

BEST-CLI – Spring ahead with BEST!

March Madness means enrollments in BEST are heating up! With the snow now melting for many BEST-CLI teams, let's pick up the pace and shoot for more subjects!

Arterial Anatomy and its Role in BEST-CLI

From the Desktop of Alik Farber MD

Arterial anatomy plays a critical role in the management of CLI. Atherosclerotic occlusive disease leads to an almost infinite number of anatomical variants. We classify lesions by arterial location, degree and length of stenosis, presence and length of occlusion, presence of calcification, etc.

How then does arterial anatomy play into the BEST-CLI trial?

Certainly, anatomical factors are key aspects of several Inclusion/Exclusion criteria as listed below:

1. A patient needs to have an artery to which a bypass could be constructed, should he/she be randomized to open surgery (*arterial target for distal anastomosis*).
2. A patient cannot have *severe common femoral artery (CFA) disease* (approximated to be >50% on angiography). However, it is OK for the patient to undergo a CFA endarterectomy, if randomized to open surgery.
3. If a patient has *significant iliac disease*, it needs to be treated so that inflow into the groin is adequate. For patients with rest pain (Rutherford Class 4), we ask for 28 days to pass after endovascular iliac intervention to see whether this alone successfully treated the patient's rest pain. For patients with tissue loss (Rutherford Classes 5 and 6), the iliacs can be treated at any time between diagnostic angiography and randomization (including at the time of index procedure). Occlusions of the aorta or iliacs are not allowed into the trial.

Beyond these concrete rules lie anatomical scenarios that may favor an investigator to choose surgery or endovascular therapy based on personal bias. Let's consider some of these scenarios! As we do that I would like to share with you results of an interesting survey. To study equipoise in CLI treatment we asked 100 vascular surgeons to share with us their opinions as to the type of treatment they would choose (bypass versus endovascular therapy) based on discrete anatomical scenarios.

1. Flush occlusion of the superficial femoral artery (SFA) biases some investigators toward bypass due to concern that they are hard to recanalize. However, many endovascular specialists are quite comfortable breaking through the flush SFA occlusion using a supported guidewire/catheter combination or a recanalization catheter. In our survey, for this type of anatomy, 11% of providers preferred bypass, 36% preferred endovascular therapy, while 54% had equipoise.
2. Occlusion of the popliteal artery with or without occlusion of part or all of the SFA can bias some investigators toward bypass. However, there are many investigators who have no qualms in attempting to recanalize such lesions using a variety of available chronic total occlusion (CTO) devices. Stents are usually required, and technical results are often excellent. No one really knows how these techniques compare to bypass surgery in the long term, although, strong opinions range across the spectrum. In our survey, 36% of surgeons preferred bypass, 22% preferred endovascular therapy, while 43% had equipoise.
3. Proximal occlusion of all tibial arteries is another common variant in patients with CLI. Again, both bypass and endovascular therapy can be used successfully in this setting. Retrograde tibial access may be required if endovascular therapy is attempted. In our survey, 51% of surgeons preferred bypass, 11% preferred endovascular therapy, while 42% had equipoise.
4. Diffuse severe tibial disease with a patent pedal target is our final scenario. Both bypass and endovascular therapy are currently used in North America to treat such patients. In our survey, for this scenario, 43% of surgeons favored surgery, 16% favored endovascular therapy, while 42% had equipoise.

There are multiple arterial variants in patients with CLI. Our survey reflects a wide range of opinion as to which treatment is best for each situation. These differences of opinion are not surprising given the incredible variability of CLI treatment patterns that currently exists in North America.

Most CLI patients have anatomical variants for which both open surgery and endovascular therapy can be successfully used, and are thus potential subjects for the BEST-CLI study. We recognize that there will be variability with respect to how comfortable investigators feel treating some of these patients with one approach or the other. There is no question that some arterial variants are technically harder to address than others. We do advise that most anatomical scenarios be considered for enrollment into the trial by the site CLI team. For difficult anatomical scenarios it may be best to have the most experienced investigator involved, either assisting or as the primary operator.

PTA DCB Catheters Now Approved for Use in BEST!

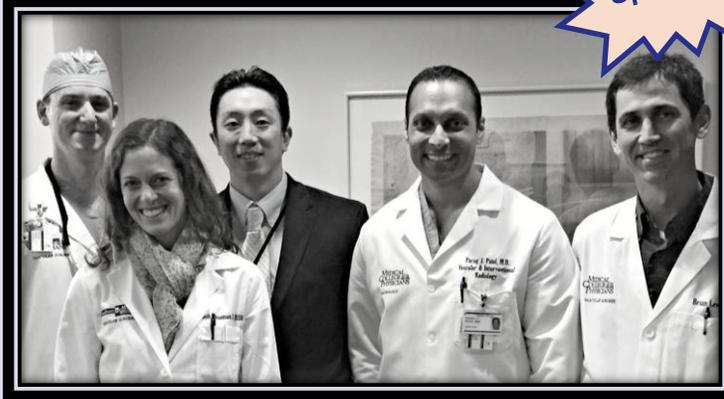
The BEST-CLI Trial leadership voted and approved the use of the Lutonix 035 and Admiral™ PTA DCB catheters in BEST. Additional details are found in Ops Memo #3, posted to NERI Connect.

[Ops Memo #3](#)
[Click here](#)

Please keep a copy of this operations memo in your regulatory files for BEST-CLI.



Medical College of Wisconsin



From left to right: Peter Rossi, MD Elizabeth Weseman, RN Cheong Jun Lee, MD Parag Patel, MD Brian Lewis, MD

“The Medical College of Wisconsin has created a successful BEST CLI Team by continuing its collaborative multidisciplinary approach and sharing the ownership of the protocol between two departments (Interventional Radiology and Vascular Surgery). The PI, Dr. Parag Patel is a member of the Interventional Radiology Department and the co-PI, Dr. Cheong Jun Lee and Research Coordinator, Elizabeth Weseman are members of the department of Vascular Surgery. The group meets weekly for a combined IR/VS conference to discuss possible patients. The joint effort between both services lends itself to open communication and frank discussions regarding patient treatment algorithms, strategies, and enrollment in the BEST CLI trial.”

Request for Screening Logs!

The next round of screening logs is due

[April 3rd](#)

Make sure to document all screen failure information on your screening logs before sending to the DCC.

Holy Name Medical Center



Back from left to right: Jacqueline Barat-Limnios, Insook Kim, RN Front from left to right: Amish Patel, MD Kevin Herman, MD Ravit Barkama, MD, MPH Yitzchak David, Darlene Dobkowski, PA-C, Yana Ryklin, RN, Lauren LoVecchio, RN, Kelly Gill, RN, and John H. Rundback, MD Bottom from left to right: Kathy Ix, RN, Marion Cyriac, MD, Maureen Murray

“Holy Name Medical Center (HNMC) boasts a strong focus on vascular patient care and draws from an incredible talent pool of interventional radiologists, interventional cardiologists and vascular surgeons. As the contact principal investigator (PI), Dr. Rundback has pushed aggressively for a multidisciplinary and collaborative approach that allows HNMC’s vascular team to focus on each patient ensuring continued expert care. Dr. Rundback has collaborated with Dr. Ravit Barkama, HNMC AVP of Clinical Development and Director of the Institute for Clinical Research, to identify research opportunities that continue to push for important developments in treating patients with complex peripheral vascular disease.

Research team members Cynthia Bredy (Regulatory Coordinator), Yitzchak David (CRC), and Marion Cyriac, MD (CRC) prioritized the BEST-CLI protocol for quick start-up and IRB submission. Once approved, the study coordinators began screening all clinic lists for patients seen by the vascular team and have maintained constant communication with all specialty PIs and sub-investigators to promote the study as well as encourage enrollment. Once patients have been identified, a study investigator and coordinator speak with each patient about the importance of the BEST-CLI protocol and what it could mean for the future of vascular care. Through this continuous effort, HNMC has successfully enrolled five patients into the BEST-CLI protocol. Furthermore, the established relationship between the team and patients has kept high retention with the study follow-up. Additionally, this team effort allows for continuous screening of potential candidates daily.”



BEST February Highlights

Number of New Sites Activated: 12
Top Enroller: Site 1055, Mount Sinai Medical Center
Sites Enrolling 1st Subject: 12

Frequently Asked Question:

Q: What do I do if I have an expected page in eCOS but no data to enter (e.g., missed questionnaire)?

A: Inform the data manager at the DCC and the page will be set to "Missing" for you. Please do not enter anything (e.g. subject ID, etc.) on the page or answer any queries for empty fields.

Note, this is only for pages where the data for the entire page is missing, not just particular questions.

Site Payments

The next data freeze for site payments is scheduled for April 1st. Make sure you enter your data and respond to queries in eCOS to ensure your site is paid.

BEST Tips from the CRAs

Unsure how to document medications?

Medications are recorded at each visit for every subject. Document the medications the subject is taking that day of the visit. On the procedure day, you only record the medications the subject is taking the morning of the procedure and not the medications taken during the procedure. You should record the medication name and total daily dose the subject is taking that day of the visit.

Baseline Data and Acceptable Windows

Acceptable windows for each Baseline measurement can be found in Version 2.0 of the MOO, Chapter 5, which is available on [NERI Connect](#).

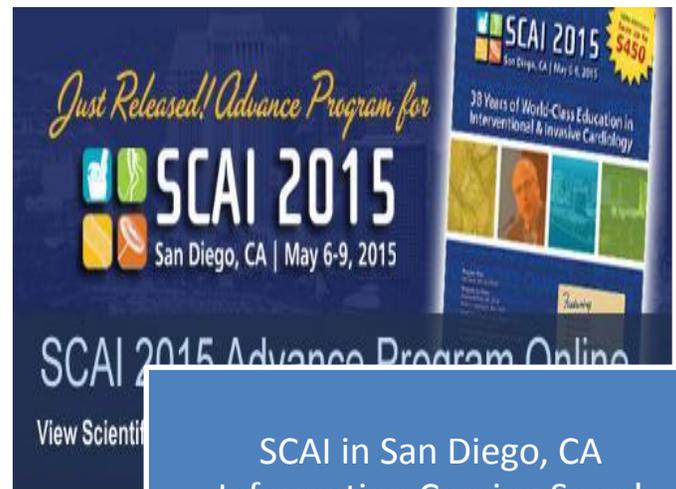
Did you know we have an enrollment worksheet?

The Enrollment worksheet includes all eCRFs needed for Randomization in one worksheet (General Information, Informed Consent, Inclusion Criteria, Exclusion Criteria, Vein Mapping, Randomization – Stratification). This is a great resource to have available when you are collecting data for Randomization! Worksheets for all eCRFs including the Enrollment worksheet can be found on [NERI Connect](#).

Upcoming Investigator Meetings



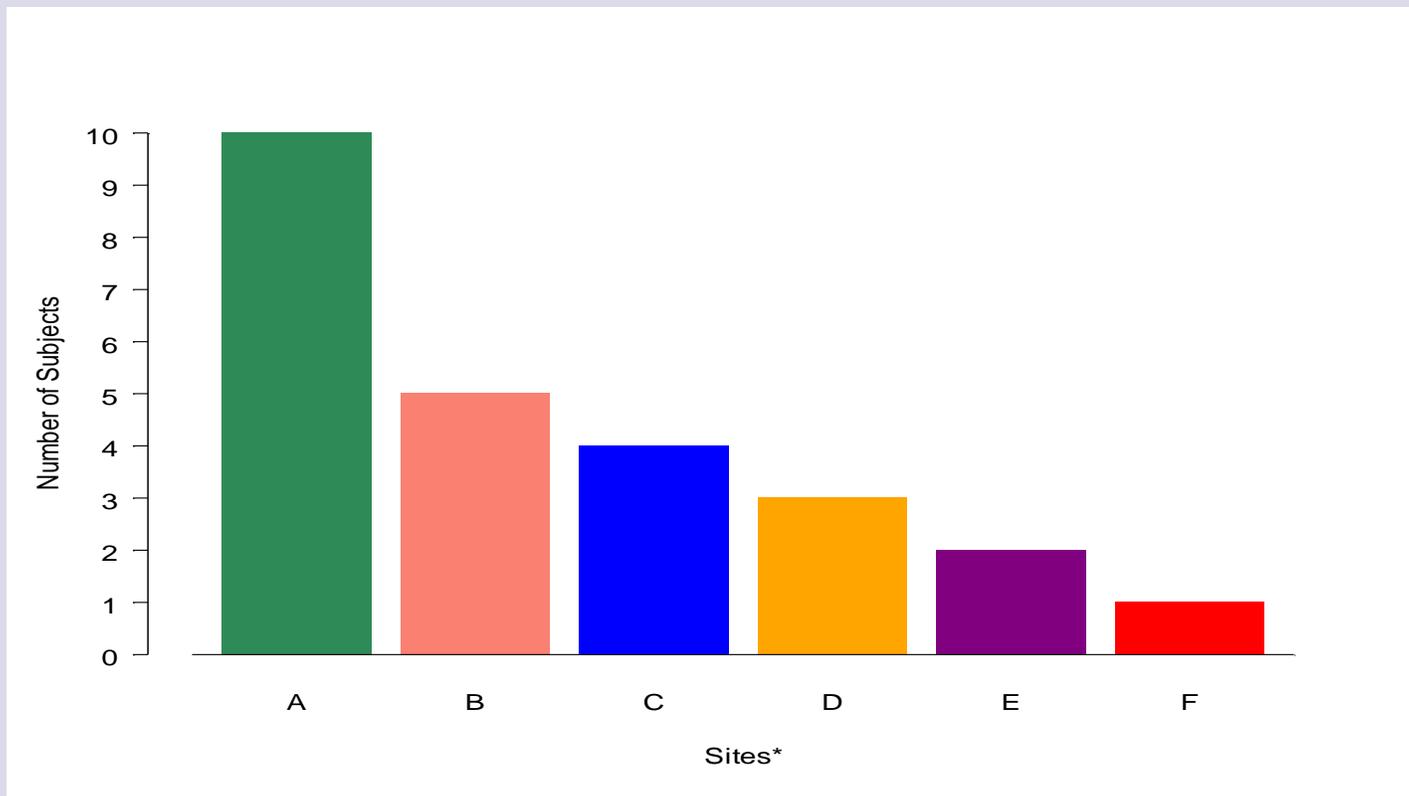
SCVS in Miami, FL
Wednesday, April 1st from 17:00-18:00ET in the Facet Meeting Room (4th Floor), Fontainebleau



SCAI in San Diego, CA
Information Coming Soon!

Enrollment Leaderboard

100th Subject Enrolled! Special Thanks to the University of California, Davis Medical Center for enrolling the 100th subject in BEST!



Sites*

- A: 1160 - Keck Medical Center of USC; 1258 - Boston Medical Center
- B: 1108 - Michigan Heart/St Joseph Mercy Ann Arbor Hospital; 1316 - Holy Name Medical Center
- C: 1105 - Medical College of Wisconsin
- D: 1005 - Brigham and Women's Hospital; 1009 - Dartmouth Hitchcock Medical Center; 1055 - Mount Sinai Medical Center; 1260 - Greenville Memorial Hospital; 1272 - St. Boniface General Hospital; 1276 - Memorial Hermann Hospital TMC; 1281 - VA Western NY Healthcare System; 1282 - Carondelet Heart & Vascular Institute; 1288 - Kaiser Foundation Hospital
- E: 1013 - Harbor-UCLA Medical Center; 1041 - San Francisco Veterans Affairs Medical Center (SFVAMC); 1095 - Johns Hopkins Hospital; 1169 - University Hospitals of Cleveland/Case Western Reserve University; 1269 - Ohio Health Research Institute; 1277 - The University of Utah; 1311 - Dallas VA Medical Center; 1318 - University of North Carolina Hospitals (Chapel Hill); 1331 - Pinnacle Health System
- F: 1029 - Michael E. DeBakey VA Med Ctr.; 1030 - Montefiore Medical Center; 1046 - Steward St. Elizabeth's Medical Center; 1104 - VA Palo Alto; 1135 - University of Pittsburgh Medical Center; 1151 - William Beaumont Hospital affiliated Beaumont Health System; 1182 - Providence Heart and Vascular Institute; 1217 - University of California Davis Medical Center; 1238 - University of Massachusetts Medical School; 1256 - Beth Israel Deaconess Medical Center; 1263 - Kaiser Permanente (San Diego); 1288 - Kaiser Foundation Hospital; 1272 - Southern Illinois University School of Medicine; 1279 - North Carolina Heart and Vascular Research; 1290 - Loma Linda University Medical Center; 1294 - North Central Heart Institute; 1309 - Mercy Hospital Medical Center; 1310 - Harborview Medical Center; 1314 - VA Boston Healthcare System; 1323 - University of Nebraska Medical Center; 1325 - Deborah Heart and Lung Center