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# Upper Extremity Vascular Access for Invasive Pulmonary Hypertension Assessment in the Pediatric Population

Jess Randall, MD; Jenny Zablah, MD; Ryan Leahy, MD; Megan Albertz, MD; Ben Frank, MD; Dunbar Ivy, MD; Gareth J. Morgan, MD, BaO, BCh

Index words: Vascular access, pulmonary hypertension, pediatric, adolescent, basilic vein

#### Abstract

#### Introduction

The aim of this study was to compare access in either the basilic or brachial vein (BVA) to other access sites for invasive assessment of pulmonary hypertension in the cardiac catheterization laboratory in patients under 18 years of age.

#### Methods

A retrospective review was performed on five patients between 12 and 18 years of age who had undergone cardiac catheterization via upper extremity venous access with a previous cardiac catheterization recorded via traditional femoral access at a single institution between July 2019 and April 2020. Medical records were reviewed for data related to pulmonary hypertensive therapy, catheterization, anesthesia care, recovery and hospital duration.

#### Results

Five patients underwent six catheterizations via BVA. Access was successful in all cases via either the right basilic or brachial vein and the right radial artery for blood pressure monitoring. All catheterizations with BVA were performed without intubation or airway adjuncts and with spontaneous respiration. Mean doses of fentanyl (4.2 vs 85mcg) were lower with BVA, with patients in 3/6 BVA procedures receiving only local anesthesia, though midazolam administration was slightly higher in the BVA group (1.3 vs 1.2mg). Diagnostic catheter time (37 vs 57 min), time to hemostasis (7 vs 10 min), and time from sheath removal to the recovery room (14 vs 20 min) was lower in the BVA group. In patients with same-day discharge, time from procedure conclusion to hospital discharge was lower in the BVA group (89 vs 187 min). There were no complications in either group.

#### Conclusions

Brachial or basilic venous access for catheter-based hemodynamic assessment in patients over 12 years of age allows accurate diagnostic assessment under physiologic conditions with decreased need for vasoactive medications and decreased time to ambulation and discharge following catheterization.

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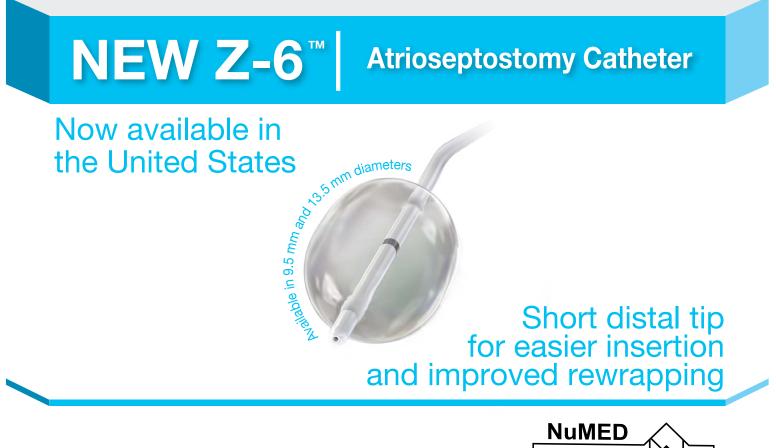
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- Clinical or biological signs of infection
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#### Introduction

Pulmonary arterial hypertension is a relatively common indication for invasive assessment in the pediatric cardiac catheterization laboratory, with more than five percent of catheterizations at our institution performed purely to evaluate or diagnose pulmonary hypertension. Venous access for catheterization in children is often performed either via a femoral or internal jugular approach, with arterial access obtained at the discretion of the operator. Upper extremity venous access for adult right heart catheterization is well-described, though reports in patients under the age of 18 are rare.<sup>1,2</sup> The aim of this study was to compare brachial or basilic venous access (BVA) with minimal sedation to the more traditional femoral or jugular access sites for invasive assessment of pulmonary hypertension in the cardiac catheterization laboratory in patients under 18 years of age.

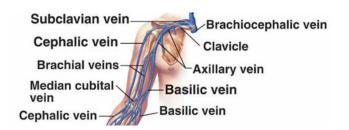
#### Methods

This was a retrospective case control study analyzing medical records of patients who underwent cardiac catheterization from July 2019 through April 2020 at the Children's Hospital of Colorado. Approval was provided by the University of Colorado Institutional Review Board. The medical records of all patients who underwent catheterization for assessment of pulmonary hypertension via basilic or brachial venous access were then reviewed for any previous catheterization at an age greater than 12 years. All previous catheterizations were performed via non-upper extremity sites and used as a control group for analysis. Medical records for all catheterizations were retrospectively reviewed for: demographic information, baseline pulmonary hypertension therapy, information related to cardiac catheterization (vascular access, hemodynamic, and radiographic information), anesthetic and vasoactive medication administration during catheterization, and information related to hospital and procedure duration.

#### Patient Preparation and Vascular Access Technique

Vascular access was obtained in all patients via the right arm in either the basilic or brachial vein (Figure 1). The basilic vein was the primary site for access, with use of the brachial vein as an alternative access point if the basilic vein was not easily cannulated or felt to be inadequate on ultrasound assessment. The right arm was abducted and supported at 60-90° from the patient's flank with the wrist extended and supported to facilitate radial arterial access. All procedures were performed with a cardiac anesthesiologist in attendance in case of patient emergency and/ or need for advanced airway management or conversion to higher level of anesthesia care. Prior to draping and skin cleansing for the procedure, ultrasound was used to identify the right brachial artery, brachial vein, and basilic vein (Figure 2). The venous access site was then marked with a non-sterile marking pen that resists fading with skin cleansing and a tourniquet loosely positioned near the axilla. Similarly, the right radial and ulnar arteries were assessed by ultrasound prior to patient draping. The skin and subcutaneous tissues were infiltrated with 1% buffered lidocaine and the tourniquet tightened on the upper arm. Ultrasoundguided modified Seldinger technique was then used to access the target vein using a Cook Medical Micropuncture needle and 0.018" wire (Cook Incorporated, Bloomington, IN). Once the wire was placed, the tourniquet was removed and wire position verified by fluoroscopy. A 6Fr,

10cm Terumo Pinnacle Precision sheath (Terumo Medical Corporation, Somerset, NJ) was then introduced over the wire in standard fashion (Figure 3). Radial access was then obtained via ultrasound guidance utilizing a modified 21 Gauge winged butterfly needle and the micropuncture wire. Once radial arterial access was obtained, a 20 Gauge leader catheter was inserted for continuous hemodynamic monitoring and sampling. The arterial catheter was secured with transparent dressings and the pressure tubing and flush were clipped and supported along the length of the patient's arm to minimize tension and risk of accidental removal. The right heart catheterization was then performed with a 6Fr Swan-Ganz thermodilution catheter.



**FIGURE 1** Typical upper extremity venous anatomy (image adapted from public domain)



**FIGURE 2** Ultrasound identification of brachial artery (Br Art), brachial vein (Br Vein), and basilic vein (Ba Vein) in short axis at the approximate mid-point of the humerus. Note the paired brachial veins located on either side of the brachial artery.



#### **FIGURE 3**

Patient preparation, draping, and access of the basilic vein. The use of a tourniquet and non-sterile marker prior to cleaning and draping can aid with vascular access once the landmarks are obscured.

#### Results

Baseline patient demographics are detailed in Table 1, with five patients undergoing six catheterizations in the BVA cohort. Baseline hemodynamic measures are summarized in Table 2. Vascular access in the BVA group was successful in all cases in either the right brachial (4/6) or basilic (2/6) vein and right radial artery (6/6). Access in the control studies was obtained in the femoral vein in four patients and right internal jugular vein in one, with four of these patients receiving femoral arterial access. In one control group patient, femoral arterial access was obtained and displayed an accurate waveform, but blood could not be withdrawn. Baseline traditional access catheterizations were performed at a mean age of 13 years and 8 months of age (11yrs 6mo - 16yrs 11mo), with BVA catheterizations performed at 15yrs 11mo (14yrs-18yrs 11mo). There was a mean difference of 23 months between traditional and BVA catheterizations (3-40). All patients in both groups received monitored care by a cardiac anesthesiologist even if spontaneously ventilating without airway adjuncts. Four of five patients in the traditional access group underwent general anesthesia, with two of five patients undergoing endotracheal intubation and three of five receiving a laryngeal-mask airway (LMA). All patients with an LMA were spontaneously breathing during their catheterization (Table 3).

Midazolam was prescribed in 2mg doses along with fentanyl in multiples of 25mcg. These were administered as needed until the desired effects

 TABLE 1
 Demographics – mean (min, max)

Patients (n)	5	5
Catheterizations (n)	5	6
	164	191
Age (mo)	(138,203)	(168,227)
Time from traditional to BVA cath (mo)	23 (3,40)	
Female (n)	4	4
Weight (kg)	52 (34, 73)	62 (55, 78)
Venous Access Site	JZ (J4, 73)	02 (00, 70)
Arm	0	6
Femoral	4	0
	<del>1</del>	0
Internal Jugular Arterial Access Site	1	0
Radial	0	6
	4	
Femoral	4	0
PH Therapy		
None	3	0
Oxygen	0	1
Ca Channel Blocker	0	2
PDE5 Inhibitor	2	6
ERA	1	3
Prostanoid Therapy	2	5
	114	
Total Sheath Time (min)	(84,131)	47 (34,58)
Diagnostic Catheter Time (min)	78 (41,109)	37 (29,46)
	161	
Total Time in Cath Lab (min)	(136,193)	97 (86,109)
Sheath Out to Lab Out Time		
(min)	20 (18,21)	14 (14,15)
Sheath Out to Discharge Time	206	103
(min)	(190,242)	(75,135)

 TABLE 2
 Baseline Hemodynamics – mean (min, max)

RV Systolic Pressure (mmHg)	55 (27, 105)	50.5 (34, 93)
RV End Diastolic Pressure (mmHg)	6 (5, 8)	10 (7, 23)
Systemic Systolic Pressure (mmHg)	86 (65, 102)	108 (97, 118)
Systemic Mean Pressure (mmHg)	64 (52, 74)	75 (66, 87)
%RV Pressure vs Systemic	60% (40, 100)	50% (30, 100)
PA Systolic Pressure (mmHg)	55 (26, 105)	52 (33, 107)
PA Mean Pressure (mmHg)	39 (18, 81)	37 (22, 82)
Pulmonary Artery Wedge Pressure (mmHg)	8 (7, 10)	10 (7, 17)
Transpulmonary Gradient	31 (9, 74)	27 (13, 65)
PVRi	12.4 (2.1, 30.3)	8.8 (3.2, 22.6)
Rp/Rs	0.5 (0.2, 1.1)	0.4 (0.2, 1.2)

were achieved. Half of the catheterizations in the BVA group did not require any anxiolytic or pain medication for sedation. In one case, 4mg of midazolam was administered, with 2mg of midazolam in two procedures. One patient in the BVA group received 25mcg of fentanyl. Half of the patients in the BVA group received isotonic fluids at an average volume of 217mL (150-300mL). Doses of sedative and analgesic medications were significantly higher in the traditional access group, with three of five patients receiving 2mg midazolam and all patients receiving fentanyl at a mean dose of 65mcg; four of five patients receiving propofol, two of five receiving ketamine, four of five receiving an inhalational anesthetic, and two of five receiving rocuronium as a paralytic agent. Crystalloid administration was generally higher in the traditional access group, with an average of 410mL of fluid administered (0-1000mL).

All patients in the BVA group underwent diagnostic catheterization without angiography or intervention. Four of five patients in the traditional access group underwent catheterization as their primary diagnostic study, with all four patients undergoing pulmonary

 TABLE 3
 Anesthetic Care – mean (min, max)

ASA Status		3.3 (3,4)	2.8 (2,3)
Anesthe	etic		
	General	0	4
	Monitored Anesthesia Care	6	1
Airway			
	Own Airway	6	1
	LMA	0	2
	Endotracheal Intubation	0	2
	Spontaneous Respiration	6	3
Propofo	I Administered		
	Yes	0	4
	No	6	1
Paralyti	c Administered		
	Yes	0	2
	No	6	3
Crystall (mL)	oid Volume Administered	108 (0,300)	410 (0, 1000)
Midazolam Dose (mg)		1.33 (0,4)	1.2 (0,2)
Fentanyl Dose (mcg)		4.17 (0,25)	65 (0,125)
Ephedrine Administered		0	1
Phenylephrine Administered		0	1

angiography, and one patient additionally undergoing transjugular hepatic biopsy as part of their catheterization procedure. There were no complications in either the BVA or traditional access groups. The diagnostic portion of all procedures was performed with a Swan-Ganz catheter, with thermodilution performed in all catheterizations. No patient in either group required additional guide wire or catheter exchanges in order to navigate intracardiac anatomy. All patients in the BVA group were assessed under two hemodynamic conditions, with two of five patients in the traditional access group undergoing two conditions. The other three patients in the traditional access group underwent three hemodynamic conditions. The BVA group demonstrated shorter average diagnostic catheter time (37 vs 75 min), shorter time to hemostasis (7 vs 10 min), and shorter duration from sheath removal to arrival in PACU (14 vs 20 min). All BVA catheterizations were performed on an outpatient basis, with a mean time from sheath removal to hospital discharge of one hour and 43 minutes (1:15-2:15). Three of five patients in the traditional access group were either performed on an inpatient basis or were admitted overnight for escalation of PH therapy, with the two remaining patients discharged between three and four hours following sheath removal.

#### Discussion

Invasive right heart cardiac catheterization remains the gold standard in diagnosis and management of pulmonary arterial hypertension. Reliable assessment of the pulmonary vascular bed and intracardiac pressures in a truly physiologic state are important considerations for the pediatric cardiologist.<sup>3</sup> The right ventricle undergoes multiple compensatory changes in the setting of chronically elevated pulmonary vascular resistance that leave it sensitive to changes in preload and afterload.<sup>4</sup> As such, avoidance of inadvertent changes in systemic and pulmonary vascular resistance, altering the effect on hemodynamics produced by mechanical ventilation are all important perioperative considerations for both patient safety and reliability of catheter-obtained hemodynamic assessments. Given the procedural risks, an attending anesthesiologist was present for all pulmonary hypertension studies, to allow timely intervention in the event of hemodynamic instability or patient intolerance of the procedure. Additionally, patients were instructed to observe routine fasting precautions in case of emergency. All BVA patients were able to avoid both endotracheal intubation and administration of anesthetic agents at doses that contribute to adverse cardiopulmonary effects.<sup>5,6</sup> In our sample, when patients underwent BVA catheterization, they had higher systemic systolic pressures compared with when they were catheterized by traditional access methods. While there was no difference in the pulmonary arterial pressures, the Rp:Rs ratio was higher during BVA catheterization. This may be due to measurement of peripheral arterial pressure vs a true central arterial pressure, as well as hemodynamic alterations induced by anesthesia. BVA patients received lower doses of sedative and pain medications when compared to controls, with many BVA patients not receiving any sedative or pain medications beyond local Lidocaine administration. There was also a difference in the volume of fluid administration in the BVA group when compared to the control cohort.

The technique of brachial/basilic venous and radial arterial access requires minor alteration to the traditional Seldinger technique. Identification of the target vessel prior to cleaning by marking the intended spot with a water-resistant marking pen facilitates ease of access following patient draping. We have preferred to assess the vein by ultrasound in short-axis along the length of the arm, though assessment and access to the basilic vein has also been described with long-axis visualization.<sup>7</sup> The presence of two distinct fascial compartments of the upper extremity without a ligamentous or tendinous sheath crossing the plane of the vessel permits significant movement of the vein during access. To overcome this, we prefer using the Cook Micropuncture needle and wire due to its easy visualization by ultrasound, sharp needle point, and ease of wire introduction. Use of the ultrasound probe to apply compressing pressure at the time of access can help stabilize the vein and ease access. An ipsilateral radial arterial line was placed in all patients to ensure adequate systemic pressure assessment and appropriate blood gas measurements, including: measured oxygen saturation, pO2, pH, and CO2 levels. Given their importance in pulmonary vascular resistance calculations, assumed values from a pulse oximeter and other non-invasive means can lead to errors in measurement, particularly if the patient is hypoxemic.8

Once access is obtained, the right heart catheterization is performed in a standard fashion, with patients in the BVA group demonstrating a reduction in diagnostic catheter duration by nearly 50% when compared to the traditional access group. An important intraprocedural consideration was the method of supplemental oxygen and nitric oxide (NO) delivery. Pulmonary vasoreactivity testing using NO delivered via a tight-fitting face mask has previously been described.<sup>9,10</sup> Our standard practice for oxygen delivery has been via face mask, with the delivery of NO achieved by the addition of nasal cannula within the face mask connected to the nitric oxide circuit. With administration of 100% oxygen at 5LPM and administration of 40ppm inhaled nitric oxide via nasal cannula, we have measured an effective fractional inspired oxygen concentration of 0.6. Standards for assessment of oxygen consumption in spontaneously breathing patients in the cardiac catheterization laboratory remains controversial, so our approach for hemodynamic calculations has been to utilize assumed oxygen consumption via LaFarge tables to permit Fick calculation and also to assess the resistance and flow using thermodilution cardiac outputs.11,12

By providing an encounter where the patient is alert with minimal painful stimulus and with pre-procedural and intra-procedural support from behavioral therapists and catheterization staff, we believe that BVA offers improved patient safety and patient experience. Patients can be provided with distracting technologies through the duration of the procedure, including music via headphones, movies via mounted tablets, and virtual reality headsets. After sheath placement, there is minimal/no painful stimuli, and the patient can determine their level of engagement with the procedure. Once the procedure is completed, application of manual pressure is applied with short time to hemostasis and ambulation. Patients in our study demonstrated shorter time to hemostasis and post-procedural time to hospital discharge when compared to femoral venous access. Without need for a "lay-flat" time and quick hemostasis, the only limits to ambulation and discharge relate to completion of necessary discharge paperwork and post-procedural consultation with the catheterization and pulmonary hypertension teams. Selection of candidates for basilic access is currently limited to those who are likely to cooperate with the procedure, and we estimate that a developmentally typical child could tolerate the procedure at a minimum age of 12 years. We have continued to expand this approach and have now performed more than 50 BVA diagnostic catheterizations in children;

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other key patient populations in whom the risk benefit profile of this strategy is favorable are patients following cardiac transplant presenting with acute rejection and patients with poorly compensated heart failure. To date, our youngest basilic access patient was 12 years of age at the time of catheterization. Though we did not perform a cost analysis on our cohort, it is anticipated that the decreased anesthetic care and hospital resource utilization translates to a net cost savings for both the patient and hospital system.

This study has multiple limitations, including its retrospective design and small patient population, which limit true statistical assessment of the impact of basilic venous access when compared to traditional forms of access.

#### Conclusion

Access via the basilic or brachial vein is an easy and reliable method for diagnostic cardiac catheterization in older children with pulmonary hypertension. Rapid turnover, and time to ambulation and discharge have widespread beneficial effects. It also facilitates assessment of the pulmonary vascular bed under awake physiological conditions compared with catheterization techniques which require general anesthesia or deep sedation. This in turn allows avoidance of the pitfalls of induction of anesthesia which can be fraught in populations with tenuous hemodynamics.

#### Declarations

#### Funding

No external funding was provided for this study.

#### Conflict of Interest

No authors have any conflicts of interest to declare related to this study.

#### **Ethics Approval**

This study was reviewed by the University of Colorado IRB and found to be exempt from review.

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# Hospital Directory 2021-2022

#### **Published Mid-August**

- Hospitals that Offer Open Heart Surgery for Children in North America
- Contact information at each hospital for Chief of Pediatric Cardiology & Fellowship Director
- Lists each hospital's Pediatric Cardiologists & Cardiothoracic Surgeons
- Lists Pediatric Cardiology
   Fellowships
- Distributed to Division Chiefs by mail
- Hard copies are available at CCT's booth at PICS 2021
- Electronic version available on CCT's website: <u>www.congenitalcardiologytoday.com</u>



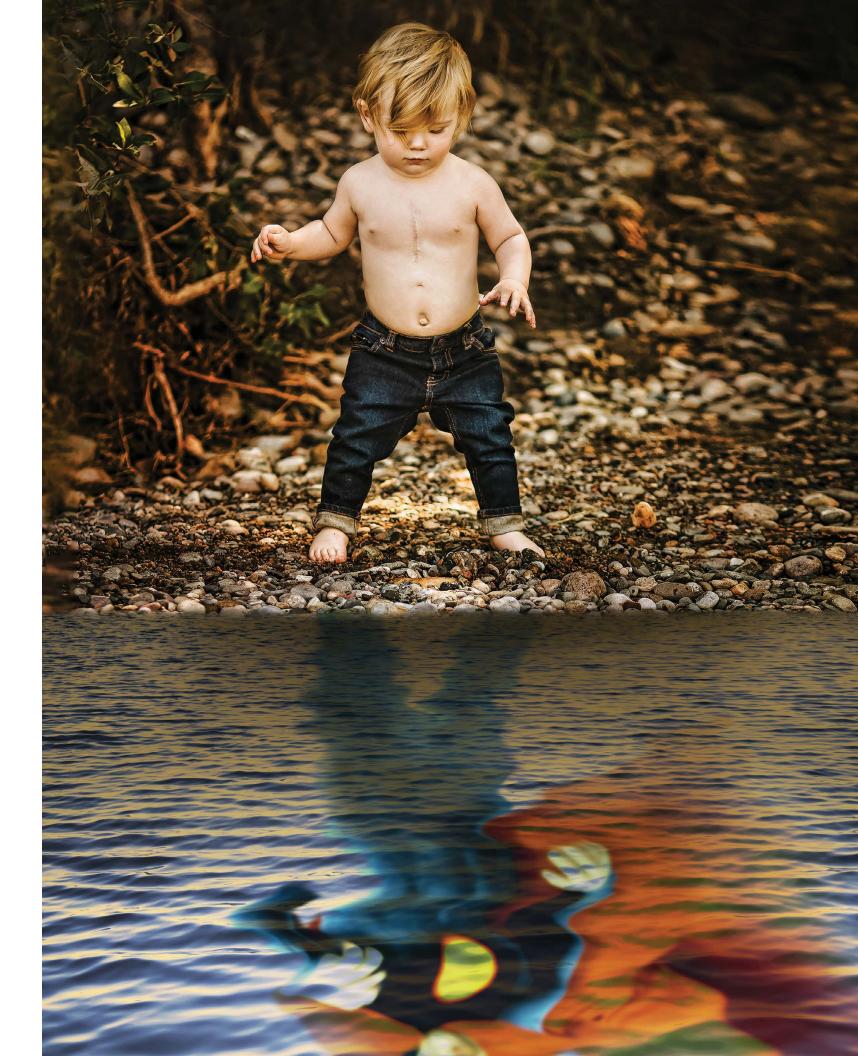




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### The PICS Society Advocacy Program: Power in Numbers! Part 2

Ziyad M. Hijazi, MD, MPH, FPICS; John P. Cheatham, MD, FPICS; Natalie Poli, Ed. S.; Kamel Shibbani, MD; Norm Linsky, MPA, MA

In last month's CCT column we started a dialogue with you about ADVOCACY—how our community can advocate for policies to improve our ability to care for patients with Congenital Heart Disease. As a global organization, are there fundamental policy goals we all share? How can we learn from—and help—one another? Do we have **Power in Numbers** through our unified global voice?

This month let's bring the patient perspective into our dialogue. Is our advocacy voice stronger when we partner with likeminded, highly motivated patients and parents?

To answer that question, we held a roundtable including one patient advocate, Natalie Poli, Ed.S (Itasca Illinois, USA) along with PICS Society President Ziyad M. Hijazi, MD, MPH, FPICS; PICS Advocacy Chair John P. Cheatham, MD, FPICS; and PICS Executive Director Norm Linsky.

#### Highlights

Tell us about life before your CHD diagnosis, Natalie: Since childhood I have always been very active. I exercised often, played sports and was pretty much symptom-free. I was even a dancer for the elite Chicago Bulls 'Luvabulls' squad, performing at professional sports events. At age 29 I had a stroke! Occasionally my chest felt heavy when I was performing, but my CHD remained undiagnosed. I was nine weeks postpartum when one minute I was fine and the next minute I hit the floor. I lost my speech and feeling in the right side of my body. After stabilization at the hospital, they identified two PFO's and an atrial septum aneurysm. I went to multiple hospitals for second opinions. One friend knew someone who previously had a similar condition treated by Dr. Hijazi, so I made the call. Dr. Hijazi carefully evaluated me, then closed my defects with two ASD devices. Thankfully, I made a full recovery. Without knowing it then, I had started my journey as a patient advocate, in this instance advocating for me!

- Career: dedication to public education and pursuit of a doctoral degree.
- Personal potential: proof you can have a great life after treatment. I subsequently won the Mrs. Itasca 2021 competition, then Mrs. Illinois International 1st runnerup. I will compete at Mrs. Illinois International this November. I also have a website: https://nataliepoli.com/
- Advocacy: as Senior Patient Advocate for The PICS Society, I work with incredible physicians to advocate on behalf of those like me born with CHD. Together we will save lives!

What did you learn from that experience, Natalie? I was lucky. Many aren't. We can change that! I learned never to take "no" for an answer, but rather to ask questions. I wasn't knowledgeable about my CHD, but I learned fast. I became my own advocate—that's so important! Working together we can advocate for better public education, funding, screening and device development.

Do you agree with that, Dr. Hijazi? Absolutely. I would advocate that everyone should undergo an echocardiogram, ideally during childhood where CHD can be effectively diagnosed and treated before symptoms such as Natalie's stroke happen. That is the gold standard test to say 'yes' or 'no' as to whether you have a congenital heart condition. As Natalie said, she went to many doctors, at times symptomatic, but her condition remained undetected. Unfortunately, holes between the upper chambers of the heart often remain undetected unless the physician is specifically looking for this defect. That's why 50% of my patients are adults with previously undetected Atrial Septal Defects. This type of CHD is very difficult to diagnose without highly specialized training and technology. Many areas of the world have mandatory pulse ox screening at birth, which detects some-but not all-types of CHD. An early screening echocardiogram must become essential for everyone. We must advocate for this!

#### "I became my own advocate—that's so important. I was lucky. Many aren't. We can change that!" – Natalie Poli, Ed.S.

*Did your life change*? Oh yes. I like to say my stroke chose ME, but after being treated I chose how to move forward and what my missions in life would be. I'm aiming high!

• Family: an amazing husband and children who support me 100%.

*Dr. Cheatham:* Dr. Hijazi brings up a vital point. An Atrial Septal Defect is one of the most common forms of CHD, yet often is undetected. Echo is the one definitive diagnostic test. Our Advocacy Committee must stress this to governments and insurers, showing with solid data that echo screening for CHD should be a covered exam available for all children.

*Dr. Hijazi:* You're so right, John. Failure to do this can be tragic; I have seen this myself. I am hopeful that hospitals, governments and insurers can agree that echo can be priced affordably. The small investment would be worth ten times as much, so we could tell a parent "your baby has a normal heart" or "we found something called an ASD but we can correct it." The joy, the ease you give to the family, you can't put a price tag on that. Natalie is living proof, so we must advocate together!

*Natalie:* We have already started. As I was preparing for my recent pageant, I connected with my own elected Congressperson—I prepared my "ask" succinctly, which was basically "we need legislation to improve access to CHD screening and make it affordable to all." I explained my survival and success story. He was very supportive, so stay tuned!

## How Has the FDA's Review Process For Interventional Devices Evolved?

Dr. Hijazi: For many years, FDA approval of CHD devices lagged behind the rest of the world, but recently that changed very positively in the US. While much remains to be done, we worked closely with the FDA. They listened and responded in a constructive dialogue. For many years, the FDA had required large clinical trials for CHD interventional devices, with trial population requirements impossible to meet-our patient populations are relatively small compared to larger medical specialties. One example among many: For the Amplatzer device for ASD closure in 1997, the FDA insisted the clinical trial had to be randomized against open heart surgery. Of course, trial enrollment was impossible. We went back to the FDA and after much effort on our part, FDA accepted alternative rigorously collected metrics to properly review these devices. The result? Thousands of lives have been dramatically improved through persistent advocacy!

AND we brought patients to the table with us. The FDA listened to us and changed! In crucial areas, FDA now understands there are several ways to demonstrate safety, quality and effectiveness.

Dr. Cheatham: Correct! Years ago, devices were developed in the United States but were first approved outside the US since the review process here was so slow. That severely limited our treatment options. Where previously "first in human" was rarely if ever performed in the US, the FDA changed that completely. Now the situation has been reversed, presenting challenges to our colleagues outside the US: the device approval process in many other countries has become more challenging. Our Advocacy Committee and the PICS Society overall has much to do in this area. There are encouraging signs on the horizon. For example, the Japanese equivalent of the FDA, has begun a project called "Harmonization," in which my colleague and Advocacy Committee Co- Chair Dr. Hideshi Tomita is playing a major role. (Editor's Note: Interviews with Dr. Tomita and Dr. Bharat Dalvi of India will be in the next issue of CCT). Similar efforts are underway by other colleagues to streamline device approval while maintaining safety and effectiveness.

#### **Final Thoughts**

*Dr. Hijazi:* The PICS Society is THE dedicated society for interventional treatment of CHD and is the voice of our community. We will continue to support our members' efforts globally as they work with legislators, policymakers, payers and others towards the best possible patient care. We collaborate with other professional societies that share our values and look forward to partnering with excellent patient advocates such as Natalie.

"Years ago, it was very, very, VERY difficult to get the FDA to consider interventional devices & techniques to treat CHD. Back then FDA said, 'We are here to protect the people.' We said, 'So are we!' And we proved it with real data." – Dr. John P. Cheatham

*Dr. Cheatham:* You're so right Z. The FDA is totally different from the FDA of years ago. Back then it was very, very, VERY difficult to get FDA to consider interventional devices and techniques to treat CHD. In that era, the FDA said "We are here to protect the people." We replied, "So are we!" and we proved it with real data. It took tremendous effort to educate them and open their minds to alternatives to surgery. The good news: We are now on the same path! FDA now has a special pathway, called "Early Feasibility Studies" for conditions such as CHD.

*Dr. Hijazi:* For years we persisted—we showed them rigorously collected trial data from outside the U.S., the number of patients impacted by CHD, the tragic consequences of untreated CHD, our profession's commitment to rigorous training and quality,

*Dr. Cheatham:* This will not be easy, but it is so important. We encourage our colleagues—wherever they live and work—to join our committee and move forward together. The Advocacy Committee (Co-Chaired by Dr. Tomita and by Dr. Cliff Kavinsky) welcomes new members—email us at info@CHDinterventions.org.

*Natalie:* Doctors, thank you for all you do. It's going to take real life stories such as mine and so many others, working with amazing physicians and nurses, to move the policy needle. We're not numbers, we are real-life individuals of all ages, able to accomplish so much IF we have access to the right diagnosis and treatment. Ready to roll up our sleeves!





#### THE PICS SOCIETY ADVOCACY PROGRAM: POWER IN NUMBERS



#### ZIYAD M. HIJAZI, MD, MPH, FPICS

PICS Society President Professor of Pediatrics & Medicine Weill Cornell Medicine Chief Medical Officer Executive Chair, Medicine Director, Sidra Heart Center Medical Director, International Affairs Office Honorary Professor, University of Jordan





Pediatric and Congenital Interventional Cardiovascular Society

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#### JOHN P. CHEATHAM, MD, FPICS

Interventional Cardiology The Heart Center, Nationwide Children's Hospital Professor Emeritus Dept of Pediatrics, Cardiology The Ohio State University Columbus, OH, USA



#### NATALIE POLI, Ed. S.

PICS Society Senior Patient Advocate Public Education Professional Successfully treated interventionally for CHD, 2006 Mrs. Illinois International 2021 1st Runner Up Former Capitain of the NRA Chicago Bulls Dan

Former Captain of the NBA Chicago Bulls Dance Team



#### KAMEL SHIBBANI, MD

Advanced Pediatric Cardiology Fellow University of Iowa Iowa City, IA, USA



#### NORM LINSKY, MPA, MA

PICS Society Executive Director nlinsky@CHDinterventions.org



# Book Review: A Multidisciplinary Approach to Perinatal Cardiology (Volumes 1 & 2)

John Moore, MD, MPH

Edited by P. Syamasundar Rao, MD & Dharmapuri Vidyasagar, MD Cambridge Scholars Publishing

Lady Stephenson Library, Newcastle upon Tyne, NE6 2PA, UK; Copyright 2021

Dr. P. Syamasundar Rao and Dr. Dharmapuri Vidyasagar are Professors Emeritus of Pediatrics; Rao most recently from the University of Texas, Houston, and Vidyasagar from the University of Illinois, Chicago. Both professors had long distinguished clinical careers and were leaders in their fields: Dr. Rao as a pediatric cardiologist and Dr. Vidyasagar as a neonatologist. Both also had extensive academic careers as authors and as educators.

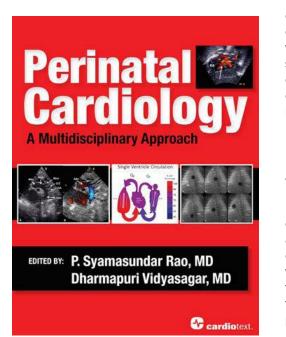
Rao and Vidyasagar have collaborated with forty-two of their former trainees and colleagues to put together these 700-page volumes, which together comprise a comprehensive textbook in Perinatal Cardiology. Doctors Rao and Vidyasagar correctly point out that excellent care of the fetus, the neonate and the infant with Congenital Heart Disease requires a big team approach; involving coordinated input and contributions from perinatologists, neonatologists, pediatric cardiologists, cardiac intensivists, pediatric cardiac and general surgeons, as well as primary care physicians and practitioners.

Over the course of 43 chapters, the editors and contributing authors provide up-to-date reviews of nearly all aspects of the pathogenesis, physiology, evaluation and comprehensive care of perinatal cardiac patients. As is often the case with textbooks covering a field having a broad array of related topics, organization can be difficult. In this text, Rao and Vidyasagar have devoted much of the first volume to a section entitled "Diagnosis and Management," and much of the second volume is a section called "Individual Cardiac Defects." The Diagnosis and Management Section includes chapters covering a diverse array of topics including diagnosis of cyanotic infants by primary care providers, echo and MR evaluation of neonatal heart disease, management of sick infants with congenital heart disease, neonatal cardiac emergencies, genetics, persistent pulmonary hypertension in the newborn, neonatal dysrhythmias, single ventricle physiology, catheter interventions, in utero interventions, and surfactant therapy. This section also continues in Volume 2 to include chapters on neonatal cardiac anesthesia and cardiac surgery, cardiac transplantation, post-operative care, and feeding strategies. The Cardiac Defect Section provides chapters covering the most common cardiac defects including the "5 T's", HLHS, Pulmonary Atresia with ITVS, Ebstein's Anomaly, Heterotaxy Syndromes, Coarctation of the Aorta, and PDA. These Defect chapters are traditional in most respects, except they focus on the perinatal patient.

The volumes contain other significant sections as well. In Volume 1, there are sections on Perinatal Circulation, The Fetus, Ethics, and newborn screening. In Volume 2 there are additional sections

on Cardiomyopathies and Hypertension. The final section entitled Conclusions is essentially a compendium of individual chapter abstracts.

In the digital era, most physicians caring for patients with heart disease are not purchasing and shelving textbooks. This fact calls to question what roles this book will have in medical education, as a reference, and in the literature in general. In my view, this text is a treasure-trove of excellent information focusing on the perinatal patient with heart disease. Most other sources do not include



the important chapters and collaborations with other specialties and disciplines, especially with neonatology. For this reason, believe A 1 Multidisciplinary Approach to Perinatal Cardiology deserves to have an important online presence which is accessible to students, trainees, and practitioners.

A final note: This textbook was published in April 2021. Volume 1 is currently available on Amazon.com. Both Volumes are available at the Publisher's website: www.cambridgescholars.com



#### JOHN MOORE, MD, MPH

Professor and Chief of Pediatric Cardiology Emeritus Rady Children's Hospital UC San Diego School of Medicine San Diego, CA, USA jwmmoore1950@gmail.com

# NuMED Receives US Clearance on Z-6<sup>™</sup> Atrioseptostomy Catheter

Z-6<sup>™</sup> Enhanced Design Now Offers Interventional Pediatric Cardiologists Another Option When Treating Patients Requiring Balloon Atrioseptostomy

Meeting the increased needs of pediatric cardiologists where the Z-5<sup>TM</sup> was the only balloon atrioseptostomy catheter available in the US, NuMED Inc. announces that the Z-6<sup>TM</sup> has received 510(k) clearance providing interventionalists a second option when treating patients requiring balloon atrioseptostomy. Leveraging the same proven materials used in construction of the Z-5<sup>TM</sup>, the new Z-6<sup>TM</sup> features design enhancements which include a short distal tip and catheter tip angulation modifications.

Designed for easier insertion through the septum and improved rewrapping allowing for easier removal into the introducer, the addition of a short distal tip provides a feature some clinicians may have been accustomed to in the past. To facilitate passage of the catheter into the left atrium, the 35 degree tip angulation was moved closer to the balloon.

The Z-6<sup>TM</sup> utilizes a non-compliant balloon which maintains its shape during pullback. The Z-6<sup>TM</sup> is available in 9.5mm and 13.5mm diameters on a 5 French shaft with an inner catheter lumen for utilization of a guidewire.

"The Z-6 septostomy balloon catheter finally is here! You complained and NuMED delivers! The new balloon has all the new features to enable you to perform safe septostomy!! Short distal tip and 35 degree angle enabling easier access to the left atrium! Still over the wire advantage, a 6fr introducer and two sizes!!! Kudos to NuMED!" said Ziyad Hijazi, MD, MPH, FACC, MSCAI; Chair, Department of Pediatrics, CEMC Director, Sidra Cardiovascular Center of Excellence, Doha, Qatar.

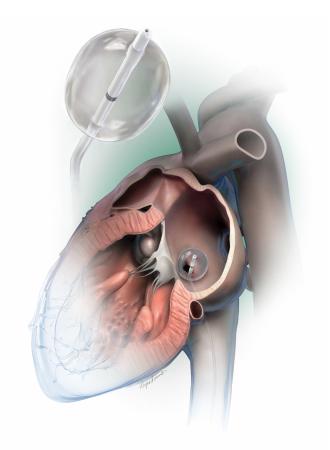
Balloon septostomy is a minimally invasive heart procedure in which an interventional pediatric cardiologist uses a balloon catheter to widen congenital heart defects such as foramen ovale, patent foramen ovale, or atrial septal defect. Thousands of these life-saving procedures are performed annually worldwide.

"With input from interventional pediatric cardiologists around the world, our R&D, Regulatory, and Production teams were able to apply 30+ years of balloon catheter expertise resulting in product enhancements and ultimately helping the lives of countless patients requiring balloon atrioseptostomy," stated Al Tower, President of NuMED.

#### About NuMED Inc.

**NuMED Inc.**, develops and manufactures high quality medical devices for diagnosing and treating congenital heart conditions or peripheral vascular disease. Through the help of our worldwide network of partners, we have improved the lives of patients in more than 100 countries by supplying the most comprehensive portfolio of innovative products, including the TYSHAK<sup>®</sup> and Z-MED<sup>™</sup> balloon catheters and CP Stent<sup>®</sup>, with a focus on pediatrics.

For more information, visit NuMED Inc. website at <u>www.numedforchildren.com</u> and connect with NuMED Inc on LinkedIn, <u>www.linkedin.com/company/numed-for-children/</u>.



#### About B. Braun Interventional Systems

B. Braun Interventional Systems is the exclusive US distributor of the NuMED Z-6<sup>TM</sup> atrioseptostomy catheter.

B. Braun Interventional Systems offers interventional solutions designed with the patient in mind. Many of the products offered have been developed in response to the needs of physicians, technicians, and nurses. The company is committed to delivering safety, precision and convenience to interventional procedures. Globally, the B. Braun Group of Companies employs more than 64,000 employees in 64 countries. Guided by its Sharing Expertise<sup>®</sup> philosophy, B. Braun continuously exchanges knowledge with customers, partners and clinicians to address the critical issues of improving care and lowering costs.

To learn more about B. Braun Interventional Systems Inc., visit <u>www.bisusa.org/about-us</u> and connect with B. Braun Interventional Systems on LinkedIn, <u>www.linkedin.com/company/b-braun-interventional-</u> <u>systems/</u>.



#### **MEDICAL NEWS**



### Innovative Cardiovascular Ultrasound Solutions Showcased at ASE's 32<sup>nd</sup> Annual Scientific Sessions

The virtual Exhibit Hall at **ASE 2021 Scientific Sessions Virtual Experience** will featured over 30 companies and organizations highlighting the latest vendor technology and other services. Demonstrations of artificial intelligence software and intracardiac echocardiography technologies, how to incorporate strain and ultrasound enhancing agents (UEAs) into lab procedures, and more were available to explore, June 18-21, 2021, during the world's premier meeting for cardiovascular ultrasound practitioners.

Highlights from the virtual exhibit hall, included:

#### ARDMS

You can now take select ARDMS examinations from your own home. ARDMS has created resources to help you to make the decision to either take your examination at a test center or online. We hope this new option helps you to meet your credentialing and career goals.

#### Biosense

Biosense Webster featured intracardiac echocardiography technologies for visitors to its virtual booth. The SOUNDSTAR® Ultrasound Catheter with the CARTOSOUND® Module delivers real-time intracardiac echocardiography imaging and navigation to enable workflow efficiencies, such as real-time monitoring of the ablation catheter tip to reduce radiation exposure and improve confidence.<sup>1,2</sup> Increase insight into the heart during transseptal punctures. The ACUSON AcuNav<sup>TM</sup> Ultrasound Catheter provides high resolution 2D grayscale and Doppler models that help better understand structural orientation, visualize cardiac chamber borders and verify tissue contact.

- Pier Luigi Pellegrino, Natale D. Brunetti, Daniela Gravina, Daniele Sacchetta, Valerio De Sanctis, Stefania Panigada, Luigi Di Biase, Matteo Di Biase and Massimo Mantica Nonfluoroscopic mapping reduces radiation exposure in ablation of atrial fibrillation. Cardiovasc Med 2013, 14:528–533
- Marian Christoph, Carsten Wunderlich, Stefanie Moebius, Mathias Forkmann, Judith Sitzy, Jozef Salmas, Julia Mayer, Yan Huo, Christopher Piorkowski, and Thomas Gaspar Fluoroscopy integrated

3D mapping significantly reduces radiation exposure during ablation for a wide spectrum of cardiac arrhythmias. Europace (2015) 17, 928–937.

#### **Canon Medical Systems**

Canon is Making Echo Easier with imaging clarity and definition with significantly enhanced resolution alongside excellent penetration, automating tedious measurements like EF and Strain, and addressing sonographer comfort with Healthy Sonographer Platforms™. Learn more at the Canon Medical Systems virtual exhibit at the ASE 2021 Virtual Experience. Canon Medical Systems USA, Inc., headquartered in Tustin, Calif., markets, sells, distributes and services CT, MR, ultrasound, X-ray and interventional X-ray equipment. For more information, visit Canon Medical Systems' website at https://us.medical.canon.

#### 1

#### **Caption Health**

With a focus on solving the issues of accessibility in ultrasound and empowering more healthcare workers to use this diagnostic tool, Caption Health offers the first FDA-cleared Al-powered guidance software in Caption AI and is a member of this year's FierceMedtech Fierce 15 class. Its booth at this year's ASE Scientific Sessions showcased Caption AI's ability to democratize both capture and analysis of cardiac ultrasounds. Caption Health staff are available to answer questions and provide additional information on how to leverage this technology for your institution. <u>CaptionHealth.com</u>.

#### CardioVillage

Do you need 15 CE hours of echocardiography content? You asked, and we listened! CardioVillage now makes it easier to customize your educational options. The Echocardiography Bundle consists of general and focused echocardiography content selected to meet the echocardiographer's 15-hour annual CE requirement. By completing all of the courses in the Bundle, you will earn certificates totaling 15 hours of CE credit. You can also purchase single courses or build your own bundle. The classic annual subscription is still available providing access to every course for one year.



Visit <u>Cardiovillage.com</u> to learn more and get started today.

#### **Epsilon Imaging**

Epsilon Imaging is further improving quality, standardization, and workflow in echo analysis with its newest solution, EchoInsight Zero Footprint (ZF). By making it easy to incorporate echo strain imaging into routine clinical practice, EchoInsight ZF provides user-friendly functionality enabling a highly efficient workflow for clinicians to analyze studies at any CVIS workstation with a web-browser. Additionally, no software is required to be loaded on client workstations with this new zero footprint architecture. EchoInsight is a vendor neutral platform with clinical strain imaging applications, automated cardiac function measurements based on ASE guidelines and seamless integration for any size echo program.

#### GE Healthcare

Visit the GE Healthcare virtual exhibit booth to learn about the latest AI-based technology with Vivid™ Ultra Edition designed to help reduce tedious tasks and improve workflow efficiency. Download our new whitepaper, The Role of AI in Streamlining Echocardiography Quantification, which shows how AI-based tools reduce exam time, minimize operator fatigue with up to 80% less clicks to get 2D measurements, and diminish inter-observer variability. And watch a presentation from Dr. Praveen Mehrotra, Director of Echocardiography at Thomas Jefferson University, on Echocardiography's Important Role in Structural Heart Interventions. Vivid Ultra Edition is Powered by AI. Elevated by You.

#### Lantheus Medical Imaging, Inc.

Echocardiography is a portable and real-time imaging modality that helps clinicians diagnose cardiac abnormalities. Lantheus Medical Imaging sponsored a symposium during the



#### MEDICAL NEWS

ASE 2021 Virtual Experience entitled Improving Quality and Efficiency in Echocardiography. Dr. Omar Husseini and Gina Conigliaro-Brito discussed how ultrasound enhancing agents (UEAs) can improve quality and efficiency in echocardiography. They provided practical insights into the implementation of UEAs to improve overall quality patient care.

#### National Board of Echocardiography (NBE)

Save the Exam Dates for 2022! www.echoboards.org/EchoBoards/Content/Verify\_Physician.aspx

#### **Trillium Technology**

The ShowCase Image Center Bundle provides an inexpensive and scalable medical image storage and review solution, with pricing starting at \$3,800 including the first year of phone support. ShowCase Image Center receives images via DICOM for storage and networked study review using the ShowCase Premier image viewer. Both in office and remote viewing are supported.

In addition to these vendor spotlights, the organization also hosted its own booths. The **ASE Headquarters** featured all the latest educational products, including two new textbooks, *ASE's Comprehensive Echocardiography 3rd Edition and ASE's Comprehensive Strain Imaging*. The show included a sales incentive, as most ASE products will be 10% off during the Scientific Sessions.

In the ASE Foundation (ASEF) Booth, participants viewed the *Hope and Resilience in Action* photo exhibit, signed up for the Cardiovascular Challenge, and supported the 2021 Annual Appeal by purchasing raffle tickets for a chance to win some great prizes including a table for 10 at the 2022 Research Awards Gala!

#### About ASE

ASE is the Society for Cardiovascular Ultrasound Professionals<sup>™</sup>. ASE is the largest global organization for cardiovascular ultrasound imaging serving physicians, sonographers, nurses, veterinarians, and scientists and as such is the leader and advocate, setting practice standards and guidelines for the field. The Society is committed to advancing cardiovascular ultrasound to improve lives. For more information about ASE, visit: <u>ASEcho.org</u> and follow us @ASE360. For more information about the ASE 2021 Scientific Sessions Virtual Experience visit: <u>ASEScientificSessions.org</u>.

#### Contact

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#### **OCTOBER** 01-03

Echo in Congenital Heart Disease: Adult and Pediatric Cases, Including Multimodality Imaging Rochester, MN, USA

https://cveducation.mayo.edu/store/echo-incongenital-heart-disease-adult-and-pediatric-casesincluding-multimodality-imaging

#### 07-09

The Genetics of Heart & Vascular Disease Nashville, TN, USA https://cveducation.mayo.edu/store/the-genetics-ofheart-vascular-disease

#### 13-15

**31<sup>st</sup> International Symposium on ACHD** Virtual <u>https://torontoachd2021.com/</u>

#### 16

11<sup>th</sup> Annual Fetal Echocardiography Symposium at UCLA: Clinical Tips and Pearls from the Experts Virtual https://www.cme.ucla.edu/courses/fetalecho21

#### 20-23

Morphology and Echocardiography in Neonates and Children Hands-on Interactive Morphology and Echo Course Birmingham, AL, USA https://www.congenitalecho.co.uk/

#### 20-23

Cases in Echocardiography, Cardiac CT, and MRI Napa, CA, USA https://cveducation.mayo.edu/store/cases-inechocardiography-cardiac-ct-and-mri

#### **MEDICAL NEWS**

# Circle Cardiovascular Imaging Announces Partnership with DiA Imaging Analysis to Deliver All-in-One Comprehensive Al-Based Cardiovascular Imaging Solutions

PRNewswire – Circle Cardiovascular Imaging Inc. and DiA Imaging Analysis Ltd. are excited to announce a multi-year partnership that leverages the companies' synergies in cardiac AI and data analytics.

As a global leader in cardiovascular imaging reading and reporting for Cardiac MR and Cardiac CT, Circle CVI has now expanded its rich product offering to a complete cardiovascular imaging portfolio, with the addition of DiA's FDA-cleared and CE-marked LVivo<sup>™</sup> Toolbox - a line of innovative AI-based cardiac ultrasound solutions. This collaboration will deliver expanded state-of-the-art multi-modality imaging solutions to Circle CVI's customers, while providing new opportunities for physicians, patients, and hospitals worldwide.

"By adding DiA's solutions, Circle CVI is broadening its extensive portfolio of cardiovascular MR and CT, to include ultrasound imaging functionality, offerings that are unparalleled in the market," said Greg Ogrodnick, CEO of Circle Cardiovascular Imaging.

Circle CVI will offer its customers DiA's LVivo Toolbox, as set of cardiac ultrasound AI solutions which will include LVivo Seamless™ – a unique system that runs "behind the scenes," automatically selecting the optimal cardiac ultrasound views and generating automated quantifications and indications of both left and right ventricles. The system then immediately extracts these results to the echo reports.

The solutions of both companies are vendor-neutral, running on any scanner, and they can easily integrate into hospital and enterprise sites, with deployments that work with any IT infrastructure.

"Joining forces with Circle CVI will accelerate our mission to rapidly deploy health providers with our most advanced and most accurate cardiac ultrasound AI solutions, which will simplify workflows and improve patient outcomes," said Hila Goldman-Aslan, CEO of DiA Imaging Analysis.

DiA spotlighted its AI-enabled solutions across its imaging portfolio at the American Society of Echocardiography (ASE) 2021 virtual event.

#### About Circle Cardiovascular Imaging Inc.

Circle Cardiovascular Imaging Inc. develops world-class, advanced reading and reporting solutions for cardiac imaging. Circle CVI is a prominent company in the global cardiac imaging community, bringing together an experienced and dedicated team of over 150 people and offering multilanguage support around the globe. Circle CVI's imaging platform, cvi42, is the bestin-class cardiovascular imaging reading and reporting solution for cardiac MR, cardiac CT, cardiac interventional planning and electrophysiology. Annually, millions of cardiac exams - in over 1,000 hospitals and in more than 50 countries – are interpreted using cvi42.



For additional information, please visit www.circlecvi.com or contact: marketing@circlecvi.com

#### About DiA Imaging Analysis Ltd.

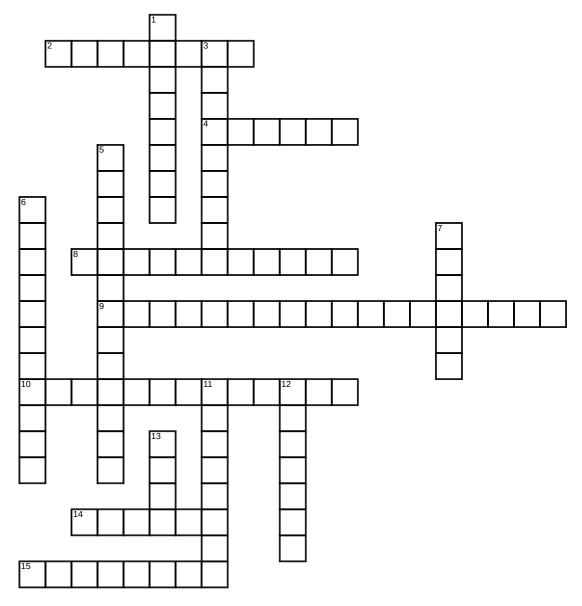
DiA Imaging Analysis is a leading provider of AI-powered ultrasound analysis solutions that make the use and analysis of ultrasound images smarter, faster and more accessible to all. The company's FDA- cleared and CEmarked LVivo<sup>™</sup> product line for automated cardiac and abdominal analysis enables clinicians with various levels of ultrasound experience to use and analyze ultrasound images on their ultrasound devices or healthcare IT systems with increased speed, efficiency and accuracy. DiA currently serves thousands of end users worldwide.

For additional information, please visit www.dia-analysis.com or contact: info@dia-analysis.com.



# CHIP NETWORK

#### **CROSSWORD HEART PUZZLE #1**



#### <u>Across</u>

2. Syndrome associated with elfin appearance.

4. Syndrome associated with Bicuspid Aortic Valve and Coarctation of the Aorta.

8. Slower than normal heart rate.

9. Birth defect in which great arteries fail to separate completely.

10. Anti-coagulant that interacts with plasminogen to result in plasmin complex.

14. Most common kind of primary cardiac tumor in adults.

15. American Surgeon who experimented with crosscirculation.

#### <u>Down</u>

- 1. Syndrome associated with Truncus Arteriosus.
- 3. Company which made the first pacemaker.

5. Stimulates myocardial Beta 1 and Beta 2 Receptors stimulating positive chronotrophy.

6. Kind of Aortic Valve with 5 Cusps.

7. Rapid influx of this ion in the myocytes causes rapid depolarization.

11. Disease that causes inflammation in the walls of blood vessels.

12. Austrian Radiologist and medical device inventor.

13. Type of Shunt which is often first step in the Norwood Procedure.

Word List: Amplatz, Bradycardia, Digeorge, Isoproterenol, Kawasaki, Lillehei, Medtronic, Myxoma, Pentacuspid, Sano, Sodium, Streptokinase, Truncus\_Arteriosus, Turner, Williams.





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