



Clinical

UPDATE

Issue 2, 2012

DEBORAH® Heart and Lung Center



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Deborah Physicians
Expand Use of
Transradial
Catheterizations

Deborah Heart and
Lung Center Enrolls
PAD Patients in
CONNECT II Global
Clinical Trial



*Welcome to
Our New
Interventionalist*



Aaron VanHise, DO
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Board Eligible: Interventional Cardiology, Endovascular Medicine

Special Interests: Preventative Medicine, Coronary Intervention, Peripheral Vascular Intervention, Venous Disease

Deborah Physicians Expand Use of Transradial Catheterizations

Deborah Heart and Lung Center has quickly moved into the regional leadership position in performing Transradial Artery Catheterizations. Last year Deborah physicians performed 1,000 wrist cath procedures at the hospital. This year Deborah's interventionalists have greatly expanded their use of this new procedure to treat peripheral vascular disease in different vascular distributions. Additionally, an alcohol septal ablation was recently performed through the radial approach to treat a patient's hypertrophic cardiomyopathy.

"This is an exciting new journey we are on," said Kintur Sanghvi, MD, Director of the Transradial Program at Deborah. "We are seeing lightning-fast changes in our increasing ability to treat more and more complex cases through wrist access."

Dr. Sanghvi pointed out the benefits to the patients of transradial procedures -- including significantly lower risk of bleeding complications, earlier ambulation, earlier discharge, and increased patient comfort—all afforded by wrist catheterizations, since patients do not have to lie flat and stay still for hours as they do with a groin procedure.

This year wrist cath procedures at Deborah have expanded to treat blockages of the subclavian, renal, superior mesenteric, iliac, external iliac, and femoral arteries in appropriate patients. This is an especially important application for patients who have diseased and blocked leg arteries, and who run a higher risk of bleeding and complications in treating their peripheral artery disease through a traditional groin catheterization.

Dr. Sanghvi reported on a successful mesenteric artery intervention.

"The patient had stenosis in this artery, causing abdominal pain, nausea and vomiting," said Dr. Sanghvi. "Gradually this causes phobias for food, and meal portions get smaller and the patient loses weight. This has traditionally been treated through the groin approach, but we were successful in using a wrist cath for this, and the patient went home within a few hours."

"We have done some complicated cases through radial access," added Dr. Sanghvi. "Our recent alcohol septal ablation was, I believe, the first reported case in the U.S. This was truly an exciting, innovative use of transradial access."

Dr. Sanghvi—who recently presented his findings at the Quebec International transradial course—is Associate Editor of *Transradial World* and has widely published. He fully expects more complex procedures to be done through the wrist.

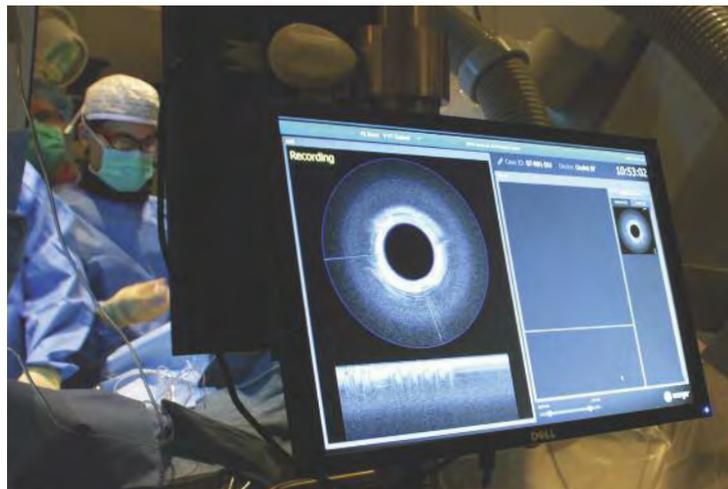
"We can now thread our catheter through the wrist and travel as far as the hip joint to treat a blocked artery. We cannot yet clear blockages below thigh level in most cases, because the treatment devices are not long enough yet, but I expect this will change."♥

Kintur Sanghvi, MD,
Director,
Transradial
Program



Deborah Heart and Lung Center Enrolls PAD Patients in CONNECT II Global Clinical Trial

New catheter combined with a camera provides real-time “inside” view of diseased peripheral arteries



Deborah Heart and Lung Center announces its participation in CONNECT II, a global clinical trial conditionally approved by the FDA that gives physicians access to a sophisticated new imaging technology tool to fight Peripheral Arterial Disease (PAD). The technology -- called Ocelot and invented by Avinger -- helps to eliminate the need for bypass surgeries and/or amputations in patients with the disease. Each year, nearly 200,000 amputations occur as a result of PAD.

Jon C. George, MD, Deborah Attending Cardiac Interventionalist, recently debuted this new imaging technology, making Deborah the first hospital in the Eastern U.S. with access to this technology. As part of CONNECT II, Dr. George's use of Ocelot helped restore a patient's blood flow in completely blocked arteries in the patient's leg through a simple two-millimeter skin incision.

Deborah is one of only 17 sites worldwide, and one of only 14 sites in the United States selected to participate in this clinical trial.

Of key note with Ocelot is its combination of a proprietary peripheral catheter design paired with real-time Optical Coherence Tomography (OCT). This groundbreaking new tool gives physicians a technique to cross segments of the peripheral vascular

system that have chronic total occlusions (blockages) using a catheter armed with a camera. Ocelot's companion Lightbox console displays the OCT image, offering the physician a real-time visualization of the blockages. Prior to the Ocelot trials, physicians had to rely on X-rays to see outside the artery. Now, Ocelot allows them to see inside the artery.

"Ocelot is aptly named for the cat that possesses excellent night vision," said Dr. George. "This is the first-ever interventional device that allows us to drill through the totally blocked arteries in the legs while using an integrated camera to see it from the inside. This is a major advance for patients with PAD, who might be facing losing a limb."

He added: "We are privileged here at Deborah to have access to this wonderful new cutting-edge research technology. By being involved in clinical trials for the next generation of technology, we are assuring Deborah's patients of the very latest and most-sophisticated PAD care."

Dr. George, as principal investigator on the CONNECT II trial, has had considerable experience with Ocelot -- along with Richard Kovach, MD, Deborah's Chair, Interventional Cardiology -- including evaluating the device in Leipzig, Germany and moderating live case studies in Muenster,

Germany as part of the Leipzig Interventional Course.

PAD, affecting between 8 and 12 million adults in the U.S. alone, is caused by a build-up of plaque in the arteries and blocking blood flow to the legs and feet. Because some blockages can become so severe and difficult to penetrate with traditional catheters, patients may undergo invasive bypass surgeries that result in health risks and lengthy, painful recoveries. Patients over 50 often face amputation, the worst-case scenario associated with PAD.

CONNECT II is a prospective, multi-center, non-randomized global clinical study that will evaluate Ocelot on 100 PAD patients with femoropopliteal chronic total occlusion lesions at 14 U.S. sites.♥

For more information, or to refer a patient for this trial, please contact Linda Dewey, RN, MSN, CCRC, Senior Study Coordinator 609-893-1200 ext. 5023; Fax (Attn: Linda) 609-893-6038 or DeweyL@Deborah.org.

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Clinical Research Department Awards

Deborah Heart and Lung Center's Clinical Research Department was recently honored with several awards.

At a recent Levant 2 Registry Meeting, Bard Medical and Lutonix awarded Deborah -- and physicians Richard Kovach, MD, Jon George, MD, with Research Coordinators Linda Dewey, MSN, CCRC and Alyssa Bruflo, CCRC -- an **"Excellence in Overall Trial Execution."** Out of 42 U.S. participating research centers, Deborah was one of only five research sites to receive this award, demonstrating fewest protocol deviations, timely data entry and query

resolution, quality ultrasounds and angiographic films, overall protocol adherence, and volume of enrolled study participants. Deborah is currently participating in the LEVANT 2 study, which preceded the registry. The current study is comparing drug-eluting balloon technology with traditional balloon angioplasty in treatment of peripheral arterial disease.

As well, Deborah physician Edmund Karam, MD, and research assistant JoEllen Schmidt, RN received a **"Data Quality Award"** for outstanding work in research data completion, execution and quality for

participation in the ECHO CRT electrophysiology study. This award, presented by Biotronik, evaluates the effectiveness of Cardiac Resynchronization Therapy in patients with heart failure, not having delayed conduction on ECG.

The awards also recognize the key support role played by Deborah's entire research team -- as well as the Ultrasound Department, Cath Lab, Radiology Interventional Team, Echo Department and Pacer Clinic -- which are pivotal in the hospital's clinical trials.♥