



PROGRAM OVERVIEW

## Vascular Care

At Indiana University Health, the vascular surgeons perform some of the most complex open, hybrid, and endovascular procedures. These include acute aortic emergencies, cerebrovascular disease, mesenteric arterial reconstruction, limb salvage, complex dialysis access, complex embolization, and fenestrated endovascular stents. Additionally, they have significant experience in vascular regenerative medicine and carotid stenting using the transcervical technique.

### Vascular Regenerative Medicine

The molecular and cellular therapeutics program at IU Health is a ground-breaking program in regenerative approaches to cardiovascular disease. This program is nationally recognized for starting the first stem cell trial for cardiovascular disease in the US and was the national leader for the recently completed multicenter Phase III Marrow Stem Treatment of Limb Ischemia in Subjects With Severe Peripheral Arterial Disease (MOBILE) trial that demonstrated a significant reduction in risk for leg amputation in patients with advanced peripheral arterial disease. The MOBILE trial is continuing as an open access registry (all patients will be treated) for patients with critical limb ischemia.

This program just initiated the Aortic Aneurysm Repression with Mesenchymal Stem Cells (ARREST) trial. The ARREST trial will assess the efficacy of immune regulatory stem cells in preventing aortic aneurysm expansion in patients with small aneurysms. This Phase I trial is the first of its kind, and is being conducted only at the Academic Health Center at IU Health.

Our program is the only center in the US offering stem cell therapy to prevent aneurysm expansion and one of only three in the country providing stem cell therapy to prevent amputation.

## Carotid Stent Program

Our division provides comprehensive evaluation and treatment of occlusive carotid artery disease. We offer screening as well as a comprehensive evaluation of extracranial carotid artery occlusive disease. The highly skilled vascular surgeons at IU Health offer patients the best possible treatment for their unique medical needs.

While we have decades of cumulative experience in traditional carotid endarterectomy (CEA) and more recently transfemoral carotid stents, our program also offers transcervical carotid stents. Transcervical carotid stent therapy is the most advanced modality for carotid revascularization.

IU Health is the only site in Indiana that is participating in the ROADSTER-2 Study, a follow-up to the Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure clinical trial. Early results have indicated that the benefits of the minimally invasive procedure are comparable to the gold standard CEA. We are one of the highest volume sites enrolling patients in the ROADSTER-2 Study and have completed 100 transcervical carotid stent procedures with a <2% stroke rate and no mortalities. (See table below.)

### Volumes, Mortality, and Strokes in Carotid Stent Program

| Post-Operative events       | IU Health 2014 N=19 | IU Health 2015 N=27 | IU Health 2016 N=54 |
|-----------------------------|---------------------|---------------------|---------------------|
| No Neuro Event <sup>1</sup> | 89.5% (17)          | 96.3% (26)          | 98.1% (53)          |
| TIA <sup>1</sup>            | 5.3% (1)            | 3.7% (1)            | 0% (0)              |
| Stroke Minor <sup>1</sup>   | 0% (0)              | 0% (0)              | 1.9% (1)            |
| Stroke Major <sup>1</sup>   | 5.3% (1)            | 0% (0)              | 0% (0)              |
| Alive at dc                 | 100.0% (19)         | 100.0% (27)         | 100.0% (54)         |
| Deceased at dc              | 0% (0)              | 0% (0)              | 0% (0)              |

<sup>1</sup>: Includes Ipsilateral and contralateral events  
 - All cases (elective, urgent, and emergent)  
 - Source VQI: 0907217 (dependent of inclusion criteria)

Inclusion criteria: Carotid artery stents that involve the carotid bifurcation or are isolated to the internal, external, or common carotid artery that may be performed by percutaneous or open (cut down) approach. Both primary and redo stenting is included. Unlike other procedures, stenting for trauma is also included. Typically, the carotid bifurcation or internal carotid artery is treated, but sometimes an isolated common carotid stenosis is treated alone, or in combination with a bifurcation/internal carotid stent. The external carotid is rarely treated, but we are including it to meet CAS recertification requirements. Exclusions: Intracranial Carotid Artery stents (above C1).

Source: Vascular Quality Initiative

PATIENT SPOTLIGHT

## A Golf Lover's Peripheral Artery Disease

It all started with a tiny crack on Chip Gagnier's finger, like a paper cut. It wouldn't go away. Gagnier's finger crack was diagnosed as scleroderma – an autoimmune disorder that causes hardening of the skin.

The scleroderma led to peripheral arterial disease (PAD), which narrows the arteries and reduces blood flow to the limbs. More and bigger wounds formed that wouldn't heal. Doctors tried an artery graft and Gagnier thought it was working, but then the arteries narrowed again.

He was in constant pain, and had given up his favorite thing – playing golf. Doctors were talking the unthinkable – amputation. But then Gagnier got a call from one of his best friends, who is a doctor. He told Gagnier that IU Health was doing a clinical trial using stem cell therapy for people with PAD.

Dr. Michael Murphy is a vascular surgeon and a research leader with the Vascular and Adult

Stem Cell Therapy Center at IU Health. More than a decade ago, Dr. Murphy was part of the first FDA-approved U.S. clinical trials using a patient's stem cells and injecting them into another part of their body to treat PAD. Since then, IU Health has become known as a hotbed for leading advancements in stem cell research.

In 2010, Gagnier enrolled in the Phase III trial and his right leg received stem cells. In 2012, his left leg went through the procedure. Soon after the injections, new capillaries were forming under Gagnier's skin. It got better day by day and then year by year. Gagnier is playing golf again. And Gagnier says he felt being part of the trial had a bigger cause than just himself. "My whole thing was if it worked for me, that was great," he says. "But if they learned something that helped someone else, that would be just as great."

