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Clinical Studies Target Fewer Complications, Better Outcomes for Vascular Surgery

Two studies at the Jefferson Vascular Center (JVC) are assessing innovative methods to reduce risk of complications — and increase positive outcomes — for vascular surgery patients. Here, Paul DiMuzio, MD, FACS, William M. Measey Professor of Surgery and Co-Director, Jefferson Vascular Center, reviews what both studies mean for patient care.

'Game-changer' for groin wounds

As Dr. DiMuzio explains, groin incisions in vascular surgery are a source of significant morbidity and healthcare costs. When groin wounds become infected, patients may have to be readmitted and undergo additional surgery. Some patients are at greater risk because of diabetes and obesity, others because of the surgical technique required for their treatment.

In exploring ways to decrease groin wound infections in high-risk patients, the JVC identified a possible solution in Prevena™ — a sponge covered in adhesive that attaches to a small suction device. The suction device removes fluids from the region, helping reduce the risk of infection. Already FDA-approved, Prevena is used by cardiac surgeons for sternal incisions and by orthopedic surgeons in total joint replacements.

"No one had conducted a prospective randomized trial to determine if Prevena is a viable option for high-risk groin wounds," he says. "We were the first."

The results of Jefferson's two-year study — which will be presented later this Spring at the 2017 Annual Meeting of the Society for Vascular Surgery in San Diego — showed a significant reduction in infections and re-admissions. Hospital costs declined by an average of \$6,000 per patient.

We are now using [the Prevena] device for every patient with high-risk groin incisions, and we expect it to become a standard of care everywhere once the findings are published.



The Jefferson Vascular Center surgeons, Drs. Paul DiMuzio, Dawn Salvatore and Babak Abai, rely on the support of advanced practice nurses Meghan McCullough, MSN, RN, FNP, AGACNP, and Cara Staley, MSN, RN-BC, AGACNP-BC (on either side of Dr. Salvatore) to manage the Prevena and ROADSTER 2 clinical trials.

"We are now using this device for every patient with high-risk groin incisions, and we expect it to become a standard of care everywhere once the findings are published," he adds. "It's a game changer."

In February, Megan Lundgren, MD, a third-year General Surgery resident and Sidney Kimmel Medical College alumna, presented the study at the Philadelphia Academy of Surgery's Annual Surgical Research Competition. Dr. Lundgren, who helped enroll and care for trial participants, won the inaugural Chris Tzarnas Surgical Research Award for the work.

Follow-up trial of new treatment for carotid artery disease

Following the promising multi-center ROADSTER trial, the ROADSTER 2 trial is observing and evaluating real-world results of a newly approved procedure for treating carotid artery disease.

The most widely used treatment for carotid artery disease has been the carotid endarterectomy (CEA) procedure, in which plaque is surgically removed from the blocked artery. For patients who may be at high medical or anatomic risk for carotid endarterectomy, carotid stenting may be a better option. Though both procedures are generally safe, heart attack risk is higher with CEA, while stroke risk is higher with stenting. Trans-carotid Artery Revascularization (TCAR) is designed to lower both risks, and the initial ROADSTER trial demonstrated its success.

"The TCAR procedure is a hybrid of the other two treatments," Dr. DiMuzio says. "It places a carotid stent through a minimally invasive incision in the carotid artery at the level of the neck. Blood flow in the artery is temporarily reversed to protect the brain from plaque fragments that may come loose during the procedure. A stent is then inserted into the blood vessel to support the artery walls and prevent blockage or collapse." Dr. DiMuzio adds that stent deployment via access directly through the common carotid artery avoids the need to traverse the aortic arch with catheters, which can lead to embolic stroke.

Though approved by the FDA, the TCAR procedure will not be marketed until the ROADSTER 2 trial is completed. To date, Jefferson is the first and only study location in the Philadelphia area. Dr. DiMuzio and his team have already performed the TCAR procedure and are actively enrolling more patients.

"Nationally, the study is more than halfway to completion — and the TCAR procedure is on its way to becoming an exciting new standard of care for carotid artery disease," he says.

For more information, contact the Jefferson Vascular Center at **215-955-8304** or visit Jefferson.edu/JVC.



Andrea DelMastro

Since joining the Department of Surgery in 2001 as an administrative assistant in the Division of Transplant Surgery, Andrea DelMastro has moved to our 1300 Wolf Street Office on the Methodist Campus. Born and raised in South Philly, she has returned and served as the Department's practice manager there for the past five years.

At Methodist, Andrea oversees day-to-day operations of 14 providers and a team of registrars, medical assistants and nurse practitioners. The practice includes several specialties within the Department of Surgery: Bariatric, Breast, Colorectal, General, Thoracic and Vascular Surgery & Vascular Medicine. The services provided there include more than just surgical consultations, as several other outpatient services are offered, including vascular ultrasound, minimally invasive vein closure, and wound care.

During the last few years she has been active at both campuses taking on a number of departmental projects: she is currently the Department's lead for the JeffConnect telehealth program and serves as a 'super user' for the EPIC Electronic Health Record implementation.

Another of DelMastro's long-term projects is contributing to the Methodist Hospital Division's Surgery White Paper. The purpose of the ongoing initiative: to identify ways to improve both patient experience and overall surgical patient throughput at Methodist. To date, such improvements have included adding a room for private family surgical consultations and staffing a patient registrar.

She appreciates the diverse challenges of her work: "Every day is different," she says. "I juggle clinic hours, department projects, as well as the unique needs of staff and patients that come up daily." DelMastro strives to make sure her employees are engaged, as she believes that "makes all the difference in patient care."

Above all, Andrea values being part of the Methodist community: "I love that I get to work in an office where I know the majority of my patients from the neighborhood. It's world-class care — with a real hometown feel."