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(two months to 16 years) with weight of 6.15 kg (3.5 to 100 kg). Accurate measurements were feasible without any procedure-related complications. The case series suggests the micromanometer pressure wire can be a safer alternative to end-hole catheters for hemodynamic assessment in children with CCHD.

Keywords: Complications, Pediatric Catheterization/Intervention; Catheterization – Diagnostic; Congenital Heart Disease, Pediatrics; Hemodynamics

Introduction

Neonates and infants with Complex Congenital Heart Disease (CCHD) often require palliation followed by multiple surgeries for complete repair. Optimal outcomes following cardiac surgery is dependent on patient-specific anatomy, pulmonary artery (PA) pressures, ventricular pressures, and hemodynamic status. Prior to each surgical procedure these patients frequently require cardiac catheterizations for complete hemodynamic assessment¹. Using end-hole catheters can lead to unreliable measurements due to occlusion of the lumen against the vessel wall. A catheter obstructing the blood flow through the shunt or entrapment while crossing a prosthetic valve may lead to inaccurate measurements and cause acute hemodynamic compromise. We describe our experience of using a micromanometer pressure wire for hemodynamic assessment in nine children with CCHD. The median age at the time of catheterization was five months

Case Series

From March 2015 to September 2017, a total of 12 cardiac catheterizations were performed in nine children (females n=5) with CCHD using a micromanometer pressure wire for pre-surgical evaluation of PA pressures or post-surgical hemodynamic assessment. Five patients had diagnosis of Hypoplastic Left Heart Syndrome (HLHS), two had tricuspid atresia, one had pulmonary atresia with coarctation of the aorta (CoA), and one had Shone's Complex characterized by mitral and aortic stenosis. The median age at the time of catheterization was five months with a range of two months to 16 years with median weight of 6.1 kg and range of 3.5 to 100 kg. Four patients with HLHS were palliated with the Norwood procedure and 3.5 mm modified Blalock Taussig (BT) shunt, and one patient with a 4 mm BT shunt. Both patients with tricuspid atresia had a 3.5 mm BT shunt. The patient with pulmonary atresia and CoA had a 3.5 mm central shunt from the aorta to the left PA. The patient with Shone's Complex had mitral and aortic valve replacement followed by modified Konno procedure (Table 1).

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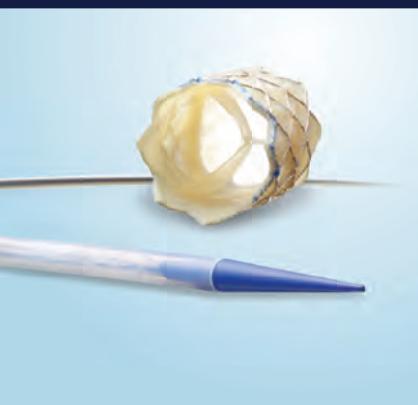


Contact: Kate@cct.bz

Table 1. Patient characteristics and pressures measured using the micromanometer wire												
Case	Diagnosis	Surgery	Catheterization study	Age (months)	Weight (kg)	RPA	Mean pressures (mmHg)					Comments
							LPA	MPA	LA	RA	Aorta	
1	HLHS, DORV, TAPVR	TAPVR repair, PA banding, DKS with 4 mm BT shunt	1	7	5.3	22	22	25	11	9	49	
			2	9	6.5	25	31	30			66	
			3	11	7.5	27	25		12	12	61	
			4	18	10.1	21	20				50	
2	Single ventricle with unbalance AVCD, Heterotaxy Syndrome, TAPVR, HLHS, TGA with pulmonary atresia	3.5 mm Modified BT Shunt	1	3	4.5		15			6	42	Significant narrowing of the RPA origin
3	HLHS, CoA	Norwood procedure with 3.5 mm right Modified BT Shunt, stent for re-CoA, Bidirectional Glenn shunt and atrial septectomy	1	3	6.4	15		15	6	6	47	
4	Tricuspid atresia, TGA	3.5 mm left BT shunt, Bidirectional Glenn Shunt	1	2	3.5			13	7	7	43	
5	HLHS, aortic arch obstruction	Norwood procedure with 3 mm BT shunt, Bidirectional Glenn Shunt	1	2	3.7		13		12	12	69	
6	Pulmonary atresia with VSD, CoA	3.5 mm central shunt from the left PA to the aorta, atrial septectomy, atrial septation, resection of CoA	1	3	5.9			9			76	
7	Tricuspid atresia with HRHS, VSD, PDA	3.5 mm modified BT shunt	1	2	5.2	12			8	5	49	
8	HLHS	3.5 mm BT shunt	1	15	8.9	18	20				37	
9	Shones Complex(MS, AS)	Aortic/mitral valve replacement	1	192	100	26	26	36		17	94	High end-diastolic pressure was noted in both the ventricles suggestive of restrictive physiology most likely constrictive pericarditis

Note. AS-aortic stenosis; AVCD – atrioventricular canal defect; BT – Blalock-Taussig; CoA – coarctation of aorta; DKS – Damus-Kaye-Stansel; DORV – double outlet right ventricle; HLHS – hypoplastic left heart syndrome; HRHS – hypoplastic right heart syndrome; LA – left atrium; LPA – left pulmonary artery; MPA – main pulmonary artery; MS- mitral stenosis; PA – pulmonary artery; PDA – patent ductus arteriosus; RA – right atrium; RPA – right pulmonary artery; TAPVR – total anomalous pulmonary venous return; TGA – transposition of the great arteries; VSD – ventricular septal defect

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"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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All catheterizations were performed under general anesthesia and aseptic precautions. Percutaneous access was achieved by standard methods with 80-100 units/kg of intravenous heparin as per established protocols. A 0.035 inch Terumo guidewire and 4F pigtail angiographic catheters were used to obtain an ascending aortogram and to define the exact location of the BT shunt. Ascending and descending aortic pressures were recorded. A 2.5 Judkins right (JR) coronary catheter was then advanced into the ascending aorta over a 0.035 inch standard guidewire and positioned at the arterial end of the BT shunt. Using the JR catheter and fluoroscopic guidance, the 0.014 inch micromanometer pressure wire was advanced into the shunt and the right and left PAs (Figure 1). The micromanometer pressure wire was calibrated and zeroed according to the instructions for use. Pressures were recorded in the PAs, femoral artery, ascending and descending aorta. The pressures obtained in the ascending and descending aorta using the pressure wire were compared with those obtained using conventional end-hole catheters.

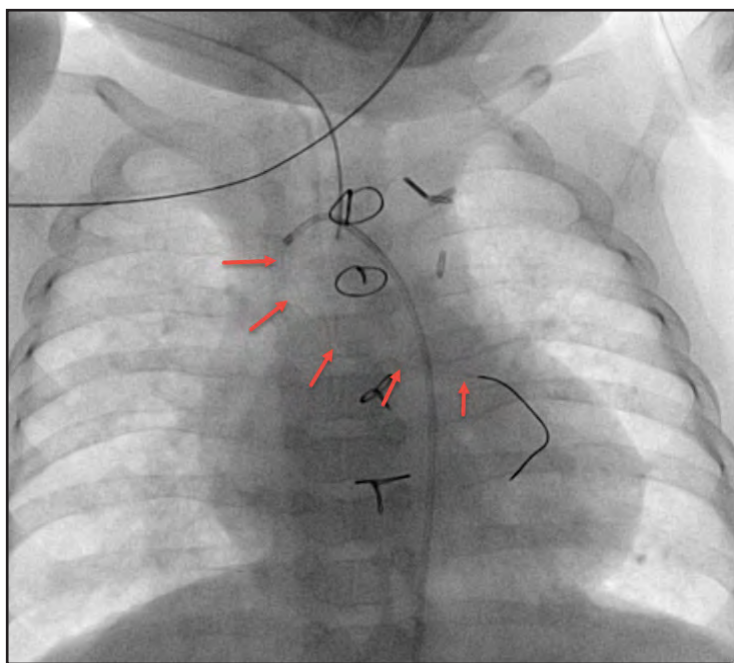


Figure 1A. Anteroposterior view showing the micromanometer pressure wire (red arrows) passed across the Blalock-Taussig shunt into the left pulmonary artery.

In the patient with Shone's Complex, the coronary pressure wire was used to cross the prosthetic aortic valve and measure the left ventricular pressure and left-ventricular-end diastolic pressure (EDP). The left ventricular pressure was measured at 94 mmHg with an end diastolic pressure of 20 to 24 mmHg. Simultaneous right atrial pressure was measured at 25/7 mmHg with a mean of 17 mmHg. The right-ventricular EDP ranged between 24 and 25 mmHg. The high EDP of both the ventricles was suggestive of restrictive physiology most likely due to constrictive pericarditis.

The access to the PAs using the micromanometer pressure wire was found to be easier than using conventional end-hole catheters. The right and left PA pressures were obtained using the micromanometer pressure wire, except in one patient with HLHS, Transposition of the Great Arteries and unbalanced atrioventricular canal defect. In this patient the left PA pressure was obtained, however, due to severe right PA stenosis, the wire could not be passed through the stenotic segment. The measured PA pressures had a range of 9 to 30 mmHg, with mean of 20 mmHg and standard deviation of 5 mmHg. The measured pressures correlated with the overall hemodynamic status of each patient. Based on the

hemodynamic findings obtained from catheterization studies done using the micromanometer pressure wire, three patients underwent successful Glenn shunt procedure without any complications. In the patient with prosthetic valves, the pressure wire was useful in crossing the aortic valve with accurate measurement of left ventricular pressures without any complications. All 12 cardiac catheterizations were performed without any significant hemodynamic instability, cardiac arrhythmia, desaturation, or valve entrapment. None of the patients required hospitalization after the study for procedure related complications.

Discussion

Infants and children with CCHD often require accurate and thorough evaluation of hemodynamics to plan surgical procedures. As the main factor determining the outcome of cavopulmonary anastomosis is the PA pressure¹, accurate evaluation is significant for timing surgery, especially in patients with HLHS requiring staged

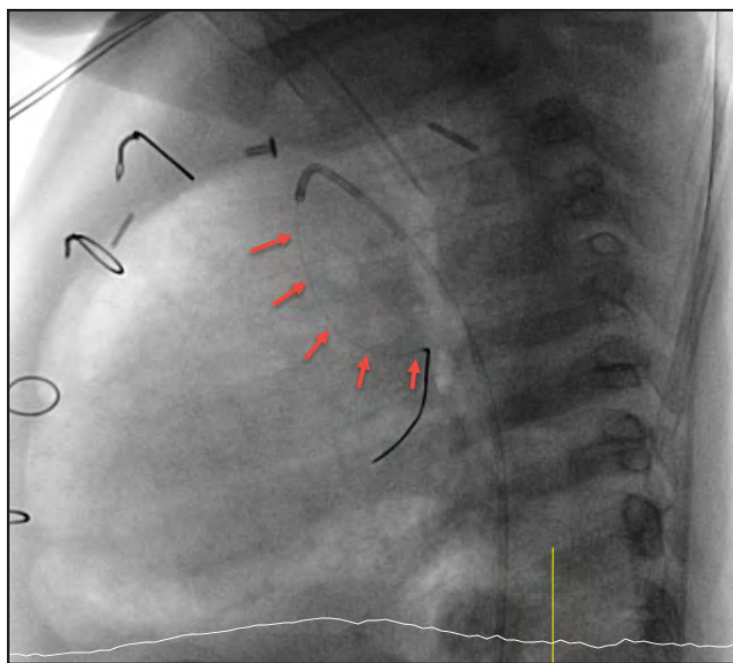


Figure 1B. Lateral view angiograms showing the micromanometer pressure wire (red arrows) passed across the Blalock-Taussig shunt into the left pulmonary artery.

procedures. Cardiac catheterization is currently the accepted approach to assess the suitability for second stage palliation in single ventricle patients. In patients with BT shunt, a detailed evaluation may be difficult due to the small size of the PAs as well as vessel tortuosity. Hemodynamic assessment of the PAs using end-hole catheters can be challenging in the setting of BT shunts due to damping of the waveform. A mismatch between the size of catheter and the shunt leads to inaccurate measurements. Using an end-hole catheter can lead to unreliable measurement due to occlusion of the lumen against the vessel wall. A catheter obstructing the blood flow through the shunt may lead to inaccurate measurements and acute hemodynamic compromise. Everett and Matherne reported successful use of pressure wires for measuring PA pressures in 11 infants². The feasibility of the pressure wire to assess PA band adequacy in the Hybrid Stage I procedure for high-risk neonates with Hypoplastic Left Heart Syndrome and variants has also been described³. In a study involving 10 patients with pulmonary atresia, Haddad et al showed the safety and efficacy of the micromanometer pressure wire for measuring PA pressures in small children after crossing collaterals⁴.

Cardiac catheterization studies are extremely important for hemodynamic assessments in patients with bio-prosthetic valves. Passing a standard catheter through a mechanical valve may cause fatal hemodynamic collapse or threaten the integrity of the valve itself. The assessment of the LV pressure measured across the aortic valve prosthesis is occasionally necessary when noninvasive imaging and Doppler echocardiography data are inconclusive or differ from the clinical findings in specific conditions such as diagnosis of constrictive or restrictive physiology. In the past, transseptal puncture or direct LV accesses were the only methods for hemodynamic assessment. In patients with prosthetic valves, the catheter is also believed to induce regurgitation across the valve, therefore, transvalvular gradients and hemodynamic measurements are considered less accurate. Overall, severity of valve regurgitation was lower for the 0.014-inch pressure wire compared with 6F pigtail catheter. As compared to 0.035-inch guidewire, the 0.014-inch guidewire had lower regurgitation for Medtronic Hall valve with equivalent regurgitation for the CarboMedics and Björk-Shiley valves⁷. Use of micromanometer pressure wire is associated with potential risk of wire entrapment, particularly across mechanical bi-leaflet valves. The above concerns were addressed in ex vivo experiments by Michaels et al in which pressure wires were inserted across several varieties of mechanical aortic valve prostheses without wire entrapment⁷. The technical feasibility and safety of using pressure wires to assess transvalvular gradients and hemodynamic parameters in patients with mechanical valve prostheses has been demonstrated in a number of case reports in adults⁸⁻¹¹.

The soft, flexible tip of the pressure wire makes it extremely easy to advance through a shunt or mechanical valves. Placing a slight curve in the tip of the pressure wire can facilitate access to the left and right PAs in difficult procedures without affecting the micromanometer function of the wire, which lies 30 mm proximal from the tip of the catheter. Finally, the small size of the pressure wire markedly decreases the likelihood of shunt obstruction, thrombosis, valve regurgitation or valve entrapment, which may be life threatening. Despite the reports of the successful use of the pressure wire in patients with shunts as well as in prosthetic valves, the utility of pressure wire in patients with CHD is obscure and underutilized.

Conclusion

The micromanometer pressure wire is a safe and effective option for hemodynamic assessment in pediatric patients with CCHD palliated with a BT shunt or those with bioprosthetic mechanical valves. Further comparative studies with a larger sample of patients are required to establish the pressure wire as the standard tool for hemodynamic assessment in pediatric patients with CCHD.

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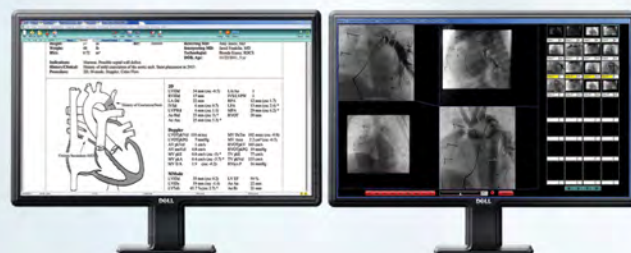
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A Review of *When I Wished Upon a Star; From Broken Homes to Mended Hearts*

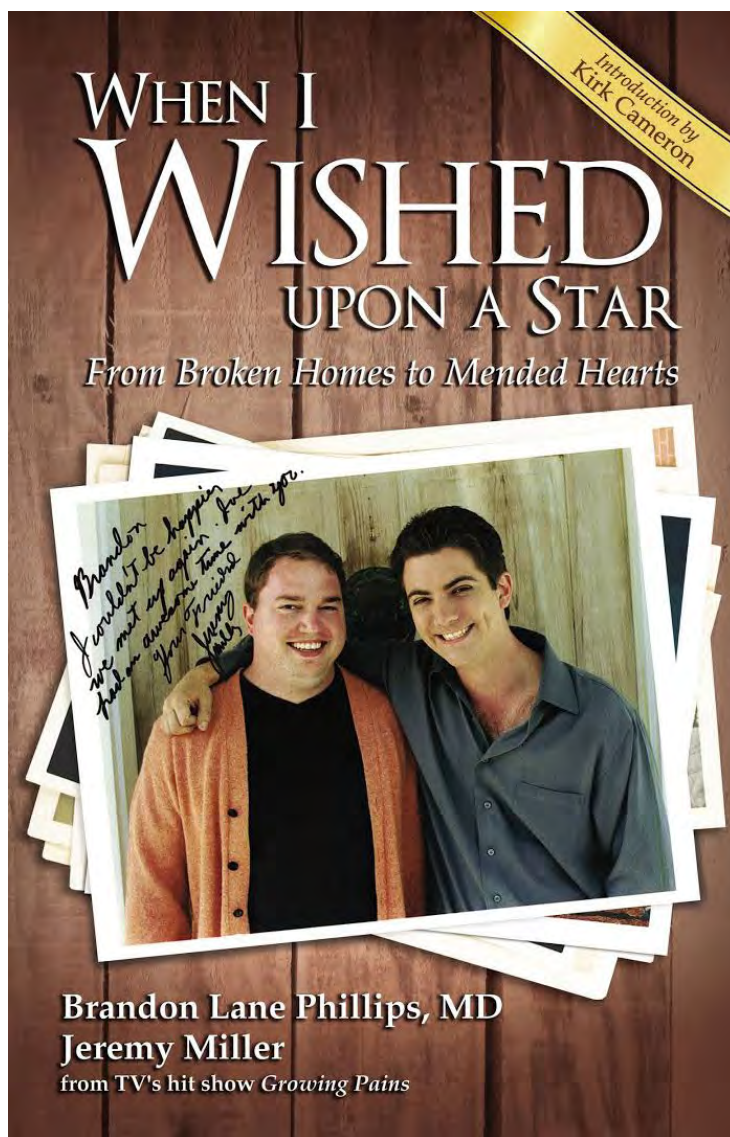
By Virginia Dematatis

When I Wished Upon a Star, From Broken Homes to Mended Hearts by Brandon Lane Phillips, MD and Jeremy Miller, chronicles the story of how Brandon Phillips, a young boy with Tetralogy of Fallot, had a wish granted that changed his life forever. The wish was to meet his "idol", Jeremy Miller, a child actor who played his favorite character, Ben Seaver, on the popular family TV show "Growing Pains." Little did Phillips know that years later, when he visited the set of a reunion movie and reconnected with his childhood "hero" Jeremy Miller, Miller's life would be changed forever as well. Both encounters came at a time when one or the other was at a low point in their lives; both encounters changed the course of one or the other's life. In the book Phillips describes the many challenges both experienced as children from broken homes, as well as obstacles they faced as adults. Their relationship is the primary focus of the book. However, there is also a subtext in the book that demonstrates the critical role a pediatric cardiologist can play in the life of his/her patient. Not only did the "stars align" when Phillips met Jeremy Miller, but also when he met Dr. Thomas Vargo, a pediatric cardiologist at Texas Children's Hospital, who had a profound impact on his belief in himself and who inspired him to one day grow up and become a board certified pediatric cardiologist.

Phillips was first diagnosed with Tetralogy of Fallot as an infant. At the age of two, his parents took him to Houston, Texas, where Dr. Thomas Vargo performed a catheterization and Dr. Denton Cooley performed open-heart surgery. The surgery went well and the family returned home to Lena, Louisiana with the understanding that over the years Phillips would be followed by Dr. Vargo. No one in the family had any idea what an important role Dr. Vargo would play in Phillips' life.

On Phillips' fifth birthday, his father announced that he was moving out. Soon thereafter, his parents divorced, and in the book, Phillips describes in detail the challenges he faced dealing with the trauma of divorce. He thought that had he been born normal, his father would never have left. Phillips missed his father and was often disappointed by him, especially when his father failed to show up when promised or lied about his whereabouts to avoid spending time with him. Between the divorce and his growing awareness of his heart condition, Phillips often felt depressed. He was haunted by his belief that he would die young and often prayed to God that he would give him a "sign" that He loved him and that he would be okay. At the same time, in spite of his depression, he still clung to his dream to become a doctor. He was always heartened when he made his periodic visits to Houston to see Dr. Vargo. "I wanted to be like Dr. Vargo, my pediatric cardiologist who would later become my mentor, advisor, professor, and ultimately my friend. In some ways he became a replacement for my father as the man I most wanted to emulate."

One day while home alone watching TV, Phillips heard about the Starlight Children's Foundation, an organization that granted wishes to critically and chronically ill children. He called the Foundation on his own and expressed his wish to visit the set of "Growing Pains" and meet his favorite actor, Jeremy Miller. He and his mother applied for his wish to be fulfilled and that "sign" from God he yearned for arrived when, just as Phillips was in Houston about to have an interventional catheterization, he learned that his wish had been granted by the Starlight Foundation and that a visit to the set of "Growing Pains" was in



the works. Thrilled and emboldened, Phillips asked Dr. Vargo to grant him another wish he had previously expressed: to be fully awake during his scheduled catheterization. Phillips argued that he would one day be a pediatric cardiologist and would work with Dr. Vargo, so he should start learning now. Dr. Vargo gave in and gave him a mild sedative. When the procedure was done, he commented to Phillips, "You're a brave kid--and one day, you'll be a brave doctor". These words, made Phillips feel better; visiting the set of "Growing Pains" soon thereafter had an even greater impact.

As Phillips describes it, "My wish changed me from the inside out and set me on a new path. I had a new way of looking at life. Even if I couldn't do everything everyone else was doing, I could still do some pretty cool stuff." He returned home to Jena with renewed hope and couldn't wait for his upcoming visit to the set of "Growing Pains" in Los Angeles. He met his "hero" Jeremy Miller and talked extensively with Kirk Cameron, another actor in the show. They both shared their belief in God with him and Cameron specifically pointed out to Phillips that God had given him a future full of promise. For a brief period after his

visit, he corresponded with Miller. He kept in closer contact with Cameron. With his spirits buoyed by his visit to the “Growing Pains” set, Phillips became even more determined to realize his dream to become a doctor. Phillips studied hard and ultimately graduated from high school, Louisiana Tech University and Tulane Medical School in New Orleans, Louisiana.

As a student at Tulane, in addition to the stress all medical students face, Phillips had to deal with some significant personal challenges. First and foremost, he learned his father had metastatic prostate cancer during his second year. Phillips dealt with the news and the anticipation of the loss of his father by burying himself in his studies. But he was soon hit with a further setback: he learned he needed to have a second heart surgery. At the end of his second year, Phillips went to the Mayo Clinic where Dr. Francisco Puga performed a pulmonary valve implant. The surgery was followed by a period of depression and Phillips wondered: “Would I continue to be held a prisoner by my condition for the rest of my life?” With the support of family, friends, Tulane classmates, Dr. Vargo and others, he recovered and returned to school. Three months before his graduation, Phillips’ father died. Dr. Vargo and his wife joined Phillips’ family at the graduation ceremony and Dr. Vargo placed his doctoral hood on Phillips’ head during the ceremony. Phillips went on to complete a residency in Pediatrics at Texas Children’s, with Dr. Vargo as his mentor and advisor. He then went to the Mayo Clinic for a fellowship in Pediatric Cardiology and today practices Pediatric Cardiology in Alexandria, Louisiana.

Besides attending Phillips’ graduation, Dr. Vargo visited him twice during his fellowship at Mayo Clinic. He modeled constancy and caring in Phillips’ life, and Phillips took up the mantle. Phillips volunteered for the Make-A-Wish Foundation, became a Global Ambassador and member of the board of the Starlight Children’s Foundation, a public speaker, and a true role model and mentor for his own patients and their families. Inspired by having his “wish” come true at eleven years old and, with the support of Dr. Vargo and a number of other mentors, Phillips worked hard to make his dream to become a pediatric cardiologist come true.

Midway through the book, Phillips shifts from telling his own story to telling the story of Jeremy Miller. As it turns out, just before Phillips graduated from medical school, the entire “Growing Pains” cast came to New Orleans to film a reunion movie. Kirk Cameron invited Phillips to visit the set and Phillips

rekindled his relationship with both Kirk Cameron and Jeremy Miller. Phillips learned a great deal more about Jeremy Miller’s life while visiting the set and during subsequent visits to Los Angeles where he visited both the Cameron and Miller families. He discovered that, just as he yearned for the ideal family life portrayed on TV, so did Miller. He also learned that Miller’s parents divorced when he was two years old. Unlike Phillips’ father, who was often emotionally distant and repeatedly failed to “show up” when Phillips needed him, Miller’s father tried to stay involved in his sons’ lives. However, once he remarried a woman with two children of her own, he became busy with his new family and had even less time to spend with his sons. Jeremy became busy, too.

Miller had an early talent for acting and began spending his afternoons going to auditions. At the age of six he was acting in commercials, by eight years old he was a guest star on the show “Punky Brewster” and he landed the role of Ben Seaver on “Growing Pains”, earning \$2,500 per episode. He continued in this role until he was fifteen when the series ended and reprised the role for two reunion movies. Miller’s TV character, Ben Seaver, seemed to have a happy family life.

Miller’s own life was far from idyllic. His mother remarried when he was twelve years old. At first, Jeremy and his younger brother adored their stepfather, but they soon discovered their stepdad was controlling and jealous of Jeremy’s success and earning power. His stepfather became his publicist, but gave Miller almost no say over his career. Miller and his stepfather did not get along and Miller slowly lost confidence in himself, developed social anxiety and would drink alcohol to feel better. Once the series was over, he found it harder to get acting roles. He began to turn to alcohol more and more. He eventually graduated from high school, attended USC briefly, and at the age of twenty-three, decided to pursue his passion for cooking by attending Le Cordon Bleu College of Culinary Arts. He developed a career as a caterer and taught cooking classes. All the while, he continued to drink.

During the filming of the reunion movie, Miller met Joanie, the mother of three young boys. They started a long-distance relationship and she eventually became his wife. After the filming, Phillips periodically visited with both Kirk Cameron and Jeremy Miller and their families in Los Angeles. Unfortunately, like Joanie, he discovered something new about his friend. He came to realize that alcohol played a prominent role in Miller’s life. Joanie was discouraged, as she would watch him

Pediatric Cardiology Consultant

Sheikh Khalifa Medical City (SKMC) is the largest hospital in the United Arab Emirates, consisting of a 586-bed tertiary hospital, 14 outpatient specialty clinics, and the Abu Dhabi Blood Bank, all of which are accredited by the Joint Commission International. SKMC is located in Abu Dhabi City and it is the flagship institution for the public health system in Abu Dhabi. SKMC has several centers of excellence and provides comprehensive services in all healthcare disciplines relevant to the needs of the community. Coming from all parts of the world, medical team’s diversity at SKMC makes the hospital stand out from all other institutions. Medical teams at SKMC include a mix of Western trained and certified physicians, aided by certified nurses – ensuring excellence and a rich ground for innovation.

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dote on her sons, then become belligerent, depending on how much he had to drink. When his drinking became unbearable, she decided to leave him.

This became a wake-up call for Miller and he tried repeatedly to stop drinking. In desperation, his mother reached out to Kirk Cameron, Brandon Phillips and Alan Thicke, the actor who played Ben Seaver's father. It was at this point that Phillips realized he needed to act to help Miller realize his "wish" to quit drinking. He vouched for Miller, convincing the recovery program director to accept him as a patient. Ultimately, Miller stopped drinking, reconciled with his wife and is now an advocate for his recovery program. He is a patient advocate as well and has recorded a videotape available on the internet in which he describes his story as a recovering alcoholic. He and Phillips remain close friends.

Little did either Brandon Phillips or Jeremy Miller appreciate how much their first encounter set them on a course that would change their lives. Phillips was buoyed by having his wish granted and meeting his "idol". Many years later, when Miller was at a low point in his life and had a wish to recover from his alcoholism, Phillips was able to be a support and help him get on his feet. Both men continue to be friends and to support one another. They have survived their rough times, broken homes, and the many challenges life has presented at their doorstep. The book is a testimony to their "wish" that others learn they are not alone and that there are always others who will support you if you can just ask for help. In Phillips' case, his relationship with his two "idols", Miller and Dr. Tom Vargo, helped inspire him to achieve his dream to become a pediatric cardiologist. In Miller's case, his connection to his "Growing Pains" family and their admirer, Brandon Phillips, helped enable him to conquer his addiction to alcohol. The book, *When I Wished Upon A Star*, is also the story of how pediatric cardiologists and cardiac surgeons often play an inspirational role in the lives of their patients by modeling hard work and caring.



Virginia Dematatis

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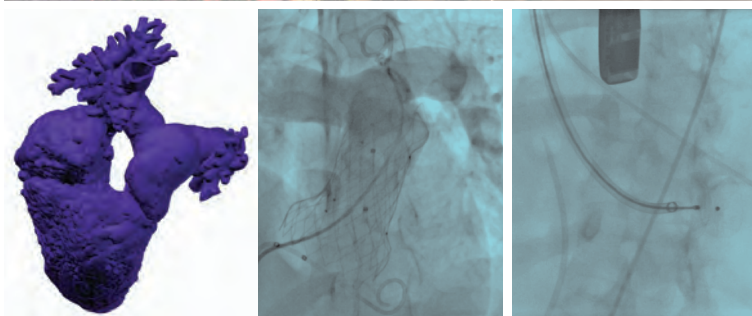
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The Greenlane Paediatric and Congenital Cardiac Service (PCCS) is a national service based at Starship Children's Health, Auckland. It is the sole provider of cardiology and cardiac surgical services for infants and children with congenital and acquired heart disease for New Zealand and a number of Pacific Island nations. It also provides a foetal and adult congenital cardiology service.

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Medical News, Products & Information

Compiled and Reviewed by Kate Baldwin and Tony Carlson

News From ACC 2019

MEDTRONIC EVOLUT LOW RISK TRIAL MEETS PRIMARY ENDPOINT

Less Invasive Evolut™ Transcatheter Aortic Valve Replacement (TAVR) System Successful in Clinical Trial When Compared to Open Heart Surgery in Healthier Aortic Stenosis Patients

Medtronic plc (NYSE:MDT) has announced first-ever clinical data from the landmark Evolut Low Risk Trial comparing the minimally invasive Evolut™ transcatheter aortic valve replacement (TAVR) system to the gold standard of open-heart surgery in characteristically younger, healthier aortic stenosis patients. The randomized trial, which met its primary non-inferiority endpoint of all-cause mortality or disabling stroke at two years compared to surgery (5.3% versus 6.7%; posterior probability of non-inferiority >0.999), was presented at the American College of Cardiology 68th Annual Scientific Session (ACC.19) and published simultaneously in *The New England Journal of Medicine* (NEJM)¹.

Key Data Highlights:

- The prespecified 30-day safety composite of all-cause mortality, disabling stroke, life-threatening bleeding, major vascular complications or acute kidney injury was significantly lower for TAVR as compared to open heart surgery (5.3% versus 10.7%), as was the rate of the composite endpoint of all-cause mortality or disabling stroke at 30 days (0.8% versus 2.6%). The pacemaker rate was greater in the TAVR treatment arm.
- TAVR demonstrated excellent hemodynamic (blood flow) performance with significantly lower mean aortic valve gradients (8.6 mm Hg versus 11.2 mm Hg) and larger EOAs (effective orifice area) than surgery (2.3 vs. 2.0) at 12 months.
- The TAVR treatment arm also showed statistically lower rates of heart failure hospitalizations (3.2% versus 6.5%) and disabling stroke (0.8% versus 2.4%) compared to surgery at 12 months.

“Low-risk aortic stenosis patients have unique characteristics due to their tendency to be younger and more active than their higher-risk counterparts,” said Michael Reardon, MD, cardiothoracic surgeon at Houston Methodist DeBakey Heart & Vascular Center, principal investigator and senior author of the Evolut Low Risk Trial. “These data suggest that not only did TAVR match the gold standard of surgery, but it demonstrated statistical superiority across several key endpoints, including quality of life and hemodynamics – important considerations for severe aortic stenosis patients who may be more active.”

The Evolut TAVR system is not approved in any geography for use in patients considered to be at a low risk of surgical mortality. These new data will need to be submitted to government regulators to support the safety and effectiveness of this device for this use.

It is estimated that 165,000 low risk patients suffer from severe aortic stenosis per year in the US, Western Europe and Japan. If left untreated, it can cause heart failure in as little as two years.

“Technological advances in the Evolut TAVR platform, including recapturability and repositionability coupled with its supra-annular valve design, have contributed to positive hemodynamic outcomes, which we continue to see with the Evolut platform across large-scale, randomized clinical trials,” said Pieter Kappetein, MD, PhD, vice president and chief medical officer for the Structural Heart and Cardiac Surgery businesses, which are part of the Cardiac and Vascular Group at Medtronic.

The global, prospective, multi-center, randomized Evolut Low Risk Trial evaluated three valve generations (CoreValve™, Evolut™ R and Evolut™ PRO valves) across a variety of valve sizes in more than 1,400 low risk severe aortic stenosis patients deemed to have a low mortality risk with surgery with a predicted risk of mortality of less than 3%.

“These ground-breaking clinical trial results are positive for patients and heart teams alike and add to the growing body of clinical evidence that will help define the future of TAVR,” said Nina Goodheart, vice president and general manager of the Structural Heart business at Medtronic. “We now have positive results from a wide range of patients with severe aortic stenosis across the surgical risk spectrum, and we hope to see that more patients will have the opportunity to receive this therapy option down the road.”

Following the launch of the self-expanding CoreValve System in the US in 2014, the CoreValve Evolut R System became the first-and-only recapturable and repositionable TAVR device approved in the U.S. for severe aortic stenosis patients at a high or extreme risk for surgery in 2015. The Evolut R system received CE (Conformité Européenne) Mark for intermediate risk severe aortic stenosis patients in 2016. In 2017, the third-generation Evolut PRO TAVR system was approved in the US and Europe for extreme-, high- and intermediate-risk patients. The Evolut PRO valve features an outer tissue wrap that adds surface area contact between the valve and the native aortic annulus to further advance valve sealing.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

Latest Issue of *Structural Heart* Features Research on Readmissions After Atrial Septal Defect Closure and Socioeconomic Disparities in Watchman Device Access in Patients with Atrial Fibrillation

The *Cardiovascular Research Foundation* (CRF) is pleased to announce that the latest issue of *Structural Heart: The Journal of the Heart Team* features original research articles on readmissions after atrial septal defect (ASD) closure and socioeconomic disparities in access to the Watchman device in patients with atrial fibrillation (AF).

Structural Heart, the official journal of CRF, is led by a distinguished Editorial Board of recognized international experts in the field. The journal is dedicated to disseminating the latest research and information to members of the Heart Team, as well as the wider medical community interested in structural heart disorders. The journal is now indexed on Embase, a biomedical research database from Elsevier.

"The second issue of Volume 3 features two research papers that may impact the treatment of atrial septal defects and atrial fibrillation," said Anthony N. DeMaria, MD, Editor-in-Chief of the journal and the Judith and Jack White Chair in Cardiology and Founding Director of the Sulpizio Cardiovascular Center at the University of California, San Diego. "A paper by Mojadidi et al evaluates readmissions data after ASD closure and indicates that compared with surgical repairs, percutaneous ASD closures are associated with lower all-cause mortality, major and minor complications, and length of hospital stay. A paper by Kupsky et al examines data regarding racial, economic, and social disparities in AF patients at elevated risk for bleeding referred to Watchman insertion."

Below are brief descriptions of the two original articles highlighted in this issue.

Incidence and Causes of 30-day Readmissions after Surgical Versus Percutaneous Secundum Atrial Septal Defect Closure: A United States Nationwide Analysis. By M. Mojadidi et al.

www.tandfonline.com/doi/full/10.1080/24748706.2018.1559963

Editorial: As If Percutaneous ASD Closure Needed More Proof. By T. Jones

www.tandfonline.com/doi/full/10.1080/24748706.2018.1559964

Researchers evaluated the incidence and reasons of 30-day readmissions following surgical versus percutaneous secundum ASD closure. They found that percutaneous ASD closure is associated with lower rates of 30-day readmissions, mean length of hospital stay, and hospital charges as compared with surgical closure.

Socioeconomic Disparities in Access for Watchman Device Insertion in Patients with Atrial Fibrillation and at Elevated Risk of Bleeding. By D. Kupsky et al

www.tandfonline.com/doi/full/10.1080/24748706.2019.1569795

This single-center retrospective case-control study examined socioeconomic and racial disparities among select atrial fibrillation (AF) patients who did or did not receive Watchman device placement. Researchers found that socioeconomic and racial disparities exist in patients with non-valvular AF at elevated risk of bleeding. African-American patients with lower income and Medicaid were less likely to be referred for the Watchman device.

www.crf.org

Dr. Daniel J. Penny Named 2018 Helen B. Taussig Memorial Lecturer - Chief of Pediatric Cardiology Among Greats to Receive Esteemed Award

Texas Children's Hospital is proud to announce Dr. Daniel J. Penny, Chief of Pediatric Cardiology, as the American Heart Association's 2018 Helen B. Taussig Memorial Lecturer. Penny received the esteemed award at the AHA's Scientific Sessions in Chicago, Illinois, on Nov. 10th, following his presentation: "Working Together towards New Levels of Excellence in the Care of Children with Heart Disease." Established in 1973, the Helen B. Taussig Memorial Lecture honors those whose work with children born with serious heart defects is lauded.

"I am truly grateful to receive this distinguished award from the AHA," said Penny. "As a pediatric cardiologist, I believe it is my responsibility to carry on the incredible legacy of innovators such as Dr. Taussig, and it is a privilege to do so at Texas Children's. Every day, my goal is to enhance the level of cardiology care we provide to our patients."

Penny was born in Cork, Ireland, where he completed his medical degree at University College Cork, The National University of Ireland. He trained and practiced at top pediatric institutions, such as The Great Ormond Street Hospital in London and The Royal Children's Hospital in Melbourne,

Australia before joining Texas Children's in 2010. In addition to his role as Chief of Pediatric Cardiology at Texas Children's, Penny serves as co-director of Texas Children's Heart Center®, which is ranked No. 1 nationally in Pediatric Cardiology and Heart Surgery by U.S. News & World Report. Building on the more than half a century of experience in caring for children's hearts, Texas Children's Heart Center provides the highest-quality cardiac care possible by combining cutting-edge technology with compassion and a family-centered approach.



"This well-deserved honor is another shining example of Dr. Penny's dedication to our patients and their families," said Mark A. Wallace, President and CEO of Texas Children's. "He is a visionary leader in his field, and continues to

guide our team as they pave the way in the treatment of children with congenital heart disease."

Previous recipients of the Helen B. Taussig Memorial Lecture feature pioneers in the world of Pediatric Heart Disease, including Dr. Dan G. McNamara who received the award in 1985. McNamara was Texas Children's first director of cardiology. Fueled by his immense passion for innovation, McNamara and his team designed and customized the hospital's first cardiac catheterization lab, which significantly advanced the diagnosis of heart ailments in children. He completed a fellowship in Pediatric Cardiology at the Johns Hopkins Hospital under Taussig, bringing her vast knowledge to those he mentored at Texas Children's.

"Dr. Penny exemplifies the best of Pediatric Cardiology," said Mark W. Kline, Physician-in-Chief of Texas Children's. "Drs. Taussig and McNamara would be proud of the work he and his team are doing to further advance the specialty."

To learn more about Texas Children's Heart Center, visit:

www.texaschildrens.org/heart.

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