CONGENITAL CARDIOLOGY TODAY
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How I Do It: Tips, Tricks, and Techniques – How I Close Systemic-to-Pulmonary Artery Collaterals Using Microparticles?

A PICS Society Education Series

Sarosh P. Batlivala, MD, MSCI, FPICS

Introduction

Pediatric and congenital interventional cardiologists deal with many patients who have systemic-to-pulmonary artery collaterals (SPC). These SPCs are common in patients with single-ventricle physiology and chronic hypoxemia. Though the SPCs increase pulmonary blood flow, they are also volume loading because much of the flow is ineffective. Since these networks arise from normal arteries (e.g., internal mammary, intercostals, etc.), traditional treatment has involved coil occlusion of the feeding vessel. However, SPCs can redevelop from those vessels, distal to the coils, which makes ongoing treatment difficult, if not impossible. Further, a general principle for optimal vessel closure is to occlude as distally as possible. Particle occlusion can, therefore, be a strong alternative since the feeding vessel remains patent and the particles occlude the distal SPC connection to the PAs.[1]

Anticipated Challenges of the Procedure

Given the flow-directed nature of particle delivery, the catheter must be securely positioned well into the feeding vessel. Back flow of particles into a major systemic or CNS-supplying artery can have devastating consequences. As above, common feeding arteries arise from:

- Subclavian system = Internal mammary, Thyrocervical trunk, Lateral thoracic
- Coronary arteries
- Thoracic Aorta = Intercostal, Bronchial
- Abdominal aorta = phrenic, celiac plexus branches

The artery of Adamkiewicz is particularly noteworthy. This vessel is the primary arterial supply for the thoracolumbar spinal cord, so occlusion can lead to spinal cord ischemia and paraplegia. Moreover, this vessel can arise from any of the intercostal arteries so interventionalists need to obtain clear angiograms of intercostal arteries to ensure this artery is not arising from a vessel intended for particle occlusion.

Tip 1 – Planning and Preparation

- Know your patient's anatomy (obviously!)
- Understand how to grade SPC flow:
  - Pre-catheterization MRI can provide quantitative data

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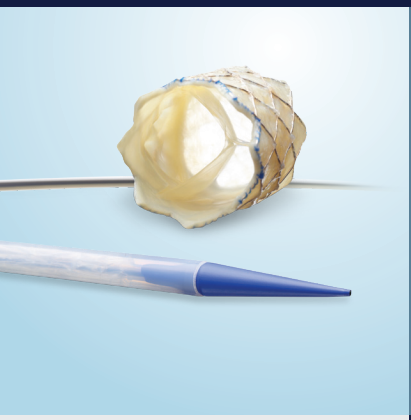
RIGHT CHOICE.



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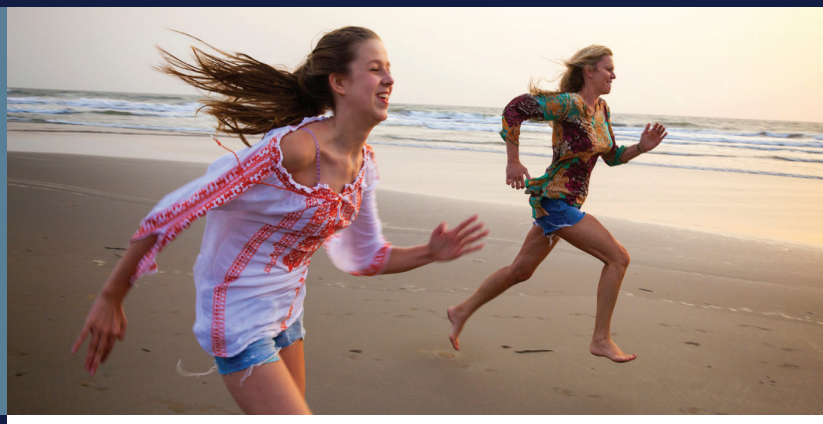

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Important Labeling Information for the United States

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- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
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- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
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Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

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

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

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

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Contraindications

- Venous anatomy unable to accommodate a 22 Fr size introducer sheath
- Implantation of the TPV in the left heart
- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

Potential Complications/Adverse Events: Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, pain, swelling or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture.* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

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

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  - Angiography[1]:
    - mild = only the segmental PA branches opacified
    - moderate = proximal PA (i.e., RPA or LPA) opacified
    - severe = contrast refluxes back into MPA or contralateral PA
  - Develop an algorithm/treatment protocol to establish thresholds for SPC occlusion. Such an algorithm can take the following factors into account:
    - Threshold % of aortic outflow (e.g., 30% or 40% SPC flow)
    - Angiographic grade
    - Systemic ventricular EDp
    - Cardiac chamber dilation
    - Planned operation(s) and timing
    - Systemic saturation
    - Hemoptysis (often an independent indication)
- Histopathologic data demonstrated SPC diameter (median) in Fontan patients ≈160 µm.[1]
- Occlusion induces an inflammatory response, which triggers ongoing SPC development; SPC flow may return to baseline and even exceed it approximately 6-8 weeks after embolization. So if performing SPC occlusion as part of a pre-operative assessment and preparation (e.g., pre-Fontan), the surgery should ideally be scheduled within a month of the particle occlusion procedure.[2]

Tip 2 – Tools Needed

- A separate cart for all the particle equipment is recommended. This will ensure that stray particles do not contaminate the primary procedural and supply tables, minimizing the risk of inadvertently injecting particles into the patient non-selectively.
- Catheters:
  - "Guide" catheter – a standard 4Fr catheter, 0.038" lumen (e.g., Bentson/JB, JR, Glide, etc.). This catheter engages the feeding artery for angiography and is a guide for the microcatheter through which the particles are delivered. If this catheter is engaged deeply enough, particles can be delivered directly through this catheter as well.
  - Microcatheter – Various options, need to ensure the lumen diameter is able to accept the specific microparticles (see particle manufacturer website, which often recommends appropriate microcatheters). We do not endorse a particular product, but the 2.8Fr Cantata (Cook®, Bloomington, IN USA) and Renegade Hi-Flo (Boston Scientific®, Marlborough, MA USA) microcatheters work well.
- Particles (two types)
  - Polyvinyl alcohol = Irregular shape, grouped by sizes (produced by pulverizing PVA then passing through sifts of different sizes). Suggest minimum size of 500 µm (we use 500-710 µm). Sizes >1000 µm may be challenging to deliver given larger requisite microcatheter.
  - Tris-acryl gelatin = precisely engineered microspheres; care must be taken as agitation can disrupt/destroy the particles.
- Other Equipment (**Figure 1**)
  - Fresh sterile towels
  - Hemostatic Y-adaptor (model of operator preference)
  - Three-way stopcock (low or high pressure)
  - Syringes: 10mL (suggest at least four - two for angiography and two as particle slurry "reservoirs"), two 1 or 3mL syringes for particle delivery
  - Three bowls/sterile cups – one each for flush, contrast, and the particle slurry
  - Flush and contrast (~50mL to start) specifically for the additional procedural table

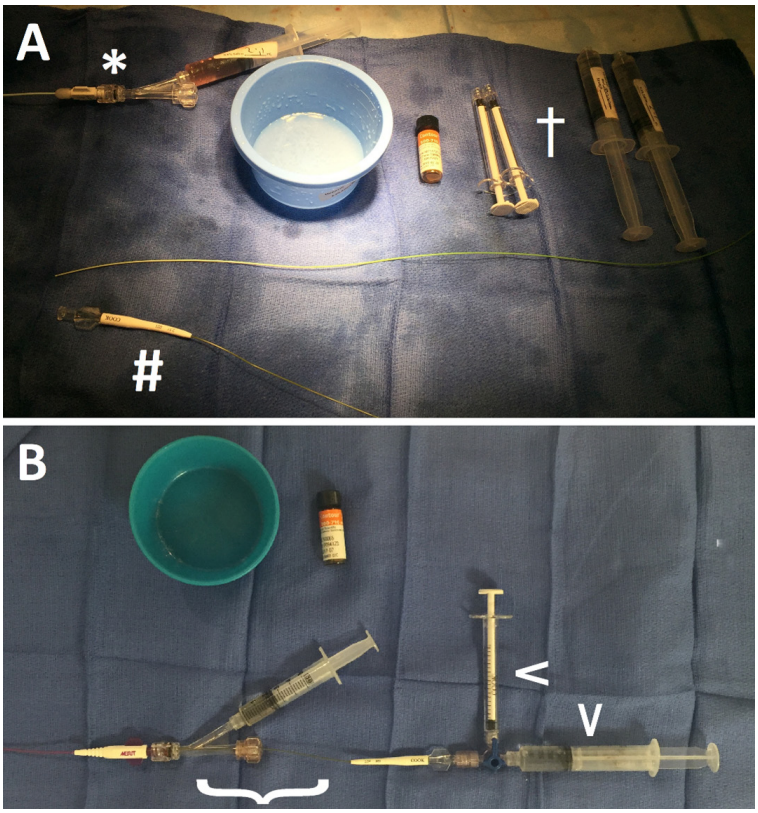

FIGURE 1 Particle Occlusion Equipment
A) *The equipment is all separated. A hemostatic adapter has been attached to the 4Fr guiding catheter (*). The microcatheter (#) is prepared for insertion through the guiding catheter and into the feeding vessel. A 10mL "reservoir" and either 1 or 3 mL injector syringes are present and marked (†).*

B) *Fresh sterile towels have been placed under this coaxial catheter system. The microcatheter is coaxially loaded through the guiding catheter ({). A 3-way stopcock, with the reservoir and injector syringes attached (arrowheads), is affixed to the microcatheter.*

Tip 3 – How I Do It

- Once baseline, non-selective angiography demonstrates a significant degree of SPCs, and the decision is made to occlude them after the diagnostic assessment, obtain all requisite equipment so that occlusion can be performed expediently.
- Set up the particle table. Obtain flush and contrast as above. Label two 10mL syringes for contrast injection, two 10mL syringes to serve as particle reservoirs, and two 1- or 3mL syringes for particle delivery. Obtain a vial of particles. Empty the particles into a clean sterile cup and add 20mL of contrast and 2mL of flush. Stir the mixture and withdraw 5-10mL into a reservoir syringe. Hold the syringe steadily in a vertical position for at least 10 seconds and observe for particle aggregation. The goal is to achieve a suspension. If the particles begin to float, the injectate is too dense and if the particles sink then the injectate is not dense enough. In those cases, empty the contents back into the particle slurry cup and add 1-2mL of contrast (to make the injectate more dense if the particles were sinking) or 1-2mL of flush (to thin the injectate if the particles were floating). Repeat this process as many times as necessary until a suspension is achieved.
- Fill the reservoir syringe with the 8-9mL of particle slurry and attach to a 3-way stopcock (position per operator comfort). Attach an empty 1 or 3mL syringe to the other port.
- Obtain microcatheter and prepare for use.
- Selective angiography in the feeding vessel(s) should be performed first. This angiogram is typically performed with the guiding catheter (noted above). Save a select frame as a roadmap; this frame should demonstrate the origin of the feeding vessel from the major systemic artery (e.g., the internal mammary and subclavian artery junction) (**Figure 2**).
- If the guiding catheter is sufficiently deep in the vessel intended for occlusion, particles can be delivered directly through the 4Fr catheter into the main feeding vessel. Great care must be taken to monitor for reflux of the injectate as infusion should cease before the injectate refluxes back into the main systemic artery.
- If using the microcatheter for particle delivery, consider flushing the guiding catheter with 1000 units/mL of unfractionated heparin given the higher potential for thrombosis. This decision may depend on the specific microcatheter, estimated duration of use during the case, patient's ACT etc.). Attach the Y-adaptor to the guiding catheter and introduce the microcatheter. Place clean sterile towels under this coaxial catheter system; these will be used to contain and ultimately wrap the particle delivery catheters to prevent contamination of the catheterization table with stray microparticles.
- Advance the tip of the guiding catheter, ideally, at least 1-2 cm deep into the feeding vessel (**Figure 2a**). The tip of this guiding catheter is an important landmark. Advance the microcatheter distally into the feeding vessel.
- Particle slurry injection: Attach the stopcock to the microcatheter and gently agitate the particle slurry between the reservoir and delivery syringes (use similar technique as for contrast-enhanced echocardiograms [i.e., bubble studies]). De-air the microcatheter, then slowly inject the slurry under fluoroscopic guidance, ensuring that only the distal vessel opacifies. Flow through the vessel will become increasingly sluggish as the particles occlude the distal branches. Continue the process until the slurry

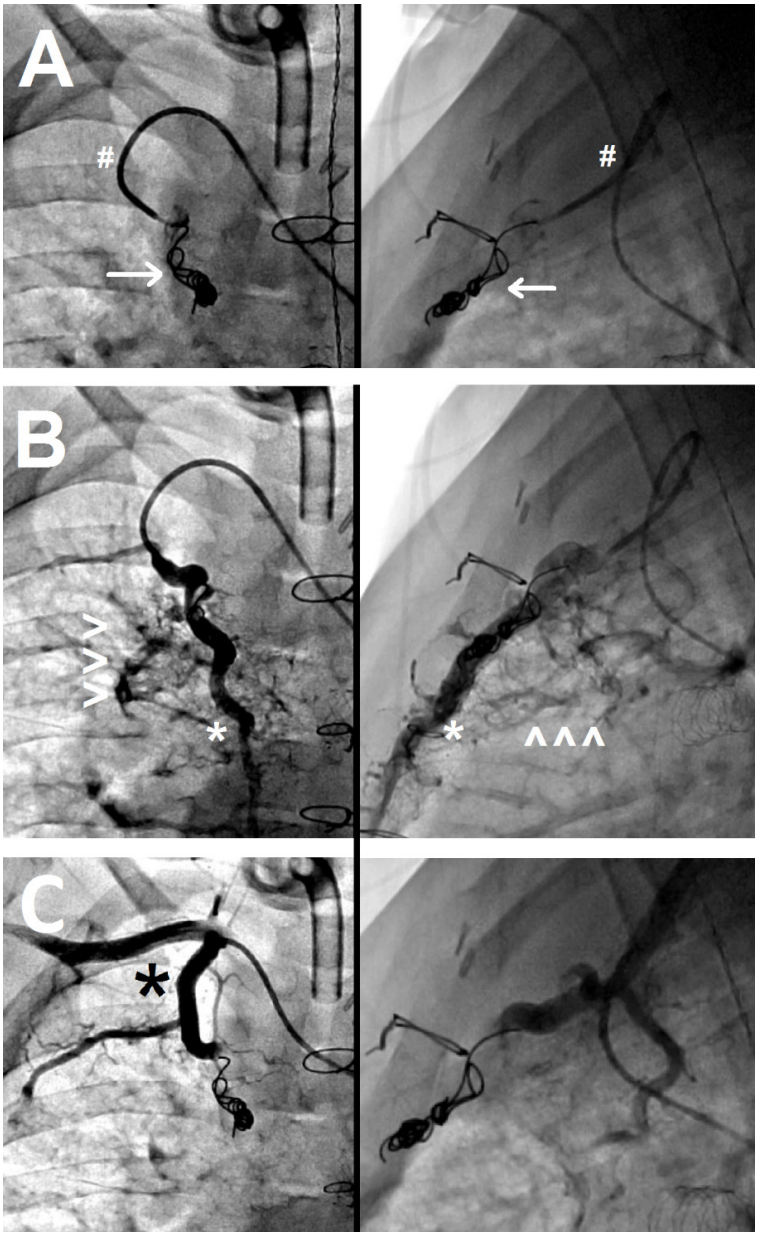

FIGURE 2 Reconstituted SPCs After Prior Coil Embolization of the Feeding Vessel
A) *The tip of the guiding catheter is ~2cm deep into the internal mammary artery (IMA) (#). Note multiple coils (arrow) in the mid-IMA after previous coil occlusion.*
B) *The IMA distal to the coils has reconstituted (*), giving rise to additional SPC networks (arrowheads).*
C) *Post-particle injection shows no residual SPC flow with a patent IMA (*).*

begins to backwash toward the feeding vessel. Particle injection should cease when the slurry backwashes to the tip of the guiding catheter (**Figure 2c**). Ceasing injection at this point ensures that particles do not reflux into the feeding artery/systemic circulation.

- Remove the microcatheter, flush with saline (ideally cover end with gauze to contain the particles) and wrap the catheters in the sterile towels. Perform a follow-up angiogram through the guiding catheter to assess SPC occlusion. If needed, repeat the procedure.

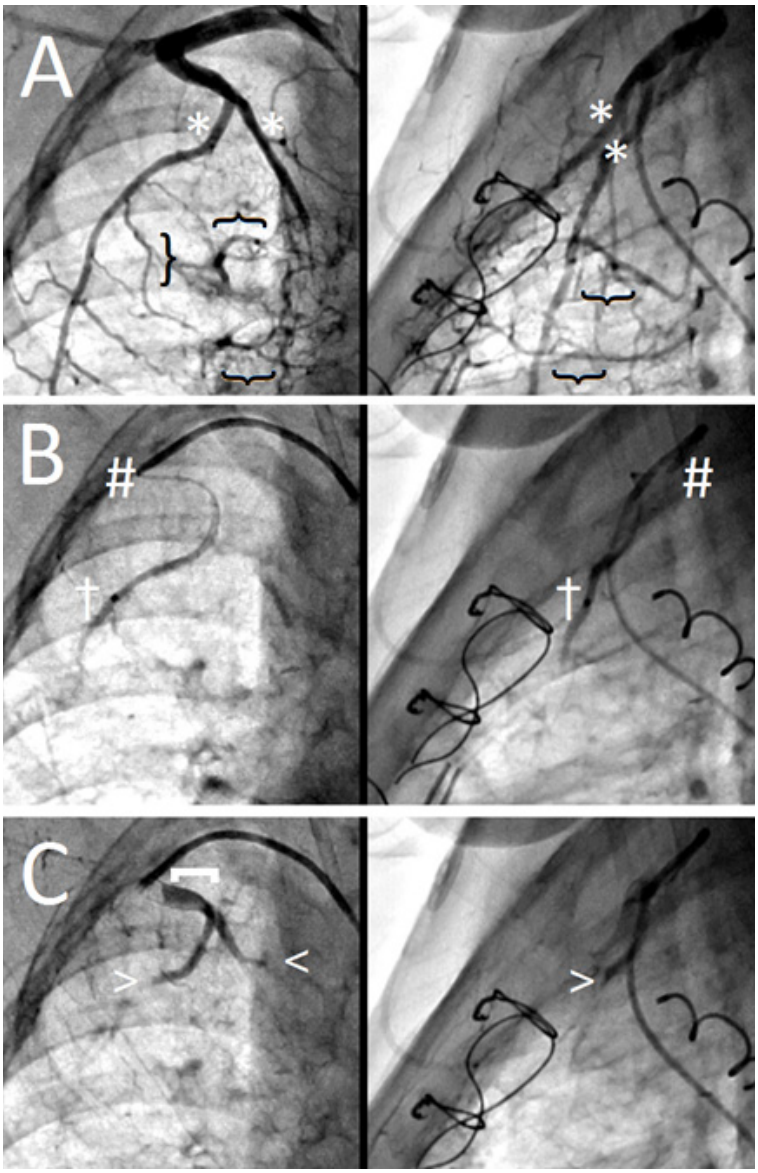

FIGURE 3 Occlusion Of "Complex" Systemic-To-Pulmonary Collaterals
A) *Note the two large branches (*) of the internal mammary artery (IMA) that give rise to multiple SPC networks (}).* ***B)*** *The two large feeding branches are individually engaged with the microcatheter for selective particle delivery (†); the guiding catheter tip remains ~1-2cm in the IMA as a landmark (#).* ***C)*** *Post-particle injection shows no residual SPC flow (arrowheads) with a patent IMA origin ([ ).*

Tip 4 – Potential Complications and How to Deal with Them

1. Most important is ensuring that the particle slurry does not reflux into the major systemic artery from which the feeding vessel arises (e.g., subclavian artery, aorta, etc.). This is accomplished as detailed above. Systemically embolized particles cannot be retrieved.
2. Microcatheter occlusion – As previously described, delivery of PVA particles is optimized when the particles are in a suspension (i.e., not sinking or floating in the injectate). The operator needs to regularly inspect the reservoir and delivery syringes to ensure the particles remain suspended. If the particles are significantly aggregated, start by re-agitating the two syringes and then observe. As above, if the particles sink or float in the reservoir syringe, then follow the steps above to reestablish a suspension. The syringes and microcatheter will become occluded with particles if they are in an aggregate clump.
3. Perform close and repeated neurologic examinations after the procedure. Have a very low threshold to obtain advanced imaging if any CNS abnormalities are detected.

Summary

Particle occlusion is an effective technique to occlude SPCs. The technique is particularly important in patients with complex SPC networks or recurrent SPCs, as outlined in **Figures 2 and 3**. The operator must have knowledge of the patient's anatomy and ensure that all appropriate equipment is available. The critical aspects of the procedure relate to understanding the arterial anatomy and ensuring particle delivery in the intended vessel is safe. The methods outlined above will minimize the risks of complications such as systemic embolization of particles.

Figures

Reproduced (per journal rights of authors) from Batlivala SP, Briscoe WE, Ebeid MR. "Particle embolization of systemic-to-pulmonary collateral artery networks in congenital heart disease: Technique and special considerations." Ann Pediatr Card 2018;11:181-6.

References

1. Batlivala SP, Briscoe WE, Ebeid MR. Particle embolization of systemic-to-pulmonary collateral artery networks in congenital heart disease: Technique and special considerations. Ann Pediatr Cardiol. 2018 Aug;11(2):181–6.
2. Glatz AC, Rome JJ, Small AJ, Gillespie MJ, Dori Y, Harris MA, et al. Systemic to Pulmonary Collateral Flow as Measured by Cardiac Magnetic Resonance

Imaging is Associated with Acute Post-Fontan Clinical Outcomes. Circ Cardiovasc Imaging [Internet]. 2012 Jan 6 [cited 2012 Jan 28]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/22228054.

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Matters of the Heart and Mind
On Pyrrhic Victories: A Very Precious Baby

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We have all had Pyrrhic victories with our work in the Catheter Lab. Unpromising complex substrate, hours of difficult catheter manipulation, device positioning, blood loss, device retrieval, patient instability, but after all that, a rewarding haemodynamic / angiographic anatomical result. And then…despite the hours of toil by the teams in the lab and CICU…a critical incident in CICU or on the floor perhaps not directly related to the substrate or the intervention… leads at best to a prolonged stay in intensive care and at worst to death.

I remember as a junior neonatal fellow (in both senses!) being given the heads up by midwives when called to the delivery rooms to standby for resuscitation. Prolonged dips in heart rate, forceps deliveries, C section, twins. The lot. One very experienced midwife, Mary, took no prisoners from junior medical staff. In short, when Mary called saying 'You need to be here', you went, no point in asking details. Mary would often call asking for standby resuscitation for reasons of 'This is a very precious baby.' Is there ever a 'non-precious' baby? We knew what she meant, of course, and greatly respected her experience and judgement but in the way that medical humour can become dark, we junior fellows would mimic: 'Fancy a very precious cup of coffee?' 'Wow, that's a very precious X Ray.' Naughty, I admit, but long hours taking their toll, if a bit of dark humour could alleviate some of the stress then it's an acceptable trade-off. Mary knew we were mimicking her, but I vouch she quite enjoyed her notoriety.

Stephanie was indeed a "very precious" baby in that she was the result of the six or seventh pregnancy of a couple who had struggled to conceive and, until now, when pregnancy did ensue, it had ended in miscarriage. Imagine that roller coaster of emotions. Happiness, euphoria even, then disaster… things can only get better. And they did. Stephanie was very much alive albeit at 34 weeks and 2.2kg. Mum and dad at 39 radiated smiles and relief. Well, this being Stephanie, she has a systolic heart murmur and saturations reaching 90%... she has Tetralogy of Fallot. But she's pink, feeding okay with a nasogastric tube, let's just hang on for a few days and hopefully get her home and see how she goes. All good, within a week she's 2.5kg, saturations high 80's. Say what you like about early repair but this is 1999 in Scotland and we were not thinking on those lines. What would you do today?

A few days later 2.6kg she's home. Parents live only a couple of miles from the hospital, easy to keep an eye on things. At three weeks of age a colleague sees Stephanie in clinic, she's doing ok, as I would say small o small k but saturations just about hitting 80%. The outflow obstruction looks almost exclusively valvar. She's very precious. She's admitted and by the time we've done a couple of ward rounds she's saturating 77% and we think at 2.7kg pulmonary balloon valvoplasty is appropriate. What would you have done? So to the Cath lab, some desaturation on induction of anaesthesia but, thanks to a 6mm Tyshak balloon (How did they get that name?), all went well. Saturations up to mid 80s %, overnight stay and home she goes. Colleague sees her quite often, she's small but making good progress. Good progress that is until about ten weeks of age. She's blue again, 3.9 kg, echo shows very obvious dynamic right ventricular outflow tract obstruction. No point in repeating a balloon procedure. She goes for a right-modified Blalock Taussig shunt 5mm GoreTex. What would you have done in 1999? All goes smoothly, she doesn't touch the sides, saturations into the 80s again. Home.

Parents and colleagues very happy. And everyone stays happy for six or seven months. Good growth, development, saturations. But life's not fair. Stephanie gets an intercurrent illness of modest fever, goes off her feeds, some rhinorrhoea. Her family practitioner sits on her nervously, but 24 hours later… she's shut down, tachycardic at 180, pale, grey, becoming unresponsive. So… into hospital, virtually straight to CICU. Saturation probe is not registering. Intubated, metabolic acidosis, pH 7.18 so off we go with resuscitation fluids, antibiotics (blood cultures were repeatedly negative). Echo showed intracardiac anatomy as before, flow out of the right ventricle looks appropriate, but we can't see flow down the shunt and the lumen of the right pulmonary artery, as I would say, is about as narrow as a gnat's urethra. So the shunt is blocked in a very sick baby 6.7 kg. I hope you agree with our decision to go to the lab and see what is going on with a view to revascularizing the shunt and the right pulmonary artery. So off we go.

It is quite late on a Wednesday night around 9 o'clock. ICU and Anaesthesia somehow manage to efficiently and effectively treat the acidosis and saturations miraculously are in the mid 60s. Access is straightforward, right femoral vein and artery. Venous catheter into the right ventricle easily, arterial catheter positioned just proximal to the shunt in the right subclavian artery. Angiography is astounding. There is a hairsbreadth of flow down the shunt but very little opacification of the pulmonary arteries from the shunt. MPA angio shows small LPA with flow distally and normal pulmonary venous return. But the RPA… OMG it is full of thrombus and resembles a piece of string tied in knots. Big knots. So…we need flow into the RPA. Flow will beget flow. That's a great Chuck Mullins mantra right? Would you balloon retrograde up the shunt from the RPA catheter and risk dislodging thrombus northwards into the right common carotid? Or…Would you balloon from the arterial side and risk dislodging thrombus and it embolising when you withdraw the Tyshak balloon catheter from the shunt? Having telephonic guidance from haematology to institute iv heparin and tPA (Alteplase) infusion dosage the plumbing side of things went quite well. We approached things simultaneously 'and at the same time' as I might have said in an attempt to take a bit of heat off. The shunt revascularised nicely, with good flow and few nubbets (my invention) of thrombus hugging the wall

of the shunt. The RPA knotted string appearance improved, but despite repeated balloon angioplasty, there was significant residual thrombus. Stephanie was stable, saturations were much better, no acidosis. So, a microcatheter was left in the RPA from the right femoral vein approach and a miniscule dose of tPA was continued through it with the plan to repeat angiography in 24 hours and think again. Stephanie had frequent echoes which appeared to show better calibre and flow down the RPA. She was unbelievably 'well behaved' in CICU where nobody took an eye off her. You name the recommended blood tests to monitor thrombolysis and she had them. Saturations in the mid 80s. Marvellous.

Early Friday morning, back to the lab, angiography of the shunt and RPA shows that they were completely thrombus free. Unbelievable. You could feel the release of anxiety in the lab and the faces of the CICU team in the viewing area said "Relief!". Catheters out. Back to CICU with the plan to continue iv tPA for 24 hours and move to intubation over the weekend. I had a big clinic on that Friday afternoon, but it seemed to pass extremely quickly and uneventfully…marred only by one family whose car had been jacked up in one of the hospital car parks and had its wheels stolen. Yup. Not funny but thank goodness their son had had a pulmonary balloon valvoplasty a month before and was doing very well with a negligible gradient. What a facer for them trying to get a new set of wheels on a Friday late afternoon.

I'm on call Saturday morning dribbling coffee onto the newspaper at the breakfast table. The phone goes. Its CICU. 'Neil, sorry but Stephanie's neuro obs have gone haywire she's got fixed dilated pupils, we're taking her for a CT scan just now'. I didn't finish the coffee and arrived at the hospital just as the CT pictures were coming up. You've guessed. She has huge bilateral haemorrhages, complete obliteration of the cerebral ventricles and herniation. Stephanie's parents had constantly been at her side, but as I walked into the room at the entrance to CICU to speak to them…they knew. They knew. The worst, cruellest most unfair Pyrrhic outcome. Those were perhaps the hardest and perhaps most silent minutes I've ever endured with parents. What would you have said?...

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InfoBionic Receives FDA 510(k) Clearance for Its Next Generation MoMe® ARC Solution

InfoBionic, the virtual telemetry company focused on the efficiency and economics of cardiac remote patient monitoring, announces FDA 510(k) clearance for its MoMe® ARC solution that encompasses our next generation remote ECG monitoring device and initial Bluetooth diagnostic 6-lead sensor designed to aid physicians in their diagnosis of cardiac arrhythmias.

InfoBionic, Inc. announced that it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for MoMe® ARC, their 3rd Generation remote ECG monitoring device paired with their inaugural Bluetooth diagnostic 6-lead sensor designed to aid physicians in their diagnosis of cardiac arrhythmias in patients with a demonstrated need for cardiac monitoring. "We're thrilled to announce FDA 510(k) clearance to market the MoMe® ARC solution, which supports our mission to create superior patient monitoring solutions for arrhythmia detection and virtual care and chronic disease management," said Dave MacCutcheon, Regulatory and Chief Operating Officer at InfoBionic.

MacCutcheon further points out that: "MoMe® ARC is a solution that includes a 4-in-1 Gateway device that seamlessly transitions between 2-day in addition to Extended Holter tests, Event and MCT modes remotely, streamlining patient monitoring time and minimizing delays. In addition, MoMe® ARC leverages a comprehensive cloud-based proprietary platform to deliver on-demand, actionable data and analytics directly to the clinicians. Further, it incorporates our initial sleek body worn Sensor in a new lightweight form factor which is decoupled from the device Gateway communicating through the latest implementations of Bluetooth connectivity and ushers in a new era of wearability convenience yet maintains the ECG quality of a multi-lead tracing, thus bringing convenience and quality together for the first time. The MoMe® ARC is designed so patients can wear it discretely and comfortably during monitoring using standard electrodes. The Sensor is paired to the ARC Gateway which leverages a cellular connection to the MoMe® Software Platform empowering physicians to transform the efficiency with which they manage cardiac arrhythmia detection and monitoring processes for their patients."

This next generation device builds on the market success of innovative MoMe® Kardia II by providing a decoupled 2-channel – 6-Lead Sensor. Added foundational technologies make the device capable of connecting to other Bluetooth-enabled health monitoring devices. K230265 is cleared for use under Product Code DSI - Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm). The ECG data is transmitted in near-real time and analyzed by the MoMe® software platform via a suite of robust server-based algorithms; and when indicated, data identified by these algorithms is flagged for clinician review. MoMe® ARC requires no patient intervention to capture or analyze data, however it does provide a patient event trigger and symptom description selection through a new screen similar to that of a smart watch.

InfoBionic expects to begin shipping the new generation MoMe® ARC Device in Q4 2023.

About InfoBionic

InfoBionic's digital technology has transformed the efficiency and economics of cardiac remote patient monitoring. The company's MoMe ARC platform vision is to remove the roadblocks hindering remote diagnosis and decision-making. The Massachusetts-based team of seasoned entrepreneurs have had successful careers in healthcare, IT, medical devices, and mobile technology and bring specific expertise in remote monitoring and cardiology.

Visit https://InfoBionic.com/.

Laguna Tech USA Announces Newly Designed Heart Valves with Advanced Engineering Successfully Implanted in First-in-Human Clinical Trial

- *New heart valves, ALPHA and ZETA, designed to provide flexibility and optionality regardless of high, low or zero calcification status*
- *Patients with aortic regurgitation achieve complete resolution of regurgitation immediately following procedure*
- *First-in-class, Aortic Valve Systems offer self-expanding or balloon-expanding versatility based on physician preference and patient case dynamics*
- *Versatile designs expected to significantly broaden patient eligibility for implant*

Laguna Tech USA, a privately-held medical technology company dedicated to innovations in structural heart solutions to broaden useability and applicability for patients, announced that the first-in-human clinical case was completed with the Zeta Balloon Expandable Aortic Valve System and additional patients have been successfully treated in the feasibility clinical study of its investigational ALPHA Self-Expanding Aortic Valve system to treat aortic regurgitation. To date, two patients have been successfully treated in the Alpha Aortic Valve study, with both achieving complete resolution of aortic regurgitation immediately following the procedure, which has been maintained at the 30-day follow-up examination.

The ALPHA system is a uniquely designed one-piece self-expanding transcatheter valve engineered with a low profile valve and delivery system, with six support arms for simpler, better positioning within the aortic annulus and cusps. The ZETA system is a novel balloon-expandable transcatheter valve with six expanding arms and a low profile covered delivery system. The six expanding arms allow for simple positioning of the valve into the aortic annulus and cusps.

The feasibility study is being conducted at the Instituto Nacional de Torax in Santiago, Chile, and Tbilisi Heart and Vascular Clinic in Georgia.

The lead primary investigator, Dr. Scott Lim, a cardiologist from the University of Virginia noted, "The Laguna Tech USA Alpha Self Expanding Aortic Valve and Zeta balloon Expandable Aortic Valves performed as designed, allowing us to successfully and percutaneously treat these first patients at high surgical risk with severe aortic regurgitation, and in one case, with concomitant significant calcific aortic stenosis. I look forward to these novel transcatheter aortic valves being further investigated in larger studies, as this initial experience is quite encouraging toward helping us address a significant unmet patient need in those with complex aortic valve disease."

Dr. Cristian Dauvergene, Chief of Interventional Cardiology, Instituto Nacional de Torax, added, "We were able to successfully implant the Zeta Aortic Valve very simply and efficiently aided by the low profile and straightforward transcatheter implantation allowing for advantageous placement in the heart. We are excited to be a part of the success of the first procedure of this important next-gen TAVI system, and we look forward to participating in Laguna Tech USA's clinical study."

"With this successful groundbreaking first in human clinical experience with the ZETA valve and the additional successful ALPHA valve implants, we have a growing body of evidence supporting the promise of our next-gen, differentiated aortic valves, which represent much-needed advancement in the field," said Gilbert Madrid, chief executive officer of Laguna Tech USA. "Specifically, our valve designs are intended to address an unfortunate, longstanding gap in the applicability of heart solutions because of rigid and unyielding technology designs that eliminate many patients as prospective candidates. With two varying valve designs, each leveraging advanced technology and engineering of existing products on the market, we look forward to the potential of our technology to significantly expand the number of patients with aortic valve regurgitation who may be treated with our minimally invasive treatment options."

Abbott and Stereotaxis Technologies Used in First Integrated Procedures in the United States

GLOBE NEWSWIRE -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced the first patients in the United States have been treated successfully utilizing Abbott's EnSite™ X EP System integrated with Stereotaxis' Robotic Magnetic Navigation System.

The integration of Abbott's leading cardiac mapping system and Stereotaxis' advanced robotic technology, first announced at Heart Rhythm 2023, combines highly detailed real-time diagnostic information with the unprecedented precision and stability of robotics during therapy delivery. The first integrated procedures in the US were completed by physicians at Weill Cornell Medical Center, Mount Sinai Morningside, Banner University Medical Center Phoenix, and Overland Park Regional Medical Center.

"We are very pleased with how well these initial procedures went and the progress toward open interoperability with robotics in electrophysiology," said Dr. Dhanunjaya Lakkireddy, Electrophysiologist and Executive Medical Director of Kansas City Heart Rhythm Institute at Overland Park Regional Medical Center. "Combining Abbott's leading cardiac mapping system with Stereotaxis' advanced robotic technology enhances precision and streamlines procedure workflow, ultimately benefiting the patients we are dedicated to treating."

"Abbott and Stereotaxis have each played leading roles in advancing care for the most complex and difficult to treat arrhythmia patients," added Dr. Jim Cheung, Associate Director of Cardiac Electrophysiology at Weill Cornell Medical Center. "We are delighted to be able to use both technologies in an integrated fashion, leveraging the combined benefits in diagnosis and therapy for our patients."

"As long-term users of both Abbott and Stereotaxis technology, we appreciate the ability to use these technologies together with a smooth integrated workflow," said Dr. Ranjit Suri, Professor of Medicine at the Icahn School of Medicine at Mount Sinai. "Increased physician choice and technology interoperability benefits patients, physicians and providers."

"The success of these procedures demonstrates the unmatched potential and importance of increased collaboration in the field of electrophysiology," added Dr. J. Peter Weiss, Director of Ventricular Arrhythmia Management and Robotics at Banner University Medicine Heart Institute. "The combined benefits of advanced mapping and robotic technologies allows us to envision a new era of cardiac care where personalized therapy is designed and delivered to each individual patient. It's a game-changer for the field."

About Stereotaxis

Stereotaxis (NYSE: STXS) is a pioneer and global leader in innovative surgical robotics for minimally invasive endovascular intervention. Its mission is the discovery, development and delivery of robotic systems, instruments, and information solutions for the interventional laboratory. These innovations help physicians provide unsurpassed patient care with robotic precision and safety, expand access to minimally invasive therapy, and enhance the productivity, connectivity, and intelligence in the operating room. Stereotaxis technology has been used to treat over 100,000 patients across the United States, Europe, Asia, and elsewhere. For more information, please visit: www.stereotaxis.com.

This press release includes statements that may constitute "forward-looking" statements, usually containing the words "believe," "estimate," "project," "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to manage expenses at sustainable levels, acceptance of the Company's products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase its technology, competitive factors, changes resulting from healthcare policy, dependence upon third-party vendors, timing of regulatory approvals, the impact of pandemics or other disasters, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release. There can be no assurance that the Company will recognize revenue related to its purchase orders and other commitments because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control and may be revised, modified, delayed, or canceled.

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