

BEST-CLI – Happy Thanksgiving!

From the Desktop of Joseph L. Mills, MD (Baylor College of Medicine)

“Latest and greatest from the father of Wifl”

In 2014, the SVS Lower Extremity (LE) Guidelines Committee published a new classification system of the threatened limb termed SVS Wifl based on grades of Wound, Ischemia, and foot Infection ([http://www.jvascsurg.org/article/S0741-5214\(13\)01515-2/fulltext](http://www.jvascsurg.org/article/S0741-5214(13)01515-2/fulltext)). Each of the three components is assigned a grade from mild/none (0) to severe (3) and the resulting score placed in one of four amputation risk stages by a Delphi Consensus process described in detail in the original manuscript. Since its publication, SVS Wifl has been rather rapidly adopted, suggesting that it serves an unmet need. There are now seven published reports from single centers that validate the ability of Wifl to stratify amputation risk. Stage 4 patients are at particularly high risk of amputation with a pooled 1-year amputation risk of 34% based on these reports published to date. The availability of a free Wifl calculator as part of an app made available for free by the SVS (SVS IPG – Interactive Practice Guidelines (<https://vascular.org/research-quality/clinical-practice-documents/interactive-practice-guidelines-app> or <https://itunes.apple.com/app/id1014644425>) has helped clinicians utilize Wifl.

The impetus to propose a new classification system arose due to dramatic changes in patient demographics, in particular the global epidemic of diabetes (now over 422 million individuals globally) and the rise of increasingly improved endovascular therapeutic options. Previous classifications failed to consider infection or adequately grade wound severity, and both Rutherford and Fontaine were often applied without the intended hemodynamic criteria. In addition, the original concept of critical limb ischemia (CLI) was extended to include patients with diabetes and the hemodynamic criteria were increasingly ignored, making it difficult to compare outcomes of various forms of therapy given that the initial limb disease burden was not carefully described. The SVS Wifl classification was intended to be an iterative process, the goal of which is to more precisely stratify at-risk limbs according to their initial disease burden, analogous to the TNM (Tumor, Node, Metastases) cancer staging system. While Wifl is intuitive and easy to use, to the non-indoctrinated, it may at first seem complex and cumbersome because it results in a grid of 64 potential at-risk limb presentations (3 components, 4 grades for each), which are then placed into one of 4 Clinical Stages. While the availability of the SVS IPG app has made using Wifl simpler, the SVS LE Guidelines committee produced a PowerPoint Tutorial to walk clinicians through the process of applying Wifl in practice. At the request of the BEST-CLI lead investigators, we are sharing this tutorial with all BEST-CLI trialists. It will be very useful to apply Wifl prospectively, and it of interest and importance to note that Wifl grades and stages are being collected both in the BEST-CLI trial and in the BASIL follow-up studies in the United Kingdom. We hope the BEST-CLI investigators and others find the tutorial helpful.

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Have an SAE to report? Don't have all the information?

That's okay. The first step is to create an initial report of the SAE (within 24 hours of learning of the event) in eCOS. Sites can then fill in the missing information by adding an AE follow-up page. DO NOT MODIFY THE ORIGINAL AE PAGE.

Overnight hospital admissions meet the definition of an SAE.

Join BEST on Social Media



Tweet us **@BEST_CLI**



Join our [LinkedIn](#) group!

CHU de Québec-Université Laval



BEST October Highlights

TOP ENROLLERS

- 1005/BWH**
- 1113/OHSU**
- 1258/BMC**
- 1273/U. Florida**
- 1351/KP NCAL**

First picture, Back row (left to right): Dr. Yvan Douville Resident, Dr. Pascal Rhéaume, Julien Bernatchez Resident; Front row (left to right): Guylaine Nadeau, RN,CRC, Valérie Gauvin Senior Resident, Dr. Nathalie Gilbert; Second picture (left to right): Dr. Mathieu Béland, Dr. Guy Dionne and Dr. François Côté; Third picture: Dr. Raymond Labbé

The BEST-CLI team at the CHU de Québec-Université Laval is led by Dr. Yvan Douville along with 5 other Vascular Surgeons, Dr. Pascal Rhéaume, Dr. Nathalie Gilbert, Dr. Ghislain Nourissat, Dr. Raymond Labbé, Dr. Mireille Methot, and 5 Interventional Radiologists, Dr. Guy Dionne, Dr. François Côté, Dr. Guillaume Garneau, Dr. Catherine Lalonde and Dr. Mathieu Béland, along with our research nurse coordinator Guylaine Nadeau and 2 research assistants. We are all part of the "Centre de référence des Maladies Vasculaires" which also includes 7 vascular internists.

We see some 20,000 vascular (both medical and surgical) peripheral patients per year. We are responsible for the vascular care of the eastern part of the province of Québec (population 1.5 million). Patients may have to travel up to 10 hours sometimes to come to Québec City for their evaluation and treatment, which has been a limitation for us to recruit in the BEST-CLI trial. Clinical nurses, residents and fellows share the responsibility to recruit patients in the trial.

Our vascular team holds weekly conferences to discuss the vascular patient population and at the same time our overall progress and updates of the ongoing trials at our site. We are proud to be part of the BEST-CLI trial which will hopefully help and guide future vascular surgeons to define the best treatment for CLI patients.

When entering AE terms...

Some sites are entering procedures (such as 'bypass graft') rather than the event that led to the procedure (e.g. 'occlusion').

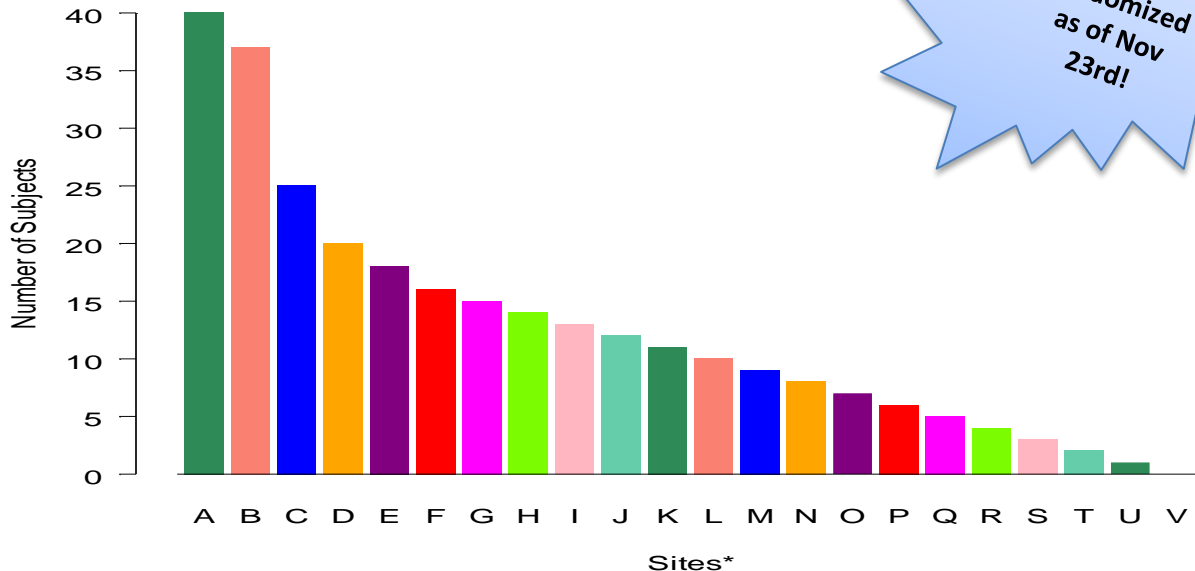
So, if you are one of these sites, you will see queries in eCOS that you need to respond to and fix ASAP. If you have any questions on how to BEST respond to the query, please contact your assigned CRA, or send your questions to the BEST Trial mailbox, BEST@neriscience.com.

Visit Windows

All follow-up visits EXCEPT the 30-Day Post-Procedure Visit are based on the date of Randomization. The 30-Day visit is based on the date of the Index Procedure, but all other visits are based on date of Randomization.

A very valuable tool in eCOS is the Visit Window Report, which lists all of your previous and upcoming patient visits and visit windows.

Enrollment Leaderboard*



772 subjects randomized as of Nov 23rd!

- A: 1258 - Boston MC
- B: 1160 - Keck MC of USC
- C: 1238 - Univ. of Massachusetts Medical School
- D: 1260 - Greenville Memorial Hosp.
- E: 1274 - Univ. of Oklahoma Health Sciences Ctr.
- F: 1009 - Dartmouth Hitchcock MC
- G: 1282 - Carondelet Heart & Vascular Institute
- H: 1154 - Yale; 1284 - Chu de Quebec
- I: 1005 - Brigham and Women's Hosp.; 1101 - Albany MC; 1261 - Indiana Univ. Medical School; 1273 - Univ. of Florida (Gainesville); 1309 - Mercy Hosp. MC
- J: 1272 - St. Boniface General Hosp.; 1288 - Kaiser Foundation Hosp.(Hawaii)
- K: 1013 - Harbor-UCLA MC; 1104 - VA Palo Alto; 1105 - Medical College of Wisconsin
- L: 1256 - Beth Israel Deaconess MC
- M: 1017 - Henry Ford Hosp.; 1030 - Montefiore MC; 1055 - Mount Sinai MC; 1113 - Oregon Health and Science Univ.; 1135 - Univ. of Pittsburgh MC; 1332 - Denver VA MC; 1342 - Regina Qu'Appelle
- N: 1041 - San Francisco VA MC; 1095 - Johns Hopkins Hosp.; 1217 - Univ. of California Davis MC; 1276 - Memorial Hermann Hosp.; 1310 - Harborview MC; 1318 - Univ. of NC Hosp.; 1340 - Wake Forest Baptist Hosp.
- O: 1061 - Baptist Hosp. of Miami; 1066 - Arizona Heart Hosp.; 1108 - Michigan Heart Hosp.; 1281 - VA Western NY Healthcare System; 1305 - Univ. of Virginia; 1306 - McGill; 1308 - The Ohio State Univ.; 1311 - Dallas VA MC; 1323 - Univ. of Nebraska MC; 1346 - Gundersen Health System
- P: 1023 - Massachusetts General Hosp.; 1029 - Michael E. DeBakey VA MC; 1169 - Case Western Reserve; 1259 - Rhode Island Hosp.; 1275 - Medical Univ. of South Carolina; 1314 - VA Boston Healthcare System
- Q: 1010 - Emory Univ.; 1046 - Steward St. Elizabeth's MC; 1054 - Univ. of Colorado Hosp.; 1072 - Univ. of Wisconsin - Madison; 1075 - Swedish MC; 1173 - SUNY Upstate; 1188 - Toronto General Hosp.; 1234 - Univ. of Toledo MC; 1264 - Minneapolis Heart Hosp; 1277 - The Univ. of Utah; 1285 - Duke Univ.; 1290 - Loma Linda Univ. MC; 1293 - LSU Health Sciences; 1316 - Holy Name MC; 1337 - Loma Linda VA MC; 1344 - Michigan Vascular Center
- R: 1003 - Alleghany General Hosp.; 1026 - Medstar Washington Hosp. Center; 1125 - Univ. of California San Francisco MC; 1134 - Univ. of Michigan Health System; 1140 - Greater Los Angeles VA; 1182 - Providence Heart and Vascular Institute; 1271 - Southern Illinois Univ. SOM; 1300 - Tampa General Hosp.; 1304 - CAMC Clinical Trials Center; 1325 - Deborah Heart and Lung Center; 1326 - The Miriam Hosp.-Brown Medical School; 1345 - Los Angeles MC, Kaiser Permanente; 1347 - Maine MC; 1349 - Queens Elizabeth II Health Science Center

Enrollment Leaderboard Continued*

- S: 1007 – Cleveland Clinic Foundation; 1008 – Columbia Univ. MC; 1034 – Ochsner MC/Clinic Foundation; 1076 - Northwestern Memorial Hosp.; 1137 - The Univ. of Vermont MC, LLC; 1269 - Ohio Health Research Institute; 1270 - Scott and White – Temple; 1307 – Univ. of Rochester; 1331 - Pinnacle Health System; 1334 – Stanford; 1341 – Meriter Wisconsin Heart; 1351 – KP NCAL; 1367 - Englewood Hospital and Medical Center
- T: 1019 - Jewish General Hosp.; 1024 – Mayo Clinic (Rochester); 1229 - Penn State Milton S. Hershey MC; 1257 - Univ. of Arkansas for Medical Services; 1287 - Providence Sacred Heart MC; 1294 - North Central Heart Institute; 1301 – UCSD-Sulpizio Cardiovascular Center; 1336 - Staten Island Univ. Hosp.; 1350 - Benaroya Res. Inst. At Virginia Mason; 1355 - Vancouver General Hospital
- U: 1059 - The Univ. of Alabama; 1116 - Rush Univ. MC; 1121 – Temple Univ.; 1126 - Univ. of Chicago Medicine; 1131 – Univ. of Maryland; 1151 - William Beaumont Hosp.; 1263 - Kaiser Permanente (San Diego); 1279 - North Carolina Heart and Vascular Research; 1283 – Univ. of Oklahoma College of Medicine; 1299 - Univ. of Tennessee MC; 1302 - UCLA-Gonda Vascular Surgery; 1315 - George Washington Univ. Hosp.; 1320 - Portland VA MC; 1339 – Cadence Health (Chicago); 1348 – New Mexico Heart Institute; 1352 - San Diego VAMC
- V: 1018 - Inova Fairfax Medical Campus; 1085 – Cedars Sinai; 1156 – Minneapolis VAMC; 1226 – St. Paul’s Hospital (U. Saskatchewan); 1278 – Univ. of California Irvine; 1292 – Munroe Regional MC; 1327 - Wellmont Holston Valley MC; 1357 – St. Francis Hospital; 1358 - Vascular Health Partners, CCP; 1359 – The Ottawa Hospital; 1360 - Midwest Cardiovascular Research Foundation; 1361 - Midwest Aortic Vascular Institute (MAVI); 1362 - Mount Sinai Medical Center (Miami, FL); 1371 – MetroHealth Cleveland

*Data frozen on 11/20/2016.

**Site names abbreviated to accommodate space.

Data Management FAQ Corner - Medications

Medications for the BEST-CLI trial should be entered as a total daily dose to provide a snapshot of what medications the patient is on at the time of their visit. The daily dose should take into consideration the frequency the medication is taken to provide the full amount. If a drug is taken multiple times a day, the doses should be added together and the unit of measure should be provided. For example, if a patient takes 20 milligrams of atorvastatin twice a day, the total dose that should be entered is 40 and the standard measure ‘mg’ should be entered. It would be incorrect to list the dose as 2 and the units as 20mg. If total daily dose cannot be provided, for example if the medication is given on a sliding scale, these questions should be left blank and the reason should be provided in the query response.

Section B: Medication Information		Section B: Medication Information	
B1. Medication Name	<input type="text" value="Atorvastatin"/>	B1. Medication Name	<input type="text" value="Atorvastatin"/>
B2. Total Daily Dose	<input type="text" value="40"/>	B2. Total Daily Dose	<input type="text" value="2"/>
B3. Dosage Units	<input type="text" value="mg"/>	B3. Dosage Units	<input type="text" value="20 mg"/>
Correct!		Incorrect	

Training Videos Available on NERI Connect

New to BEST-CLI? Need to complete training at your site? Training videos for [Investigators](#) and [Coordinators](#) can be found on NERI Connect. Be sure to complete your training log and send a copy to NERI for our records. Have questions about training? Please contact your assigned CRA or send questions to BEST@neriscience.com.