NEONATAL HYBRID PROCEDURES STRATEGIES TO REDUCE MORBIDITY AND MORTALITY

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MITERA – HYGEIA HOSPITALS, ATHENS, GREECE

HYBRID PROCEDURES - BACKGROUND

1. CHD is the most common congenital anomaly and cardiac disease is the most common cause of death in infants and children

2. Progress in CHD surgery has increased the pool of **complex** and **multi-operated patients**

3. **Repetitive surgical trauma** and **bypass** may affect the outcome of patients

4. Percutaneous interventions may be associated with an increased risk due to **occluded vessels** or **vascular access small for the purpose, especially in neonates**

Combining operative and interventional approaches with *direct puncture of the heart or the great vessels* may facilitate completing the procedure and implanting large devices and stents.

HYBRID PROCEDURES

1972: First combined hybrid procedure by Bhati et al

1. Introduced in the settings where routine cardiac surgery or cardiac interventions would not bring satisfactory results

2. Hybrid procedures in children and adults with congenital heart defects combine the experience of cardiac surgery and interventional cardiology as each technique has its own limitations, which could impair the anticipated result

3. Additional alternative option for selected group of borderline patients

4. Hybrid procedures shorten cardiopulmonary bypass, reduce morbidity of surgery and reduce duration of stay in the intensive care unit and the hospital

Di Bernardo S. Hybrid procedures in congenital heart disease. Rev Med Suisse. 2008

HYBRID PROCEDURES IN NEONATES WITH CONGENITAL HEART DISEASE

1. Premature birth with low birth weight
2. Genetic Syndromes
3. Inability to go on bypass
4. Congenital diaphragmatic hernia

HYBRID PROCEDURES

1. Hypoplastic left heart syndrome (Selective RPA and LPA banding + PDA stenting)
2. RVOT and Branch Pulmonary artery stenting
3. Hybrid transventricular closure of mVSD
4. Hybrid transatrial closure of ASD I
5. Valvuloplasty / valvotomy
6. Hybrid transcatheter valve implantation (Melody or Sapien valves)

HYBRID PROCEDURES

Single - ventricle circulation in 60% of the procedures

1. Patent ductus arteriosus (PDA) stent placement (n = 55)
2. Vascular rehabilitation (n = 25)
3. Ventricular septal defect (VSD) device closure (n = 7)
4. Valvotomy (n = 3)
5. Diagnostic hybrid procedures (n = 38)

Adverse events

1. Arrhythmias (n = 6)
2. Hypoxia or hypotension (n = 3)
3. Vessel or cardiac trauma (n = 2)
4. Other events (n = 5).

The incidence of AE related to PDA stent placement with surgical exposure (5/50, 10%) was significantly lower when compared with PDA stent placement performed percutaneously (4/5, 80%, P= .002).

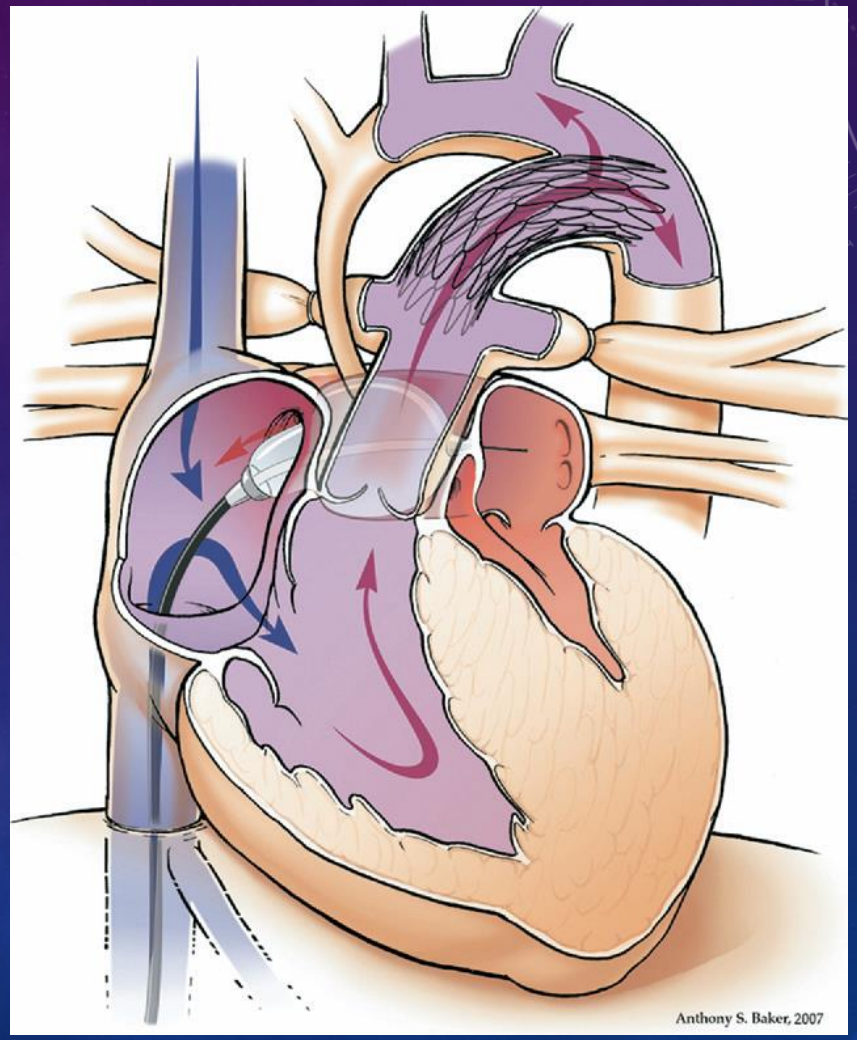
Holzer R. Hybrid procedures: adverse events and procedural characteristics: results of a multi-institutional registry. Congenit Heart Dis. 2010

HYBRID PROCEDURE FOR HLHS

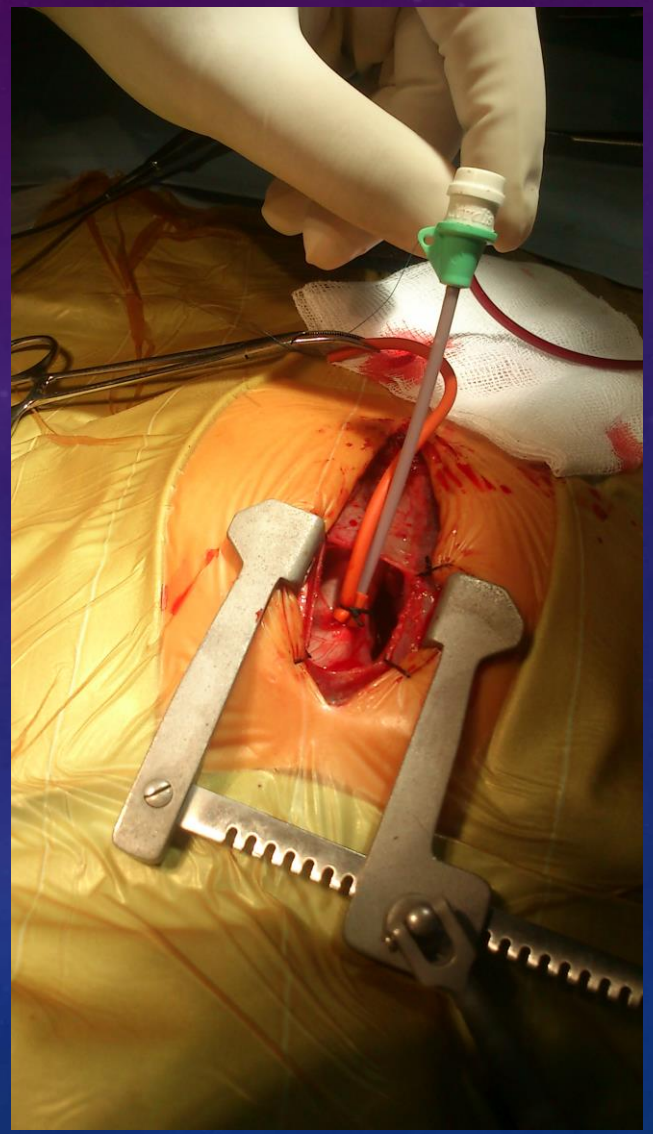
- Branch PA banding
- PDA stenting
- Atrial septostomy

- HLHS with INTACT SEPTUM

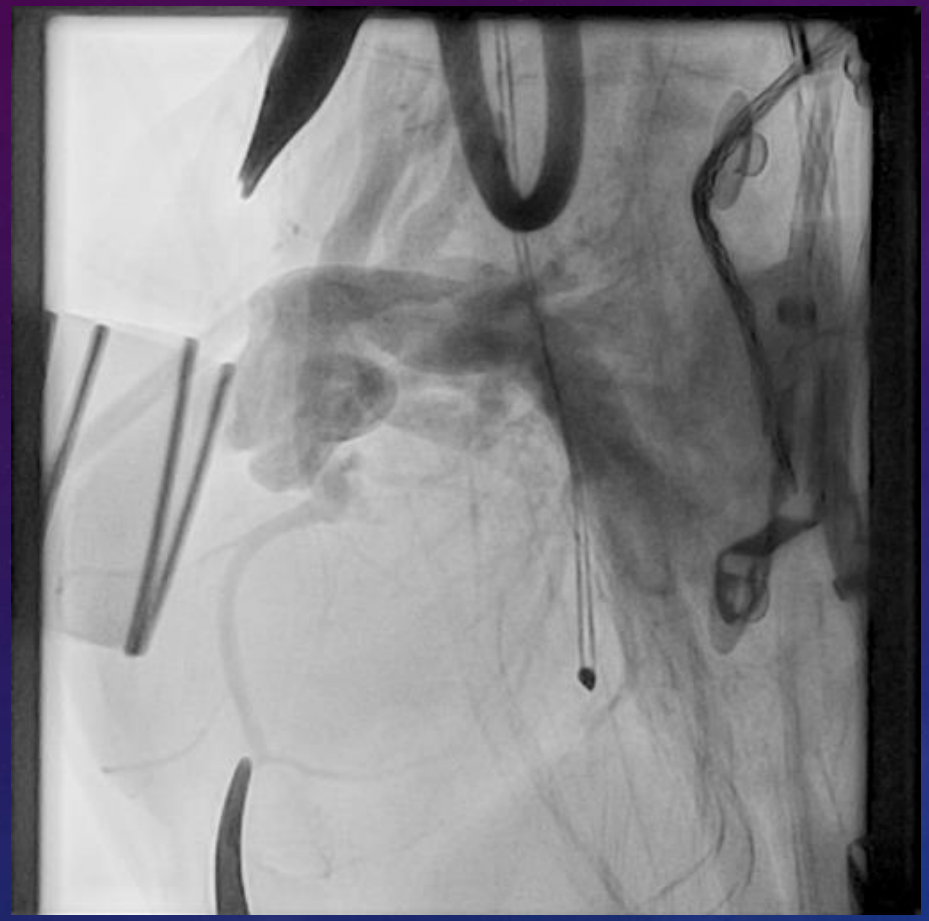
- Surgical septectomy F/B
- PDA stenting and PA banding in cath lab



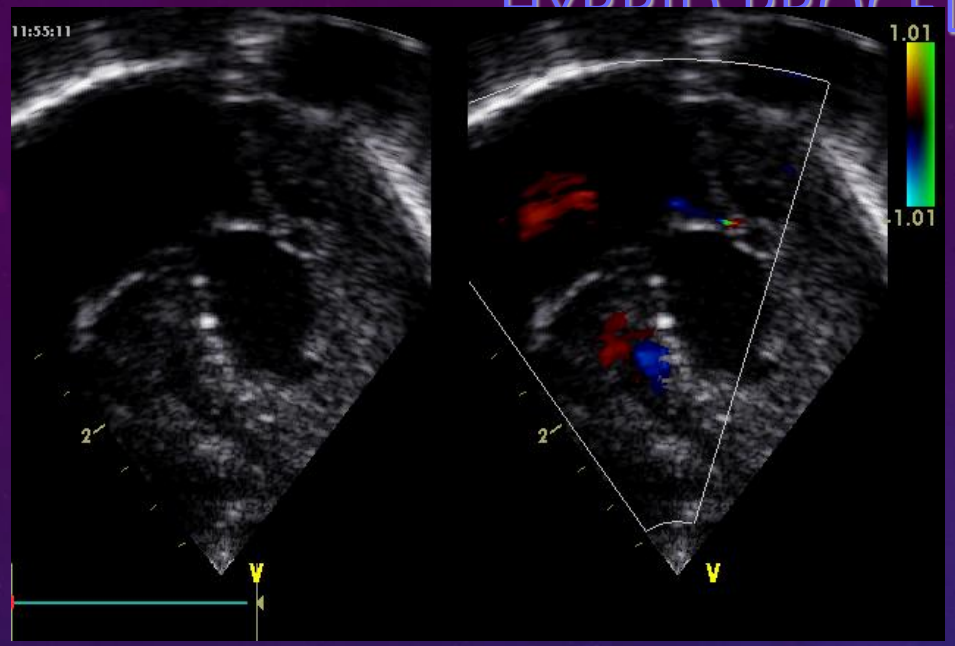
HYBRID PROCEDURE FOR HLHS

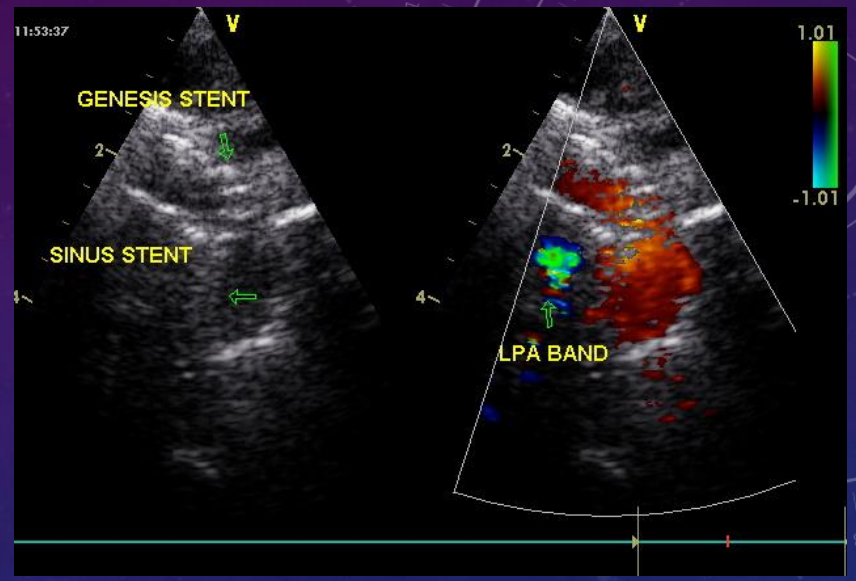


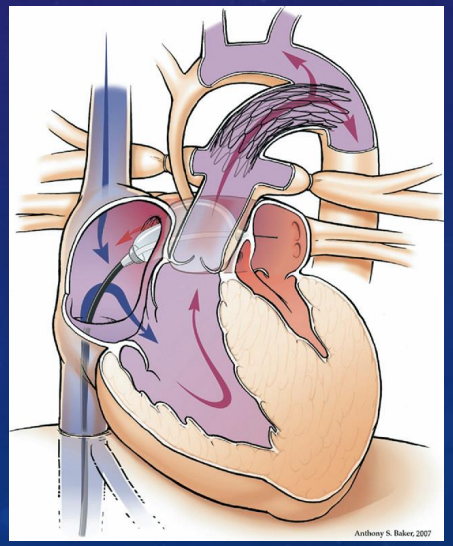
HYBRID PROCEDURES / HLHS



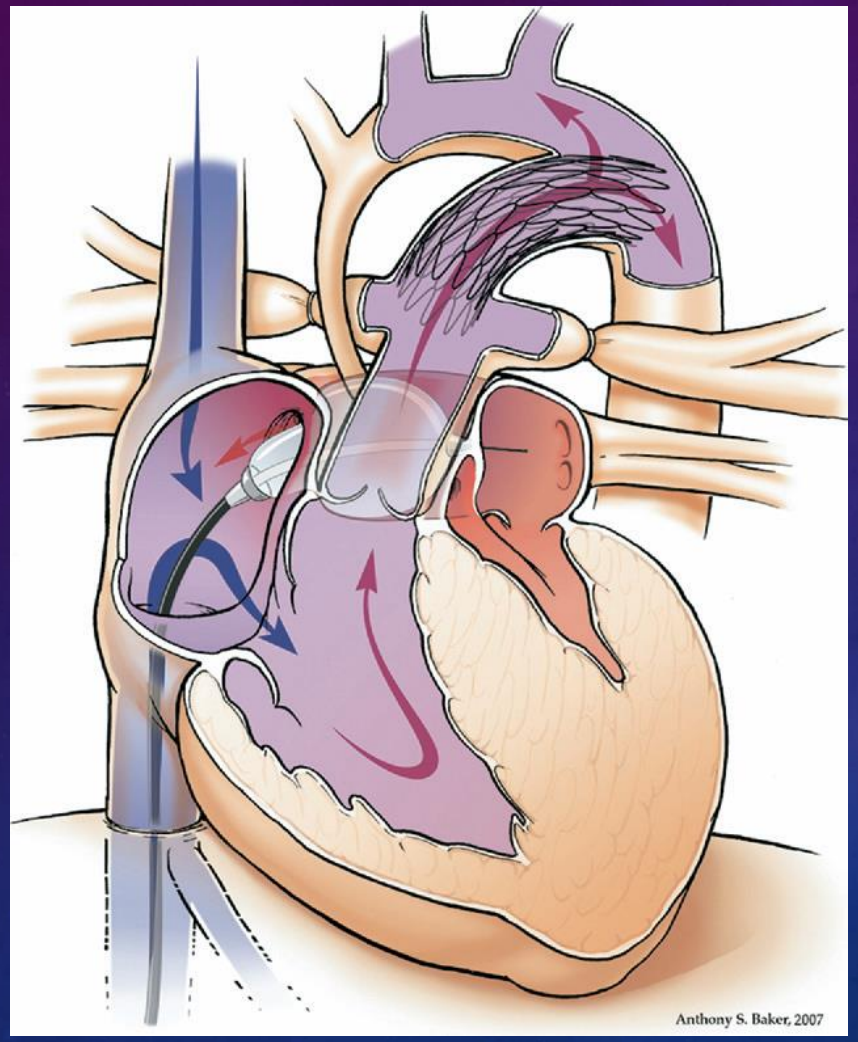
HYBRID PROCEDURE FOR HLHS

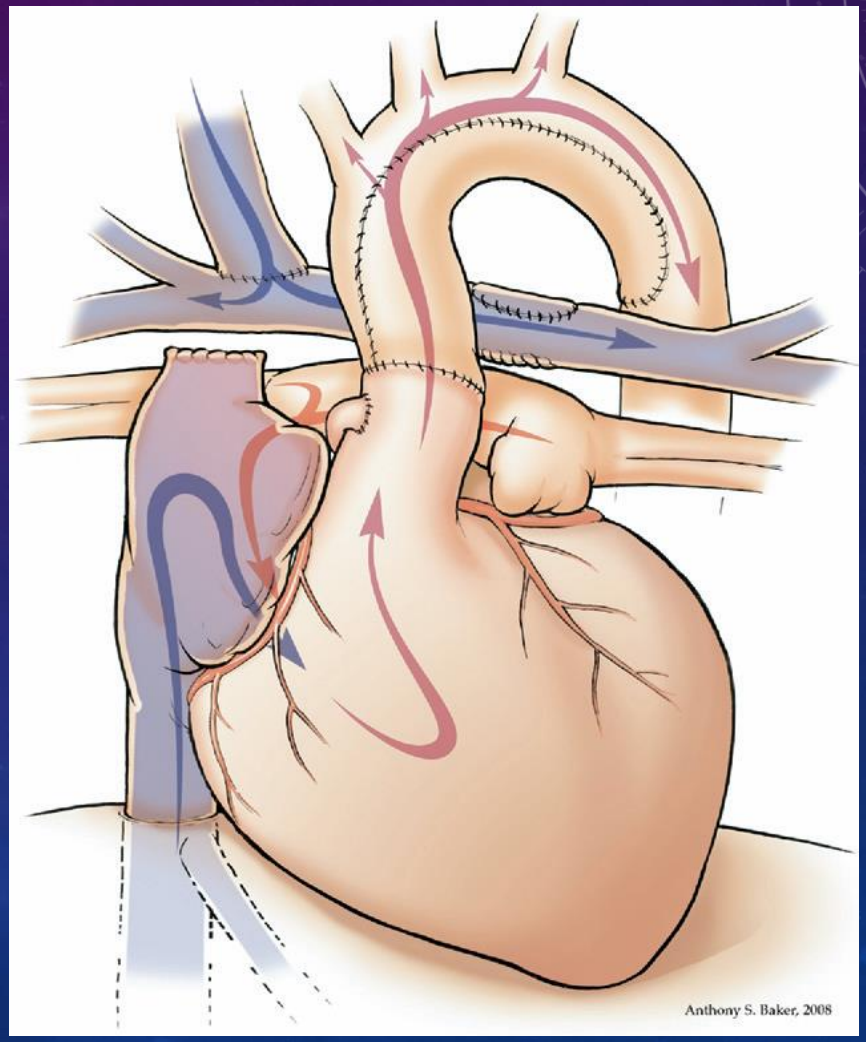






STAGE II POST INITIAL HYBRID





HYBRID APPROACH FOR HLHS

- **Long-term results of biventricular repair after initial Giessen hybrid approach for hypoplastic left heart variants.** (2015, Yerebakan et al. J Thorac Cardiovasc Surg 2015;149:1112-22)
- This article presents the long-term results of our 154 patients with a diagnosis of hypoplastic left heart syndrome (HLHS), hypoplastic left heart complex (HLHC), and variants who received a biventricular repair following hybrid stage I with ductal stenting and bilateral pulmonary artery banding.
- All patients survived hybrid stage I. Median survival after biventricular correction is 7.9 years. Overall mortality was 10% at 4 weeks, 5 weeks, 6 weeks, and 4 months after biventricular correction, respectively. One patient had to be switched to univentricular circulation and another patient underwent orthotopic heart transplantation 3 and 4 months after biventricular correction, respectively.
- **The Giessen hybrid approach is an alternative** to the conventional strategy to treat neonates with HLHS, HLHC, and variants. Biventricular repair after hybrid stage I is feasible and can be performed with satisfactory long-term survival.

HYBRID APPROACH TO BPAB

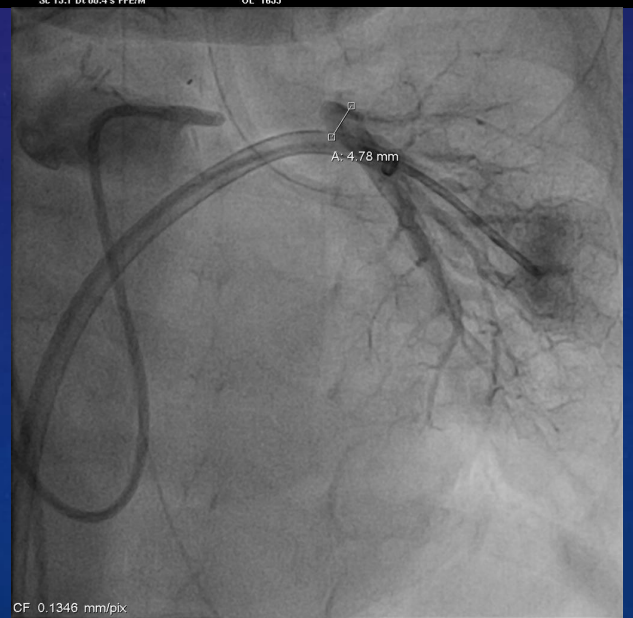
- **Bilateral pulmonary arterial banding results in an increased need for subsequent pulmonary artery interventions.** (2014, Davies et al. J Thorac Cardiovasc Surg 2014;147:706-12))
- Despite increasing use of bilateral branch pulmonary artery banding (bPAB), both as a temporary stabilizing treatment and as part of comprehensive hybrid management of hypoplastic left heart syndrome, little is known about the long-term outcomes of the pulmonary arteries (PAs) in banded patients.
- A retrospective review of all patients with ductal-dependent systemic circulation (2001-2013) undergoing bPAB placement at a single institution (bPAB, n = 50); patients who underwent a stage I Norwood procedure were used for comparison. The need for PA interventions (surgical arterioplasty, balloon angioplasty, and stent implantation) and PA growth were assessed.
- CONCLUSIONS: Patients with bPAB require additional interventions at earlier time points than Norwood patients. Patients with smaller bands and longer duration of banding are at high risk. Despite stenoses requiring additional interventions, Fontan candidacy is maintained.

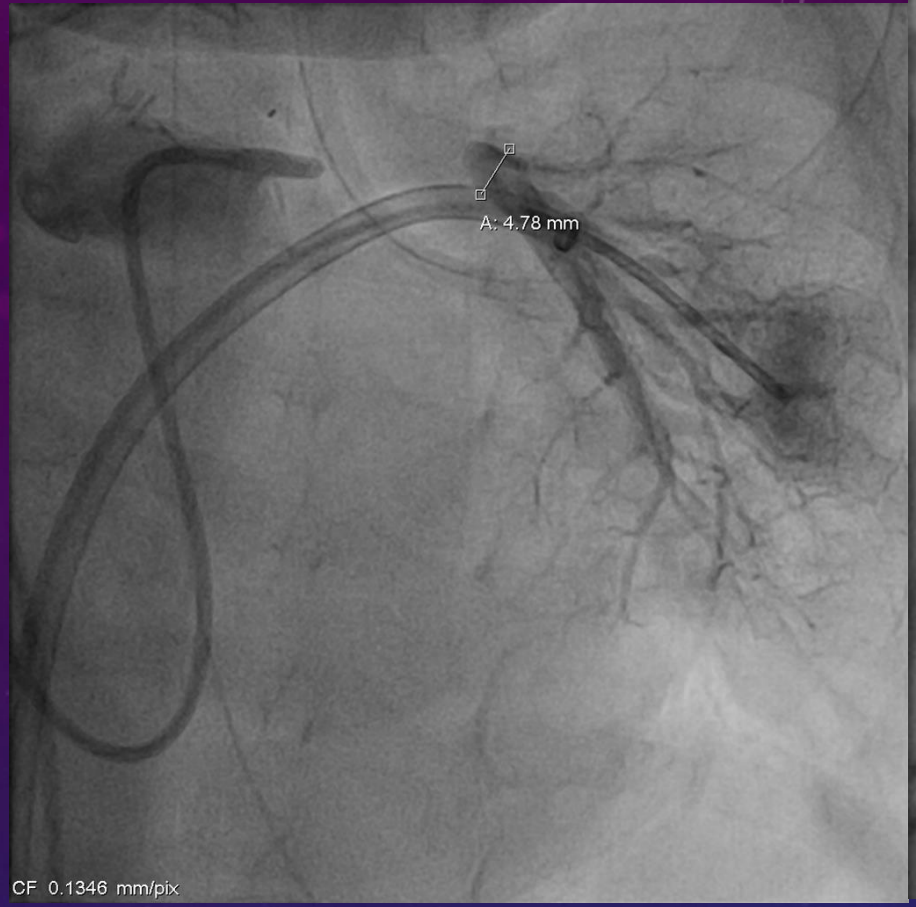
BRANCH PULMONARY ARTERY STENTING

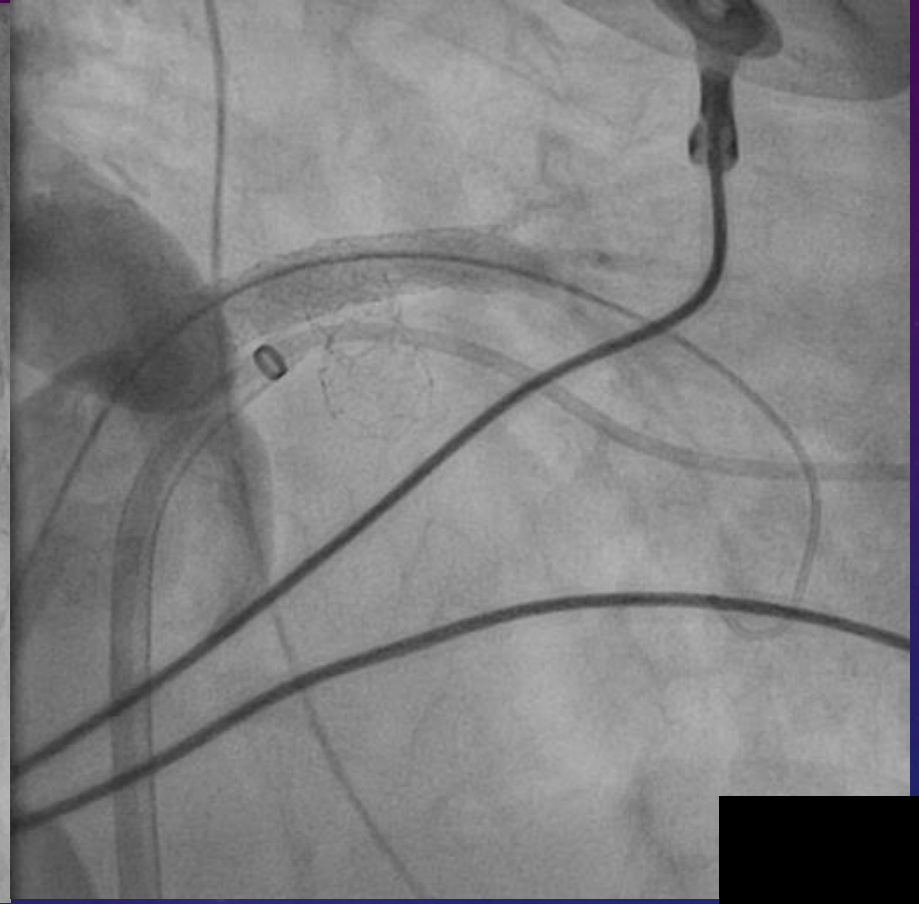
AND RVOT STENTING

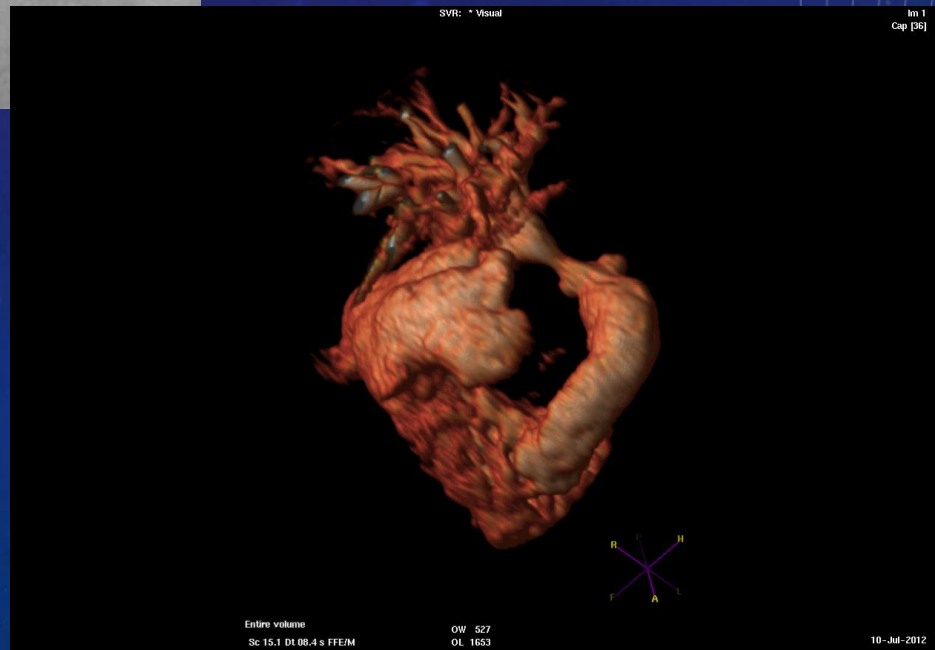
HYBRID PROCEDURES FOR PA STENOSIS / OCCLUSION

- Pulmonary venous wedge angiograms are used to delineate the distal PA anatomy and serve to guide the recanalization process.
- Creation of a track is performed with small diameter balloons after passage of a 0.014” or 0.018’’ guide wire
- Establishment of a vessel lumen is achieved with the placement of premounted stents.



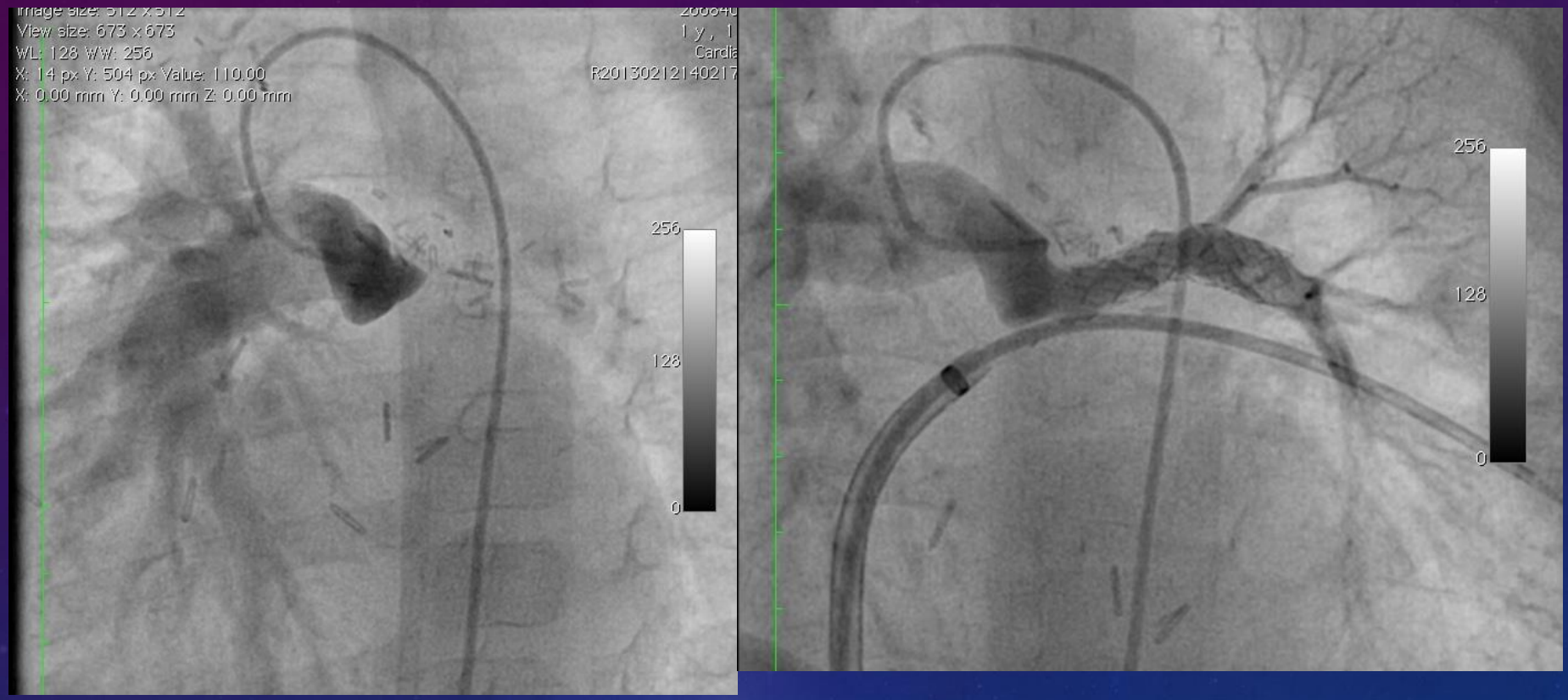






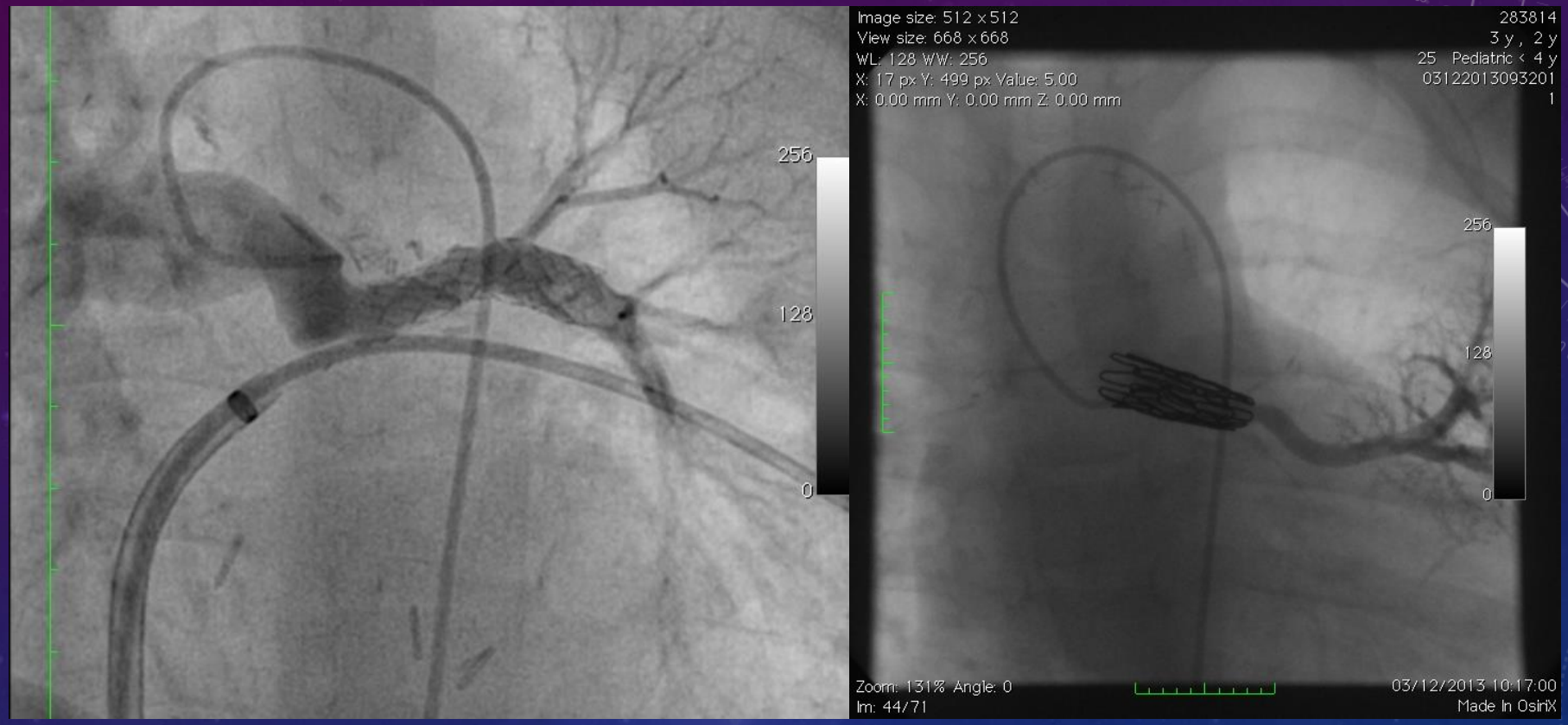
LPA occlusion: recanalization post Fallot repair with Contegra conduit.

HYBRID APPROACH



Occluded LPA in Fallot with pulmonary atresia post RtBTS and LPA patch augmentation. LPA recanalization through BT shunt.

PERCUTANEOUS APPROACH



LPA stenting:

Small diameter stents
HYBRID APPROACH

LPA stenting

Large diameter stents

HYBRID APPROACH FOR RVOT

- **Perforation and right ventricular outflow tract stenting: Alternative palliation for infants with pulmonary atresia/ventricular septal defect. (2018, Aurigemma et al.)**
- RVOT stenting in conjunction with radiofrequency perforation as a means for establishing reliable pulmonary blood flow in patients with PA/VSD has not previously been reported. The aim is to report experience with using perforation of plate-like pulmonary valve atresia combined with stenting of RVOT as an alternative and equally efficacious intervention for infants with PA/VSD, as compared to a surgical pulmonary artery shunt (SPS).
- Twenty-seven patients received palliation for PA/VSD. Five underwent RVOT stenting and 22 underwent surgical SPS. Of the patients who received an RVOT stent, 3 underwent guidewire perforation and balloon dilation of the plate-like pulmonary valve, and 2 underwent radiofrequency perforation of the pulmonary plate, followed by balloon dilation. Post procedure saturations averaged 93% in the stent group and 89% in the shunt group. One of the patients who underwent RVOT stenting required additional stenting of the PDA for isolation of the LPA, but none required re-intervention. Four patients in the SPS cohort required re-intervention (18%). Two required stenting of the shunt, and 2 required surgical revision of the shunt. There was one death in the stent group, however this was secondary to withdrawal of support given an underlying genetic diagnosis (trisomy 13). There was one fatality in the SPS cohort prior to hospital discharge.
- CONCLUSIONS: Perforation followed by RVOT stenting may be a safe and effective alternative to surgical SPS in infants with PA/VSD.

HYBRID APPROACH FOR RVOT

- **Hybrid approach for pulmonary atresia with intact ventricular septum: early single center results and comparison to the standard surgical approach. (2014, Zampi et al.)**
- A subset of PA-IVS patients with the prospect of biventricular circulation typically undergo surgical or transcatheter right ventricular (RV) outflow tract opening. A recently described hybrid procedure, involving perventricular pulmonary valve perforation, was shown to be safe and effective in single-center series.
- Seven patients with PA-IVS underwent a hybrid procedure; **the procedure was technically successful in all attempts, and none required CPB**. No patients required surgical re-intervention prior to hospital discharge, and none died during the study period. Surgical RV decompression was performed in 17 patients with a median CPB time of 80 min. Patient outcomes were nearly identical between cohorts. By systematic review, the transcatheter approach has a procedural success of 75-95% but up to 75% of patients require operation in the neonatal period.

- The hybrid approach is a safe and feasible alternative to the standard surgical and transcatheter approaches to PA-IVS. Acute and mid-term patient outcomes are comparable with those treated with a standard surgical approach and neonatal CPB is completely avoided.

HYBRID APPROACH FOR RVOT

- **Evolution of Approach to Right Ventricular Outflow Tract Stenting in Infants ≤ 2Kgs** (2018,Niall Linnane et al.)

- Surgical palliation or repair of symptomatic Tetralogy of Fallot in the neonatal period is associated with a relatively high mortality rate. Stenting of the right ventricular outflow tract is a newer procedure that has evolved to allow its performance in low birth weight neonates.

- Although a successful outcome with a transcutaneous approach is possible, complications may occur and are poorly tolerated. A hybrid approach provides the most direct route to the RVOT with the least hemodynamic instability, providing concurrent angiography through the delivery sheath to facilitate optimal stent position. This small case series may not provide sufficient experience to support a perventricular approach as first-line for all infants ≤ 2 kg requiring RVOT stenting. However, early conversion to this approach should be considered in those infants who do not tolerate attempts at percutaneous stent delivery.

HYBRID TRANSCATHETER VALVE IMPLANTATION

Hybrid approach to mitral valve repair – Melody

- ***Simplified surgical-hybrid Melody® valve implantation for paediatric mitral valve disease (2015, Hofmann et al.)***
- **Background:** A 2.5-year-old boy was suffered a severe LAVV stenosis nearly 2 years after a satisfactory correction of a complete AV canal which coincided with the diagnosis of acute myeloidleukaemia.
- **Results:** In the subsequent course during the first postoperative week, the left ventricular outflow tract gradient stabilized at 10 mmHg. The mean gradient across the Melody® valve remained <5 mmHg and the previous pulmonary venous congestion resolved completely.
- **Conclusions:** hybrid-surgical implantation of a Melody® valve in the mitral position is an elegant option that can be safely performed and reproduced, the till date published experiences remain anecdotal

HYBRID APPROACH TO MITRAL VALVE REPAIR – MELODY VALVE

- ***Pediatric Melody® mitral valve replacement in acute endocarditis — alternative surgical-hybrid technique* (2017, Haponiuk et al.)**
- **Background**: Emergency mitral valve replacement with the use of Melody balloon expandable stented bioprosthesis in a two-year-old patient with AE and subsequent mitral (bicuspid) valve incompetence after aggressive infective destruction with the symptoms of critical multi-organ failure.
- **Results:** The patient, with a history of rapid deterioration after two-week-long septicaemia in the course of AE, was operated urgently after initial antibiotic treatment because of huge vegetations into the mitral valve orifice. A Melody TVP 22 valve was expanded over a 16-mm TyShak balloon and implanted into a mitral position (Melody-MVR) with good result.
- **Conclusions:** Infected mitral valve in children should be primarily repaired; nevertheless, the Melody valve could be reasonably considered as a mitral prosthesis in such conditions.

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CASE REPORT

CASE REPORT

Simplified surgical-hybrid Melody® valve implantation for paediatric mitral valve disease

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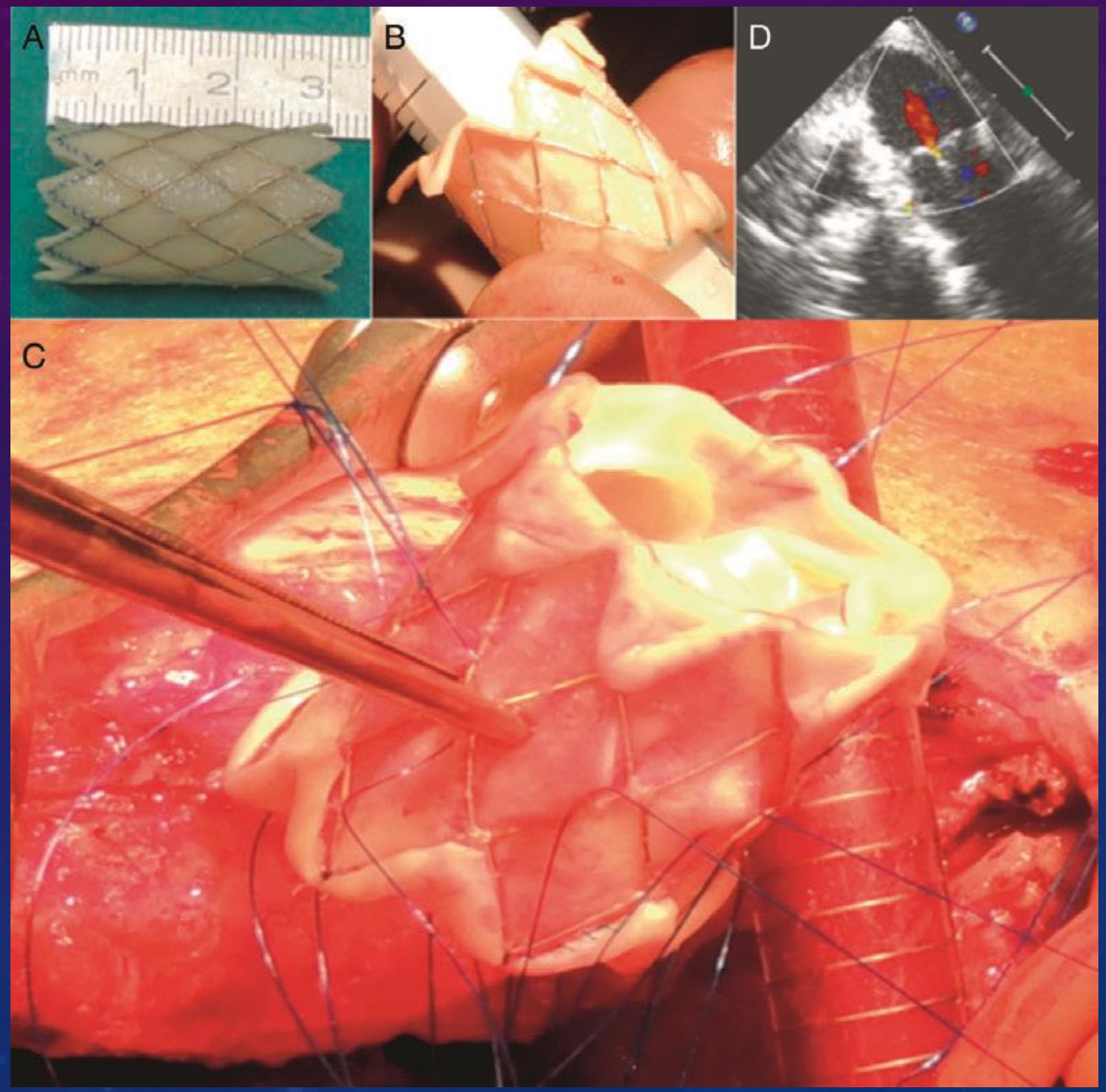
Abstract

Children suffering from left atrioventricular valve (LAVV) disease not amenable to repair represent a significant challenge. The results of surgical reconstruction are not optimal. Valve replacement as an alternative is associated with poor results. The surgical-hybrid approach with implantation of a stented biological valve (bovine jugular vein graft, Melody® valve) seems to represent a new therapeutic option. Here we demonstrate our case, the consideration and the approach to extreme clinical findings in a small child. We describe a simplified surgical-hybrid Melody valve implantation in a LAVV position. The technique of implantation is relatively simple and the immediate post-operative result very good.

Keywords: Congenital mitral valve stenosis • Mitral valve replacement • Melody® valve implantation • Hybrid approach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Assessment of the Melody Valve in the Mitral Position in Young Children by Echocardiography

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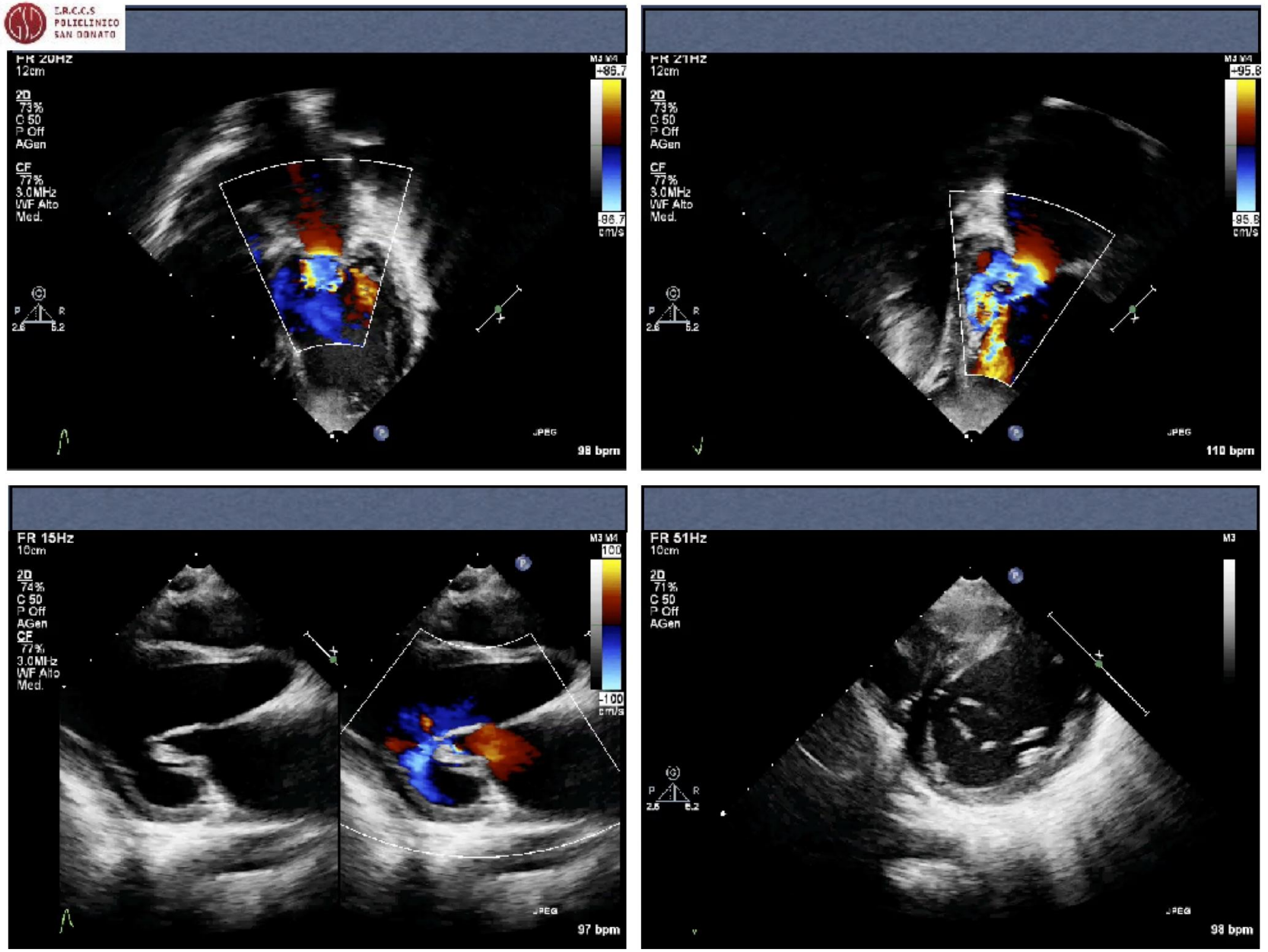
Abstract

Objectives—Mitral valve replacement (MVR) in young children is limited by lack of small prostheses. Our institution began performing MVR with modified, surgically placed, stented jugular vein grafts (Melody valve) in 2010. We sought to describe key echocardiographic features for pre- and post-operative assessment of this novel form of MVR.

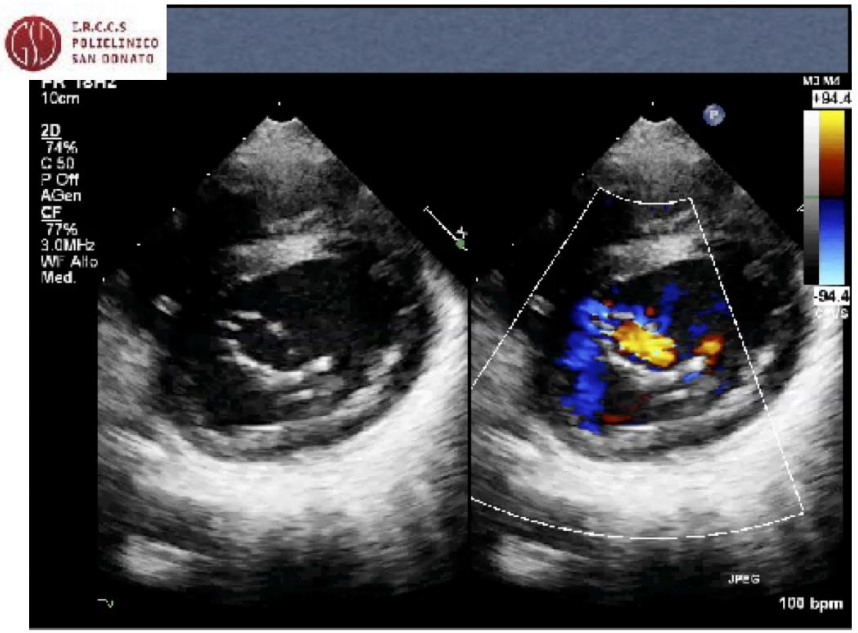
Methods—The pre- and post-operative echocardiograms of 24 patients who underwent Melody MVR were reviewed. In addition to standard measurements, pre-operative potential measurements of the mitral annulus were performed whereby dimensions were estimated for Melody sizing. A ratio of the narrowest subaortic region in systole to the actual mitral valve dimension (SubA:MV) was assessed for risk of post-operative left ventricular outflow tract obstruction (LVOTO).

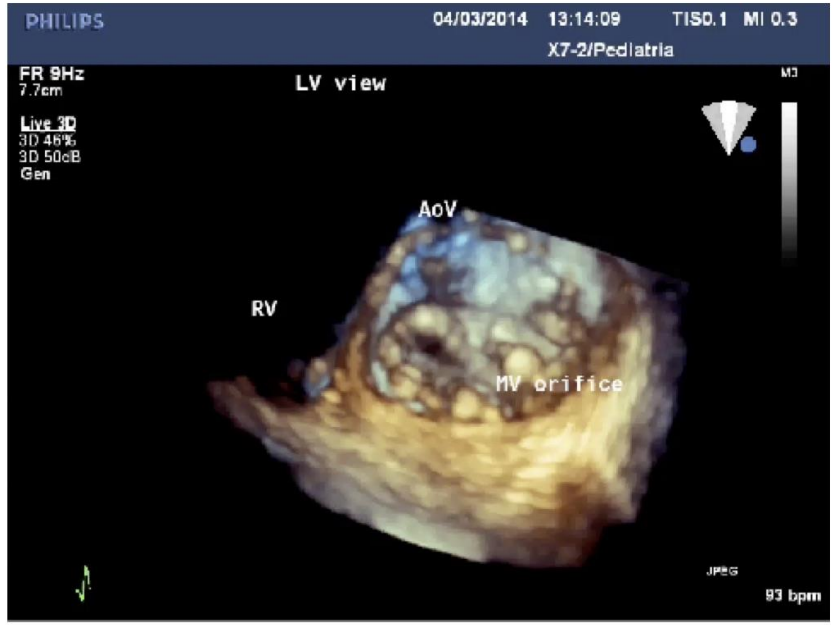
Results—Melody MVR was performed at a median of 8.5 months (5.6 kg) for stenosis (5), regurgitation (3), and mixed disease (16). Pre-operatively, actual mitral z-scores measured hypoplastic (median −3.1 for the lateral (lat) dimension; −2.1 for the antero-posterior (AP) dimension). The potential measurements often had normal z-scores with fair correlation with intra-operative Melody dilation (ρ=0.51 and 0.50 for lat and AP dimensions, both p=0.01). A pre-operative SubA:MV <0.5 was associated with post-operative LVOTO, which occurred in four patients. Post-operatively, mitral gradients substantially improved, with low values relative to the effective orifice area of the Melody valve. No patients had significant regurgitation or perivalvar leak.

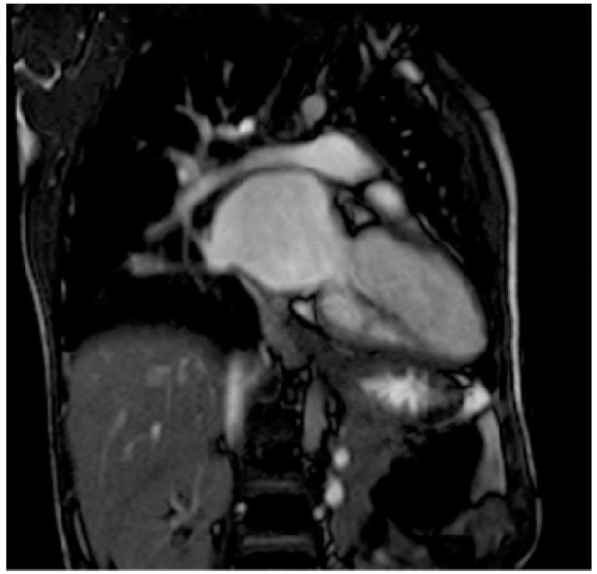
Conclusions—Pre-operative echocardiographic measurements may help guide intra-operative sizing for Melody MVR and identify patients at risk for post-operative LVOTO. Acute post-operative hemodynamic results were favorable; however, on-going assessment is warranted.

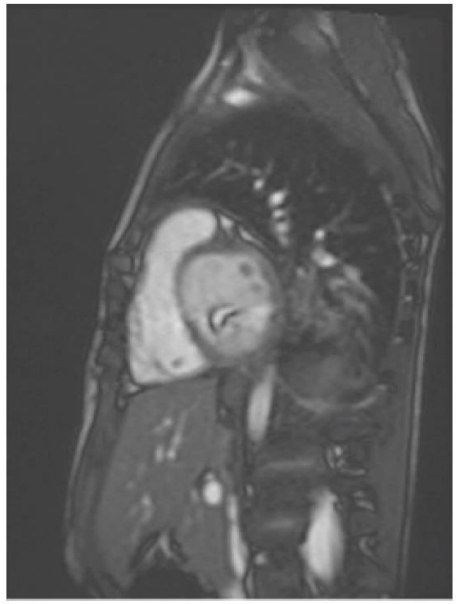


Courtesy G Butera, Milan



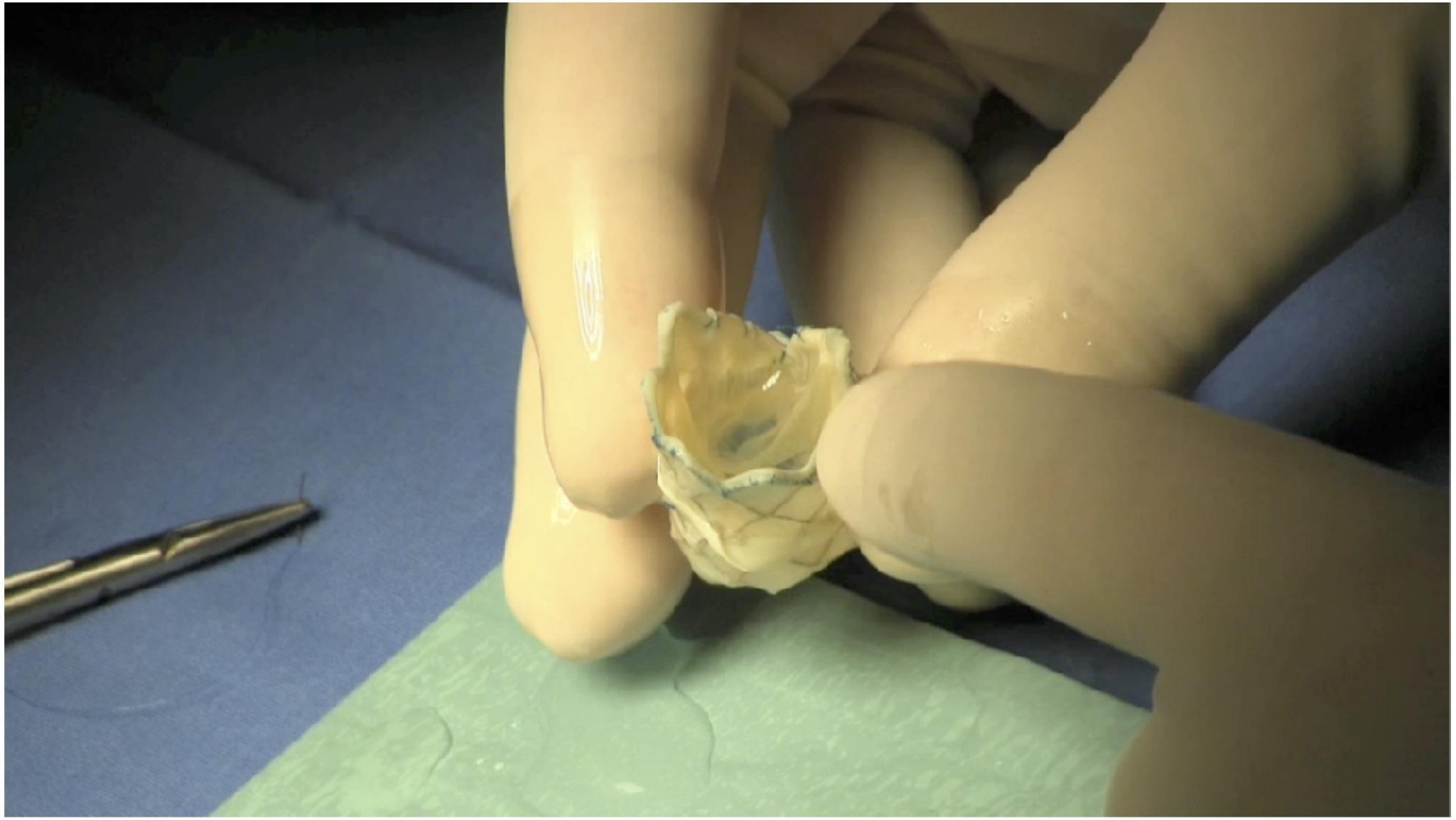






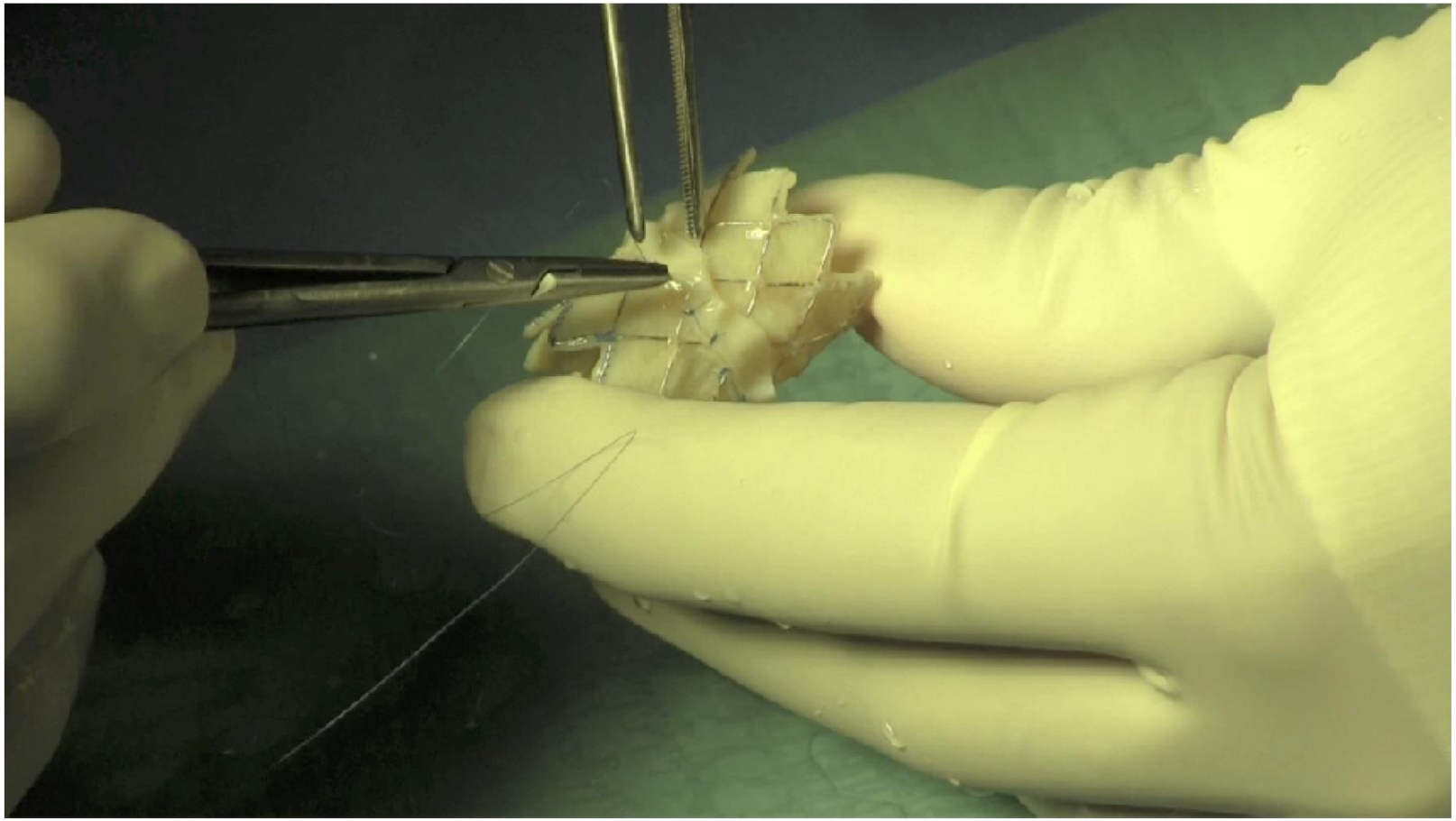
Courtesy G Butera, Milan

Trimming the Melody



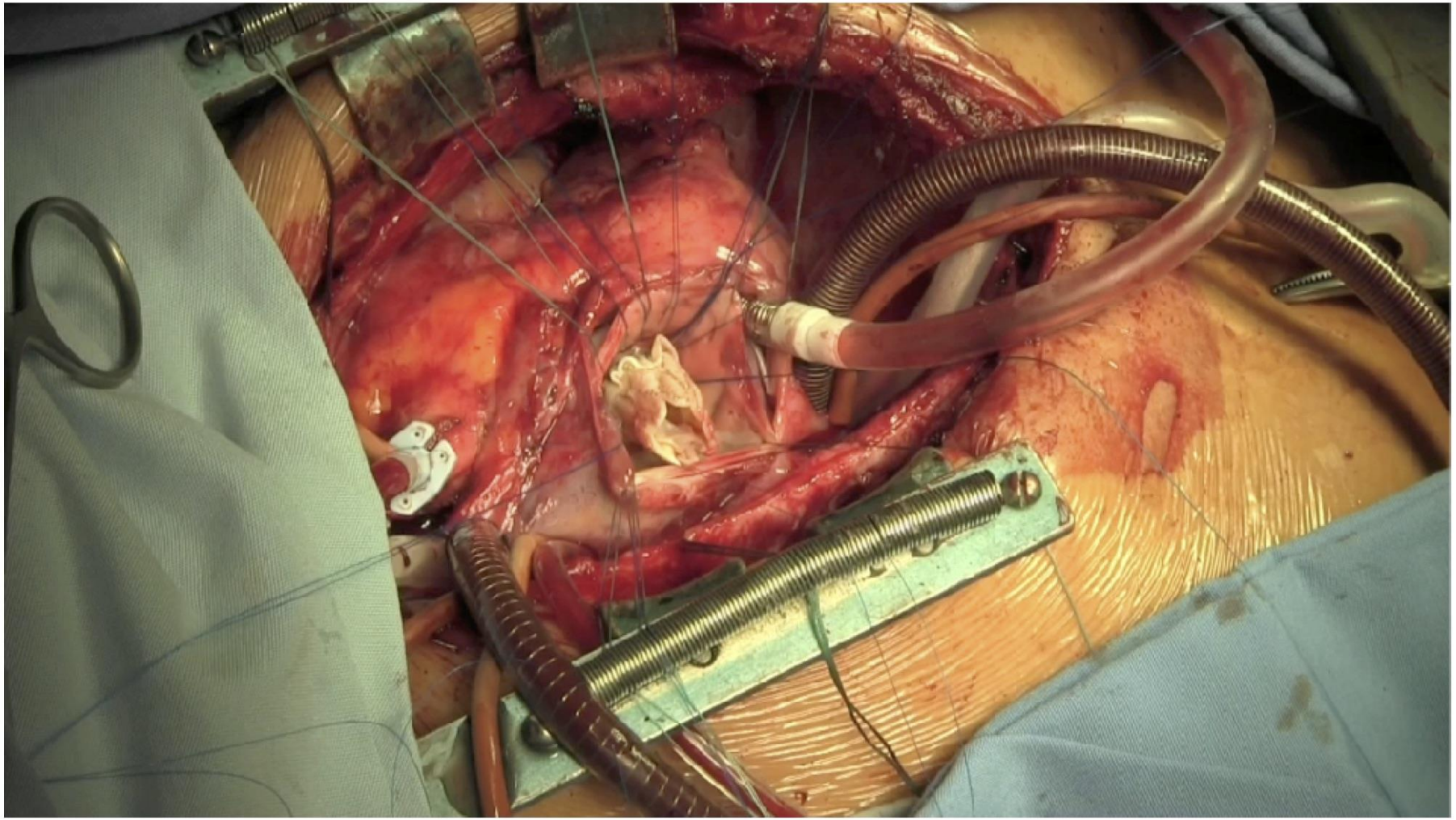
Courtesy G Butera, Milan

Suture of pericardial cuff



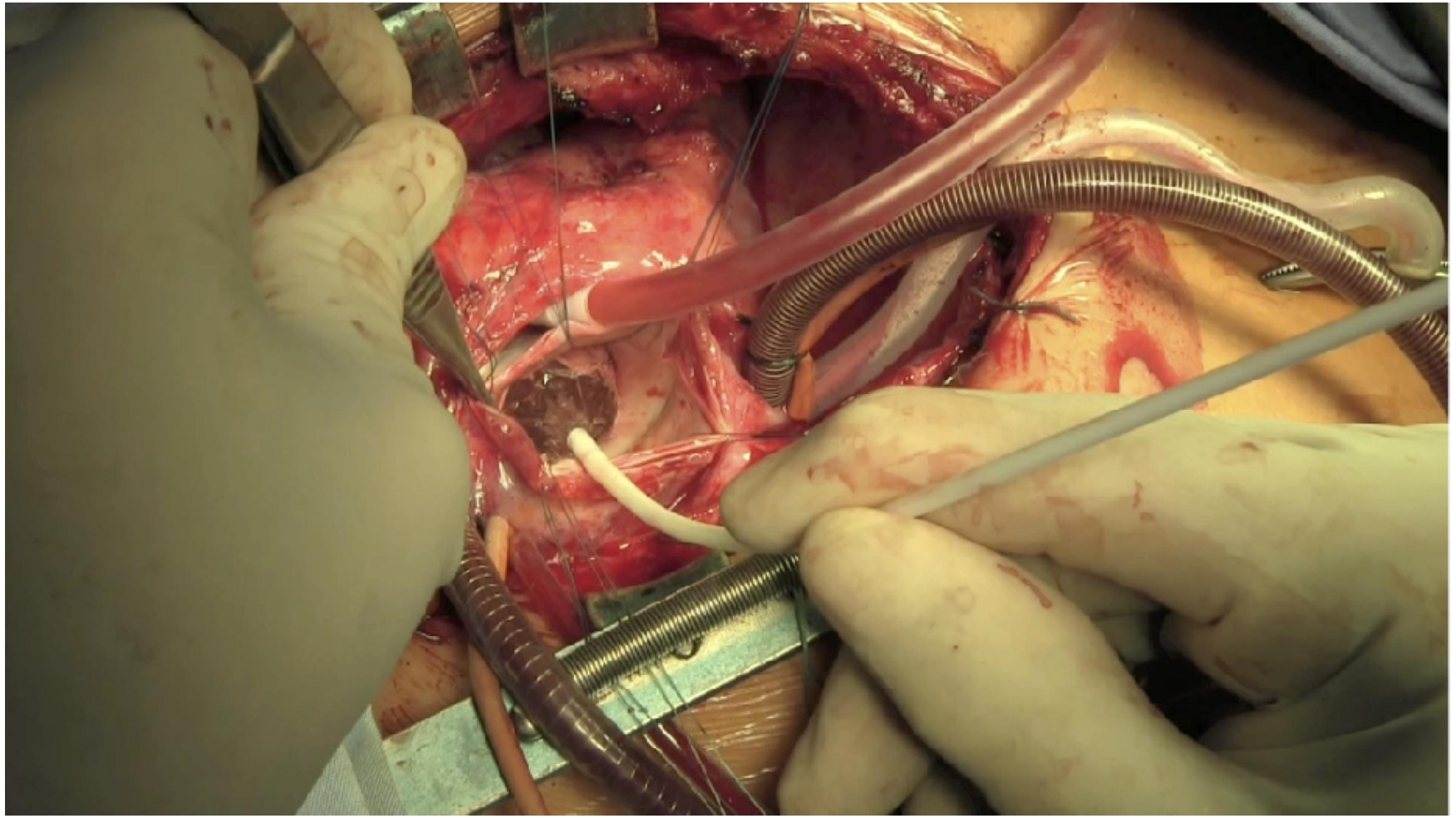
Courtesy G Butera, Milan

Melody insertion



Courtesy G Butera, Milan

Balloon inflation



Courtesy G Butera, Milan

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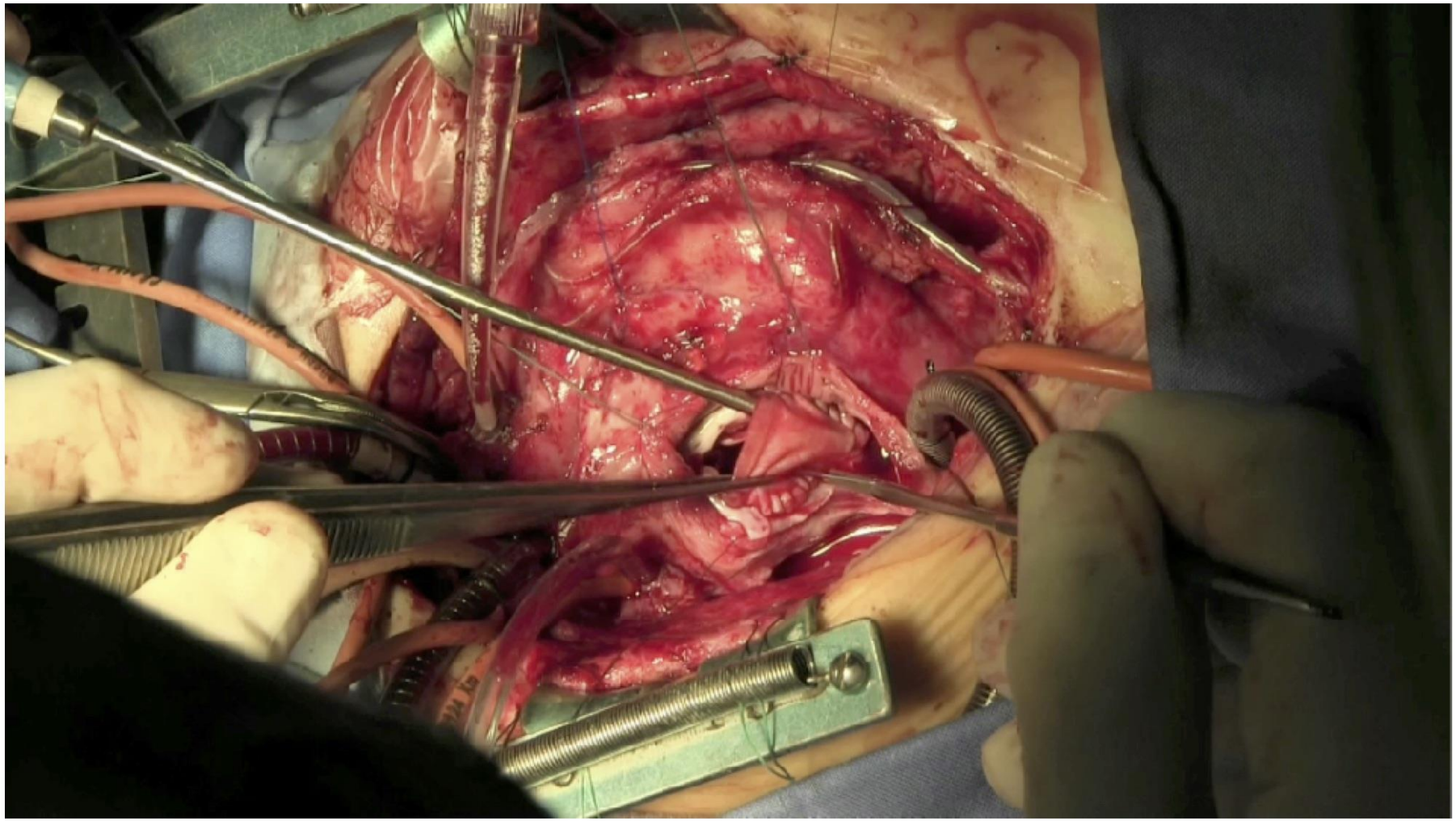
ASD closure leaving a fenestration



Courtesy G Butera, Milan

Results – Patient Characteristics

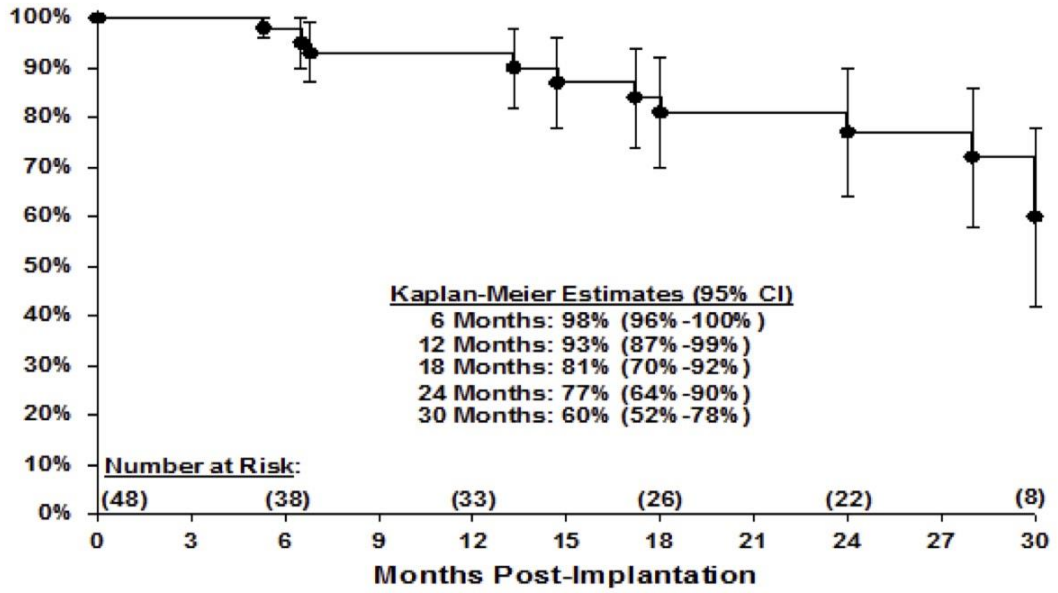
- 55 patients
  - Mitral (n= 50); Tricuspid (n= 5)
- Diagnosis
  - Congenital MS (n= 28)
  - Atrioventricular canal (n= 18)
  - Congenital MR (n= 7)
  - PA/IVS (n= 2)

Courtesy Dr Emani

Freedom from Valve Replacement

- Freedom from valve replacement was 93% at 12 months, and 77% at 24 months, excluding early deaths
- Median time was 18 months (range: 5-50 months)
- 7 of those with eventual replacement underwent BD

Freedom from Structural Valve Deterioration



Courtesy Dr Emani

HYBRID APPROACH FOR NEONATAL AORTIC STENOSIS

- **Hybrid balloon valvuloplasty through the ascending aorta via median sternotomy in infants with severe congenital valvular aortic stenosis: feasibility of a new method.** (2015, Pan et al.)
- Eighteen infants (<90 days of age) with severe congenital aortic stenosis were included in this study. Hybrid balloon valvuloplasty procedures were performed in a hybrid operating room. Patients were followed up at 3 months, 6 months, 1 year and then annually following the procedure.
- The hybrid balloon valvuloplasty procedure was successful in all patients. Eight patients were successfully rescued from left ventricular systolic dysfunction by cardiac compression under direct vision. The aortic valve pressure gradient decreased from 80.3 ± 20.8 mmHg preoperatively to 16.0 ± 3.6 mmHg immediately postoperatively ($P < 0.001$). None of the patients developed significant aortic insufficiency. The fluoroscopy time was 6.2 ± 2.9 min. Intraoperative blood transfusions and pacing were not required. The patients were all alive and healthy at the end of the follow-up period (mean 21.3 months; range 3-41 months), and the aortic valve pressure gradient remained low (21.7 ± 5.3 mmHg). Reintervention was not required in any of the patients.
- CONCLUSIONS: Hybrid balloon valvuloplasty through the ascending aorta via median sternotomy is an effective and safe procedure for infants with severe congenital aortic stenosis.

HYBRID APPROACH FOR NEONATAL AORTIC STENOSIS

- **Hybrid approach as bridge to biventricular repair in a neonate with critical aortic stenosis and borderline left ventricle.** (2009, Brown et al.)
- A newborn presented with severe aortic valve stenosis and a borderline hypoplastic left ventricle due to disproportionate left ventricular hypertrophy (maternal diabetes). The aortic valve was balloon dilated and the infant tolerated a biventricular circulation. However, severe retrograde pulmonary hypertension and mitral regurgitation developed, indicating that biventricular circulation was not possible at that stage.
- **A hybrid approach with ductal stenting, atrial septostomy and bilateral dilatable pulmonary artery band placement was followed on day 25.**
- This allowed the left ventricle several months to adapt to lower pressure and normoglycemic conditions. At re-evaluation after 8 months biventricular repair appeared possible: the ductus was closed with Amplatzer occluders and the pulmonary artery bands were opened up with bilateral balloon angioplasty of the dilatable bands. At the age of 3 years, the infant is doing well with a biventricular circulation and normal pulmonary artery pressure.
- **The hybrid approach allowed adequate time (months) for careful consideration and acted as a bridge to biventricular repair in this infant.**

HYBRID APPROACH FOR NEONATAL AORTIC STENOSIS

- **Severe Aortic Stenosis and Severe Coarctation of the Aorta: A Hybrid Approach to Treatment.** (2017, McLennan et al.)
- Here is a case of a patient with aortic stenosis (AS) and coarctation of the aorta (CoA). Case: a 1-month-old baby presented with severe AS and CoA. The decision was made to perform a hybrid surgical procedure. The patient underwent a lateral thoracotomy for repair of the CoA and carotid cutdown for aortic balloon valvuloplasty (Above).
- Optimal treatment has long been difficult to achieve. Using a hybrid technique by performing AoVP, surgical resection, and end-to-end anastomosis, the best treatment option for each lesion was provided. Known procedure-related complications were avoided with the use of surgical carotid cutdown. Long-term risks of neurological and developmental impairment were reduced with the avoidance of cardiac bypass and DHCA.

HYBRID APPROACH FOR VSD CLOSURE

- ***Hybrid approach for closure of muscular ventricular septal defects (2013, Haponiuk et al.)***
- **Background**: Hybrid therapies aim to combine the advantages of surgical and interventional techniques in an effort to reduce the invasiveness. The aim of this study was to present an approach with mVSD patients and initial results in the development of a mini-invasive hybrid procedure.

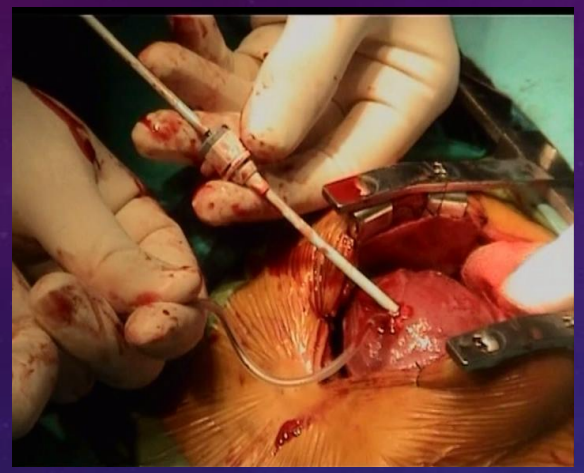
- **Results:** The implants of choice were Amplatzer VSD Occluder and Amplatzer Duct Occluder II (AGA Med. Corp, USA). The position of the implants was checked carefully before releasing the device with both transesophageal echocardiography and epicardial echocardiography. All patients survived and their general condition improved. No complications occurred. The closure of mVSD was complete in all children.

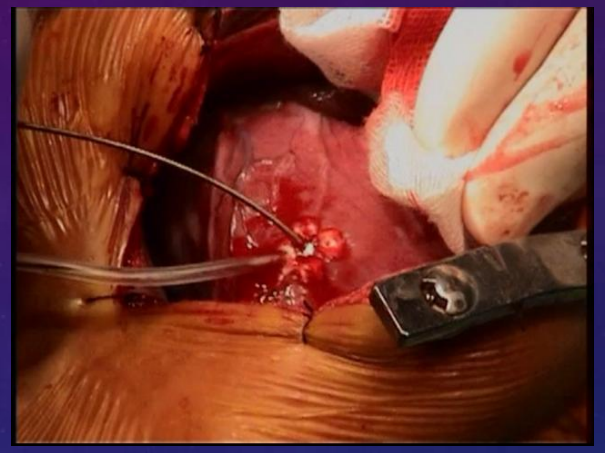
- **Conclusions:** Hybrid procedures of periventricular muscular VSD closure appear feasible and effective for patients with septal defects with morphology unsuitable for classic surgical or interventional procedures. The modern strategy of joint cardiac surgical and interventional techniques provides the benefits of close cooperation between cardiac surgeon and interventional cardiologist for selected patients in difficult clinical settings.

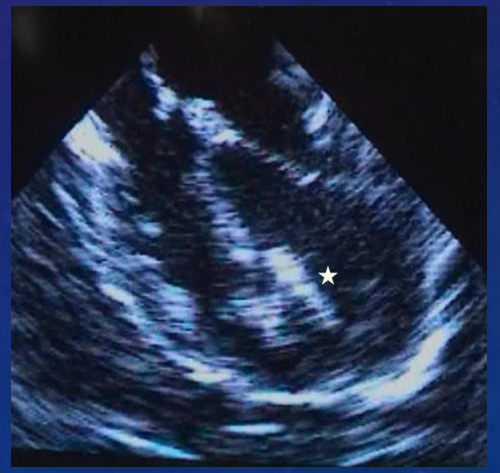
HYBRID VSD CLOSURE

- 2 patients
- 4 and 6 months of age
- Sizeable muscular ventricular septal defect
- Median sternotomy, off-pump
- Intraoperative device closure with the use of an Amplatzer occluding device
- Right perventricular approach
- Intraoperative TOE

VSD DEVICE CLOSURE







RESULTS

- No Intraoperative death or postoperative complication
- ICU stay: 1 and 2 days respectively
- Hospital stay: 5 and 10 days respectively
- Echo prior to discharge: no residual VSD
- At 48 and 56 months of follow-up:
  - intact ventricular septum
  - both patients are asymptomatic

Acute and midterm results following perventricular device closure of muscular ventricular septal defects: A multicenter PICES investigation.

Gray RG[1], Menon SC[1], Johnson JT[2], Armstrong AK[3], Bingler MA[4], Breinholt JP[5], Kenny D[6], Lozier J[7], Murphy JJ[8], Sathanandam SK[9], Taggart NW[10], Trucco SM[11], Goldstein BH[12], Gordon BM[13].

Catheter Cardiovasc Interv. 2017 Aug 1;90(2):281-289.

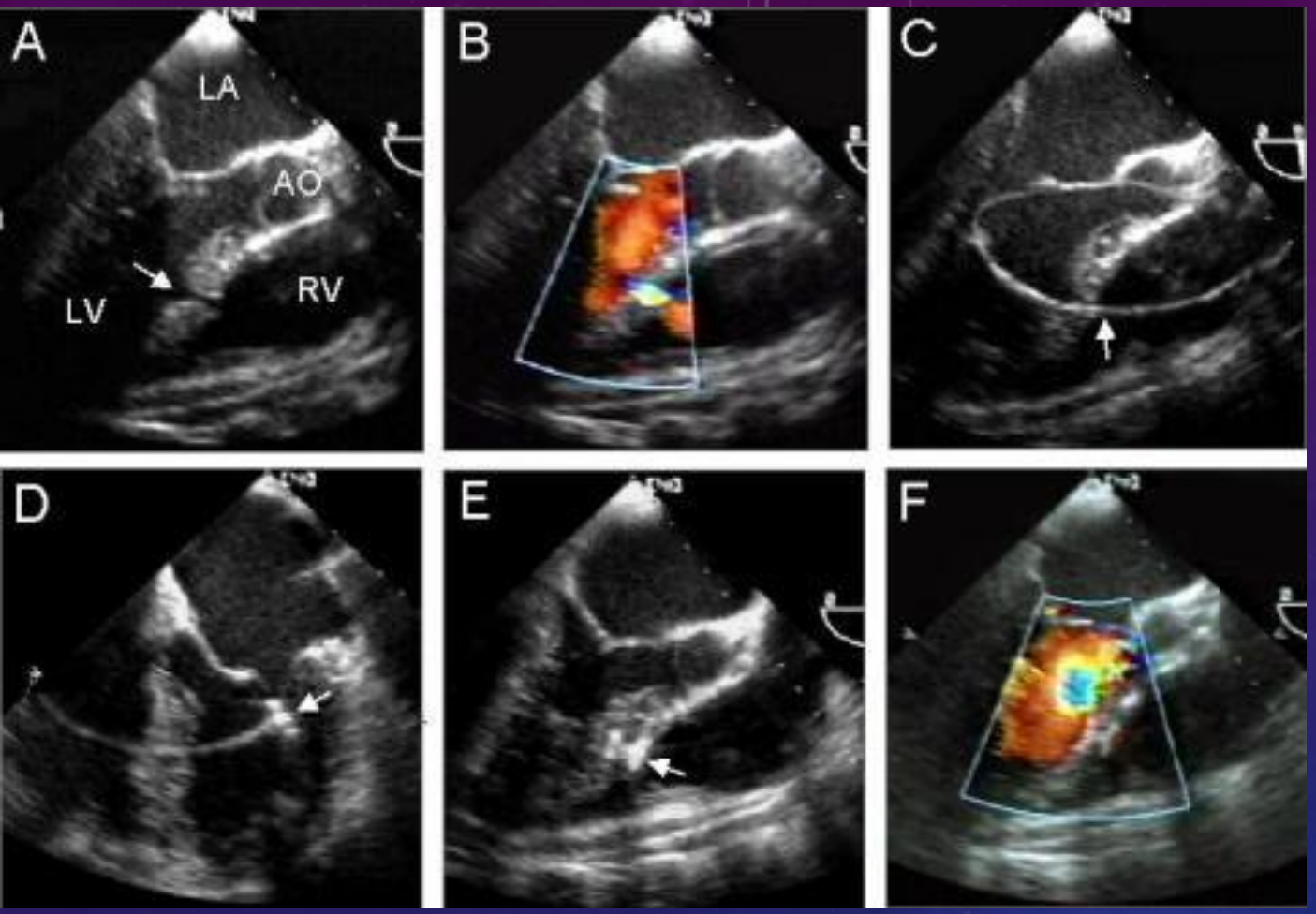
This is a multicenter retrospective cohort study of patients undergoing hybrid perventricular mVSD device closure from 1/2004 to 1/2014. Procedural details, adverse events, outcomes, and follow-up data were collected. Patients were divided into two groups: (1) simple (mVSD closure alone) and (2) complex (mVSD closure with concomitant cardiac surgery).

RESULTS:

Forty-seven patients (60% female) underwent perventricular mVSD device closure at a median age of 5.2 months (IQR 1.8-8.9) and weight of 5.1 kg (IQR 4.0-6.9). Procedural success was 91% [100% (n = 22) simple and 84% (n = 21/25) complex]. Adverse events occurred in 19% (9/47) [9% (2/22) simple and 28% (7/25) complex]. Hospital length of stay (LOS) was shorter in the simple vs. complex group (4 vs. 14 days, $P < 0.01$). At mid-term follow-up of 19.2 months (IQR 2.3-43) 90% of pts had complete mVSD closure; none developed late heart block, increased atrioventricular (AV) valve insufficiency or ventricular dysfunction.

CONCLUSIONS:

Perventricular device closure of simple mVSD was associated with a high rate of procedural success, few adverse events, and short hospital LOS. Procedural adverse events were associated with the presence of concomitant complex surgery. Residual mVSD, AV valve insufficiency, or ventricular dysfunction were uncommon at mid-term follow-up.



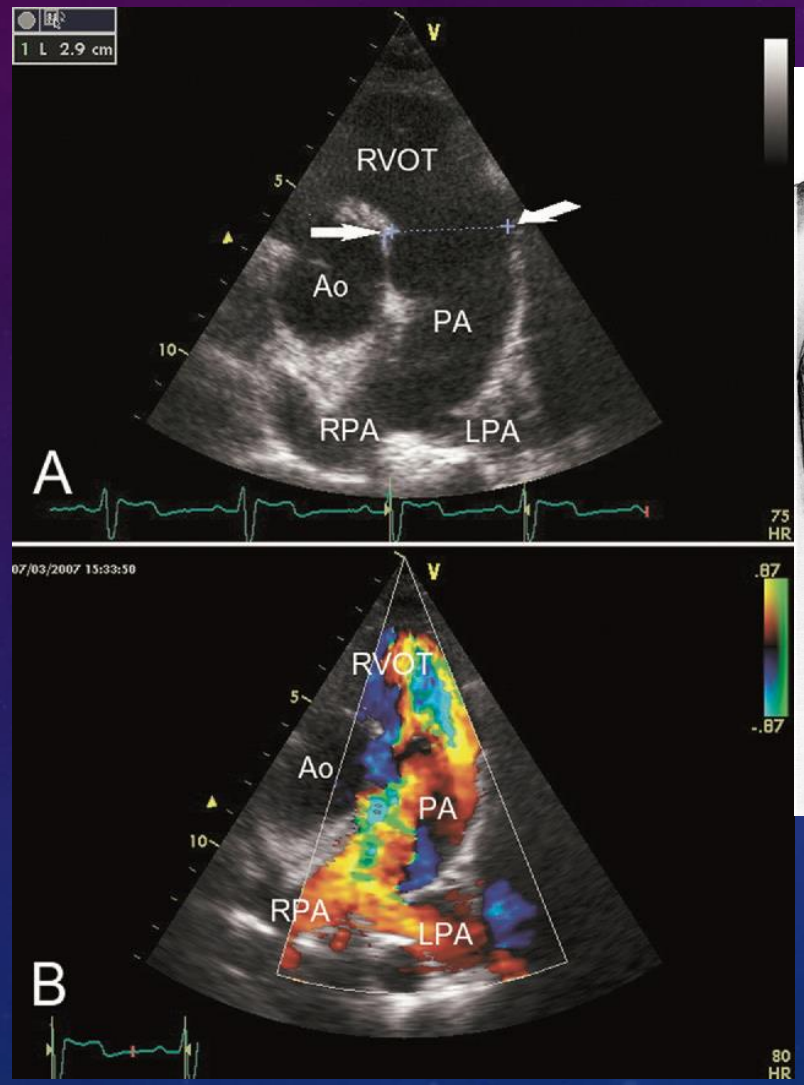
VSD closure
HYBRID APPROACH

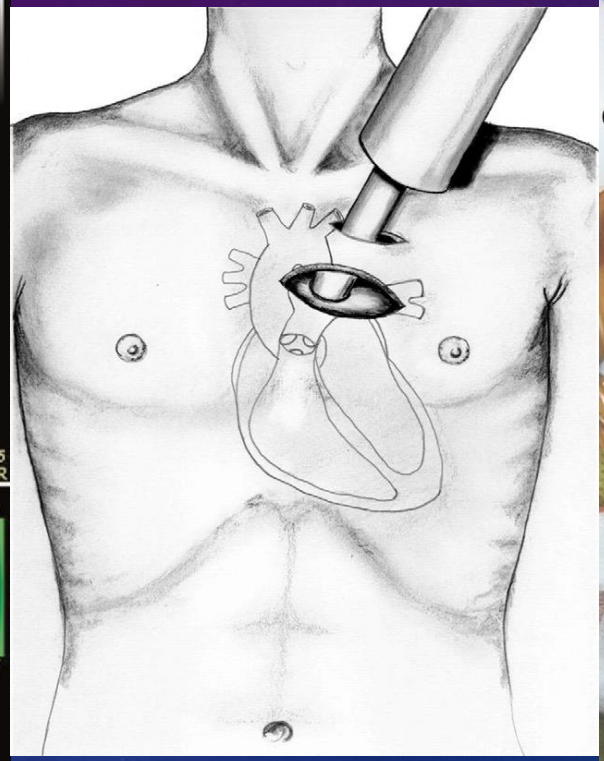
A novel hybrid technique for transcatheter pulmonary valve implantation within a dilated native right ventricular outflow tract

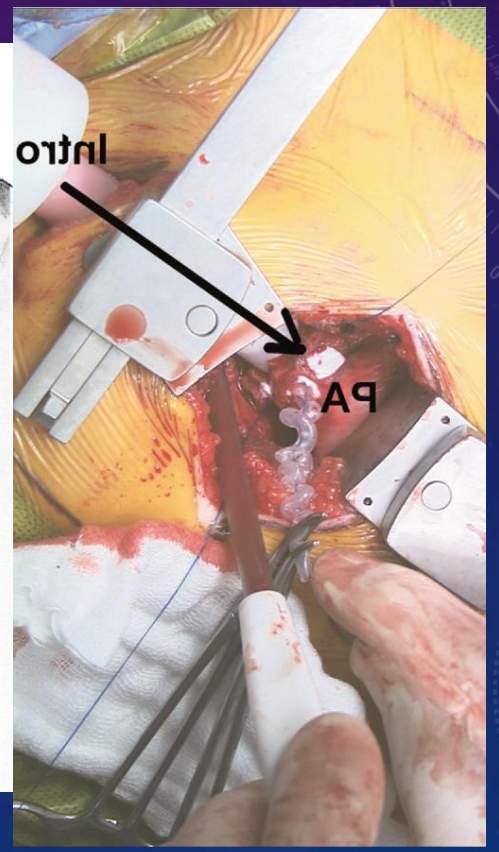
Frances C. Travelli, MD, Cynthia S. Herrington, MD, Frank F. Ing, MD

The Journal of Thoracic and Cardiovascular Surgery
Volume 148, Issue 2, Pages e145-e146 (August 2014)
DOI: 10.1016/j.jtcvs.2014.04.046

HYBRID IMPLANTATION OF PULMONARY VALVE IN EXTREMELY DILATED RV / MPA WITH POOR FUNCTION

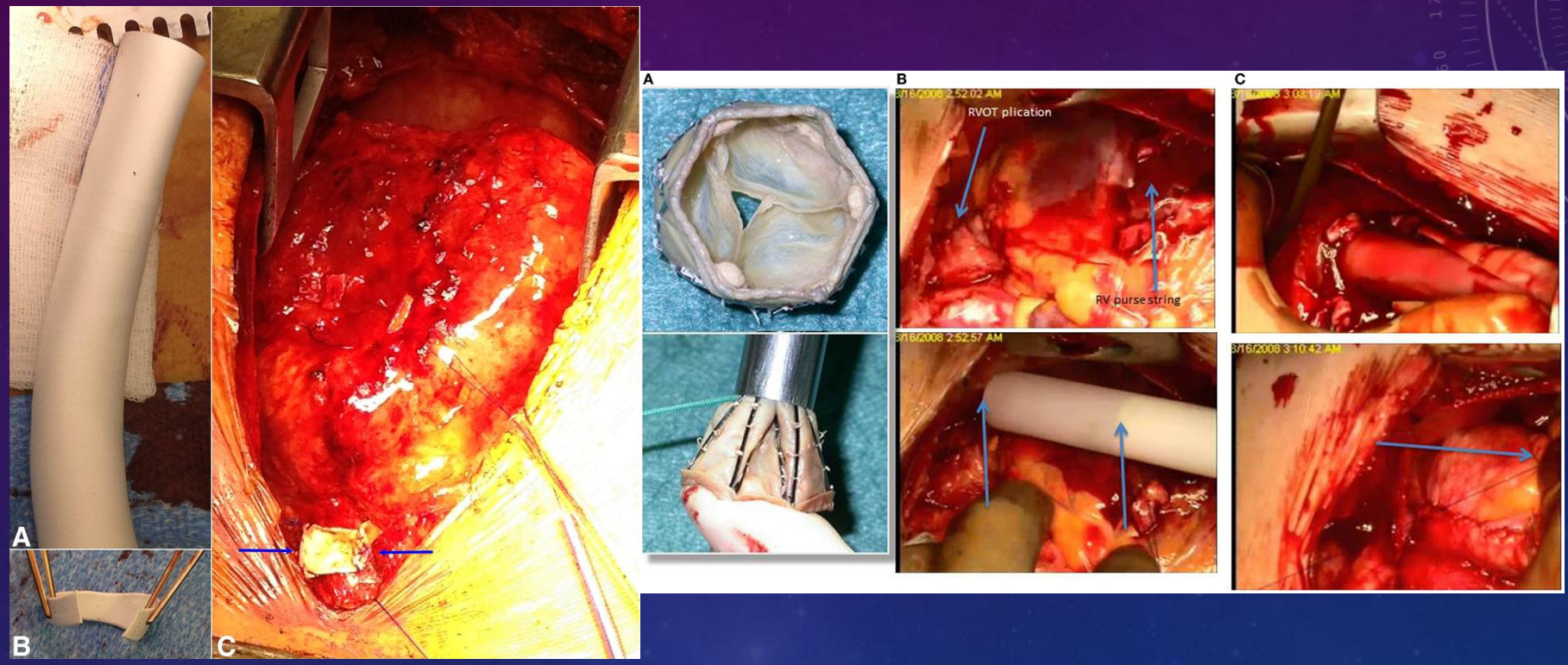






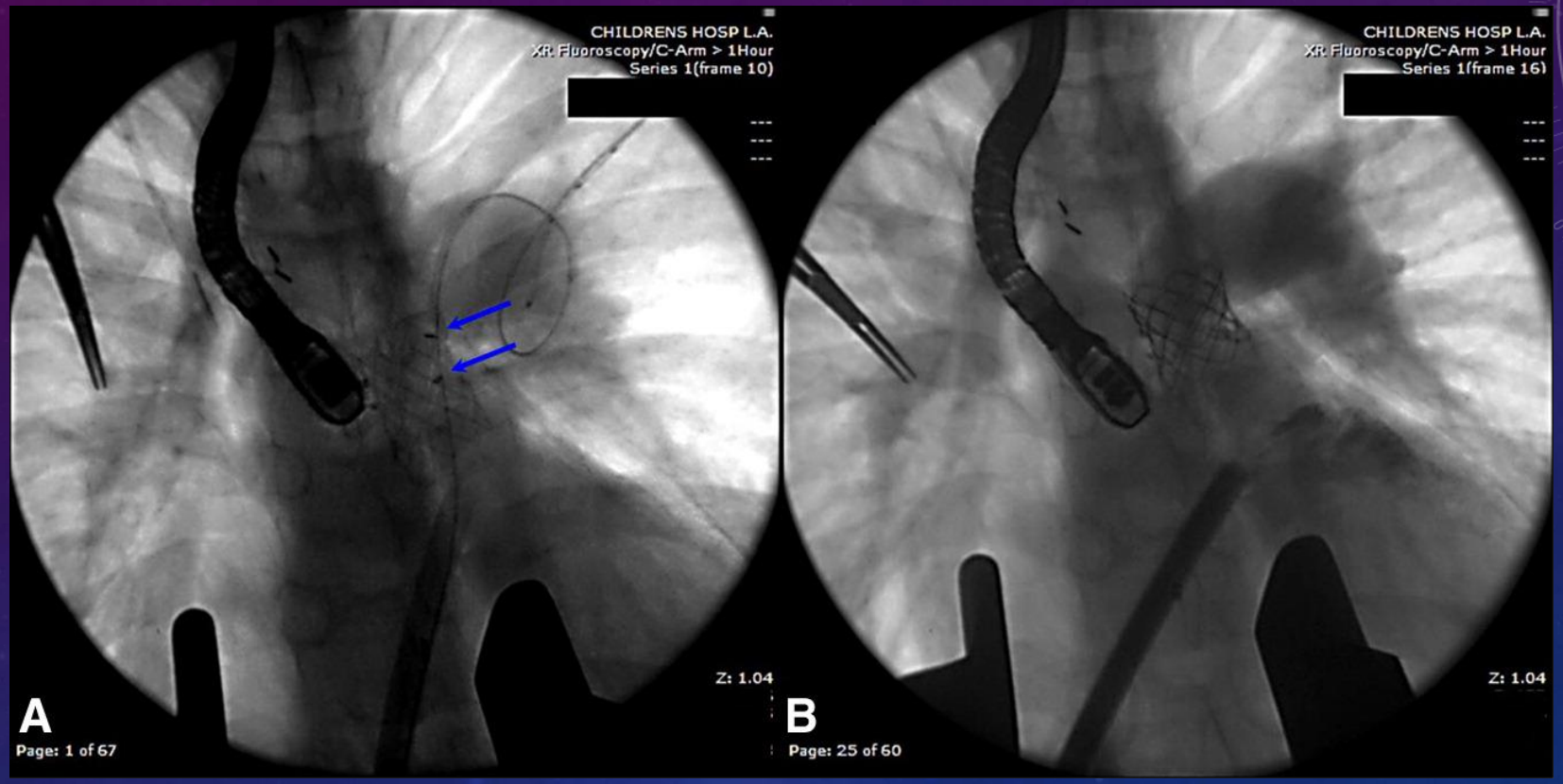
Dittrich S et al. Annals Thoracic Surgery 2008

Figure 1

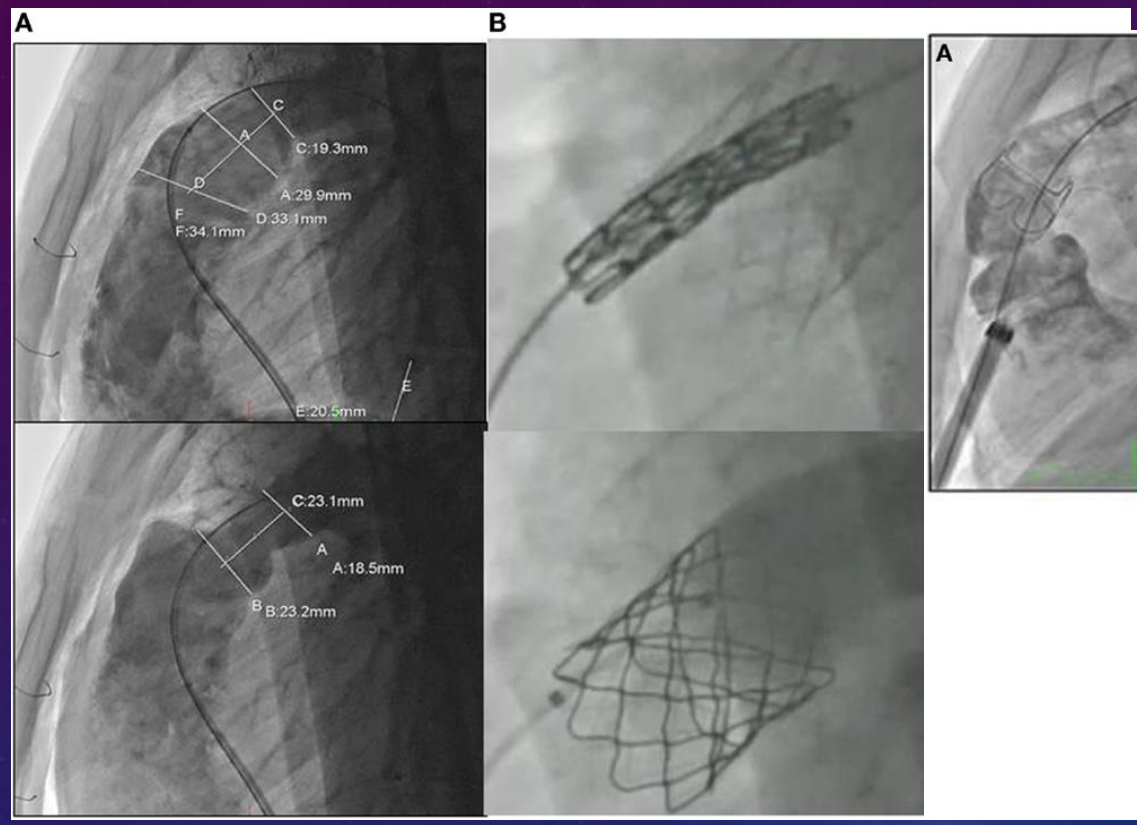


The Journal of Thoracic and Cardiovascular Surgery 2014 148, e145-e146DOI: (10.1016/j.jtcvs.2014.04.046)

Figure 2



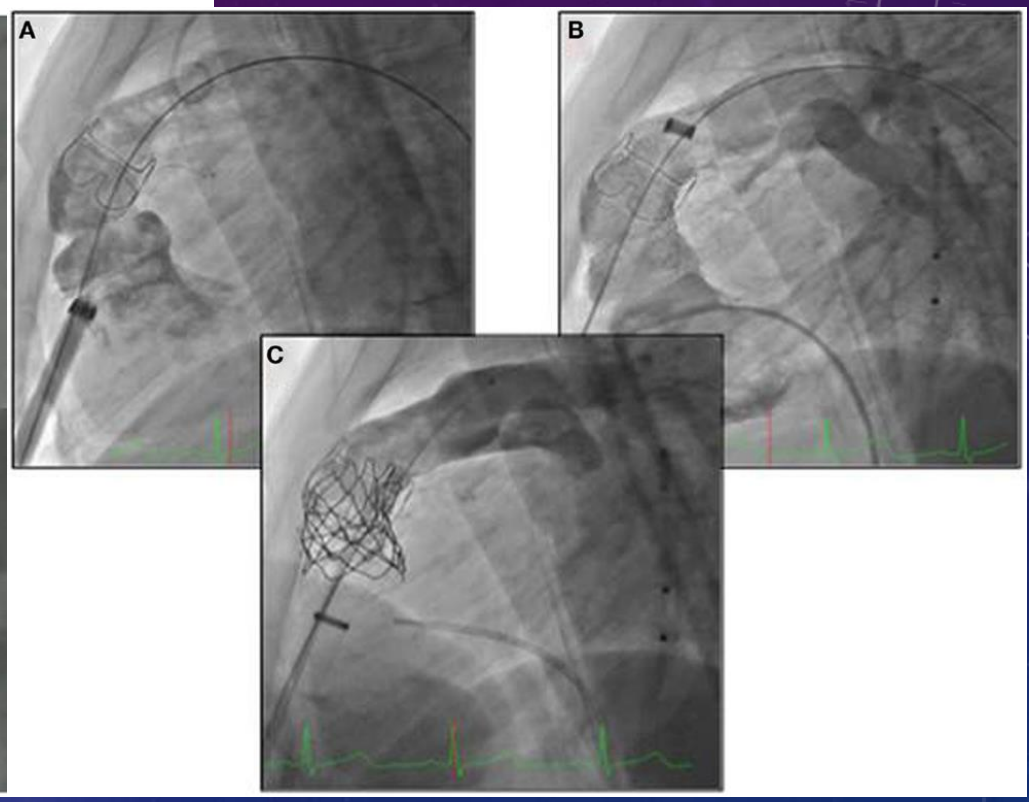
The Journal of Thoracic and Cardiovascular Surgery 2014 148, e145-e146DOI



Hybrid pulmonary artery plication followed by transcatheter pulmonary valve replacement:

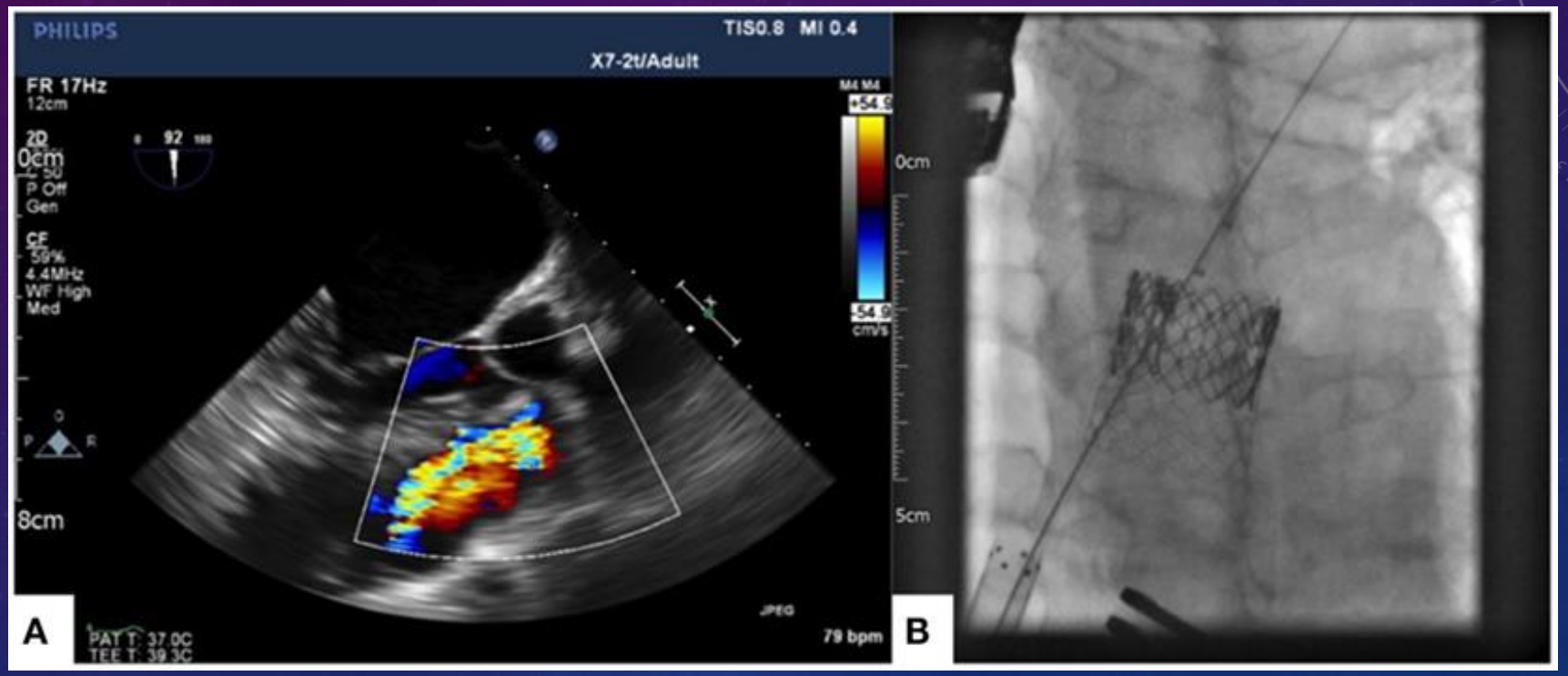
Comparison with surgical PVR

Sosnowski C . Catheter Cardiovasc Interv 2016



Hybrid PV implantation due to occluded vessels

29-MM EDWARDS SAPIEN XT PROSTHESIS WITHIN AN ANDRAMED AS43XXL STENT IMPLANTED IN THE PULMONARY POSITION



Rapetto F et al. Hybrid Surgery Options for Complex Clinical Scenarios in Adult Patients with Congenital Heart Disease, 2017

CONCLUSIONS

As disease complexity and patient pathology are increasing, the neonatal population suitable for hybrid procedures broadens

- Hybrid procedures allow Surgeons and Cardiologists to achieve complex procedures that would not be possible in another way.
- In some case the combined approach might reduce the total number of interventions
- Possible Reduction total hospital stay, morbidity, mortality and cost