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Tricuspid Atresia with Common Arterial Truncus: A Rare Association

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Abstract

The coexistence of both Tricuspid Valve Atresia and Common Arterial Truncus is extremely rare. We report a case of antenatal diagnosis of this anomaly which was confirmed postnatally and discuss the management options.

Key Words

Tricuspid Valve Atresia and Common Arterial Truncus (CAT).

Introduction

Tricuspid Valve Atresia (TA) and Common Arterial Truncus (CAT) are rare anomalies, accounting for only 2.5%, and 0.7% of all Congenital Heart Diseases (CHD), respectively.^{1, 2} The coexistence of both anomalies is extremely rare. We report a case of antenatal diagnosis of this anomaly, which was confirmed postnatally, and the management options.

Case Report

An 18-year-old primigravida mother was referred for fetal echocardiography at 26 weeks of gestation. There were no antenatal risk factors. There was a history of consanguineous marriage. Fetal

“Tricuspid Valve Atresia (TA) and Common Arterial Truncus (CAT) are rare anomalies, accounting for only 2.5%, and 0.7% of all Congenital Heart Diseases (CHD), respectively.^{1, 2} The coexistence of both anomalies is extremely rare. We report a case of antenatal diagnosis of this anomaly, which was confirmed postnatally, and the management options.”

echocardiography showed a single ventricle with atretic tricuspid valve and small right ventricle. Only a single semilunar valve and no crossing of great vessels was seen. A 3.2 kg male infant was delivered at 38 weeks of gestation by emergency Caesarean Section (indication fetal distress) with Apgar of 2/10 and 9/10. On examination his blood pressure was normal in all four limbs and TcSats was 96% in room air. Cardiac examination revealed single second heart sound and

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grade 2/6 ejection systolic murmur heard over left sternal border. His chest x-ray showed cardiomegaly. Echocardiography (Figure 1 and 2) confirmed: the antenatal diagnosis of situs solitus, bilateral superior vena cavae, normal drainage of inferior vena cava to right atrium, normal pulmonary venous drainage to left atrium, restrictive Atrial Septal Defect (ASD) with right-to-left shunt, Tricuspid Valve Atresia (TA) with small right ventricle (RV), non-restrictive Ventricular Septal Defect, common arterial trunk (CAT) giving rise to small main pulmonary artery (PA) branching into right and left branch pulmonary arteries with left aortic arch and no truncal valve regurgitation (Collet and Edwards Type I).

The child was asymptomatic initially, and was started on diuretics. On follow-up, there was poor weight gain. The child was prepared for predicted univentricular pathway. At 2 months of age, the child underwent banding of the main pulmonary artery and systemic to pulmonary artery shunt. The post-operative course was complicated, and the infant died Day 5 post-operatively from proven Gram negative sepsis. Permission for postmortem examination was denied.

Discussion

The combination of TA with CAT is extremely rare, and constitutes only 0.01% to 0.02% of Congenital Heart Disease cases.¹ The first reported case was by Tandon in 1974.³ Until 1991, only eight cases were reported and all of them died due to cardiac failure before reaching three months of age. Since then, an additional nine cases have been reported. The first successful palliation by disconnecting the pulmonary arteries from the CAT, and placement of a systemic-to-pulmonary artery shunt was reported by Sreeram et al.⁴

Only five patients are reported to have undergone successful surgical palliation. Malec et al² published a three-stage procedure consisting of initial disconnection of the PA from the trunk, atrial septectomy and systemic-pulmonary shunt, a hemi-Fontane procedure at 27 months of age, and a final fenestrated Fontan completion at 51 months. An excellent result was achieved with follow-up to 8 years of age.

Numata et al¹ undertook a different approach: banding the main pulmonary artery at one month of age, creating a modified Blalock-Taussig shunt (BT shunt) at 6 months, a bidirectional Glenn (BDG) shunt at five-years of age and Fontan completion at six-years of age. Despite several further operations in the interim to control the pulmonary blood flow, including a repeat BT shunt and reconstruction of the pulmonary arteries at three-years of age. The end results were satisfactory, but the authors concluded that a better approach would have been to perform

primary separation of the pulmonary arteries from the aorta and installation of a systemic to pulmonary shunt.

In 2014, Roland et al⁵ described another approach, disconnection of PA from CAT and central RV to PA shunt (Sano) with atrial

septectomy at 12 days of age. The child was readmitted with respiratory distress and saturation of 50% at 2 months of age. Cardiac catheterization showed an unobstructed, but small calibre Sano shunt. Hence, a redo modified BT shunt was done. At 6 months of age the BDG was done.

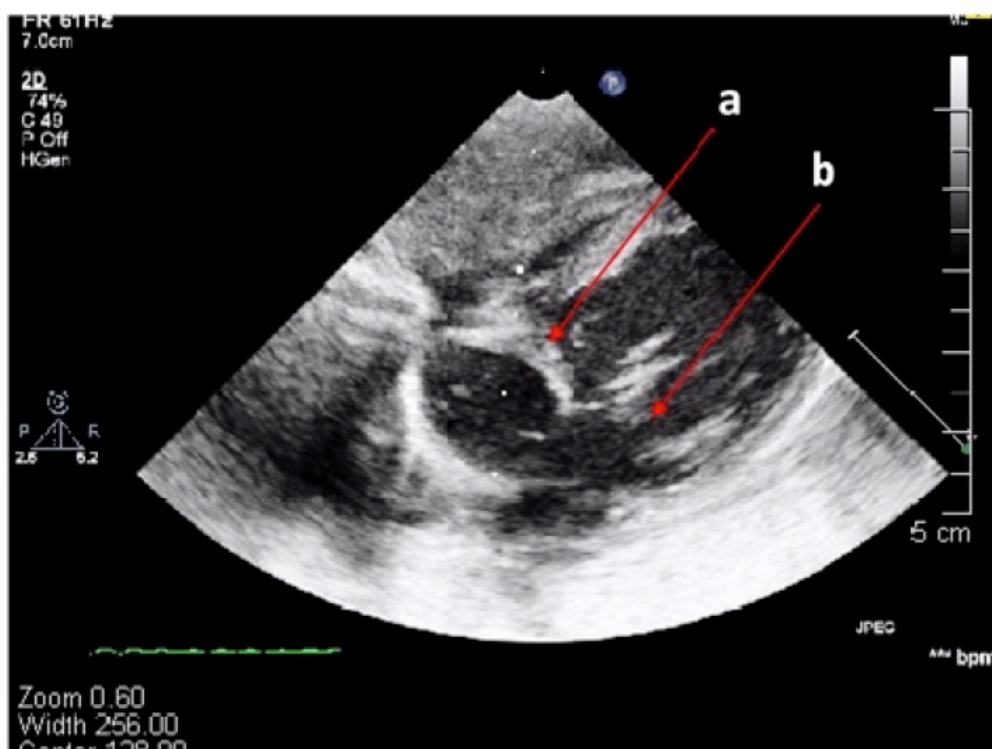


Figure 1. Subcostal four chambered view
a = Tricuspid Valve Atresia (TA); b = Single (left) ventricle.

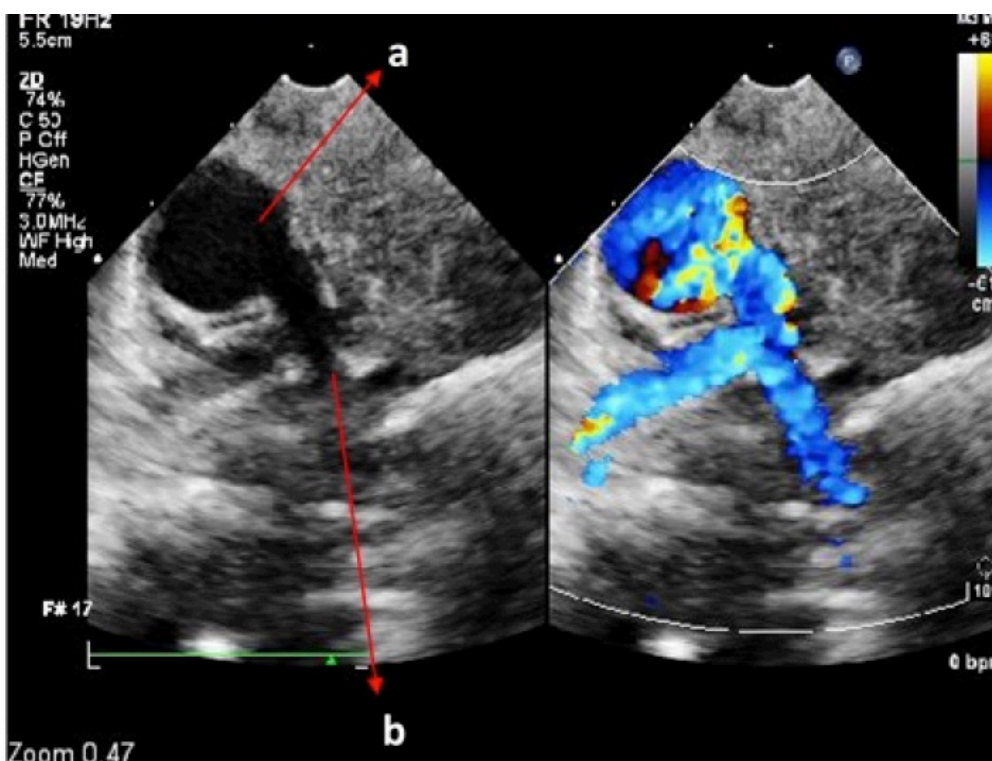
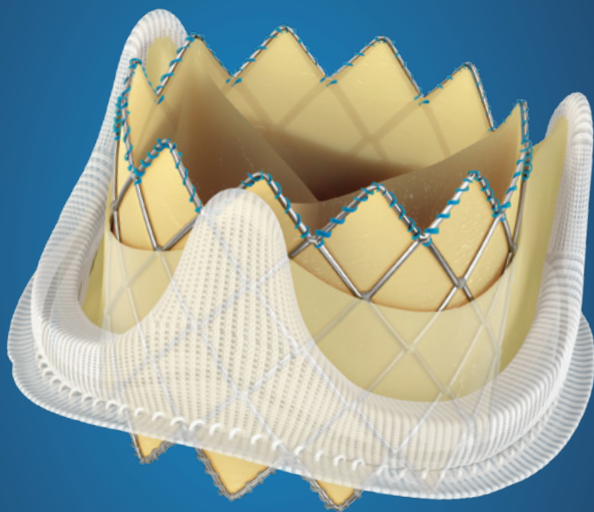


Figure 2. Parasternal short axis view
a = Ascending Aorta; b = Common Arterial Truncus (CAT) with branching pulmonary arteries.

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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.

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MR image quality may be compromised if the area of interest is in the same area, or relatively close to the position of the device. In nonclinical testing, the image artifact caused by the device extends approximately 3 mm from the Melody™ TPV when imaged with a spin echo pulse sequence and 6 mm when imaged with a gradient echo pulse sequence and a 3 T MRI System. The lumen of the device was obscured.

Scanning under the conditions defined above may be performed after implantation.

The presence of other implants or medical circumstances of the patient may require lower limits on some or all of the above parameters.

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

Contraindications:

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

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

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

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

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

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

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Table 1. Literature Review of TA and CAT Reported Cases		
Year	Author	Outcome
1974	Tandon et al ³	Died
1974	Bharati et al ⁸	Died
1975	Dick et al ⁹	Died
1977	Anderson et al ¹⁰	Died
1981	Sharma et al ¹¹	Died
1987	Areias JC et al ¹²	Died
1990	Diogenes et al ¹³	Died
1991	Rao et al ¹⁴	Died
1991	Sharma et al ¹¹	PA disconnection & Ao to PA shunt. No further follow-up
1999	Wang et al ¹⁵	Died
2000	Malec et al ²	Fontan completion
2003	Alva et al ⁷	No follow-up
2004	Numata et al ¹	Fontan completion
2008	Ramirez et al ¹⁶	PA disconnection & Ao to PA shunt, but died after 24 hours
2010	Tonnig et al ¹⁷	Prenatal diagnosis – pregnancy termination at 22 weeks
2014	Rolden et al ⁵	Fontan completion
2015	Lopez et al ⁶	Stage 1- PA disconnection & Ao to PA shunt Stage 2 -Bidirectional Glenn shunt, On follow up for Stage 3 Fontan completion

PA – Pulmonary artery; AO - Aorta

Lopez et al⁶ reported a case of TA and CAT with partial anomalous pulmonary venous drainage of the left upper pulmonary vein into the retro aortic innominate vein. The neonate underwent right modified BT shunt, atrial septectomy and disconnection of the PAs from CAT on Day 1 of Life (DOL). At 5 months of age, a second stage BDG and connection of LUPV to left atrial appendage was carried out.

Deletion of chromosome 22q11 is well-documented in conotruncal anomalies. Alva et al reported this rare anomaly with chromosome 22q11 deletion proven by Fluorescent in situ hybridization (FISH).⁷

Conclusion

TA and CAT is an extreme rarity, and only 17 cases (Table 1) are reported in the literature. An accurate diagnosis of this unique form of Congenital Heart Defect is mandatory for an early treatment. Early palliation to prevent cardiac failure with primary separation of the PAs from the CAT, and placement of a BT shunt would be an optimal first-stage palliation to prevent early mortality.

References

1. Numata S, Umbra H, Kagisaki K, Yagihara T. Tricuspid atresia with common arterial trunk: successful treatment using Fontan procedure. *Interact Cardiovasc Thorac Surg* 2004; 3:161–2.

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2. Malec E, Mroczek T, Pajak J, Kordon Z. Operative treatment of truncus arteriosus coexisting with tricuspid atresia. *Ann Thorac Surg* 2000; 69:278–80.
3. Tandon R, Moller JH, Edwards JE. Persistent truncus arteriosus. *Minnerva Medica* 1974; 57:448–50.
4. Sreeram N, Alvarado O, Peart I. Tricuspid atresia with common arterial trunk: surgical palliation in a neonate. *Int J Cardiol* 1991; 32:251–2.
5. Roldan S, Piles G, Caputo M, Morgan G, Stoica S. Tricuspid atresia with truncus arteriosus: successful surgical treatment. *Ann Thorac Surg* 2014; 98:721–3.
6. López MTG, Crucean A, Seale A, McGuirk S. Truncus arteriosus, tricuspid atresia and partial anomalous pulmonary venous drainage: a unique form of univentricular heart. *Interactive CardioVascular and Thoracic Surgery* 2015; 1–2.
7. Alva C, David F, Hernandez M, et al. Tricuspid atresia associated with common arterial trunk and 22q11 chromosome deletion. *Arch Cardiol Mex* 2003; 73:271–4.
8. Bharati S, McAllister HA JR, Tatroles CJ, et al. Anatomic variations in underdeveloped right ventricle related to tricuspid atresia and stenosis. *J Thorac Cardiovasc Surg* 1976; 72: 383-400.
9. Dick M, Fyler DC, Nadas AS. Tricuspid atresia: clinical course in 101 patients. *Am J Cardiol* 1975; 36:327-37.
10. Anderson RH, Wilkinson JL, Gerlis LM, et al. Atresia of the right atrioventricular orifice. *Br Heart J* 1977; 39:414-28.
11. Sharma D, Mehta AB, Bharati S, Lev M. Tricuspid atresia with persistent truncus arteriosus. *Chest* 1981; 79: 363-365.
12. Areias JC, Lopes JM. Common arterial trunk associated with absence of one atrioventricular connection. *Int J Cardiol* 1987; 17:329–32.
13. Diogenes TCP, Atik E, Aiello VD. Common atrial trunk associated with absence of right atrioventricular connection. *Int J Cardiol* 1990; 27:385–8.
14. Rao PS, Levy JM, Nikicicz E, Gilbert-Barness EF. Tricuspid atresia: association with persistent truncus arteriosus. *Am Heart J* 1991; 122:829–35.
15. Wang JN, Wu MH, Wang JK, Lue HC. Tricuspid atresia with persistent truncus arteriosus. *J Formos Med Assoc* 1999; 98: 290-291.
16. Ramírez Ramírez L, Lazaro Castillo JL, Gayosso Dominguez A, et al. Tricuspid atresia associated with common trunk. A case report [in Spanish] *Archi Cardiol Mex* 2008; 78: 413–6.
17. Tonni G, Panteghini M, Ventura A, et al. Prenatal diagnosis of tricuspid atresia with hypoplastic right ventricle associated with

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Oct. 8-11, 2017; Rochester, MN USA
cveducation.mayo.edu/marketing/echocardiography-in-pediatric-and-adult-congenital-heart-disease-case-studies--2#overview

LAA - How to Close the Left Atrial Appendage

Nov. 17-18, 2017; Frankfurt, Germany
www.csi-congress.org/laa-workshop.php?go=0

CSI Africa

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Device Therapies for Heart Failure

Dec. 15-16, 2017; Berlin, Germany
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NeoPREP - An Intensive Review & Update of Neonatal/Perinatal Medicine, Sponsored by the American Academy of Pediatrics and the AAP Section on Neonatal-Perinatal Medicine

Jan. 20-26, 2018; Atlanta, GA USA
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Mar. 10-12, 2018; Orlando, FL USA
<https://accscientificsession.acc.org/Information-Pages/future-meetings>

SCAI 2018 Scientific Sessions

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NeoHeart 2017 - Abstract Title: Transcatheter Echocardiographic-Guided Closure of Patent Ductus Arteriosus in Extremely Premature Newborns: Early Results and Mid-Term Follow-up

By Evan Zahn, MD; Dan Peck, MD; Ruchira Garg, MD; Marion McRae, NP; Phillip Nevin, RN; Kaylan Basaker; Alistair Phillips, MD; Charles Simmons, MD

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Objectives: The goal of this study was to describe early and mid-term outcomes of extremely premature newborns (EPN) who underwent transcatheter echocardiographic-guided Patent Ductus Arteriosus (PDA) closure.

Background: The treatment of hemodynamically significant PDA in EPN is controversial. Treatment with cyclooxygenase inhibitors induces ductal constriction and closure in some EPN; however, this therapy is only successful in an estimated 50%-60% of cases and carries a risk of pharmacologic complications such as renal insufficiency and bleeding. Surgical ligation of PDA in EPN confers significant risk of procedural morbidity, including Post-Ligation Syndrome (PLS) and may adversely affect long-term outcomes. This has led to an era of conservative expectant management of these EPN, despite the obvious ill effects PDA can have on their clinical course and outcomes.

Methods: A retrospective review of all EPN who underwent transcatheter echocardiographic guided closure of PDA at our institution between 3/13 and 10/16 was performed. Pre-procedural clinical variables, imaging data, procedural elements and clinical follow-up data were collected to evaluate acute, early- and mid-term results. Post-Ligation Syndrome (PLS) was defined using previously published parameters. Patients were followed at pre-specified intervals and prospectively collected data was reviewed retrospectively.

Results: Transcatheter closure was attempted in 36 EPN (median gestational

age/birth weight = 27 (24-33) weeks /848 (480-2480)g; procedural age/weight = 22 (5-80) days/1153 (755-2380)g and successful in 33/36 (92%). The three procedural failures were all related to the potential development of left pulmonary artery stenosis caused by the device and all devices were removed uneventfully during the implant procedure. Complications included two instances of device malposition, resolved with device repositioning (no long-term sequelae), and one instance of left pulmonary artery stenosis, requiring a left pulmonary artery stent at a later date.

There were no procedural deaths, residual PDA or device embolization. While most patients exhibited a transient decrease in LV systolic function, there were no clinical cases of PLS. One baby who required a complex device repositioning (noted above) had an increase in ventilatory requirements for 24 hours and prolonged diminished LV function believed secondary to the complexity of the procedure. Survival to discharge was 97% (35/36) with a single late death (3 months post-procedure) unrelated to the procedure.

"This newly described technique can be performed safely with a high success rate and minimal procedural morbidity in EPN. Early and mid-term follow-up is encouraging. Future efforts should be directed towards developing specific devices for this unique population and determining if this new treatment option results in better long-term outcomes than traditional medical and surgical therapies."

At a median time from the procedure of 2.1 years all patients were alive and well, with no patients exhibiting residual PDA flow or the development of pulmonary artery stenosis or aortic coarctation of the aorta.

Conclusions: This newly described technique can be performed safely with a high success rate and minimal procedural morbidity in EPN. Early and mid-term follow-up is encouraging. Future efforts should be directed towards developing specific devices for this unique population and determining if this new treatment option results in better long-term outcomes than traditional medical and surgical therapies.

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Medical News, Products & Information

Compiled and Reviewed by Tony Carlson, Senior Editor

Abbott Initiates Ground-Breaking U.S. Pivotal Study of AMPLATZER Device to Correct Common Congenital Heart Defect in Newborns

On August 30th, 2017 – Abbott announced it has initiated a U.S. pivotal clinical study evaluating the safety and effectiveness of a modified version of its AMPLATZER™ device designed to correct a common Congenital Heart Defect (CHD) that occurs in approximately 80,000, pre-term infants in the U.S. each year.

Patent Ductus Arteriosus, or PDA, is a life-threatening vascular pathway, or duct, in the heart that remains open due to failure of the fetal duct to close after birth. The duct, which serves as a bridge between blood vessels and is located between the main two arteries exiting the heart, is present in normally developing fetuses and typically seals itself after birth. In some cases, primarily in premature babies, the PDA fails to spontaneously close, which can result in serious difficulty breathing and an inability to feed – two critical tasks for newborn babies.

Abbott is developing the AMPLATZER Duct Occluder II Additional Sizes (ADO II AS) device, which is already approved for use in Europe, with the goal of providing physicians with a nonsurgical treatment option for closing the PDA defect in newborns and pre-term infants. The wire mesh device is placed non-surgically through a catheter inserted through the leg and guided through vessels to the heart, where it is placed to seal the duct. The new device is similar to the AMPLATZER Duct Occluder II product, available in larger sizes, and it builds upon more than 15 years of clinical success for AMPLATZER Occluder therapies.

"Patent Ductus Arteriosus is one of the most common heart defects, accounting for 5% to 10% of all congenital heart disease," said Evan Zahn, MD, Director of the Guerin Family Congenital Heart Program and Director of the Division of Pediatric Cardiology at the Cedars-Sinai Heart Institute in Los Angeles, and principal investigator for the study. "Surgery has many risks in this delicate population and a minimally invasive approach is desperately needed."

Pharmaceuticals can sometimes be used to promote closure of the duct, but are less effective in pre-term infants. For pre-term infants not responsive to pharmaceuticals, current treatment options are limited to surgery, which is not always possible, or to leave the duct open, which is not optimal for young infants. When the duct remains open, blood is redirected away from the body to the lungs and heart. Left untreated, the condition can lead to serious complications, including heart and kidney failure, damage to the intestines, bleeding in the brain, altered nutrition and growth, and ultimately, becomes a risk factor for chronic lung disease and death.

The study will enroll approximately 50 patients at up to 10 centers across the United States. The first seven patients were enrolled at Le Bonheur Children's Hospital in Memphis, Tenn., and treated by Shyam Sathanandam, MD, Associate Professor at the University of Tennessee.

If successful, the U.S. trial results will support Abbott's application for U.S. Food and Drug Administration (FDA) approval for pediatric use in the U.S..

"This modified AMPLATZER device has been designed with our youngest and tiniest patients in mind," said Michael Dale, Vice President of Abbott's structural heart business. "These smaller sizes may offer physicians greater flexibility to, hopefully, help these infants live healthy, normal lives."

The ADO II AS trial is a single-arm, prospective, multicenter, non-randomized clinical investigation designed to characterize the safety and effectiveness of the ADO II AS device in patients with a Patent Ductus Arteriosus who are more than three days old. Co-primary endpoints are the rate of major complications through 180 days after an attempted implant, and the rate of effective closure of the ductus arteriosus among patients with a successful implant at six months. The secondary endpoint is the rate of significant obstruction of the pulmonary artery or aorta through six months.

For more information about the ADO II AS study, please visit: <https://clinicaltrials.gov/ct2/show/NCT03055858>.

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Testing to See Whether Bone Marrow-Derived Cells Will Benefit Children with the Congenital Heart Defect

In a first-in-children randomized clinical study, the University of Maryland School of Medicine (UMSOM) and the Interdisciplinary Stem Cell Institute (ISCI) at the University of Miami Miller School of Medicine have begun testing to see whether bone marrow-derived cells will benefit children with the Congenital Heart Defect Hypoplastic Left Heart Syndrome (HLHS).

"Allogeneic Human Mesenchymal Stem Cell Injection in Patients with Hypoplastic Left Heart Syndrome: An Open Label Pilot Study" is a Phase I/IIb clinical trial to test the therapeutic effects of the allogeneic mesenchymal stem cells (MSCs) in children with HLHS. ISCI will be providing the MSCs and clinical site for the trial is at UMSOM.

Even with extensive surgical treatments, HLHS babies still do not have optimal outcomes. The researchers hope the cells will increase the babies' chances of survival as HLHS limits the heart's ability to pump blood from the heart to the body because of poor right ventricle function.



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"The premise of this clinical trial is to boost or regenerate the right ventricle, the only ventricle in these babies, to make it pump as strongly as a normal left ventricle," says lead researcher Sunjay Kaushal, MD, PhD, Associate Professor of Surgery, University of Maryland School of Medicine and director, pediatric cardiac surgery, University of Maryland Medical Center. "We are hoping this therapy will be a game-changer for these patients."

This is the first HLHS research in the United States to use stem cells known as allogeneic mesenchymal stem cells (MSC). The allogeneic nature of the MSCs makes it possible for stem cells from one bone marrow donor to provide all the stem cells for this study. In adult patients, MSCs in the heart have been shown to reduce scar tissue, reduce inflammation, cause new small vessels to grow, and stimulate the heart to regenerate itself by improving ejection fraction by 7%, causing heart muscle cells and cardiac stem cells to grow.

This trial is intended to address the remaining obstacles to long-term cardiac function in HLHS patients. We propose that a stem cell-based therapy for these patients may prevent right heart failure and, therefore, improve survival outcomes and reduce the need for transplantation. The MSCs are directly injected into the right ventricular myocardium during the 2nd out of three standard operations (Glenn procedure/Bidirectional Cavopulmonary Anastomosis)—when the baby is about four months of age.

To date, our three enrolled patients are all showing early signs of safety and feasibility. This trial will be testing a total of 30 patients, after proving that this stem cell therapy works in strengthening the heart function. If you would like more information, and have a patient who might want to consider participation in this landmark trial, please contact: Dr. Sunjay Kaushal at 410-328-5842 or by email: SKaushal@som.umaryland.edu.

Siemens Healthineers Receives FDA Clearance for TrueFusion Structural Heart Disease Feature

The Food and Drug Administration (FDA) has cleared TrueFusion,¹ a new cardiovascular application from Siemens Healthineers that integrates ultrasound and angiography images to guide cardiac teams when administering treatment for structural heart disease. Available on the new Release 5.0 of the ACUSON SC2000 cardiovascular ultrasound system, TrueFusion is designed to maximize not only interventional cardiology procedures, but also routine diagnosis and follow-up of patients with structural heart disease. With cardiovascular imaging applications such as TrueFusion, as well as laboratory and point-of-care diagnostics solutions in addition to therapy guidance tools, Information Technology (IT), and services, Siemens Healthineers innovates to improve outcomes and reduce costs in cardiovascular care.

Fused imaging for structural heart procedures

Treatment options for structural heart disease are evolving rapidly. Increasingly, these minimally invasive procedures involve multimodality imaging and multidisciplinary clinical teams. To reliably diagnose structural heart disease and perform these complex interventions, clinical teams need detailed, real-time imaging information – specifically, real-time soft tissue and blood flow information from echocardiography as well as 2D imaging information from fluoroscopy – to be visible in one view for common orientation.

Addressing the need for fused images, the new TrueFusion application sends anatomical and functional markers as well as valve models from the ACUSON SC2000's True Volume transesophageal echocardiography (TEE) transducer to an Artis with PURE angiography system, overlaying ultrasound information with live fluoroscopy images to navigate structural heart procedures. By directly and seamlessly integrating co-registration of Artis fluoro and ACUSON SC2000 echo into the workflow via machine learning-based probe detection and automated registration updates, TrueFusion enables clinical teams to identify soft tissue-based structures that are provided directly from the integrated ultrasound system. With TrueFusion, not only can echocardiographers and interventionists better communicate and achieve more intuitive anatomical orientation during challenging procedures, but clinical teams potentially can reduce contrast usage and procedure time as well as patient and clinician X-ray exposure.

"With the availability of the TrueFusion cardiovascular application, Siemens Healthineers provides our customers with an invaluable tool to aid in the diagnosis, treatment, and follow-up of patients with structural heart disease," said David Pacitti, President and Head of Siemens Healthineers North America.

Footnote ¹: TrueFusion represents a workflow consisting of syngo TrueFusion (syngo X Workplace) and TrueFusion echo-fluoro guidance (ACUSON SC2000 Ultrasound System, PRIME edition).

Florida Medical Center Appoints Cinthia Rodrigues as Director of the Cath Lab and Interventional Services

Cinthia Rodrigues joins the staff at Florida Medical Center as the director of the cath lab and interventional services. In this role, she will be planning, directing, leading and evaluating care provided by the cardiac catheterization laboratory. Rodrigues will also be working closely with other department heads to ensure safe, quality patient care is provided.

"We are excited to have Cinthia join our team at Florida Medical Center. Cinthia has a proven track record, and with her experience and proven leadership abilities, this makes her highly qualified to serve as our new director of our cath lab and interventional services," said Trey Abshier, CEO of Florida Medical Center.

Rodrigues comes to Florida Medical Center from a 3- hospital non-profit health system in Southeastern Massachusetts. She has been both a cardiac catheterization and electrophysiology manager. Rodrigues has a proven track record in the successful development of new programs and has played an integral part in the development of the structural heart program at one of her previous hospitals which now includes TAVR, BAV, mitral clip, and watchman procedures. Prior to her career in nursing, she held positions that allowed her to gain extensive business experience which has helped her in the managerial positions in healthcare that she has held.

Rodrigues has a Bachelor of Science Degree in Food and Natural Resources from the University of Massachusetts and an Associate of Science Degree from Bristol Community College.

Florida Medical Center, a campus of North Shore is a 459-bed acute care hospital founded in 1973. Located at 5000 West Oakland Park Boulevard in Fort Lauderdale, Fla., Florida Medical Center is the

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The hospital is one of the only Comprehensive Stroke Centers in Western Broward County as designated by the Florida Agency for Healthcare Administration, allowing physicians and staff to offer a higher level of stroke care to its patients. Florida Medical Center's Surgical Weight Loss Center is also a designated Bariatric Center of Excellence by the American Society for Metabolic and Bariatric Surgery.

Florida Medical Center offers a broad range of medical and surgical services including: neurology and neurosurgery, a comprehensive orthopedics program, urology, psychiatry, gynecology, diagnostic imaging, pain center, wound care, diabetes education and 24-hour emergency services. Florida Medical Center has also recently opened a dedicated Senior Care Unit and Senior ER to accommodate the needs of the aging community.

Florida Medical Center is the first hospital in Florida to achieve full Chest Pain Center with Primary PCI Resuscitation Accreditation from the Society of Cardiovascular Patient Care. Florida Medical Center received the following awards from Healthgrades, the leading online resource that helps consumers search, compare and connect with physicians and hospitals: ranked among the top 10% in the nation for cardiology services and coronary interventional procedures in 2014, five-star recipient for Coronary Intervention Procedures for three years in a row (2013-2015), five-star recipient for coronary interventional procedures for three years in a row (2013-2015), and five-star recipient for the treatment of heart failure (2014-2015 and 2017).

Florida Medical Center has also received recognition from the American Heart Association's Get With The Guidelines Gold Plus Performance Achievement Award in stroke care and the target stroke honor roll, the highest distinction awarded for stroke care. Florida Medical Center is fully accredited by The Joint Commission, the nation's oldest and largest hospital accreditation agency. To learn more about Florida Medical Center, visit www.FloridaMedCtr.com.

Firmware Update to Address Cybersecurity Vulnerabilities Identified in Abbott's (formerly St. Jude Medical's) Implantable Cardiac Pacemakers: FDA Safety Communication

Date Issued: August 29, 2017

Audience:

- Patients with a radio frequency (RF)-enabled St. Jude Medical implantable pacemaker
- Caregivers of patients with an RF-enabled St. Jude Medical implantable cardiac pacemaker
- Cardiologists, electrophysiologists, cardiothoracic surgeons, and primary care physicians treating patients with heart failure or heart rhythm problems using an RF-enabled St. Jude Medical implantable cardiac pacemaker

Medical Specialties:

Cardiac Electrophysiology, Cardiology, Cardiothoracic Surgery, Heart Failure

Devices:

Abbott's (formerly St. Jude Medical's) implantable cardiac pacemakers, including cardiac resynchronization therapy pacemaker (CRT-P) devices, provide pacing for slow or irregular heart rhythms. These devices are implanted under the skin in the upper chest area and have connecting insulated wires called "leads" that go into the heart. A patient may need an implantable cardiac pacemaker if their heartbeat is too slow (bradycardia) or needs resynchronization to treat heart failure.

The devices addressed in this communication are the following St. Jude Medical pacemaker and CRT-P devices:

- Accent
- Anthem
- Accent MRI
- Accent ST
- Assurity
- Allure

This communication does NOT apply to any implantable cardiac defibrillators (ICDs) or to cardiac resynchronization ICDs (CRT-Ds).

Purpose:

On August 23, 2017, the FDA approved a firmware update that is now available and is intended as a recall, specifically a corrective action, to reduce the risk of patient harm due to potential exploitation of cybersecurity vulnerabilities for certain Abbott (formerly St. Jude Medical) pacemakers. "Firmware" is a specific type of software embedded in the hardware of a medical device (e.g. a component in the pacemaker).

For the purposes of this safety communication, cybersecurity focuses on protecting patients' medical devices and their associated computers, networks, programs, and data from unintended or unauthorized access, change, or destruction.

The FDA recommends that patients and their health care providers discuss the risks and benefits of the cybersecurity vulnerabilities and the associated firmware update designed to address such vulnerabilities at their next regularly scheduled visit.

Summary of Problem and Scope:

Many medical devices - including St. Jude Medical's implantable cardiac pacemakers - contain configurable embedded computer systems that can be vulnerable to cybersecurity intrusions and exploits. As medical devices become increasingly interconnected via the Internet, hospital networks, other medical devices, and smartphones, there is an increased risk of exploitation of cybersecurity vulnerabilities, some of which could affect how a medical device operates.

The FDA has reviewed information concerning potential cybersecurity vulnerabilities associated with St. Jude Medical's RF-enabled implantable cardiac pacemakers and has confirmed that these vulnerabilities, if exploited, could allow an unauthorized user (i.e. someone other than the patient's physician) to access a patient's device using commercially available equipment. This access could be used to modify programming commands to the implanted pacemaker, which could result in patient harm from rapid battery depletion or administration of inappropriate pacing.



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There are no known reports of patient harm related to the cybersecurity vulnerabilities in the 465,000 (US) implanted devices impacted.

To address these cybersecurity vulnerabilities and improve patient safety, St. Jude Medical has developed and validated this firmware update as a corrective action (recall) for all of their RF-enabled pacemaker devices, including cardiac resynchronization pacemakers. The FDA has approved St. Jude Medical's firmware update to ensure that it addresses these cybersecurity vulnerabilities, and reduces the risk of exploitation and subsequent patient harm.

After installing this update, any device attempting to communicate with the implanted pacemaker must provide authorization to do so. The Merlin Programmer and Merlin@home Transmitter will provide such authorization.

The firmware update will be available beginning August 29, 2017. Pacemakers manufactured beginning August 28, 2017 will have this update pre-loaded in the device and will not need the update.

Firmware Update Details:

The firmware update requires an in-person patient visit with a health care provider – it cannot be done from home via Merlin.net. The update process will take approximately three minutes to complete. During this time, the device will operate in backup mode (pacing at 67 beats per minute), and essential, life-sustaining features will remain available. At the completion of the update, the device will return to its pre-update settings.

As with any firmware update, there is a very low risk of an update malfunction. Based on St. Jude Medical's previous firmware update experience, installing the updated firmware could potentially result in the following malfunctions (including the rate of occurrence previously observed):

- Reloading of previous firmware version due to incomplete update (0.161%),
- Loss of currently programmed device settings (0.023%),
- loss of diagnostic data (none reported), or
- complete loss of device functionality (0.003%).

Recommendations for Health Care Providers:

- The FDA and Abbott do NOT recommend prophylactic removal and replacement of affected devices.
- Discuss the risks and benefits of the cybersecurity vulnerabilities and associated firmware update with your patients at the next regularly scheduled visit. As part of this discussion, it is important to consider each patient's circumstances, such as pacemaker dependence, age of the device, and patient preference, and provide them with Abbott's Patient Guide.
- Determine if the update is appropriate for the given patient based on the potential benefits and risks. If deemed appropriate, install the firmware update following the instructions on the programmer.
- For pacing dependent patients, consider performing the cybersecurity firmware update in a facility where temporary pacing and pacemaker generator can be readily provided.
- Print or digitally store the programmed device settings and the diagnostic data in case of loss during the update.
- After the update, confirm that the device maintains its functionality, is not in backup mode, and that the programmed parameters have not changed.
- The firmware update process is described in Abbott's Dear Doctor Letter issued on August 28, 2017.
- Contact your Abbott representative, or Abbott's customer technical support hotline at 1-800-722-3774 if you have any questions about the firmware update.

Recommendations for Patients and Caregivers:

- Consult with your physician(s) for determining when you should receive the update and if you have any questions or concerns about the vulnerabilities of the update. Your ongoing medical management should be based on your own medical history and clinical condition.

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- Visit www.sjm.com/cyberupdate for additional information, or if you have any questions or issues regarding your St. Jude Medical implantable cardiac pacemaker.

FDA Actions:

The FDA will continue to assess new information concerning the cybersecurity of Abbott's implantable cardiac devices and the

Merlin@home Transmitter, and will keep the public informed if the FDA's recommendations change.

The FDA reminds patients, patient caregivers, and health care providers that any medical device connected to a communications network (e.g. Wi-Fi, public or home Internet) may have cybersecurity vulnerabilities that could be exploited by unauthorized users. However, the increased use of wireless technology and software in medical devices can also often offer safer, more efficient, convenient, and timely health care delivery.

The FDA will continue its work with manufacturers and health care delivery organizations, as well as security researchers and other government agencies—to develop and implement solutions to address cybersecurity issues throughout a device's total product lifecycle. The FDA takes reports of vulnerabilities in medical devices very seriously and has issued recommendations to manufacturers for continued monitoring, reporting, and remediation of medical device cybersecurity vulnerabilities.

Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks related to the use of medical devices. If you suspect or experience a problem with these devices, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Additional Resources:

- Abbott Press Release
- Abbott Patient Communication
- Abbott Physician Communication
- Department of Homeland Security ICS-CERT Advisory
- Cybersecurity Vulnerabilities Identified in St. Jude Medical's Implantable Cardiac Devices and Merlin@home Transmitter: FDA Safety Communication (January 9, 2017).
- Postmarket Management of Cybersecurity in Medical Devices Final Guidance (12/28/16).

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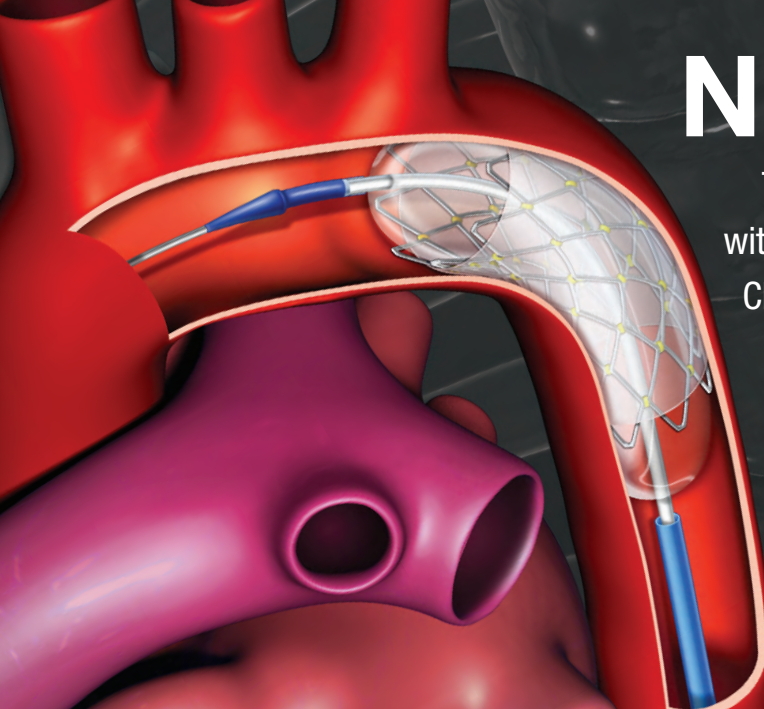
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