

Studies in the Division of Vascular Surgery

Meghan Dermody, MD

Chief of Vascular Surgery
Penn Medicine LGHP Surgical Group

Heather Madara

Regulatory and Outreach Manager
Penn Medicine LG Health Research Institute

Roy S. Small, MD

Medical Director of Clinical Research
Penn Medicine LG Health Research Institute



Dermody

Madara

Small

Editor's note: This is the 14th in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Other active studies have been described in previous issues of this journal.

The Research Institute welcomes Dr. Meghan Dermody of the LGHP Surgical Group as the guest co-author of this Spotlight. Physicians who wish to refer patients for any of the studies mentioned below are encouraged to contact the LG Health Research Institute at 717-544-1777. Other members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH at 717-544-8004.

The Penn Medicine Lancaster General Health Physicians Surgical Group has three board-certified vascular surgeons and a recent graduate who is board eligible in vascular surgery. We all perform a wide breadth of open and endovascular surgery from treatment of carotid and peripheral artery occlusive disease to aneurysms to creating dialysis access.

LG Health's Division of Vascular Surgery began entering surgical cases into a national database, called the Vascular Quality Initiative, in 2018. We are able to track all peripheral endovascular procedures, aneurysm repairs, leg bypasses, as well as carotid endarterectomy and stent procedures, through this database. We have a direct line of sight on our patients' outcomes and how we compare to our regional and national colleagues. Across the board, LG Health continues to lead the way in excellent patient outcomes. We hope to continue using our wide range of experience to improve the devices we use to treat these diseases and improve patient outcomes in the years to come.

In this article, we report on two studies. First, we recently obtained institutional review board approval to begin enrolling patients into a national clinical trial of transcatheter aortic valve replacement in standard

surgical risk patients (ROADSTER-3). In addition, we began enrolling dialysis patients into a post-market registry, which will follow their fistula patency over time after we perform a paclitaxel-coated balloon angioplasty to treat stenosis within the access.

The post-market registry includes cohort analysis, into which we will further enroll, which looks at durability of thoracic aortic endovascular stent grafts to treat thoracic aortic aneurysms and dissection. Our hope is to be able to provide long-term surveillance data for these complicated conditions and procedures that are not typically followed in our national database.

The ROADSTER-3 Study: Post-approval Study of Transcatheter Aortic Valve Replacement in Standard Risk Patients with Significant Aortic Atherosclerosis

Sponsor: Silk Road Medical

Principal Investigator: Meghan Dermody, MD

This open-label, multicenter, single-arm, prospective post-approval study (PAS) plans to evaluate the ENROUTE Transcatheter Aortic Valve System when used with the ENROUTE Transcatheter Aortic Valve Neuroprotection System. The study will explore the treatment of patients at standard risk for adverse events from carotid endarterectomy who require carotid revascularization and meet the study eligibility criteria. The sponsor plans to enroll a maximum of 400 patients at up to 65 U.S. and European sites. There are two primary outcome measures:

1. Composite of Major Adverse Events defined as any death, stroke, or myocardial infarction (MI) within 30 days of the procedure.
2. Ipsilateral stroke within 31-365 days following the procedure.

Multiple secondary outcomes will be measured, including incidence of cranial nerve injury, stroke, death,

MI, access site complications, serious bleeding complications, and rates of stent thrombosis or occlusion and carotid dissection. To be included in the study, patients must have either symptomatic stenosis of $\geq 70\%$ by ultrasound or $\geq 50\%$ by conventional or CT angiogram or have asymptomatic stenosis of $\geq 70\%$ by ultrasound or $\geq 60\%$ by conventional or CT angiogram.

Patients must be between the ages of 18 and 80 years. Exclusion criteria include patients with high anatomic risk (contralateral carotid occlusion, tandem stenoses, stenosis distal to C2 vertebra, restenosis after endarterectomy, bilateral severe carotid stenoses, or a hostile neck) or those with clinical high risk (≥ 2 vessel coronary artery disease, history of angina or congestive heart failure, ejection fraction $< 30\%$, MI within six weeks, severe chronic obstructive pulmonary disease, or late-stage renal failure).

There are multiple additional exclusion criteria, the most common being patients with chronic atrial fibrillation, those with a potential cardiac source of embolism, a recently implanted heart valve, or severe ipsilateral intracranial carotid stenosis.

LG Health was activated as a site in October 2022 and plans to enroll 20 participants.

**PSR-APV: Product Surveillance Registry —
Aortic, Peripheral & Venous**

Sponsor: Medtronic

Principal Investigator: Meghan Dermody, MD

The Product Surveillance Registry (PSR) collects data about the safety and effectiveness of Medtronic products on the market. The original registry has been active for many years, but there are multiple cohorts under the PSR umbrella. LG Health recently received approval to enroll participants in two of the cohorts.

IN.PACT™ AV Access Cohort

This Post Approval Study (PAS) specifically evaluates the safety and effectiveness of the IN.PACT™ AV Access Drug Coated Balloon (DCB). It will compare the DCB to transluminal angioplasty (PTA) by collecting data about target lesion primary patency (measured at six months post-procedure) and any serious adverse events that occur within 30 days post-procedure. Additional data will be collected about revascularizations, additional required reinterventions, and occurrence of access circuit thrombosis.

The study enrolls patients who have a documented de novo or non-stented restenotic obstructive lesion of

native arteriovenous dialysis fistulae (AVF) in their upper extremity. Enrolled participants will be followed as long as they have the AVF or until the study closes. LG Health plans to enroll one to two patients per month over an enrollment period of approximately eight years.

Aortic Cohort

This cohort seeks to enroll patients who received any eligible Medtronic product (stent graft) used to treat diseases of the thoracic aorta, such as aneurysms or dissections. Participants are followed per standard of care post-implant procedure with data collected at their regularly scheduled visits. The registry will collect data regarding reinterventions, current health status, adverse events, imaging results, and device issues. Enrolled participants will be followed as long as they have the eligible implanted Medtronic product or until the study closes.

**Active Clinical Studies
at Lancaster General Health**

A complete list of active clinical studies at Lancaster General Health is available online. To access the most current list, scan the QR code, or find the link on the Resources/Links page at JLGH.org. To make a referral to any study on the list, call the Penn Medicine Lancaster General Health Research Institute at 717-544-1777.



Meghan Dermody, MD, RPVI, FACS, FSVS
Penn Medicine LGHP Surgical Group
2104 Harrisburg Pike, Suite 200, Lancaster, PA 17601
717-544-3626
Meghan.Dermody@pennteam.upenn.edu

Heather Madara
Penn Medicine LG Health Research Institute
131 E. Frederick St., Lancaster, PA 17602
717-544-1777
Heather.Madara@pennteam.upenn.edu

Roy S. Small, MD
The Heart Group of Lancaster General Health
217 Harrisburg Ave., Lancaster, PA 17603
717-544-8300
Roy.Small@pennteam.upenn.edu