at 3 month. In the last patient were implanted 2

Memopart excentric pmVSD devices successfully. There was an embolization in a pt with multiple mVSD. 2nd degree AV block was present and retrograde 48hs after corticoid therapy. There was no onset of new AV block on follow up.

Transcatheter VSD closure using devices in relation to VSD anatomy are effective and safe with a low incidence of minor and major complications at immediate and mid-term FU

#0186

LONG TERM FOLLOW-UP POST CATHETER INTERVENTION FOR CRITICAL PULMONARY VALVE STENOSIS AND ATRESIA WITH INTACT VENTRICULAR SEPTUM. A 25 YEAR SINGLE INSTITUTIONAL EXPERIENCE UTILIZING VARIOUS TECHNIQUES

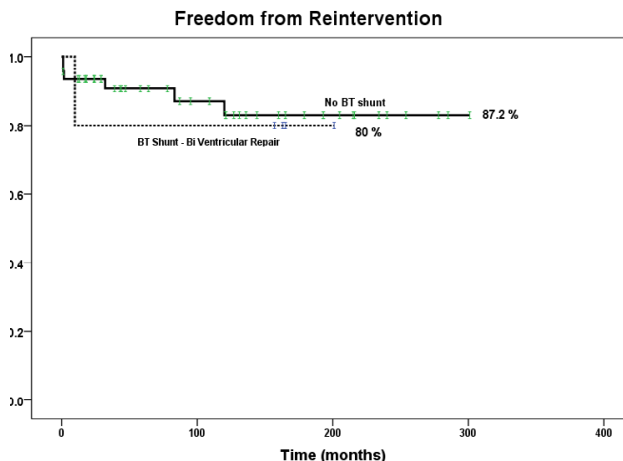
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Background: Various catheter interventions (I) and procedural success have been described for critical pulmonary stenosis (PS) or valve atresia with intact ventricular septum (PA).

Methods: From 1990- 2015, 62 patients (pts) underwent catheter I for PS or PA.

Results: The mean age at I was 3.6 days (range 0-69 days) and mean weight was 3.3kg (range 1.8-5.4). 51 pts (82%) had PS and 11 pts (18%) had PA via angiography. Early catheter I experience included 5 PA pts requiring stiff guide wire perforation (4 required arterial snare assistance technique). More recent experience included excimer laser perforation (0.9mm) in 9 pts while the remaining 48 pts required only a JR4 catheter and floppy tipped coronary guide wire. 40% had bipartite RV (bRV) vs 60% tripartite RV (tRV). There was 1 procedural mortality (1.6%). 60 pts (97%) required PGE1 pre I and 25 pts (40%) post I. 11 of these pts (44%) required surgical BT shunts. Out of these pts, 6 (55%) required univentricular palliation (UniV). Fluoro exposure trended lower in those patients undergoing laser perforation. In a multivariate analysis, initial TV Z score was an independent predictor for BT shunt placement but not UniV (-3.1; CI: -2.2 to -3.9 vs -1.9; CI: -1.3 to -2.5, $p=0.017$). Reduced PV Z score was found to be an independent predictor for both BT shunt placement (-1.6; CI: -2.1 to -1.1 vs -0.4; CI: -0.6 to -0.2, $p<0.001$) and UniV (-1.4; CI: -2.2 to -0.67 vs -0.5; CI: -0.8 to -0.3, $p=0.029$). Mean follow up duration is 99 months (range 1-301 mths) and overall survival is 93%. 25 yr freedom from reintervention (Frl) for non- BT shunt was similar to pts requiring a BT shunt and subsequent BiV repair. 4 pts (7%) required late surgical pulmonary valve replacement (PVR).



Conclusion: Smaller TV annulus was an independent variable predictive for BT shunt placement. Smaller PV annulus is an independent predictor for BT shunt placement and subsequent UniV. There was a trend toward reduced fluoro exposure in those patients undergoing laser perforation. Overall 25 year survival for the entire cohort is excellent with a low incidence of PVR.

#0187

THE FEASIBILITY AND FUNCTIONALITY OF ELIXIR PEDIATRIC SCAFFOLD IN THE CENTRAL ARTERIES OF A PORCINE MODEL

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Background: Polymer-based bioabsorbable scaffolds (PBBS) have been assessed for coronary artery revascularization in pre-clinical and clinical trials with excellent outcomes. However a PBBS designed specifically for growing arteries in pediatric patients has yet to be evaluated. The objective of this pre-clinical study was to compare the performance of the Elixir Pediatric Scaffold, a low profile larger diameter bioresorbable scaffold system, to a standard low profile bare metal stent (BMS) in the descending aorta and branch pulmonary arteries of weaned piglets.

Methods: A total of 42 devices ((Elixir pediatric scaffold 6x18mm, Elixir Sunnyvale, CA) and control BMS (Cook Formula 418 6x20mm, Cook Medical, Bloomington, IN)) were implanted in the descending aorta and pulmonary arteries of 12 female Yucatan miniswine piglets weighing approximately 5-10 kg. The position of the BMS and the Elixir Pediatric Scaffold within the aorta and respective branch pulmonary arteries was randomly selected and documented for each animal. Immediately prior to device deployment, initial angiography was performed and quantitative angiographic measurements were collected of the implantation vessels (ANOVA two-way followed by Bonferroni post hoc test). Follow up angiography was performed at 30 and 90 days post-device implantation to compare device patency and integrity.

Results: Aortic angiography demonstrated that both late lumen loss (LL) and percent diameter stenosis (%DS) were greater for the

bioresorbable scaffold as compared with BMS at 30 days post device implantation (LL: 1.083 ± 1.072 vs 0.1220 ± 0.388 ; %DS: 17.89 ± 19.14 vs 1.688 ± 6.588 , respectively; $p < 0.05$). However, the late loss and percent diameter stenosis were comparable between groups at 90 days follow-up time point (LL: scaffold = -0.4325 ± 0.4975 vs stent = 0.0325 ± 0.1936 ; %DS: scaffold = -8.895 ± 10.59 vs stent = 0.3600 ± 3.456 ; $p > 0.05$). There was no difference between bioresorbable scaffold and BMS in the pulmonary arteries at 30 day (LL: 0.4650 ± 0.7654 vs 0.3160 ± 0.3613 ; %DS: 7.884 ± 12.45 vs 5.114 ± 5.711 , respectively; $p > 0.05$) and 90 day (LL: -0.6075 ± 1.344 vs 0.3675 ± 0.1008 ; %DS: -11.50 ± 25.32 vs 5.958 ± 1.819 , respectively; $p > 0.05$) follow-up time points.

Conclusion: The Elixir pediatric bioresorbable scaffold maintains vessel patency in the descending aorta and branch pulmonary arteries comparable to a low profile BMS control at 90 days. It is hoped that further follow-up intravascular ultrasound and histopathological findings from this pre-clinical trial will provide the platform for clinical testing of the Elixir pediatric scaffold in infants and children with vessel stenosis in the setting of congenital heart disease.

#0188

TRANSCATHETER CLOSURE OF PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECTS USING AMPLATZER DUCTAL OCCLUDER TYPE -1

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Objectives: To evaluate efficacy and safety of Amplatzer Ductal Occluder type I in transcatheter closure of perimembranous ventricular septal defects (PM VSD) in different locations.

Patients and Methods: Between September 2013 and May 2015, 134 non-selected patients with PM VSDs were enrolled for transcatheter closure using ADO type I. Only patients with malalignment type VSD were excluded from this study. The mean age of patients was 9.5yrs (1 – 44yrs) and the mean weight was 19 kg (7 – 95kg). The peak and mean PA pressure were ranged from 20-75 mmhg and 10- 55 mmhg respectively. Anatomical locations were PM – Outlet in 14 patients , PM – Muscular in 78 patients and PM - Inlet in 42 patients. Of these defects, 3 patients had significant post- surgery residual shunt and one patient had dextrocardia with situs inversus. Fourteen patients found to have RVOTO and 6 patients had subaortic ridge which has been captured by the device. The procedures were done under deep sedation and TTE guidance. . Aortogram and LV angiogram were done before and after device deployment. Each patient was followed at 1 day , 1, 6 and 12 months post-closure. The mean period of follow up was 11 months (3 – 20 months).

Results: Aneurysmal septal tissue was found in 38% and prolapsed cusps in 35.8 % of patients (RCC in 20, NCC in 16 and both cusps in 12 patients) . Multiple defects were observed in 12 patients ; in 4 of them the defects closed by 2 occluders . Successful closure was achieved in 129/ 134 patients (96.2%) and complete closure was found to be 92.2% at 24 hrs. post closure & 95.5% & 97.7% at one month and 6 months respectively. The mean procedure time was 58 min (23 – 120 min) and the mean fluoroscopic time was 22 min (9 – 50 min). Failure of closure was occurred in 5 cases ; 2 PM- outlet , 2 PM- inlet and 1 PM- muscular due to large defect with insufficient rims in 2 cases and aortic valve contact with new onset of AR in 3 cases. No major compli-

cations were reported at follow up including aortic valve insufficiency or complete heart block.

Conclusion: The ADO type I is suitable, effective and safe in closure of perimembranous VSD in different locations with or without aneurysm or prolapsed aortic cusps and has high rate of successful closure with no significant adverse events.

#0189

TRANSCATHETER PATENT FORAMEN OVALE CLOSURE

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Introduction: Patent foramen ovale (PFO) is considered a risk factor for serious clinical syndromes, the most important of which is cryptogenic stroke in the setting of paradoxical embolism. Optimal management of patients with PFO and cryptogenic stroke is still debated; Moreover, data from long-term studies on large patient populations are lacking. Aim of the study is to assess The safety and feasibility of transcatheter PFO closure, its immediate and long-term clinical outcome.

Methods: We enrolled 20 patients (13 female, 7 male, mean age 43.0 ± 3.7 years) referred to our department over a 2 year period, all had PFO-related stroke, except one had severe, disabling, medication-refractory migraine aura, Criteria for intervention after routine investigations included: basal shunt and shower/curtain shunt pattern on transcranial Doppler (TCD) and transoesophageal echocardiography (TEE), Primary endpoints were death, recurrent stroke or TIA. Residual right-to left shunt (RLS) was monitored by TEE and TCD at 3 months and 6 months' follow-up.

Results: 20 consecutive patients underwent percutaneous PFO closure for secondary prevention of stroke. Device malalignment was observed in one patient during the procedure and was realigned successfully. No peri-procedural or in-hospital complications, no recurrent embolic events were observed within the first 12 months of follow-up. Of the 20 patients only one (0.05%) submitted to TEE or TCD at 3 months' follow-up, presented a residual small RLS.

Conclusion: Transcatheter PFO closure is associated with low incidence of in-hospital complications and low frequency of recurrent stroke at follow-up.

References: Percutaneous closure of patent foramen ovale in cryptogenic embolism. Meier B, Kalesan B, Mattle HP, et al. N Engl Med 2013;368:1083-91

#0190

TRANSCATHETER CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECTS: RESULTS OF THE FIRST RANDOMIZED CLINICAL TRIAL BETWEEN THE OCCLUTECH FIGULLA FLEX-II AND THE AMPLATZER SEPTAL OCCLUDER

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Transcatheter closure of secundum atrial septal defect (ASD) has be-

come an accepted alternative to open heart surgery. Currently, the only approved devices in the United States are the Amplatzer Septal Occluder (ASO) and the Gore Helex Device. The Occlutech Figulla Flex II (OFF) is a new device designed to close ASD. The purpose of this study is to report on the results of the first randomized controlled multicenter clinical trial of the efficacy and safety of the OFF with that of the ASO for the closure of secundum ASD. The randomization scheme was 2:1 in favor of the study device (OFF).

Methods: The primary efficacy end point, early efficacy success rate, was defined as the rate of successful device placement and successful closure of the defect without major complications, surgical reintervention, device embolization or presence of moderate or large residual shunt at discharge from the hospital. Safety end points were defined as the rate of major and minor complications. The decision was made to perform interim analysis when 70% of the patients were treated and one of three decisions had to be made: stop the trial due to proven non-inferiority (reject the null hypothesis that OFF is inferior to ASO), stop the trial due to futility (accept the null hypothesis) or continue the trial with recalculated sample size. At the interim analysis data cut, 158 patients were randomized (107 OFF/51 ASO) at a median age of 12 yr (range 3-79 yrs) and median weight of 42 kg (range 13-125 kg), underwent device closure. 65.2% were female. Of the 158 patients, only 120 (76%) completed the 6-months follow up.

Results: The device was placed successfully from the 1st attempt in 99.1% of the OFF device group vs 90.2% of the ASO group ($p < 0.05$). 94.393% of the OFF group achieved early efficacy success vs 90.196% of the ASO group ($p = 0.000556$) indicating that the null hypothesis is rejected since the p value was less than 0.0082, the nominal significance level at the interim analysis. The incidence of major complications for all 158 patients was 5.6% for the OFF group compared to 9.8% for the ASO.

Conclusion: The Occlutech Figulla Flex II device was not inferior to the Amplatzer septal occluder with less complications and more efficacy than the ASO. Based on these data, the trial was discontinued due to the improved results of the OFF.

#0191

OUR EXPERIENCE OF THE PFM MEDICAL COILS FOR PDA AND VSD USAGE

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There are many simple congenital heart diseases with small left-to-right shunts, which cannot be closed with occluders. The most common of those is ventricular septal defect (VSD) and patent ductus arteriosus (PDA). The best option for these small shunts is coils. Amosov National Institute of cardiovascular surgery has extensive experience in usage of the new coils manufactured by the PFM Medical Company (Germany, Cologne). From 2008 to 2015 in our institute 296 PDA in 294 pts and 19 VSD in 19 pts were occluded with PFM production (Nit-Occlud® PDA and Nit-Occlud® Lè VSD coils). The short-term and the long-term results of the treatment is promising. Mean follow-up period was 21 ± 6.5 month. No serious complications had been observed in the short-term and medium-term follow-up. No heart block or other serious rhythm disturbances have been observed in perimembranous VSD cases. 5 VSD pts and 8 PDA pts had small residual shunt on discharge from the hospital. Three month after procedure, 3

VSD pts and 2 PDA pts had trivial residual shunt.

Conclusion: PFM coils are safe and effective devices for percutaneous PDA and perimembranous VSD closure.

#0192

CARDIAC CT FOR EVALUATION OF SEPTAL DEFECTS - LOW RADIATION EXPOSURE USING 128 SLICE DUAL-SOURCE CT

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Introduction: Although cardiac CT has been accepted as a useful imaging modality for documentation of vascular lesions, its role in evaluation of intra-cardiac lesions such as ASD and VSD has not been established. Using 128 slice dual-source CT, we analyzed its usefulness in anatomical assessment for ASD and VSD.

Subjects and Methods: Using prospective ECG gated method, we reconstructed volume rendering images and multi-planar reconstruction images in 22 patients of ASD (median 46 years), and 5 of VSD (median 2 months). Transesophageal echocardiography (TEE) was performed in 11 patients of ASD, transthoracic echocardiography (TTE) was performed in all patients of VSD, respectively.

In ASD, we compared the defect diameter and existence of appropriate rims ≥ 5 mm by CT and TEE. In VSD, we evaluated its location and the diameter of VSD in 2 methods. In all patients, effective radiation dose was calculated from age corrected dose-length product.

Results:

1. There was a strong correlation between CT and TEE measurement in both the long axis and the short axis diameter of ASD (Long axis, $CT = 0.96 \times TEE + 1.76$, $r = 0.96$, $p < 0.0001$; Short axis, $CT = 0.86 \times TEE + 1.52$, $r = 0.88$, $p = 0.001$). Existence of appropriate rim in 2 methods agreed in all for SVC and aortic rims, in 10/11 for IVC rims, and 9/11 for posterior rims.
2. The location of VSD in 2 methods agreed in all patients. The defect diameter by CT in patients of muscular was closely related to that by TTE, however measurement of the diameter was difficult in patients of perimembranous VSD.
3. The effective radiation dose ranged 0.26-4.24 (1.57 ± 1.22 , mean+SD) in ASD and 0.31-1.52 (0.86 ± 0.53) in VSD, respectively.

Discussion: In ASD, measurement of the defect diameter by cardiac CT was reliable. Although there might be some limitation in the flimsy rim, existence of appropriate rims could be qualitatively assessed. Both location and the diameter may be evaluated by cardiac CT in muscular VSD, however, measurement of the diameter in perimembranous VSD is still a problem to be solved. Prospective ECG-triggered method could decrease radiation dose.

In conclusion, dual-source CT is now a valuable tool for evaluation of the intracardiac septal defect in low dose radiation.