BEST-CLI Trial Update at 1 Year of Enrollment

Principal Investigators Alik Farber, MD; Matthew T. Menard, MD; and Kenneth Rosenfield, MD, discuss the trial's progress and recent protocol modifications.

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The BEST-CLI trial, which has recently completed its first successful year of enrollment, is a prospective, randomized, controlled, superiority trial that has a pragmatic design as a central feature. The trial aims to compare treatment efficacy, functional outcomes, and cost in patients with critical limb ischemia (CLI) who are candidates for both infrainguinal bypass and endovascular therapy. Patients are randomly selected to receive one of the two treatments. Details of the treatment rendered are not prescribed and are left up to the discretion of the participating investigators.

OVERVIEW

The trial is a multidisciplinary effort that involves all specialists who treat patients with CLI, including interventional cardiologists, interventional radiologists, vascular medicine physicians, and vascular surgeons. BEST-CLI is currently enrolling patients at 120 active sites in the United States and Canada. Nearly 80% of these sites have multidisciplinary CLI teams that are collaboratively working to identify and enroll patients into the trial. The trial is sponsored by the National Heart Lung and Blood Institute and is led by Drs. Alik Farber (Boston Medical Center), Matthew Menard (Brigham and Women's Hospital), and Kenneth Rosenfield (Massachusetts General Hospital).

To date, the BEST-CLI trial has randomized 305 of the targeted 2,100 patients. A number of new initiatives have recently been incorporated to facilitate subject accrual, including modification of the protocol exclusion criteria, distribution of additional funds to all partici-

pating and enrolling centers, and expansion to 140 trial sites.

PROTOCOL MODIFICATIONS

The protocol changes serve to bring the trial criteria more in line with common practice, while preserving the aims and integrity of the study. Highlights of the protocol amendment include:

- The presence of > 50% stenosis of the ipsilateral common femoral artery will no longer be an exclusion. Treatment of a severe stenosis or an occlusion of the common femoral artery either by open (surgical endarterectomy and patch angioplasty) or endovascular means will now be allowed and will be irrespective of the randomized treatment of the more distal occlusive disease.
- A femoropopliteal Trans-Atlantic Inter-Society Consensus II A pattern of disease will no longer be an exclusion.
- Hypercoagulability will no longer be an exclusion.
- The required delay following a previous open vascular or endovascular procedure (surgical bypass, balloon angioplasty, atherectomy, or stenting) performed on the index limb has been reduced from 6 months to 3 months. The required delay following a previous surgical inflow procedure performed on the index limb has been reduced from 6 months to 6 weeks.
- Treatment of an aortic or ipsilateral iliac artery occlusion will now be allowed.
- Immunosuppressive medication will no longer be an exclusion.

SUMMARY

BEST-CLI is a timely cost-effectiveness trial that addresses a range of questions of ongoing clinical interest, and it aspires to significantly affect clinical practice by defining an evidence-based standard of care for patients with CLI. Recent changes in the design of the trial should serve to facilitate enrollment into this landmark study. ■