The Evolution and Feasibility of Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk: A Review

TAVR in Low-Risk Patients

By Aditya Sengupta, MD; Sophia L. Alexis, MD; Gilbert H. L. Tang, MD, MSc, MBA

Introduction

Since its first clinical application in 2002, Transcatheter Aortic Valve Replacement (TAVR) has evolved dramatically and has surpassed Surgical Aortic Valve Replacement (SAVR) as the standard of care for patients with severe symptomatic aortic stenosis who are at an intermediate or higher risk for surgery. Trial data now suggest that TAVR with a balloon-expandable or self-expanding transcatheter heart valve (THV) is at least as safe and effective as SAVR in patients at low surgical risk. Here, we critically assess the data from the recent low-risk TAVR studies in the context of its evolving clinical indications. Outstanding issues, including long-term adverse events and durability, are also discussed.

Landmark Low-Risk Trials

Four landmark trials comparing TAVR with SAVR in patients at low surgical risk are discussed below (Table 1).

Recruit with CCT

Recruitment advertisements are listed
- In print and electronic monthly issue
- On our website
- In our monthly email blast

Contact: Kate@cct.bz
TAVR = Transcatheter Aortic Valve Replacement; THV = Transcatheter Heart Valve. STS-PROM = Society of Thoracic Surgeons-Predicted Risk of Mortality; SVD = Structural Valve Deterioration; Nordic Aortic Valve Intervention; PARTNER = Placement of Aortic Transcatheter Valves; PPM = Permanent Pacemaker; SAVR = Surgical Aortic Valve Replacement; BVF = Bioprosthetic Valve Failure; CI = Confidence Interval; HALT = Hypoattenuated Leaflet Thickening; HR = Hazard Ratio; NORDIC = 6-Year Outcomes; MedStar Low Risk TAVR\(^1\) vs. SAVR: 42.5% vs. 37.7% (P = 0.58). The PARTNER 3 & Evolut Low-Risk Trials

The PARTNER 3 & Evolut Low-Risk Trials

The PARTNER 3 Trial evaluated the noninferiority and superiority of the Edwards SAPIEN 3 THV (N = 503) versus SAVR (N = 497) in low-risk patients (Society of Thoracic Surgeons Risk of Mortality, or STS-PROM, <4%). The composite endpoint of death from any cause, stroke, or re-hospitalization at one year was significantly lower with TAVR. While the vast majority of the 30-day safety end points were similar between the two treatment arms, the rates of new-onset atrial fibrillation (AF) at 30 days, death or stroke at 30 days, and length of hospitalization were significantly lower with TAVR.\(^2\)

Similarly, the Evolut Low-Risk Trial tested the non-inferiority of the Medtronic self-expanding THV (N = 725) against surgery (N = 678) in low-risk patients. Here, three different self-expanding prostheses were used for TAVR due to their availability during the study period (CoreValve, Evolut R, or Evolut PRO). Compared to the PARTNER 3 trial, this study had a longer follow-up period of two years with regards to the composite primary endpoint of death or disabling stroke (5.3% vs. 6.7%, posterior probability = 0.999 for noninferiority). Furthermore, at 30 days, TAVR patients had a lower incidence of AF and life-threatening bleeding, but a higher incidence of at least moderate aortic regurgitation (AR).\(^3\)

Both trials demonstrated that TAVR is at least as efficacious and safe as SAVR in low-risk patients at 1-2 years. In particular, new permanent pacemaker (PPM) implantation, at least moderate paravalvular leak (PVL), and coronary artery obstruction occurred with equal frequency in both arms of the PARTNER 3 study. This is in contrast to previous trials where the aforementioned complications occurred more frequently with SAVR as compared to TAVR.\(^4\) Furthermore, both studies showed low rates of aortic valve re-intervention at one year with TAVR (0.6% in PARTNER 3, 0.7% in Evolut). As expected, new left bundle-branch block (LBBB) and mild PVL were lower in TAVR than SAVR. Of note, TAVR in the Evolut Trial resulted in a higher incidence of PPM implantation (17.4% at 30 days and 19.4% at one year) than SAPIEN 3 TAVR (8.6% at 30 days and 7.5% at one year), the design differences between a balloon-expandable and self-expanding valve may partly explain this discrepancy.

There were a number of limitations common to both studies, the most obvious of which was the lack of follow-up beyond 12-24 months (note that the recently published FinValve trial, with follow-up of up to three years, corroborate the aforementioned findings).\(^5\) Structural valve deterioration (SVD), along with the implications of PVL and patient-prosthesis mismatch, will have to be assessed.\(^6\) In particular, the Evolut Trial demonstrated a lower rate of severe patient-prosthesis mismatch at one year in the TAVR group (1.8% vs. 8.2%), albeit larger valve areas; the long-term sequelae of this finding will need to be ascertained, especially since severe patient-prosthesis mismatch occurred less frequently compared to prior studies.\(^7\) Furthermore, a stronger selection bias may have occurred in the PARTNER 3 trial since a third of screened patients were excluded for various reasons. This study had a longer follow-up period of two years with regards to the composite primary endpoint of death or disabling stroke (5.3% vs. 6.7%, posterior probability = 0.999 for noninferiority). Furthermore, at 30 days, TAVR patients had a lower incidence of AF and life-threatening bleeding, but a higher incidence of at least moderate aortic regurgitation (AR).\(^8\)

The PARTNER 3 & Evolut Low-Risk Trials

The PARTNER 3 & Evolut Low-Risk Trials

The PARTNER 3 Trial evaluated the noninferiority and superiority of the Edwards SAPIEN 3 THV (N = 503) versus SAVR (N = 497) in low-risk patients (Society of Thoracic Surgeons Risk of Mortality, or STS-PROM, <4%). The composite endpoint of death from any cause, stroke, or re-hospitalization at one year was significantly lower with TAVR. While the vast majority of the 30-day safety end points were similar between the two treatment arms, the rates of new-onset atrial fibrillation (AF) at 30 days, death or stroke at 30 days, and length of hospitalization were significantly lower with TAVR.\(^2\)

Similarly, the Evolut Low-Risk Trial tested the non-inferiority of the Medtronic self-expanding THV (N = 725) against surgery (N = 678) in low-risk patients. Here, three different self-expanding prostheses were used for TAVR due to their availability during the study period (CoreValve, Evolut R, or Evolut PRO). Compared to the PARTNER 3 trial, this study had a longer follow-up period of two years with regards to the composite primary endpoint of death or disabling stroke (5.3% vs. 6.7%, posterior probability = 0.999 for noninferiority). Furthermore, at 30 days, TAVR patients had a lower incidence of AF and life-threatening bleeding, but a higher incidence of at least moderate aortic regurgitation (AR).\(^3\)

Both trials demonstrated that TAVR is at least as efficacious and safe as SAVR in low-risk patients at 1-2 years. In particular, new permanent pacemaker (PPM) implantation, at least moderate paravalvular leak (PVL), and coronary artery obstruction occurred with equal frequency in both arms of the PARTNER 3 study. This is in contrast to previous trials where the aforementioned complications occurred more frequently with SAVR as compared to TAVR.\(^4\) Furthermore, both studies showed low rates of aortic valve re-intervention at one year with TAVR (0.6% in PARTNER 3, 0.7% in Evolut). As expected, new left bundle-branch block (LBBB) and mild PVL were lower in TAVR than SAVR. Of note, TAVR in the Evolut Trial resulted in a higher incidence of PPM implantation (17.4% at 30 days and 19.4% at one year) than SAPIEN 3 TAVR (8.6% at 30 days and 7.5% at one year), the design differences between a balloon-expandable and self-expanding valve may partly explain this discrepancy.

There were a number of limitations common to both studies, the most obvious of which was the lack of follow-up beyond 12-24 months (note that the recently published FinValve trial, with follow-up of up to three years, corroborate the aforementioned findings).\(^5\) Structural valve deterioration (SVD), along with the implications of PVL and patient-prosthesis mismatch, will have to be assessed.\(^6\) In particular, the Evolut Trial demonstrated a lower rate of severe patient-prosthesis mismatch at one year in the TAVR group (1.8% vs. 8.2%), albeit larger valve areas; the long-term sequelae of this finding will need to be ascertained, especially since severe patient-prosthesis mismatch occurred less frequently compared to prior studies.\(^7\) Furthermore, a stronger selection bias may have occurred in the PARTNER 3 trial since a third of screened patients were excluded for various anatomical reasons. In contrast, this rate was approximately 15% in the Evolut trial.\(^8\)

These results may also be not universally applicable. For one, bicuspid valvulopathy was an exclusion criterion in both studies, whereas bicuspid disease accounts for approximately 50% of all
That mortality and BVF rates were similar between the two groups; larger valves also tend to have lower baseline MGs. Partly explain the unusually high rate of PPM implantation in low-risk patients from the STS database. The SAVR stroke rates may never be quite as low given the risks associated with cardiopulmonary bypass, post-operative AF, and debridement of diseased valves. The validity of the SVD definition used in this study is limited by the initial THV type and root anatomy. The number of key limitations deserve special attention. First, the indications for new PPM implantation were not entirely clear; coupled with the use of an older generation, non-repositionable self-expanding valve and older deployment techniques, this may have led to low-risk patients in the United States. Moreover, the LRT study had remarkably low stroke rates at one year. In contrast, SAVR stroke rates may never be quite as low given the risks associated with cardiopulmonary bypass, post-operative AF, and debridement of diseased valves. The Paravalvular Leak Five-year data from the NOTION Trial showed a significant difference in TAVR versus SAVR with mild PVL in 45.9% vs. 16.7% and moderate PVL in 71.1% vs. 0%. The clinical implication of this is still unclear as both groups had similar NYHA functional class and all-cause mortality, even for patients with moderate to severe PVL at three years. One-year results from PARTNER 3 and Evolut showed a significant difference in outcomes in patients with mild PVL. Paravalvular Leak Conduction Abnormalities Conduction abnormalities are a well-known complication of TAVR. For instance, Nazif et al. found a 15.4% rate of LBBB at hospital discharge in 1,179 patients at intermediate risk from the PARTNER II Trial and S3 Registry. These patients had a significantly higher mortality at two years. Currently, prophylactic PPM implantation is not merited since ~40% of LBBB resolves at one year; the incidence of new LBBB was not reported. While the PARTNER 3 Trial did not show a difference in PPM insertions, new LBBB at one year was almost three times as high in the TAVR group vs. SAVR. In contrast, there was a higher PPM implant rate in the Evolut Low Risk Trial, but we do not know how many of these patients remained pacer-dependent at one year; the incidence of new LBBB was not reported. The NOTION Trial was able to correlate pacemaker implantation with a difference in mortality of 38.2% versus 21.7% at five years. Conduction abnormalities are a well-known complication of TAVR. Even though the outcomes of the NOTION Trial were favorable compared to data from the SAVORY (Subclinical Aortic Bioprosthetic Valve Thrombosis Assessed With Four-Dimensional Computed Tomography) and RESOLVE (Assessment of Transcatheter and Surgical Aortic Bioprosthetic Valve Thrombosis and Its Treatment with the Sentinel Cerebral Protection System) observational registries. This is discussed in greater detail below. The PARTNER 3 Trial did not show a difference in PPM insertions, new LBBB at one year was almost three times as high in the TAVR group vs. SAVR. In contrast, there was a higher PPM implant rate in the Evolut Low Risk Trial, but we do not know how many of these patients remained pacer-dependent at one year; the incidence of new LBBB was not reported. The NOTION Trial was able to correlate pacemaker implantation with a difference in mortality of 38.2% versus 21.7% at five years. Conduction abnormalities are a well-known complication of TAVR. Even though the outcomes of the NOTION Trial were favorable compared to data from the SAVORY (Subclinical Aortic Bioprosthetic Valve Thrombosis Assessed With Four-Dimensional Computed Tomography) and RESOLVE (Assessment of Transcatheter and Surgical Aortic Bioprosthetic Valve Thrombosis and Its Treatment with the Sentinel Cerebral Protection System) observational registries. This is discussed in greater detail below. The PARTNER 3 Trial did not show a difference in PPM insertions, new LBBB at one year was almost three times as high in the TAVR group vs. SAVR. In contrast, there was a higher PPM implant rate in the Evolut Low Risk Trial, but we do not know how many of these patients remained pacer-dependent at one year; the incidence of new LBBB was not reported. The NOTION Trial was able to correlate pacemaker implantation with a difference in mortality of 38.2% versus 21.7% at five years. Conduction abnormalities are a well-known complication of TAVR. Even though the outcomes of the NOTION Trial were favorable compared to data from the SAVORY (Subclinical Aortic Bioprosthetic Valve Thrombosis Assessed With Four-Dimensional Computed Tomography) and RESOLVE (Assessment of Transcatheter and Surgical Aortic Bioprosthetic Valve Thrombosis and Its Treatment with the Sentinel Cerebral Protection System) observational registries. This is discussed in greater detail below. The PARTNER 3 Trial did not show a difference in PPM insertions, new LBBB at one year was almost three times as high in the TAVR group vs. SAVR. In contrast, there was a higher PPM implant rate in the Evolut Low Risk Trial, but we do not know how many of these patients remained pacer-dependent at one year; the incidence of new LBBB was not reported. The NOTION Trial was able to correlate pacemaker implantation with a difference in mortality of 38.2% versus 21.7% at five years.
**Valve Reintervention**

For young patients who may need multiple aortic valve interventions, questions remain regarding the feasibility of redo-TAVR and the ability to extract the THV surgically without replacing the aortic root. TAVR-in-SAVR is approved for high- or extreme-risk patients and is a relatively simple procedure, but comes with a higher risk of coronary obstruction41-42. In patients with small surgical valves, balloon valve fracture may be feasible in certain bioprostheses43. These choices must be weighed carefully, especially since re-operative SAVR is safe with low mortality in low-risk, younger patients44. In failing THVs, redo-TAVR has seldom been described. In contrast to TAVR-in-SAVR, the THV stent frame in redo-TAVR is typically higher than surgical valves with an associated higher risk of coronary obstruction. To this end, Tang et al. have devised a classification scheme using angiographic data describing the aortic valve root anatomy relative to valve positioning and stent frame dimensions to determine the feasibility of redo-TAVR45. Furthermore, because THV orientation relative to native commissures tends to be random and the native aortic valve leaflets become barriers to the coronary orifices, leaflet management techniques, such as Bioprosthetic or native Sclap, Intentional Laceration to prevent iatrogenic Coronary Artery obstruction during TAVR (BASILICA), may not adequately reduce coronary obstruction risk in redo-TAVR46.

**Endocarditis**

Rates of prosthetic valve endocarditis (PVE) after TAVR and SAVR have reportedly been similar, around 1.5% within a year. In 20,006 patients who underwent TAVR, Regueiro et al. discovered a 1.1% incidence per person-year of PVE with a higher risk cohort. Eighty-two percent of patients who underwent TAVR and SAVR were found to have no significant difference in risk (3.4/1,000 person-years vs. 2.9/1,000 person-years over an 8-year observational time period)47. Yeo et al. similarly found younger age as an independent risk factor when looking at 41,025 patients with TAVR (OR 0.92, 95% CI 0.89 to 0.95), and so did Kolle et al. in an evaluation of 29,306 TAVR patients. Larger stent posts, groin access, involvement of pacemaker leads (given higher rate of implantation), and decreased sterility outside of a main operating room could be possible reasons48-50.

**Conclusion**

TAVR is rapidly becoming an appealing option for a younger, low-risk population that may not wish to undergo surgery. Given recent trial data, estimated surgical risk no longer directs the dichotomy between TAVR and SAVR. As this paradigm shifts, issues such as new conduction abnormalities, coronary reaccess, structural valve deterioration and long-term durability all need to be discussed with the patient. Appropriate patient selection based on clinical and anatomic factors is of the utmost importance when considering candidacy for TAVR versus SAVR.

**References**

13. Mack MJ, Leon MB, Thourani VH et al. Transcatheter Aortic Valve Replacement with a Balloon-Expandable Valve in
Melody® Transcatheter Pulmonary Valve | Ensemble® Transcatheter Valve Delivery System

Important Labeling Information for the United States

Indications: The Melody® TPV is indicated for use in the management of pediatric and adult patients who have clinical indications for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic pulmonary valve that has a moderate or severe regurgitation and/or a mean RVOT gradient ≥ 35 mm Hg.

Contraindications:

Contraindications

If a stent fracture is detected, continued monitoring of the stent should be performed until clinical judgment indicates it is safe to discontinue implantation.

DO NOT implant if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.

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/leaks, 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 fractures, stent fracture resulting in recurrent obstruction, embolization, migration or embolization of the device, valve dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

The term “stenosis” refers to the fractioning of the Melody TPV, however, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stenosis fractions to the Melody frame versus another stent.

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

The Melody Transcatheter Pulmonary Valve and Ensemble Transcatheter Delivery System have received CE Mark approval and are available for distribution in Europe.


A Melody for the Elderly

By Aphrodite Tzifa, MD, FRCPC; Dimosthenis Avramidis, MD; Dimitra Loggiati, MD, PhD; Konstantinos Spargias, MD, PhD

Transcatheter implantation of pulmonary valves for treatment of Right Ventricular Outflow Tract dysfunction was first reported in 2000. Since then, over 10,000 patients have received transcatheter therapy with a Melody percutaneous valve for failed pulmonary conduits. The vast majority of these patients have been children or young adults, mostly because Complex Congenital Heart Disease surgery started taking place after the 1970s.

However, older patients who have received a pulmonary conduit for other indications, such as the Ross procedure for Aortic Valve Disease, may present with conduit failure at a more advanced age. A contributing factor to the latter is the fact that the homograft homograft longevity is superior in the Ross setting rather than in other Congenital Heart Disease entities.

We report the case of an 81-year-old patient who presented with pulmonary homograft dysfunction and received transcatheter valve therapy in the pulmonary position whilst retaining the Melody valve inside it for a 31-year-old pulmonary homograft. To the best of our knowledge, this is the oldest patient to date who has received transcatheter pulmonary valve implantation therapy.

The patient presented with aortic stenosis at the age of 50 years after a Ross operation in 1986 by Professor Donald Ross. His homograft was noted to be calcified and stenosed 14 years later, but due to good clinical condition, the patient had refused a re-operation. He remained under frequent follow-up and became symptomatic with clinical signs of pedal oedema and ascites, requiring multiple hospitalisations, one year before the patient was referred for transcather therapy.

Non-invasive imaging with CT and MRI showed a heavily calcified and stenosed homograft (Figures 1, 2). Since then, over 10,000 patients have received transcatheter therapy with a Melody percutaneous valve for failed pulmonary conduits. The vast majority of these patients have been children or young adults, mostly because Complex Congenital Heart Disease surgery started taking place after the 1970s.

By Aphrodite Tzifa, MD, FRCPC; Dimosthenis Avramidis, MD; Dimitra Loggiati, MD, PhD; Konstantinos Spargias, MD, PhD

Transcatheter implantation of pulmonary valves for treatment of Right Ventricular Outflow Tract dysfunction was first reported in 2000. Since then, over 10,000 patients have received transcatheter therapy with a Melody percutaneous valve for failed pulmonary conduits. The vast majority of these patients have been children or young adults, mostly because Complex Congenital Heart Disease surgery started taking place after the 1970s.

However, older patients who have received a pulmonary conduit for other indications, such as the Ross procedure for Aortic Valve Disease, may present with conduit failure at a more advanced age. A contributing factor to the latter is the fact that the homograft homograft longevity is superior in the Ross setting rather than in other Congenital Heart Disease entities.

We report the case of an 81-year-old patient who presented with pulmonary homograft dysfunction and received transcatheter valve therapy in the pulmonary position whilst retaining the Melody valve inside it for a 31-year-old pulmonary homograft. To the best of our knowledge, this is the oldest patient to date who has received transcatheter pulmonary valve implantation therapy.

The patient presented with aortic stenosis at the age of 50 years after a Ross operation in 1986 by Professor Donald Ross. His homograft was noted to be calcified and stenosed 14 years later, but due to good clinical condition, the patient had refused a re-operation. He remained under frequent follow-up and became symptomatic with clinical signs of pedal oedema and ascites, requiring multiple hospitalisations, one year before the patient was referred for transcatheter therapy.

Non-invasive imaging with CT and MRI showed a heavily calcified and stenosed homograft (Figures 1, 2). Since then, over 10,000 patients have received transcatheter therapy with a Melody percutaneous valve for failed pulmonary conduits. The vast majority of these patients have been children or young adults, mostly because Complex Congenital Heart Disease surgery started taking place after the 1970s.

The patient presented with aortic stenosis at the age of 50 years after a Ross operation in 1986 by Professor Donald Ross. His homograft was noted to be calcified and stenosed 14 years later, but due to good clinical condition, the patient had refused a re-operation. He remained under frequent follow-up and became symptomatic with clinical signs of pedal oedema and ascites, requiring multiple hospitalisations, one year before the patient was referred for transcatheter therapy.

Non-invasive imaging with CT and MRI showed a heavily calcified and stenosed homograft (Figures 1, 2). Since then, over 10,000 patients have received transcatheter therapy with a Melody percutaneous valve for failed pulmonary conduits. The vast majority of these patients have been children or young adults, mostly because Complex Congenital Heart Disease surgery started taking place after the 1970s.
drugs to just 20mg of Furosemide once a day.

Discussion

Transcatheter valve implantation has become routine therapy for elderly patients with Aortic Valve Disease and for selected congenital patients with pulmonary or Tricuspid Valve Disease. Moreover, reports of hybrid or transcatheter implantation of valves in the mitral position have been on the rise. The benefit of a transcatheter approach versus open-heart revalvulation is greater in multi-operated patients with significant comorbidities or in patients of advanced age. Valve-in-valve therapy in the pulmonic position is particularly important as modern transcatheter therapies are continuously expanding their potential applications and, on the other hand, the congenital population is growing older.

References

The NuDEL™ Stent Delivery System is designed for the efficient and effective treatment of Coarctation of the Aorta.

The NuDEL™ Stent Delivery System is an all-in-one aortic stent system that includes a triaxial balloon in balloon designed catheter with a covered mounted CP Stent™, which is then covered by a sheath as an all-in-one system. Combining the proven technologies of our NuMED BIB® balloon catheter and our Covered CP Stent™, the NuDEL System employs both our compact delivery method and the “zig” pattern stent design.

The NuDEL System is available for immediate purchase in the EU. Contact us or your local distributor to place an order.

Medical News, Products & Information

Real-time magnetic resonance imaging (MRI) guidance enables excellent soft tissue visualization and does not use ionizing radiation to perform diagnostic and interventional cardiac catheterizations, a particularly important consideration in congenital heart defect patients who often need multiple procedures throughout their lifetime, including X-ray-dependent cardiac catheterization. In addition to reduced X-ray exposure for patients and clinicians, MRI enables additional and more detailed imaging, which in many cases improves diagnostics.

“Cardiac catheterization in the MRI suite has been primarily limited to diagnostic procedures due to lack of MRI compatible guidewires and other interventional equipment. The availability of the EmeryGlide guidewire in the United States, the only 510(k) cleared MR conditional guidewire, has enabled me to advance catheters to places that were previously not possible, especially in complex congenital heart disease patients,” said Dr. Suren Reddy from UT Southwestern/Children’s Medical Center, Dallas. “This guidewire has the potential to significantly advance the field of MR guided cardiac catheterizations and interventions.”

Dr. Madhav Swaminathan Elected President of the American Society of Echocardiography

Madhav Swaminathan, MD, MBBS, MMCI, FASE, has taken the helm as President of the American Society of Echocardiography (ASE). His presidency, which will last one year, marks the first time that an anesthesiologist has been elected to head ASE in its 44-year history.

Dr. Swaminathan addressed the members of the Society at their annual business meeting and shared his excitement for leading ASE for the next year. He said, “ASE has taken an unprecedented step of tapping the first anesthesiologist as its president. It is a bold statement about celebrating diversity. I look forward to leading the Society that has opened its arms to everyone who is interested in cardiovascular ultrasound. In addition to guiding ASE into a new strategic plan beginning in 2020, I am committed to building a network of leaders that supports the well-being of the entire cardiovascular ultrasound community.”

Dr. Swaminathan is Board-Certified in Anesthesiology and Perioperative Transesophageal Echocardiography. He is Vice Chair for Faculty Development, Duke Anesthesiology, and Professor of Anesthesiology, Duke University School of Medicine. He joined the faculty at Duke in 2002 and rose rapidly to the rank of professor with tenure, winning teaching and community service awards along the way. Administratively, he served as Director, Perioperative Echocardiography Service from 2004-2014, where he transformed Duke’s research in echocardiography, developed new echo educational initiatives, and brought practitioners of cardiovascular ultrasound together. In his role as the vice chair for faculty development, he is responsible for nurturing the faculty with the vision, mentorship, opportunities, and infrastructure they need to be leaders in changing the face of perioperative medicine. His research interests focus on diastolic dysfunction as well as kidney outcomes after cardiac surgery. He has published over 160 papers in peer-reviewed journals and has written several editorials and book chapters, and is a co-editor of a popular textbook on perioperative echocardiography.

In 2015, Dr. Swaminathan was named the 16th Feigenbaum Lecturer at the ASE Scientific Sessions. This was the first time an anesthesiologist was given this honor, which is awarded to a young investigator in recognition of their significant contributions to research in the field of cardiovascular ultrasound and their potential to continue at a high level of achievement. Dr. Swaminathan has held many significant roles on ASE committees, including chair of the Membership Committee and chair of the Council on Perioperative Echocardiography.
Forty-four New Cardiology Sites in 2018 – Geneva Health

Geneva University Founded in 2018 – Geneva University

Increased Patient Outreach – Today, more than 30,000 are

Employee Growth – In response to the company's

(COPE). He has also served on the Industry Relations Committee, Education Committee, and as co-chair and chair of the Perioperative Echocardiography track for ASE's Scientific Sessions from 2011-2015. He currently serves on the editorial board of CASE, ASE's cardiovascular imaging case reports journal. He has participated on other writing groups and taskforces, including Governance, Public Relations, and Non-Traditional Users.

Dr. Swaminathan is active in a number of other professional societies, including the American Medical Association, the Society of Cardiovascular Anesthesiologists, the American Heart Association, the Association of University Anesthesiologists, and the International Anesthesia Research Society.

He attended college in India, earning an MBBS with distinction at Delhi University. He completed residencies and fellowships in Anesthesiology and Critical Care at the Royal Victoria Hospitals Trust, Belfast, Northern Ireland; Catholic University of Louvain, Belgium; and FASE, Duke University Medical Center, Durham, NC (Pediatric Council Steering Committee Chair); Aline Nicoara, MD, FASE, Duke University Medical Center, Durham, NC (Perioperative Council Steering Committee Chair); S. Pearlman, MD, FASE, Seattle, WA (Past President); Peter Ranko, MD, FASE, University of Wisconsin, Milwaukee, WI; Jennifer Scharf, BS, ACS, RDCS, FASE, The Christ Hospital Health Network, Cincinnati, OH; Vandana Sachdev, MD, FASE, National Institute of Health, Bethesda, MD; and Kathy West, MSc, DMU (CARDIAC), AMS, EACVI CHD, FASE, Royal Brompton Hospital, London, UK (International); Geoffrey Rose, MD, FASE, Sanger Heart & Vascular Center, Charlotte, NC, will also serve on the board after being appointed for his exceptional service.

Edwards PASCAL Transcatheter System Receives CE Mark

PRNewswire – Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovators for Structural Heart Disease and Critical Care monitoring, today announced the Edwards PASCAL transcatheter valve repair system has received a CE Mark for the treatment of patients with mitral regurgitation.

“Mitral valve disease is complex, varied and prevalent, and patients are in significant need of multiple safe and effective therapies to treat debilitating symptoms that can lead to a high rate of mortality,” said Bernard J. Zovighian, Edwards' Corporate Vice President, Transcatheter Mitral and Tricuspid Therapies. “The introduction of the PASCAL system to clinicians and patients in Europe provides a differentiated, minimally-invasive therapy to address the needs of patients with mitral regurgitation.”

The PASCAL system is designed for effective reduction of mitral regurgitation while respecting the native anatomy. It features contoured, broad paddles to maximize coaptation of the mitral leaflets, and a central spacer that fills the regurgitant orifice area. The delivery system allows for independent leaflet capture and the ability to optimize leaflet position.

“The PASCAL system is uniquely designed for optimized valve leaflet capture and coaptation, and to help operators achieve their ultimate goal of safe and effective treatment of mitral regurgitation reduction for their patients,” said Konstantinos Sparagis, THV Director, Hypeia Hospital, Greece, and an investigator in the multi-national prospective CLASP Study.

The PASCAL system is one of multiple transcather repair or replacement therapies designed to address mitral and tricuspid valve diseases that are under development by Edwards. It represents the culmination of 20 years of innovation by Edwards to develop a novel, differentiated and advanced platform for patients in need. The company is building upon a long history of knowledge, experience and commitment to advance transformative therapies and develop a robust body of clinical evidence.

The PASCAL system is not approved in the United States; the CLASP IID U.S. pivotal trial is currently enrolling patients with symptomatic primary mitral regurgitation.

Dr. Sparagis is a consultant to Edwards Lifesciences.

Geneva Health Solutions Hits Critical Milestones Driving Growth; Predicts Cardiac Data Explosion in 2019

Geneva Health Solutions (GHS), the leading cloud-based technology platform and service for managing data from implantable cardiac devices, announces triple-digit revenue growth in 2018, an indicator of the explosive growth of implantable cardiac device data expected in 2019. GHS has also tripled its client base and workforce, quadrupled the number of devices being monitored through its service and increased its revenue more than ten-fold.

“Data deluge from implanted cardiac devices has hit critical mass for cardiac practitioners, manufacturers and our ability to become an extension of their team and implement an effective remote monitoring program is truly improving patient care,” said Yuri Suthahar, CEO of Geneva Health Solutions. “Armed with actionable information every day, cardiologists can proactively reach out to patients with device issues and arrhythmias like atrial fibrillation and heart failure diagnostics well in advance of a significant health problem.

The GHS patient-pending platform aggregates cardiac device data from all major implantable cardiac device manufacturers’ remote monitoring portals and in-office checks. The GHS remote monitoring service helps providers manage the incoming data and alerts, improves patient compliance and has significant clinical benefits including the early detection of device issues and arrhythmias as well as a reduction in hospitalizations, and thus patient care costs.

Significant Milestones for 2018 Include:

• Forty-four New Cardiology Sites in 2018 – Geneva Health Solutions' client list has grown from 16 clinics to over 65 cardiology sites in one year, with 45 of those sites also using the Geneva Health Solutions Remote Monitoring Service.

• Improved Remote Monitoring Pathway Financials – GHS eliminates workflow inefficiencies, optimizes reimbursement, and provides device clinic resource support to ensure clinics can properly implement the remote monitoring standard of care. With the GHS service, cardiology providers have experienced over a 70% improvement in the profitability for the standard of care by optimizing reimbursement and reducing costs.

• Increased Patient Outreach – Today, more than 30,000 are being monitored by the GHS Remote Monitoring Service, a 4x growth from last year. GHS has become an extension of the device clinic, assisting overextended clinic staff, improving patient adherence and compliance as well as mitigating liability.

• Geneva University Founded in 2018 – Geneva University is a rigorous training program in data analytics and preparation for cardiac device technicians to help them achieve the highest standards in cardiac remote monitoring.

• Employee Growth – In response to the company’s unprecedented growth, GHS nearly tripled its employee count this year. More than 40 new cardiac device
Texas Children’s Hospital Again Ranks Among the Best Children’s Hospitals Nationally by US News & World Report

Texas Children’s Heart Center and Pulmonology Rank 1st Nationwide

Texas Children’s Hospital is proud to consistently be recognized as a leader in pediatric care by U.S. News & World Report, tying for third overall in their 13th annual Best Children’s Hospitals rankings. Again, Texas Children’s is named as the best place in the country for children in need of both pediatric cardiology and heart surgery, as well as pulmonary care. Additionally, six of the hospital’s subspecialties rank in the top three and all rank within the top 10.

For more than 60 years, the integrated, multidisciplinary team at Texas Children’s Heart Center has combined cutting-edge technology with a compassionate and family-centered approach to care. Annually, nearly 1,000 surgeries and more than 1,300 cardiac catheterization procedures are performed in the new, state-of-the-art Lester and Sue Smith Legacy Tower, the home of Texas Children’s Heart Center, where a team-based approach brings experts in every aspect of cardiac care to the bedside.

Texas Children’s Heart Center cardiologists, congenital heart surgeons, cardiac anesthesiologists and cardiac intensivists are world-renowned leaders in the field and work together to treat some of the rarest and most complex heart cases from Houston, across Texas, the U.S. and around the world. The multidisciplinary team strives to provide unparalleled care at every point from diagnosis through treatment and follow-up, in order to achieve the best possible care for each patient.

Areas of special expertise of the Heart Center include: cardiac catheterization, congenital heart surgery, electrophysiology, adult congenital heart disease, cardiac nursing, cardiac critical care, coronary artery anomalies, pulmonary vein stenosis, Marfan syndrome and connective tissue disorders, and one of the largest cardiac transplant and ventricular assist device programs in the world.

The Destination for Children with Lung Disease

Offering services to treat children dealing with any breathing problem, Texas Children’s pulmonary team manages a wide range of common and rare pediatric lung disorders. With more than 16,000 outpatient visits annually, the hospital has numerous specialty clinics focused on severe asthma, cystic fibrosis, pulmonary hypertension, lung transplant clinic, tracheostomy and ventilator, aerodigestive multispecialty clinics, sleep disorders, and more.

The hospital’s pulmonary team offers a wide array of specialized programs. Texas Children’s Cystic Fibrosis (CF) Care Center is the only accredited pediatric CF center in Southeast Texas. Its Pulmonary Hypertension Program is one of the few programs in the U.S. dedicated to treating children. Because of this, Texas Children’s has extensive experience in the diagnosis and treatment of infants, children and teens with this rare condition. Additionally, Texas Children’s has one of the largest and most successful pediatric lung transplant programs in the world and is one of only two institutions worldwide that performs an average of 10 pediatric lung transplants each year. With a typical wait time of four to six months for new lungs, Texas Children’s transplants children from all areas of the United States. As a result of these programs and others, Texas Children’s is also one of the largest training programs of future pediatric lung specialists.

Texas Children’s Heart Center and Pulmonology is ranked 1st nationwide.

For more information, visit www.CongenitalCardiologyToday.com

Subscribe Electronically to CCT
Free on the Home Page
www.CongenitalCardiologyToday.com

Recruit with CCT
Recruitment Advertisements are Listed
- In print and electronic monthly issue
- On CCT’s website
- In CCT’s monthly email blast
Contact: Kate@cct.bz

Global Leader in Pediatric Heart Care

www.healt.usnews.com/best-hospitals/pediatric-rankings

Find us on Facebook, Twitter, and Instagram
NIT-OCCLUD® Coil System
for PDA Closure
Designed For the Safe and Atraumatic Occlusion of the Congenital Heart Defect PDA (Patent Ductus Arteriosus)

INDICATIONS FOR USE:
The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm.

NIT-OCCLUD BRIEF STATEMENT:
Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Wood Units), thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the vicinity of the implantation site at the time of the implantation or patients with a body weight < 11 lbs. (5kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfm medical implantation delivery catheter should be used to implant the device. Administration of 50 units of heparin per kg bodyweight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 dose) and after implantation (2 doses) to prevent infection during the implant procedure. Do not implant the Nit-Occlud coil through heart valves or ventricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to this device due to small amounts of nickel that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, he/she should be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent infective endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Allergic reaction to drug/contrast, Anea, Arrhythmia requiring medical treatment or pacing, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteritis, False aneurysm of the femoral artery, Fever, Headache/ Migraine, Heart failure, Hemolysis after implantation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial infarction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (centrals or pulmonary), Vascular Regurgitation, Vessel damage at the site of groin puncture (loss of pulse, hematoma etc.).

Nit-Occlud is a registered trademark of pfm medical Inc.
Rx only

Distributed by:
B. Braun Interventional Systems Inc.
824 Twelfth Avenue | Bethlehem, PA 18018 | USA
Tel 877 836 2228 | Fax 610 849 1334 | www.bisusa.org