A Message from the Medical Director:

This edition of the Hartford HealthCare Heart & Vascular Institute Research Newsletter will continue to highlight the many research endeavors of investigators across all HVI departments, and will also focus on several important new themes and advances made possible by multidisciplinary collaboration within and outside the scope of institute operations.

Finding ourselves in the midst of another wave of the COVID-19 pandemic, this issue will begin by highlighting the work of Jeffrey Mather, MS in his efforts to maintain and publish from the Hartford HealthCare COVID-19 Registry. While the pandemic has placed considerable stress on our entire healthcare system, Jeff has taken the lead in data collection and analysis to gain valuable insight in the pathophysiology and treatment of SARS-CoV-2 infection.

Correcting ethnic and racial disparities in the care we provide our patients is a critical goal for Hartford HealthCare. As an example of the care imbalance between minorities and Caucasians treated by the HVI, our Structural Heart Department team recently published a report on the use of transcatheter aortic valve replacement (TAVR) in Afro-American and Latino subgroups at Hartford Hospital and across the state (Ali A, et al. Racial and ethnic disparities in the use of transcatheter aortic valve replacement in the State of Connecticut. Cardiovasc Revasc Med. 2021 Jun 25:S1553-8389(21)00453-X). Notably, in an analysis of more than 2,000 patients treated with TAVR at Hartford Hospital since 2012, fewer than 3 percent of procedures were performed in minorities.

In this issue of the research newsletter, Dr. Trevor Sutton from the Department of Anesthesia outlines his efforts to collaborate with multiple HVI departments to identify and correct racial/ethnic disparities. This includes results from a recent study that shows success in improving disparities in patients undergoing coronary artery bypass grafting at Hartford Hospital with the adoption of the Enhanced Recovery after Cardiac Surgery (ERACS) clinical pathway. Similarly, we will highlight the investigative work of Patty Bozeman, APRN in her current collaborative efforts with Dr. Sutton, Dr. Edward Gifford and colleagues from Vascular Surgery to describe local and national disparities in the use of lower extremity amputation.


In concert with investigators from the Massachusetts Institute of Technology Operations Research Center and Sloan School of Management and the USC Marshall School of Business, Dr. Hagberg and colleagues examined outcomes of 383,550 mitral valve surgery procedures from the STS Adult
Cardiac Surgery Database between 2008 and 2017. They derived risk models that were more accurate than the existing STS risk calculator, particularly for mortality, prolonged ventilation and renal failure. The results of this landmark study represent one of the first published analyses on the use of advanced machine learning methods for the prediction of surgical risk in the context of mitral valve surgery.

As an example of multidisciplinary collaboration within HVI, Drs. Bryan Piccirillo (Interventional Cardiology) and Sabeena Arora (Advanced Heart Failure) will serve as principal investigators for the CorCinch-HF Trial (Ancora Heart, Inc; ClinicalTrials.gov Identifier: NCT03533517). This study will evaluate the safety and efficacy of the AccuCinch ventricular restoration system in patients having symptomatic heart failure with reduced left ventricular ejection fraction. The transcatheter AccuCinch system is used to treat the enlarged left ventricle by improving the structure and function of the heart, and help bring relief to heart failure patients who remain symptomatic despite current guideline-directed medical care. During the minimally-invasive AccuCinch procedure, a flexible implant is attached to the inner wall of the left ventricle and then cinched. The implant is intended to reduce the size of the left ventricle, reduce ventricular wall stress and support and strengthen the heart wall. The AccuCinch system may enable improved functional capacity and quality of life for patients, while potentially slowing or reversing left ventricular remodeling associated with their heart failure progression. Drs. Piccirillo and Arora will lead a team of interventional cardiologists, heart failure specialists and echocardiographers in the recruitment and treatment of patients.

Finally, we are proud to announce the establishment of a new HVI Research website that will be available to all in the near future. Designed by Noa Mencher RN, BSN, MPA, we hope this will serve as a critically important tool for communication among investigators and a useful resource for patients interested in participating in one of our many HVCI research trials.

Raymond G. McKay MD  
HVI Director of Research
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Research Personnel Profile:

Each issue, we will profile a member of the Hartford HealthCare and HVI research program who provides critical support for the research endeavors of our many investigators. Jeffrey F. Mather, MS has served as the Director of Data Management at Hartford HealthCare since 2005. The Data Management Group (DMG) creates and maintains data warehouses for research projects, quality management, and operational support. In his current role, he directs all facets of data mining, abstraction and statistical support for the entire healthcare system. Leading a team of five data managers armed with an intimate knowledge of Hartford HealthCare’s administrative and research data sources (EPIC, Allscripts ED, EPSI, SIS, STS, TVT, NCDR, CARES), Jeff has been instrumental in the development, governance and quality control of numerous hospital registries (Covid-19, STROKE, Bariatric Surgery, Prostate Cancer, Bladder Cancer, Histocompatibility), including multiple HVI research databases (Interventional Cardiology, Transplant, TAVR, OHCA). In the past, Jeff has developed the HHC Research Department database for registering protocols, tracking and routing both pre- and post-award approval process, and managing finances. He has also provided direction and metrics for several of Hartford Hospital’s strategic goals, including heart failure and pneumonia readmissions, ED throughput, patient falls, and patient satisfaction.

Jeffrey F. Mather, MS
Director of Data Management

What is your educational background? Your work background prior to HHC?
After receiving a Bachelor of Science degree in Biology from Trinity College in 1980, I went on to receive a Master of Science in Animal Science from the University of Connecticut in 1986. I joined HHC in 1990 as a Research Analyst in the Department of Transplant and Surgical Research and moved to Research Administration in 2000 as a business system analyst and then to his present position in 2012.

Can you discuss your recent efforts to collect and manage data on the COVID-19 pandemic?
Early in the pandemic, I lead efforts to construct the Hartford HealthCare COVID-19 Registry. This registry includes all consecutive patients screened for COVID-19 starting from February 24, 2020 to present at Hartford HealthCare. All patients who tested positive for SARS-CoV-2 by nasopharyngeal polymerase chain reaction and who required inpatient admission are included in the registry. The database has been made available to all investigators across Hartford HealthCare and has led to multiple studies.

What publications have come from the COVID-19 Registry?
Several months after collecting data on COVID-19 inpatients, I noticed in our analysis of risk factors for severe disease and death that asthma was not a significant predictor of poor outcomes. In fact, logistic regression analysis demonstrated that asthma was an independent predictor of both lower mortality and combined death/intubation.

How long have you been involved in heart and vascular research?
Over the last two decades, I have co-authored more than 70 manuscripts and abstracts with HVI investigators, including multiple reports on perfusion imaging, safety and efficacy of drug-eluting stents, use of pharmaco-invasive therapy for STEMI patients, factors underlying post-CABG atrial fibrillation, assessment of BNP monitoring in patients with heart failure, and multiple reports on TAVR.

What is the biggest challenge you face in research?
It’s been said that 80 percent of clinical data is buried in unstructured physician notes. The challenge is to convert this to structured data, institute-reliable natural language processing (NLP) or text-mining algorithms to access this data so it can be used to make advanced decisions using machine learning/artificial intelligence.

What do you do for fun?
Bike riding, hiking, skiing and traveling.
Investigator Profiles:

Trevor Sutton, MD, MBA, CPE
Cardiothoracic, Vascular and Transplantation Anesthesiologist,
Integrated Anesthesia Associates, LLC

What is your educational background? Your work background prior to HHC?
I studied biochemistry at Harvard College, attended medical school at the University of California, San Francisco School of Medicine (UCSF), completed an internship in medicine, residency in anesthesiology, and fellowship in cardiothoracic and vascular anesthesia at Massachusetts General Hospital.

I began my career at Barnes Hospital and the Washington University School of Medicine, where my clinical focus was anesthesia for vascular surgery and liver transplantation. There, my interest in the intersection between research, quality and organizational science was sparked. I joined the faculty at Brown Medical School, with clinical work and research activities at Rhode Island Hospital. I was recruited as chairman and director of cardiac anesthesia for St. Mary’s Hospital and the Waterbury Heart Program, and subsequently served as assistant regional medical director and regional medical director for the North Division of a national anesthesia practice management company.

I joined HHC in 2018 as a member of Integrated Anesthesia Associates, LLC. I am a member of the cardiothoracic and vascular anesthesia team, and the liver transplantation anesthesia team at Hartford Hospital.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?
I have always considered research to be a complement to my focus in patient care. Research has supported my ability to develop in-depth perspectives on important aspects of patient care in cardiovascular and transplantation surgery. Research has also provided a platform for innovation and mentoring throughout my career. Finally, I find research collaboration intellectually stimulating, and I believe it generates value in medicine by identifying solutions to challenges in patient care.

How long have you been involved in research in general? In heart and vascular research?
I have been involved in research since my freshman year in college when I was a work-study student in laboratories at Harvard Medical School studying human circadian physiology. As an undergraduate, I wrote a thesis on a mouse cell transformation model that incorporated the ras oncogene.

What is your favorite research project to date and why?
Through a recent collaboration between the Heart & Vascular Research Institute, Hartford Hospital Clinical Research Center, and departments of Anesthesiology, Cardiac Surgery and Cardiology at
Hartford Hospital, we conducted a five-year retrospective study utilizing the Society of Thoracic Surgery clinical data registry. We found that Hartford Hospital’s enhanced recovery for cardiac surgery clinical care pathway, implemented in 2018, improved overall outcomes regarding patient safety, mobilization and decreased opioid consumption following coronary artery bypass surgery. What was novel was that we found there was also a reduction in racial and ethnic disparities in postoperative length of stay and intensive care unit readmission. We believe this may be the first demonstration that enhanced recovery after cardiac surgery care pathways can function as a health equity initiative as well as a quality improvement initiative.

What are your current research projects?
My current projects focus on health equity in the domain of perioperative care for patients undergoing cardiovascular surgery and solid organ transplant surgery. One will determine regional and national trends in disparities regarding management of peripheral vascular disease, limb salvage, and restoration of ambulation status with prosthesis management and rehabilitation within one year of lower extremity amputation. Another project will explore the effect of structural health system incentives, physician beliefs and patient concerns and preferences on utilization of cardiovascular surgical services.

If money and time were not an option, what medical question would you research?
I would perform research designed to provide accessible and effective

Impact of the Affordable Care Act on Disparities in Lower Extremity Amputation and Post-Amputation Rehabilitation in the United States: Retrospective Review of the Vascular Quality Initiative (VQI) and Vascular Study Group of New England (VSGNE) Data Registry

Background:
The number of lower limb amputations in the United States has grown over the last two decades, and it is thought that this reflects the prevalence of peripheral vascular disease (PVD) and diabetes in the United States (1). In 2005, there were approximately 1.6 million lower limb amputations in the United States (2). It is currently projected that there will be more than 3.6 million amputations in the United States by 2050 (3). This estimate considers that approximately 185,000 patients undergo lower limb amputation each year in the United States (2).

Patient and societal costs associated with limb amputation are substantial. In one report, the direct cost and lifetime costs, respectively, associated with lower extremity amputation were greater than $80,000 for the index amputation procedure, and greater than $500,000 for lifetime costs (4). Although these calculations may vary with study time frame and methodology (5,6), it is clear that lower extremity amputation is an expensive procedure for both patients and healthcare systems (2).

Current public health debates regarding the growth of limb amputation in the United States are associated not only with concerns related to financial costs, but also concerns regarding the following: (1) mortality, morbidity, and quality of life following limb amputation (1); (2) disparities in risk for amputation based on race, ethnicity, gender, socioeconomic level, and geographic area of residence (2); (3) quality of life frequently decreases following limb amputation (2,7). This may reflect changes in mobility, activity levels, employment, and ability to function independently (2,7). Amputees have higher rates of depression, anxiety, and negative body image (8). Mortality rates within 1-3 years following limb amputation are significantly higher for amputees than non-amputees with PVD (9).

Regarding disparities associated with limb amputation, the lower extremity assessment project (LEAP) demonstrated that poverty, lack of private insurance, and non-white race were predictors of worse health status following lower extremity amputation (9). Racial, ethnic, socioeconomic, and geographic disparities have been reported for the management of limb ischemia and the risk of lower extremity amputation (10,11). Although a higher prevalence of diabetes, more severe vascular disease, and low socioeconomic level have been suggested as causes for higher rates of amputation in minorities, when these variables were controlled race and ethnicity remained independent predictors for amputation (13,14).
population-based treatment of diabetes and hypertension.

**What is the biggest challenge you face in research?**
Health equity research is challenging because the causes of disparities in access to care and outcomes of care are typically multi-factorial. Health equity research is, at its core, quality improvement research. The discipline of health equity research, however, spans not only traditional scientific methods in epidemiological and public health science, but also social science, and public health policy.

**What do you feel research has contributed to the field in the past two or three decades?**
Scientific reports from the U.S. Surgeon General, World Health Organization, Institute of Medicine, National Institute of Health and health scientists have promoted widespread recognition that both social determinants of health and structural bias in medicine can contribute to disparities in access and outcomes of medical care. Importantly, this research has indicated that these disparities are not only mutable, but their resolution is also a public health imperative.

**If you weren’t a heart and vascular researcher, what would you be doing?**
I would be engaged in organizational quality improvement, physician leadership, education, mentoring.

**What do you do for fun?**
I look forward to spending quality time with my wife and daughter. We enjoy travel, museums, culinary arts, gardening and sports such as golf, tennis, squash and platform tennis.
Patty Bozeman, APRN, CVN  
Vascular Surgery

What is your title? Your educational background? Your work background prior to HHC? When did you join HHC?

My title is vascular surgery APRN, and System Quality Manager of the Vascular Quality Initiative, an international data base designed by a group of vascular surgeons in New England as the standard by which quality is measured in vascular surgery. I earned my bachelor’s in nursing at St. Anselm College, and master’s in perioperative nursing at the University of Connecticut. I am certified by the American Nursing Credentialing Center in adult nursing and vascular nursing.

I’ve been a nurse for 35 years, starting at Hartford Hospital on the dedicated vascular unit. After I earned my master’s degree, I worked at Bristol Hospital as a case manager, Waterbury Hospital as an educator, Windham Hospital as CNS, and the University of Connecticut Health Center as a vascular APRN. I joined HHCMG in May 2009.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?

From the day I began my nursing career, I found a passion in caring for patients with vascular disease. Since that time, in any of my positions, vascular patients have been at the forefront of my practice. This is a great population to care for because vascular disease, in most cases, is chronic. Therefore, you have the opportunity to see patients year after year. They almost become your family.

In 1989, I attended my first meeting of the Society for Vascular Nursing (SVN) and attending its annual meetings exposed me to great practice and research. I presently serve on the SVN Board of Directors and as liaison to the research committee.

My philosophy is that best practice is guided by research. In my role with the Vascular Quality Initiative, robust data is collected and analyzed. This is a great jumping off point to ask questions, identify problems and develop a research proposal.

How long have you been involved in research?

More than 30 years.

What is your favorite research project to date and why?

Before joining HHCMG, I coordinated several carotid stenting post-marketing trials. Two papers were published as a result of these trials, examining patient outcomes after undergoing carotid angioplasty and stenting.
What are your current research projects?
I am working with Drs. Trevor Sutton, Ray McKay and Ted Gifford on a very exciting research project examining disparities in patients being treated for symptomatic peripheral arterial disease. This will be an ongoing project, eventually looking at functional outcomes and quality of life in patients with amputations. All of this evolved from asking a question, which in turn led to formulating a research proposal. The goal is that, ultimately, this will lead to improved care for a patient population. That is the beauty of research - to improve care and positively impact quality of life for patients, the essence of what healthcare providers want to achieve.

If you weren’t a heart and vascular researcher, what would you be doing?
I love being a nurse. Developing relationships with patients and providing them with the best care that I can is very satisfying. However, I do enjoy traveling, sports, and attending sporting events, hiking and skiing. I also very much enjoy food! My husband is a teacher and writer. So, if I had to do something else, I would very much enjoy being a traveling food critic.

What do you do for fun?
Exploring new places, trying food, critiquing food and then having my husband do the hard part and write all about it. That “career” would probably be incredibly satisfying!!
Robert Hagberg, MD
Chief of Cardiac Surgery

What is your educational background? Your work background prior to HHC?
Undergraduate degree in chemistry, master’s in biology, medical degree and cardiac surgery fellowship, all from Stanford University. Private practice in Norfolk, Virginia, through 2005, then Beth Israel Deaconess Medical Center, Boston, until joining HHC as chief of cardiac surgery in 2012.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?
Research allows us to change how we take care of patients and improves the quality of that care. I loved cardiac physiology and human anatomy classes in my first year of medical school. A cardiac surgeon lecture in anatomy class hooked me on cardiac surgery as a career.

Machine learning models for mitral valve replacement: A comparative analysis with the Society of Thoracic Surgeons risk score

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Affiliations  expand
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Abstract
Background: Current Society of Thoracic Surgeons (STS) risk models for predicting outcomes of mitral valve surgery (MVS) assume a linear and cumulative impact of variables. We evaluated postoperative MVS outcomes and designed mortality and morbidly risk calculators to supplement the STS risk score.

Methods: Data from the STS Adult Cardiac Surgery Database for MVS was used from 2008 to 2017. The data included 383,550 procedures and 89 variables. Machine learning (ML) algorithms were employed to train models to predict postoperative outcomes for MVS patients. Each model’s discrimination and calibration performance were validated using unseen data against the STS risk score.

Results: Comprehensive mortality and morbidity risk assessment scores were derived from a training set of 287,862 observations. The area under the curve (AUC) for mortality ranged from 0.77 to 0.83, leading to a 3% increase in predictive accuracy compared to the STS score. Logistic Regression and extreme Gradient Boosting achieved the highest AUC for prolonged ventilation (0.82) and deep sternal wound infection (0.78 and 0.77), respectively. Extreme Gradient Boosting performed the best with an AUC of 0.815 for renal failure. For permanent stroke prediction all models performed similarly with an AUC around 0.67. The ML models led to improved calibration performance for mortality, prolonged ventilation, and renal failure, especially in cases of reconstruction/repair and replacement surgery.

Conclusions: The proposed risk models complement existing STS models in predicting mortality, prolonged ventilation, and renal failure, allowing healthcare providers to more accurately assess a patient’s risk of morbidity and mortality when undergoing MVS.

Keywords: artificial intelligence; heart; machine learning; mitral valve surgery.

How long have you been involved in research in general? In heart and vascular research?
I have been involved in research since I was an undergraduate in the Department of Chemistry, and started heart/vascular research as a medical student. I received an American Heart Association scholarship to do research as a medical student working on cardiac transplantation. My research interests have changed as my career have evolved, however, my interests have remained in the field of cardiac surgery since medical school.

What is your favorite research project to date and why?
My favorite research project was the initial trans-catheter aortic valve trials. It was very exciting, groundbreaking and rewarding work which eventually changed how we treat aortic stenosis.

More recently, we have published a collaborative study with MIT examining the use of artificial intelligence in predicting outcomes for mitral valve replacement surgery.
What are your current research projects?

A. Transcatheter Mitral Valve Replacement.
B. Alternative anticoagulation strategies for mechanical aortic valves.
C. Single side branch aortic arch stent grafts.

If money and time were not an option, what medical question would you research?
The mechanism and prevention of tissue valve failure.

What is the biggest challenge you face in research?
Time.

What do you feel research has contributed to the field in the past two or three decades (or more)?
It has changed the way we treat patients with cardiovascular diseases in such a positive way.

If you weren’t a heart and vascular researcher, what would you be doing?
Climate change research.

What do you do for fun?
Swim, scuba diving, bike riding and traveling.
Jeffrey Kluger, MD
Director, Arrhythmia Services

What is your educational background? Your work background prior to HHC? When did you join HHC?
I did my undergraduate at Columbia College, medical school at New York Medical College, residency at Beth Israel in New York City and cardiology fellowship at New York Hospital-Cornell Medical School, where I was on the faculty, director of the CICU and did research in cardiovascular drugs. I came to Hartford Hospital in November 1980.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?
My interest in research has always been to answer clinically relevant questions and focus on practical diagnostics and therapeutics and outcomes (what happens to our patients and can we predict the future).

How long have you been involved in research in general? In heart and vascular research?
I started doing research in my cardiology fellowship and had great mentors. I continue to work on projects throughout my time at Hartford Hospital and now HHC.

What is your favorite research project to date and why?
The Atrial Fibrillation Suppression Trials I, II and III has been my most successful research accomplishment, as these were studies that were prospective, double blind placebo intervention trials investigator initiated with both internal and external funding with important therapeutic implications, in addition to multiple sub studies that contributed to our understanding of post-cardiac surgery observations and complications. I am proud that these studies were relatively uncommonly done at HH.

What are your current research projects?
I have a working group of collaborators looking to identify why some patients with an internal cardioverter defibrillator respond to painless rapid pacing therapies to terminate serious arrhythmias like ventricular tachycardia while others require a “shock.” Our research in this area has won three Paul D. Thompson Fellow Research prizes in the last four years.
If money and time were not an option, what medical question would you research?
In our current environment of high patient volumes and acuity, a critical question is how to train providers to be efficient but to avoid cognitive biases that contribute to medical missed opportunities and unfortunate outcomes.

What is the biggest challenge you face in research?
The time and financial support and an environment that values, encourages and rewards research accomplishments.

What do you feel research has contributed to the field in the past two or three decades (or more)?
The technologic and pharmaceutical advances have been phenomenal backed by basic science in genetics, biomedical engineering and clinical trials.

If you weren’t a heart and vascular researcher, what would you be doing?
Photographing birds.

What do you do for fun?
Photographing birds, landscapes and my young grandchildren.
Sean McMahon, MD
Associate Director of the Echocardiography Laboratory, Director of Quality for the Division of Cardiology

What is your educational background? Your work background prior to HHC? When did you join HHC?
I graduated from St. Lawrence University with a bachelor's degree in science and took a few years off before going to medical school. After graduating from SUNY Upstate Medical University, I moved to the University of Vermont Medical Center where I completed an internal medicine residency, chief year, and fellowship. I joined HHC in 2017.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?
I enjoy the journey of research, starting with an unmet need or unanswered question to the final revisions. Another important aspect is the opportunity to collaborate with colleagues. My research experience started back in Vermont where I was involved with the Cardiovascular Research Institute and worked on projects ranging from nuclear medicine to platelet function.

How long have you been involved in research in general? In heart and vascular research?
I began research as a second-year resident. This was my introduction to both general and heart and vascular research.

What is your favorite research project to date and why?
There isn’t one that I like more than the other. They each have been rewarding in different ways. I am excited about continuing to work on platelet function, something I have not been able to maintain until recently. I really enjoy anything that involves the mitral valve as well.

What are your current research projects?
I currently have projects exploring strain and amyloid cardiomyopathy, LA strain in patients with CVA, a few involving the structural heart database, and I support the structural heart teams research in therapies for the mitral valve and heart failure.
In addition, I recently became principal investigator of an externally-funded trial at Hartford Hospital assessing the prognostic implications of a novel marker of platelet function (FcyRIIa) and long-term cardiovascular risk which has recently been approved by the HHC IRB.

**What is the biggest challenge you face in research?**
Finding time.

**If money and time were not an option, what medical question would you research?**
The same ones I am now, maybe just to a larger scale.

**What do you feel research has contributed to the field in the past two or three decades (or more)?**
The cardiovascular research developed over past decades has shaped every aspect of our patient care. We are fortunate to practice in a field so rich in data that has been extraordinarily impactful on cardiovascular outcomes.

**If you weren’t a heart and vascular researcher, what would you be doing?**
My day job, practicing cardiology and echocardiography.

**What do you do for fun?**
Spending time with family.

My wife and two kids keep my busy outside of work. We spend a lot of time outdoors skiing, hiking, biking, camping, swimming, water sports and whatever else the kids are getting into. We like to travel and have an affinity for anywhere coastal.

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**Assessment of Individual Risk of Cardiovascular Events by Platelet FcγRIIa (FcyRIIa)**

**Study Description:** A Prospective, Observational Multicenter Non-Interventional Cohort Study

**Objectives:** The primary objective is to determine whether platelet expression of FcyRIIa is associated with risk of myocardial infarction (MI), stroke and death. Secondary objectives include:
- Develop a score that combines characteristic plus platelet expression of FcyRIIa to determine the risk of MI, stroke, and death.
- Determine whether platelet expression of FcyRIIa is associated with risk of major bleeding.

**Endpoints:** The primary endpoint is the composite of death, MI, and stroke. A secondary endpoint is the incidence of clinically significant bleeding according to the Bleeding Academic Research Consortium (BARC) scale type 2-5.

**Study Population:** Approximately 800 male and female subjects with confirmed MI (ST-segment elevation MI (STEMI) or non-ST-segment elevation MI (NSTEMI)) will be enrolled before hospital discharge for the index event. Subjects with increased risk of an event, defined as ≥2 of the following risk factors, will be eligible:
- Age ≥65
- Multi-vessel coronary artery disease (MVD) defined as ≥2 vessels or left main with a stenosis ≥50%
- Chronic Kidney Disease (CKD) defined as estimated glomerular filtration rate (eGFR) <60 ml/min/1.73 m²
- Diabetes mellitus (DM)
- Prior MI

**Phase:** Not Applicable

**Number of Sites:** Approximately 10 sites in the United States will participate in this study.

**Study Intervention:** Not Applicable

**Study Duration:** It is anticipated that it will take approximately 12 months to enroll approximately 800 subjects. The study and subject follow-up will continue until 1) at least 80 ischemic events (MI, stroke, and death) have occurred, and 2) the last subject enrolled has completed at least 18 months of follow-up.

**Participant Duration:** After enrollment, all subjects will be followed until the end of the study that will be at least 18 months after enrollment of the last subject. Based on an annual ischemic event rate of 10%, the overall length of participation in the study is anticipated to be up to 5 years.

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**Assessment of Cardiovascular Risk by the Combination of Clinical Risk Scores Plus Platelet Expression of FcyRIIa**

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**Abstract**
Platelet expression of FcyRIIa was quantified after myocardial infarction (MI) and we found that patients with high platelet FcyRIIa expression (>1000/platelet) had a fourfold greater risk of subsequent MI, stroke, and death. This analysis of the original cohort of 197 patients was designed to determine whether platelet expression of FcyRIIa could be used in combination with clinical risk scores (GRACE [Global Registry of Acute Coronary Events] and DAPT [Dual Antiplatelet Therapy]) to refine cardiovascular risk assessment. Platelet expression of FcyRIIa quantified with the use of flow cytometry was broadly distributed in patients stratified into high and low risk groups based on clinical risk scores. In patients identified as high risk by the GRACE score, 82% had high platelet FcyRIIa expression. Similarly, in patients identified as high risk by DAPT, 85% had high platelet FcyRIIa expression. High platelet FcyRIIa expression discriminated high and low risk cohorts in patients with high cardiovascular risk defined by either the GRACE score (high platelet FcyRIIa 18.9% vs low platelet FcyRIIa 0%, odds ratio = 16.7, p = 0.06) or the DAPT score (high platelet FcyRIIa 18.4% vs low platelet FcyRIIa 3.7%, odds ratio = 6.6, p = 0.03). Platelet expression of FcyRIIa merits additional study to determine whether low platelet FcyRIIa expression can be used to guide early transition to aspirin monotherapy and high platelet FcyRIIa expression can be used to guide continuation of DAPT.

**Trial registration:** ClinicalTrials.gov NCT020505157.
Brett Nowlan, MD
Director, preventive cardiology; director, Men’s cardiovascular health

What is your educational background? Your work background prior to HHC? When did you join HHC?
Attended medical school at University of Cape Town, South Africa. Medicine residency at Maimonides Medical Center in Brooklyn, cardiology fellowship at the University of Connecticut. I worked for one year in rural medicine in South Africa, followed by four years’ work in the United Kingdom, primarily in psychiatry. After fellowship, I worked in private practice capacity at Cottage Grove Cardiology before joining HHC in July 2021.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?
I was always drawn to internal medicine disciplines, and cardiology encompasses an excellent balance of chronic and acute care, scientific and evidence-based rigor, interpersonal finesse, and office, imaging and procedural mix.

How long have you been involved in heart and vascular research?
In the past, I served as an investigator for the GOULD trial, tracking LDL-C treatments patterns in the US over a 2 year period.

What are your current research projects?
I’m in the early phases of evaluating advanced lipid panel responses to equivalent weight loss from medical versus surgical strategies, and then evaluating the persistence of these responses.

If money and time were not an option, what medical question would you research?
Without question, I would launch a large, randomized, closed-ward, long-term, prospective, multi-arm trial evaluating dietary strategies versus cardiovascular and cardiometabolic hard outcomes.

What is the biggest challenge you face in research?
TIME based on multiple competing professional and family demands.

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Use of Lipid-Lowering Therapies Over 2 Years in GOULD, a Registry of Patients With Atherosclerotic Cardiovascular Disease in the US

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IMPORTANCE Guidelines for patients with atherosclerotic cardiovascular disease (ASCVD) recommend intensive statin therapy and a proton pump inhibitor to lower LDL-C. However, whether these guidelines are followed and, if so, in what way, is unknown. The GOULD registry is a large, observational study of ASCVD patients followed over 2 years to evaluate the use of lipid-lowering medications and adherence to guidelines in real-world practice.

DESIGN SETTING AND PARTICIPANTS GOULD is an observational registry study involving multiple centers. Patients with ASCVD and taking lipid-lowering therapies (LLT) were eligible. Between December 2015 and July 2018, 17,174 patients were enrolled in 17 sites in the US. The mean age was 67.7 years, 62% were male, and 73% were non-Hispanic white.

MAIN OUTCOMES AND MEASURES The primary outcome was the change in LDL-C levels from baseline to 2 years.

RESULTS Of the 17,174 patients (661 women [39.7%], 11,413 white non-Hispanic [66.7%]; 62 years [77.2%]), 6613 (38.6%) had LLT initiation in the cohort with LDL-C levels at 70 mg/dL or more and 7726 (45.1%) had LLT initiation at 70 mg/dL or less. Of the patients with LLT initiation, 2024 (59.2%) had LLT initiation at 70 mg/dL or more and 4599 (59.8%) had LLT initiation at 70 mg/dL or less. The mean change in LDL-C from baseline to 2 years was 17.7 mg/dL (95% CI, 16.5 to 18.9 mg/dL). The number of patients with LDL-C levels at 70 mg/dL or more, 7726 (45.1%), 2024 (59.2%), and 4599 (59.8%) had a change in LDL-C levels at 70 mg/dL or less from baseline to 2 years.

CONCLUSIONS AND RELEVANCE Patients with ASCVD treated with atherosclerotic cardiovascular disease (ASCVD) who were enrolled in the GOULD registry had a LDL-C level of 70 mg/dL or less from baseline to 2 years; however, adherence to the current ASCVD guidelines was low.
What do you feel research has contributed to the field in the past two or three decades (or more)?
In cardiology, we are spoiled for a dynamic field of large, high-quality studies almost continually, stretching in all directions that are highly relevant to our daily clinical practice. There are far too many to mention! As a preventive cardiologist, there is no question that our medical therapy options are leagues beyond those of 30 years ago.

If you weren’t a heart and vascular researcher, what would you be doing?
Nothing else appeals, really...

What do you do for fun?
Lots of time spent with my daughters, indoor rock-climbing, hiking will always make me happy, travel (pre-COVID).
Bryan Piccirillo, MD
Interventional and Structural Heart Cardiologist

**What is your educational background? Your work background prior to HHC? When did you join HHC?**
I attended college at the University of Notre Dame (Go Irish!) and medical school at the University of Connecticut. I then did post-graduate training in Boston, with internship and residency at Beth Israel Deaconess and general cardiology fellowship at Boston Medical Center (Boston University). I did a two-year interventional cardiology fellowship at Brigham and Women's Hospital, one year focusing on coronary interventions and one year dedicated to structural heart interventions. I joined Hartford Hospital in 2018.

**What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?**
I enjoy the research process because it forces us to ask questions about our patient's care in a scientific and methodological manner. For example, we have to ask ourselves, “What hypothesis are we trying to prove?” Or, more statistically speaking, “What is our null hypothesis?” We are thus able to take complex physiologic systems and treatments and break these down to one specific idea, hypothesis or statistical proof.

I was first introduced to heart and vascular research as a medical student. I joined a project establishing predictors for hypotension in patients following carotid endarterectomies. The complexities of the cardiovascular system fascinated me back then, and still do.

**How long have you been involved in research in general? In heart and vascular research?**
I first became involved in research at UCONN during summers as an undergraduate. I did work in the neuroscience lab, running PCR tests and creating gene constructs to target novel proteins in regeneration of neurons for patients with spinal cord injuries. My first true experience with heart and vascular research came as a medical student, joining Dr. James Menzoian, a vascular surgeon at UCONN, on a project to predict post-procedural hypotension in patients following carotid endarterectomy.

**What is your favorite research project to date and why?**
My favorite and most influential research project is assessing indices of frailty in TAVR patients. I participated in a small single center pilot study as a resident, exploring how frailty could be assessed in this high-risk population. While this project was never published, I was exposed to minimally-invasive transcatheter interventions and how to use complex and multidisciplinary decision-making processes to determine appropriate candidates. This project began my interest in structural heart therapies.
What are your current research projects?
I am involved in:

CORCINCH – HF study - a large multi-center randomized trial to evaluate the implant of the AccuCinch® Ventricular Restoration System in patients who present with symptomatic heart failure with reduced ejection fraction. This device is a novel transcatheter therapy for heart failure patients, designed to directly repair, cinch and reduce the size of the dilated left ventricle and, thus, strengthen the myocardium. This study is revolutionary and can help bring relief to heart failure patients who remain symptomatic despite current guideline-directed medical care.

PROTECTED – TAVR study - a randomized trial to explore the hypothesis that the use of the Sentinel® Cerebral Protection System significantly reduces the risk of peri-procedural stroke (≤72 hours) after transcatheter aortic valve replacement (TAVR). Despite advances in TAVR technology, stroke rates remain constant, from 2 to 2.5 percent. Thus, cerebral protection remains a hot topic. The FDA initially approved the Sentinel® protection device following results of the pivotal SENTINEL; however, it failed to meet statistical significance for the primary endpoint of new brain lesions on MRI and stroke at 30 days. This trial, published in 2016, enrolled 363 patients. The PROTECTED – TAVR study aims to enroll roughly 3,000 patients in hopes of adequately powering the data to detect any clinical reduction in stroke at 72 hours.

If money and time were not an option, what medical question would you research?
In the world of structural heart interventions, one of the most challenging management decisions is how to treat and monitor patients with moderate to severe aortic stenosis who are asymptomatic. Should we wait to intervene until the patient has symptoms? Or, will the patient become higher risk due if we wait too long? The ideal timing for intervention, either surgical or catheter, for asymptomatic patients with even moderate aortic stenosis has yet to be determined. Fortunately, there are several trials that begin enrollment in the near future. Stay tuned!

What is the biggest challenge you face in research?
The biggest challenge for anyone in research is time, and being able to balance clinical responsibilities with research activities. We are fortunate enough to have a great support staff in our research department, which continues to expand and grow as our participation in clinical trials has increased.

What do you feel research has contributed to the field in the past two or three decades (or more)?
One of the most revolutionary treatments to emerge in the field of interventional cardiology has been the growth and expansion of TAVR, taking a previously deadly and only surgically treatable disease in aortic stenosis and expanding the availability of a less invasive procedure to a wide patient population. The remarkable success story of TAVR involved unprecedented cooperation and teamwork between
interventional cardiologists, cardiac surgeons and the medical device industry. The multidisciplinary nature of TAVR is why the technology and the research in the field has been so successful.

**If you weren’t a heart and vascular researcher, what would you be doing?**
Spending time with my wife and two twin boys, who just turned four. I would also try to bring down my golf handicap as much as possible.

**What do you do for fun?**
When I’m not chasing my twin boys around, I enjoy traveling, playing golf and playing guitar.
Steven Zweibel, MD, FHRS, CCDS
System Director, Cardiac Electrophysiology

What is your educational background? Your work background prior to HHC? When did you join HHC?
I went to the NYU School of Medicine, followed by internship and residency at Columbia-Presbyterian Medical Center and cardiology and electrophysiology fellowship at Montefiore Medical Center. In 1999, I joined a private practice electrophysiology associated with Lenox Hill Hospital. In 2008, I was recruited to Hartford Hospital as director of electrophysiology. In 2013, I became system director of Cardiac Electrophysiology.

What intrigues you about research, and how did you come to focus on heart and vascular disease specifically?
When I was a medical student, I vividly remember sitting in a cardiac physiology lecture with an electrophysiologist describing WPW and how this extra pathway in the heart caused a rapid arrhythmia. I was immediately intrigued. During internship and residency, whenever I was awakened in the middle of the night to treat a patient with a heart condition, especially an arrhythmia, I was excited to take care of the patient. I figured if I enjoyed treating these conditions in the middle of the night, it would be a field I would enjoy for the rest of my career! As someone who is constantly learning and asking questions, research was a natural extension of that curiosity. I see research as a way to not only help the patients I care for but also help scores of other patients.

How long have you been involved in research in general? In heart and vascular research?
My first research project was as a medical resident when I worked with an electrophysiologist on heart rate variability research. That resulted in an oral presentation at the American Heart Association and publication in the American Journal of Physiology.

What is your favorite research project to date and why?
My favorite was the VEST Trial, examining if a wearable defibrillator vest resulted in reduced mortality in patients after a myocardial infarction. I felt this was a very important question to answer in post-MI patients with reduced ejection fractions. The paper was published in the New England Journal of Medicine.
**What are your current research projects?**
We just finished enrolling in the EKG Belt trial, examining a novel technology to look at ventricular activation in patients undergoing cardiac resynchronization therapy (CRT) using a multi-electrode belt wrapped around the chest. It is possible that using the belt to optimize ventricular activation could improve response to CRT.

**If money and time were not an option, what medical question would you research?**
I am very interested in using “big data” to answer important questions in cardiology. Specifically, I think we can do a much better job determining which patients with atrial fibrillation might benefit from anticoagulation, beyond the present CHA2DS2VaSC scoring system we presently use.

**What is the biggest challenge you face in research?**
The biggest challenge is having enough time given my numerous clinical and administrative responsibilities.

**What do you feel research has contributed to the field in the past two or three decades (or more)?**
Research has led to improvements in morbidity and mortality for cardiovascular patients. In electrophysiology, we have made tremendous strides in reducing sudden death with ICDs, improving heart failure with CRT, and improving quality of life with ablation of atrial fibrillation.

**If you weren’t a heart and vascular researcher, what would you be doing?**
I can’t think of anything else I would rather be doing besides what I am doing now!

**What do you do for fun?**
Right now, I am getting my MBA from MIT, so most of my fun time is taken up with studying! However, I do enjoy cooking with my wife, watching movies, exercising on my Peloton, and spending time with my two sons.
What is your educational background? Your work background prior to HHC? When did you join HHC?

After I received my medical degree from Gauhati Medical College and performed my internship and medical residency at Saint Vincent Hospital, I performed my Cardiology Fellowship and Interventional Cardiology Fellowship at Hartford Hospital. I joined the catheterization laboratory as an interventional cardiologist in July 2019.

What is your favorite research project to date and why?

I was recently involved in the care of a TAVR patient on prednisone that experienced an annular rupture during the procedure. Working with the Structural Heart team, we examined the impact of systemic steroids on aortic annular complications. The results of our study have impacted the use of TAVR in this subgroup of patients.

What are your current research projects?

I am currently examining difficulties with coronary access in patients following TAVR valve implantation.

Outcomes of Transcatheter Aortic Valve Replacement in Patients Treated With Systemic Steroids

Saurabh Joshi, MD; Wassim Mosleh, MD; Mostafa R. Amer, MD; Mays Tawayha, MD; Jeffrey F. Mather, MS; Francis J. Kieman, MD; Raymond G. McKay, MD; Bryan Piccirillo, MD

Abstract

Background. Chronic steroid therapy is associated with higher vascular complication rates in patients undergoing transcatheter aortic valve replacement (TAVR). The effect of corticosteroids on aortic annular complications has not been directly assessed in this population. Methods. A retrospective analysis of 1095 patients undergoing transfemoral TAVR was performed. Patients treated with chronic steroids at the time of the procedure (n = 99) were compared with those who received no steroids (n = 996). The primary outcome included a composite of aortic annular complications, defined as a combination of aortic annular rupture, aortic dissection/periﬁer, and left ventricular perforation. Results. The primary outcome was signiﬁcantly higher in the steroid group (4.0% vs 0.5%, P= .03). This ﬁnding was primarily driven by higher rates of acute annular rupture in the steroid group (2.0% vs 0.2%; P= .04). Steroid use was associated with higher rates of intraoperative cardiac arrest (5.2% vs 1.5%; P= .03), device capture/retrieval (4.0% vs 0.8%; P= .01), and emergent conversion to open heart surgery (4.0% vs 0.6%; P= .01). There were no differences with respect to inhospital mortality, stroke, myocardial infarction, need for permanent pacemaker, bleeding complications, minor vascular complications, hospital length of stay, hospital 30-day readmission, or 30-day echocardiographic ﬁndings. Within the steroid group, there was a trend toward more composite aortic annular complications with balloon-expandable vs self-expanding prostheses. Conclusion. Chronic steroid therapy increases the risk of aortic annular complications in patients undergoing TAVR, with detrimental consequences including intraoperative cardiac arrest and conversion to open heart surgery. Steroid use should be considered in patient selection and determination of procedural technique for TAVR.

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Keywords: coronary perforation, corticosteroids, steroid therapy, transcatheter aortic valve replacement


## Impact of Chronic Obstructive Pulmonary Disease on Quality-of-Life Outcomes in Patients Undergoing Transcatheter Aortic Valve Replacement

Nicole Hoover, PA-C, Lauren Cutts, APRN, Agnieszka Piekholta, APRN, Susan Erwin, APRN, Cary Patel, APRN, Talatat Azemi, MD, Immad Saadiq, MD, Brian Roccio, MD, Frances Kavanagh, MD, Bayrond Motie, MD, Robert Hoppe, MD, Mohiuddin Cheema, MD

### Methods

From a total cohort of 200 TAVR patients, we compared QoL outcomes in 97 patients with moderate or severe COPD (FEV1 < 50%) to 103 patients with mild or no COPD. Relative improvements in QoL were measured by Kansas City Cardiomyopathy Questionnaire (KCCQ) scores measured at baseline, 30 days, 1 year and 1 year from index post-TAVR. A KCCQ-12 score of 40 or a decrease in KCCQ-12 > 10 points TAVR at 1 month follow-up was defined as a suitable procedure for both groups.

### Results

<table>
<thead>
<tr>
<th></th>
<th>Mod-Sev COPD</th>
<th>No-Mild COPD</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>40.4±23.9</td>
<td>50.4±25.5</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>30 Days</td>
<td>72.1±21.9</td>
<td>78.6±19.8</td>
<td>P&lt;0.001</td>
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<tr>
<td>1 Year</td>
<td>74.5±20.9</td>
<td>80.8±20.3</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>&gt;1 Year</td>
<td>78.3±20.3</td>
<td>85.3±10.7</td>
<td>P&lt;0.001</td>
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</table>

### Conclusions

Despite having a higher pre-TAVR risk, worse in-hospital outcomes and lower levels of KCCQ at all time intervals, the overall improvement in QoL post-TAVR and the percentage of futile procedures was similar for both COPD and non-COPD patients.

### Disclosures

1. Nicole Hoover, PA-C, DO NOT have a financial interest/arrangement or affiliation with any commercial entity that may be perceived as having a possible conflict of interest in the context of the content of this presentation.
Mid-Term Outcomes of Transcatheter Aortic Valve Replacement With the Edwards SAPIEN 3 Valve in Patients With Extremely Large Annuli: A Single Center Report

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Background:

The first-in-human experience of the Edwards SAPIEN 3 valve first device implantation in transcatheter aortic valve replacement in 12 patients with bioprosthetic annuli of less than 29 mm has been reported. The current study reports on the safety and efficacy of this new valve in patients having an annulus size no larger than the recommended 29 mm.

<table>
<thead>
<tr>
<th>Method</th>
<th>Post-Procedure</th>
<th>Follow-Up</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td>4</td>
<td>38</td>
</tr>
<tr>
<td>Trace</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Mild</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>Mild-Moderate</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table:**

<table>
<thead>
<tr>
<th>Mean Aortic Valve Gradient (mmHg)</th>
<th>7.2±13.83</th>
<th>9.6±12.93</th>
</tr>
</thead>
<tbody>
<tr>
<td>LV Ventricular Ejection Fraction (%)</td>
<td>51.9±15</td>
<td>50.2±14.0</td>
</tr>
</tbody>
</table>

**Results:**

- A total of 23 patients with aortic annuli ≤28 mm were treated between March 2020 and October 2020.
- Patient outcomes follow-up 39.6±14.9 months.
- Mean hospital stay was 7.2±1.7 days. No in-hospital death were observed.
- No significant events or complications were observed in the follow-up period.
- All patients had a low rate of reintervention, with a 9-month survival of 99.1%.

**Conclusions:**

In this limited series, use of the 29 mm 3S valve in patients with an aortic annulus ≤28 mm resulted in favorable post-procedure and mid-term echocardiographic outcomes.
Impact of TAVR implantation Technique on Need for Permanent Pacemaker Implantation

Inmad Sadiq,1 Muhammad Umar Bakhsh,1 Sarfaraz Memor,2 Hossein Quarani,3 Hadi Mahmoud,4 Siddhanta Gurung,2 Nicole Hoover,1 Asid Hirt1,2, Robert Hughey,1 Talhat Azemi3
1Harvard Hospital, Hartford, Connecticut, USA; 2University of Connecticut, West Hartford, Connecticut, USA, 3Harvard Healthcare, Hartford, Connecticut, USA, 4University of Connecticut, Hartford Hospital, West Hartford, Connecticut, USA, 5Harvard Hospital, South Glastonbury, Connecticut, USA

BACKGROUND: The incidence of electric conduction disturbances (ECDs) and permanent pacemaker (PPM) implantation is higher after transcatheter aortic valve replacement (TAVR) than after surgical aortic valve replacement. Multiple anatomical factors and implantation depth are critical variables that affect the incidence of this complication. We postulate that a modification in deployment technique (DT) may optimize the depth of valve implantation, reducing the incidence of ECDs and the need for PPM implantation.

METHODS: In January 2020, we modified our DT of the (Medtronic) self-expanding valve to include biplane caudal overlap at the time of valve implantation. This DT uses right anterior oblique and left anterior oblique angiographic imaging to estimate implantation depth at the noncoronary and left coronary sinuses, respectively. To study the effect of technique modification, we analyzed the data on our TAVR patients over 2 consecutive years between January 2019 and January 2021 and divided them into 2 groups: standard technique (ST) (January 2019 to January 2020) and modified technique (MT) (January 2020 to January 2021). Demographic, clinical, imaging, and electrocardiographic data were analyzed at baseline and outcomes at 30 days. The following procedural outcomes were compared: left ventricular ejection fraction, paravalvular leak, transient ischemic attack or cerebrovascular accident, CD requiring PPM, and length of stay.

RESULTS: One hundred four patients underwent TAVR in the ST group and 78% in the MT group. Demographics, baseline clinical characteristics, and mean Society of Thoracic Surgeons risk score were similar between the ST and MT groups. In-hospital and 30-day outcomes (Table 1) between the 2 groups were similar, with a strong trend toward a lower need for permanent pacemaker implantation in the MT group.

CONCLUSION: Modification of DT for the Medtronic TAVR valve allows optimization of valve implantation depth, reducing the incidence of CD requiring permanent pacemaker implantation. No increase is noted in the incidence of transient ischemic attack or stroke, paravalvular leak, and length of stay.

Impact of Moderate and Severe Tricuspid Regurgitation on Quality-of-Life Outcomes in Patients Undergoing Transcatheter Aortic Valve Replacement

BACKGROUND: Previous studies have shown that tricuspid regurgitation (TR) is commonly observed in patients referred for transcatheter aortic valve replacement (TAVR), does not always improve post TAVR, and is a marker for long-term morbidity and mortality. There have been few reports on the impact of TR on quality-of-life (QoL) outcomes post TAVR in high-risk patients deferred from surgical intervention.

METHODS: From a total cohort of 2,058 TAVR patients treated since 2012, we compared QoL outcomes in 491 patients with moderate or severe TR with 1,567 patients with mild or no TR. Relative improvements in QoL were measured by Kansas City Cardiomyopathy Questionnaire (KCCQ-12) surveys measured at baseline, 30 days, 1 year, and 1 year time points post TAVR. A KCCQ-12 score < 40 or a decrease in KCCQ-12 ≥ 10 post TAVR at 1 year follow-up was defined as a futile procedure for both subgroups.

RESULTS: In comparison to the non-TR cohort, TR patients were older (83.1±8.4 vs 80.8±8.6, p=0.001), were more likely female (50% vs 44%, p=0.017), had a lower BMI (27.5±12.8 vs 29.7±14.4 kg/m2, p=0.015), had more comorbidities including atrial fibrillation, requirement for dialysis, and NYHA Class III-IV heart failure, and had a higher baseline KCCQ-12 score (12.2±11.5 vs 9.2±11.0, p<0.001). There were no differences between TR and non-TR patients with respect to procedural technique, other than the TR cohort had a higher use of aortic valve-in-valve procedures (9% vs 5%, p=0.002). In addition, there were no differences between TR and non-TR patients with respect to major in-hospital outcomes including death, stroke and vascular complications, although the TR cohort had a lower requirement for permanent pacemaker implantation (12% vs 16%, p=0.03) and a longer length of stay post TAVR (4.1±2.4 vs 3.5±1.2 days, p=0.034). KCCQ-12 outcomes for both groups are shown below.

<table>
<thead>
<tr>
<th>TR</th>
<th>Non-TR</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>42.82±15.11</td>
<td>48.96±15.46</td>
</tr>
<tr>
<td>30-Days</td>
<td>72.05±21.68</td>
<td>77.69±20.28</td>
</tr>
<tr>
<td>1 Year</td>
<td>76.84±22.20</td>
<td>78.57±20.73</td>
</tr>
<tr>
<td>Futility Procedure</td>
<td>4.7%</td>
<td>6.0%</td>
</tr>
</tbody>
</table>

CONCLUSIONS: Despite having a higher pre-TAVR risk and lower levels of KCCQ at baseline at 30 days, the 1 year KCCQ, the overall improvement in QoL post-TAVR and the percentage of futile procedures was similar for both TR and non-TR patients.
IMPACT OF PRE-OPERATIVE ATRIAL FIBRILLATION ON ONE YEAR MORTALITY
AND POOR QUALITY OF LIFE FOLLOWING TRANSCATHETER AORTIC VALVE
REPLACEMENT

BACKGROUND: Although prior studies have shown that new onset atrial fibrillation (AFIB) is
common after transcatheter aortic valve replacement (TAVR) and is associated with higher risk
of long-term stroke and mortality, the impact of pre-operative AFIB on TAVR outcomes remains
uncertain.

METHODS: From a total cohort of 2,058 TAVR patients, we compared clinical outcomes in
786 patients with pre-operative paroxysmal (n=390) or permanent (n=396) AFIB with 1,272
non-AFIB patients. Relative improvements in Quality of Life (QOL) were measured in 800
patients with completed baseline and 1-year Kansas City Cardiomyopathy Questionnaire
(KCCQ-12) surveys. Logistic regression was used to identify a poor TAVR outcome in all
patients, defined as mortality, a KCCQ-12 score < 60 or a decrease in KCCQ-12 ≥ 10 post
TAVR at 1-year follow-up.

RESULTS: In comparison to the non-AFIB cohort, AFIB patients were older (83.0 ± 7.5 vs
vs 80.3 ± 9.0 yr, p<0.001), more likely male (58% vs 53%, p=0.017), and had more
comorbidities including hypertension (91% vs 89%, p=0.04), chronic lung disease (55% vs 44%,
p=0.01), prior stroke (14% vs 9%, p<0.001) and prior transient ischemic attacks (8% vs 9%, p=
0.009). AFIB patients had a higher baseline STS-PROM (11.71 ± 7.80 vs 8.81 ± 7.09, p<0.001)
and a lower pre-procedure KCCQ-12 score (42.4 ± 24.6 vs 50.7 ± 25.6, p<0.001). There were no
differences between AFIB and non-AFIB patients with respect to major in-hospital outcomes
including death, stroke, need for permanent pacemaker and vascular complications, although the
AFIB cohort had a longer length of stay post TAVR (4.11 ± 4.84 vs 3.45 ± 3.84 days, p=0.014).
Logistic regression revealed that pre-operative AFIB was an independent predictor of a poor 1-
year TAVR outcome for both paroxysmal (HR 2.25, 95% CI 1.25-4.25, p=0.007) and permanent
(HR 4.26, 95% CI 2.49-7.89, p<0.001) subgroups.

CONCLUSIONS: Both pre-operative paroxysmal and persistent AFIB are independent
predictors of mortality and poor quality of life one year following TAVR.
**Can Transcarotid TAVR Achieve Outcomes As Good As Transfemoral TAVR For High Risk Patients Who Need Alternative Access?**

Mohuiddin Cheema, Raymond McKay, David Underhill, Hossein Oraimos,
Hartford Hospital, Hartford, USA

**OBJECTIVE:**

Can Transcarotid TAVR achieve outcomes as good as Transfemoral TAVR for high risk patients who need alternative access?

**METHODS:**

A retrospective analysis was performed on consecutive TransCarotid (TC) and TransFemoral (TF) TAVR procedures performed at a single tertiary care medical center between 2016 and 2021. All outcomes are reported in accordance with the Valve Academic Research Consortium definitions.

**RESULTS:**

In the study period, a total of 1894 patients were included: 92 patients received TC TAVR and 1802 received TF TAVR. STS risk score was higher in TC group (79% high or extreme risk vs 62% in TF group). Major comorbidities included prior MI (32% vs 21%), prior CABG (29% vs 16%), nonobstructive COPD (23% vs 27%), PAD (60% vs 18%), and bilateral carotid stenosis (6% vs 7%). General anesthesia was used in 98% in the TC group vs 26% in TF group. OR time trended equal TC vs TF cases (2.1 ± 1.3 vs 1.9 ± 0.9 hours, p = 0.053). There was a significant difference in fluoro dose (Kerm) (641.50 ± 1019, p < 0.004) but not in fluoro time (21.04 ± 8.5 vs 21.32 ± 14.3, p=0.85) for TC vs TF respectively. There were no differences in bleeding events (TC 3% vs TF 3%, p=0.3), periprocedural stroke events (TC 4% vs TF 2%, p=0.26), major vascular complications (TC 9% vs TF 2%, p=0.18), unplanned cardiac surgery procedures (TC 8% vs TF 2%, p=0.7), and requirement for PPM (TC 10% vs TF 15%, p=0.37). Additionally, there were no differences in 30-day mortality (TC 0.9% vs TF 2%, p=0.22), ICU stay and hospital LOS (TC 3.6 days vs TF 3.3 days, p<0.4).

**CONCLUSIONS:**

The Transcarotid approach to TAVR is safe and able to achieve outcomes comparable to Transfemoral

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**Is Transcarotid TAVR Using Either Balloon Expandable (BE) or Self Expanding (SE) TAVR Valves Equally Efficacious?**

Mohuiddin Cheema, Talhat Azemi, Jawad Haider, Immad Sadiq, Raymond McKay, David Underhill.
Hartford Hospital, Hartford, CT, USA

**OBJECTIVE:**

Is transcarotid (TC) TAVR using either Balloon Expandable (BE) or Self Expanding (SE) TAVR valves equally efficacious?

**METHODS:**

A retrospective analysis of consecutive TC TAVR procedures was performed at a single tertiary care medical center between 2016 and 2020 utilizing both valves. All outcomes are reported in accordance with VARC definitions.

**RESULTS:**

Total of 92 patients were included in the study: 56 patients received BE and 36 received SE TC TAVR. Both groups were comparable for comorbidities and STS PROM. TC BE TAVR group had slightly higher previous MI (41% vs 17%, p=0.014) Anesthesia was GA in 98% BE vs 97% in SE Group. OR time was equivalent. There was a significant difference in contrast volume (71 cc vs 95 cc, p=0.009) and fluoro time (18.6 vs 24.7 min, p=0.009) for BE vs SE respectively. The total radiation dose (Kerm) was higher in SE group (804.56 vs BE 536.68, p=0.06). There were no differences in bleeding events (BE 5% vs SE 6%, p=0.15), perioperative stroke (BE 4% vs SE 6%, p=0.60), vascular complications (BE 9% vs SE 6%, p=0.55). Day Mean gradient (mm Hg) were lower in SE group (7.6 vs 10.7, p=0.001) and there was higher 30 days mild PVL with SE vs BE group (50% vs 17%, p=0.001) but this was reduced to 33% vs 13% b 1 year.

**CONCLUSIONS:**

The transcarotid approach to TAVR is safe and efficacious and can provide excellent outcomes utilizing both TAVR valve platforms. There is less of contrast and radiation with BE valves.
Impact of Intra-Operative Platelet Administration on Thienopyridine-Related Post-CABG Complications

David Yaffee MD, Joseph Ingrassia MD, Trevor Sutton MD, Deborah Loya RN, Robert Hagberg MD, Sabet Hashim MD, Raymond McKay MD

OBJECTIVE: Increased risk of peri-operative bleeding in patients undergoing coronary artery bypass grafting (CABG) who receive oral antiplatelet therapy with thienopyridines within 5 days of surgery is well documented. However, the impact of intra-operative platelet administration on thienopyridine-related CABG bleeding has not been fully explored.

METHODS: From July 2017 to July 2020, 1277 patients underwent elective or urgent CABG at an urban tertiary referral center. 247 patients (19.3%) were exposed to thienopyridine therapy within 5 days before surgery. We performed a retrospective analysis of the effects of intra-operative platelet administration on patient outcomes over this time.

RESULTS: Within the thienopyridine group, 66 of the 247 CABG patients received intra-operative platelet administration (26.7%; mean 1.8±1.3 platelet dose packs/patient). Patients who received intra-operative platelet transfusion had higher rates of post-operative blood product transfusion, higher mortality, and longer post-operative length of stay. There were no differences in rates of reoperation for bleeding, permanent stroke, or significant (≥ 5 units) red blood cell (RBC) transfusion.

CONCLUSIONS: Intra-operative platelet administration is not associated with decreased peri-operative complications in CABG patients with pre-operative thienopyridine exposure within 5 days of surgery.

<p>| Table: Peri-Operative Outcomes in CABG Patients Who Received Pre-Operative Thienopyridines |
|----------------------------------|------------------|------------------|------------------|</p>
<table>
<thead>
<tr>
<th></th>
<th>Platelets (n=66)</th>
<th>No Platelets (n=181)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reoperation for Bleeding</td>
<td>4.5%</td>
<td>4.4%</td>
<td>&gt; 0.99</td>
</tr>
<tr>
<td>Post-Operative Blood Product Transfusion</td>
<td>59.1%</td>
<td>29.3%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Post-Operative RBC Transfusion ≥ 5 Units</td>
<td>6.1%</td>
<td>3.9%</td>
<td>0.49</td>
</tr>
<tr>
<td>30-Day Mortality</td>
<td>3.0%</td>
<td>0.9%</td>
<td>0.02</td>
</tr>
<tr>
<td>30-Day Permanent Stroke</td>
<td>1.5%</td>
<td>0.6%</td>
<td>0.46</td>
</tr>
<tr>
<td>Median (IQR) Post-Operative Length of Stay [Days]</td>
<td>5 (3-7.75)</td>
<td>5 (4-6)</td>
<td>0.006</td>
</tr>
</tbody>
</table>

AATS (submitted)
Enhanced Recovery After Cardiac Surgery Reduces Duration of Ventilation and Likelihood of Re-intubation Following Urgent and Emergency Isolated Coronary Artery Bypass Surgery
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Introduction - The effects of enhanced recovery after cardiac surgery (ERACS) on urgent and emergency cardiac surgery are not known. Coronary artery bypass (CABG) is commonly performed under urgent and emergency priority. We sought to determine if ERACS had effects on outcomes following urgent and emergency CABG.

Methods - We conducted a 5-year, retrospective study for consecutive adults undergoing urgent/emergency CABG at an urban teaching hospital. Patient demographics, clinical data, and postoperative outcome data were collected from the Society of Thoracic Surgery (STS) Adult Cardiac Surgery Database and hospital medical records. Analyses were performed for two periods: 1) prior to implementation of ERACS (2016-2017); and 2) following implementation of ERACS (2018-2020). Chi-square tests were used to compare categorical variables, t-tests for continuous variables, and Mann Whitney U test was used when continuous variables did not meet assumptions for normal distribution. Using 80% power and alpha = 0.05, 190 patients in each cohort were required to detect statistical significance based on a reported reduction in readmission rate associated with enhanced recovery implementation.12 Statistical analyses were performed with SPSS 21.0 (SPSS, Chicago, Illinois).

Results - The pre-ERACS and post-ERACS cohorts were similar regarding demographic data, cardiovascular risk factors, comorbidities, beta blocker utilization, cardiac catheterization data, and STS risk score (Table 1). The post-ERACS cohort had a statistically higher mean left ventricular ejection fraction, was less likely to have dyslipidemia, and was more likely to have prior percutaneous coronary intervention, prior cardiac artery surgery/stent, aortic stenosis, mitral stenosis, liver disease, and intra-aortic balloon pump (Table 1). The pre-ERACS subgroup had a longer mean aortic cross clamp duration longer mean bypass duration, and higher likelihood of bilateral internal mammary harvest (Table 1). Regarding ERACS outcomes, there was a trend toward increased likelihood of early extubation in the post-ERACS cohort (Table 2), and the post-ERACS cohort had a shorter median duration of ventilation, lower likelihood of re-intubation, and lower morphine milliequivalent utilization without adverse effect on discharge to home, 30-day re-admission, or 30-day mortality (Table 2, Figures 1-3).

Conclusions - These data provide a novel report that ERACS decreased morphine milliequivalent utilization, decreased ventilation duration, and decreased likelihood of re-intubation following urgent/emergency CABG. A limitation of our retrospective study design is that we could not determine which ERACS protocol elements conferred benefits following urgent/emergency CABG. Future prospective studies should evaluate the effect of ERACS on outcomes following cardiac surgery procedures performed under urgent and emergency priority.

IARS (Submitted)