A Multidisciplinary Approach to CLI Management

Why your hospital should support the development of a dedicated limb salvage team.

BY JAMES F. McKINSEY, MD, FACS; THOMAS P. DAVIS, MD; AND GAUTAM V. SHRIKHANDE, MD

eripheral arterial disease (PAD) is a chronic, progressive, systemic disease that affects more than 12 million Americans, with more than 1 million new patients diagnosed each year. Up to 20% of patients over the age of 70 years are afflicted with PAD.1 Critical limb ischemia (CLI) results in 120,000 to 150,000 amputations per year.² The incidence of complications after limb amputation is significantly increased, especially in this elderly patient population, and the reported mortality rate after amputation approaches 50% at 2 to 4 years. Perioperative cardiac complications are approximately 10%. Long-term outcomes are dismal in patients with diabetes and end-stage renal disease.3 In 2007, the Centers for Disease and Control and Prevention reported that the cost of treating the diabetic patient population was approximately \$116 billion in direct costs, with approximately 31% of that going to the management of peripheral vascular complications.4

The formal study of the treatment of lower limb ischemia and foot disease was initially founded by Maurice Lewi (1857–1957) at the College of Podiatric Medicine in New York City. Lewi also authored one the first textbooks of Chiropody in 1911. The first program dedicated to management of the diabetic foot was established by Elliott Joslin at New England Deaconess Hospital in 1928. Joslin aggressively treated patients with diabetes in an attempt to decrease the overall mortality as well as the incidence of lower extremity gangrene. He created a multidisciplinary team to not only treat a patient's diabetes but also provide foot care, nutritional support, and treatment of foot infections to decrease the incidence of gangrene and amputation.

Drs. Frank W. LoGerfo and Jay D. Coffman described the arterial pathophysiology that dispelled the concept that diabetes was associated with arteriolar disease but rather was more a disease involving the tibial vessels. This realization prompted the use of angiography to identify the ischemic limb's arterial anatomy, and in the 1980s, tibial and pedal surgical bypass was utilized to revascularize the ischemic limb. More recently, percutaneous endovascular intervention has significantly replaced surgical intervention as a minimally invasive technique to improve limb arterial perfusion in the 21st century.⁵ Egorova et al have shown that the incidences of mortality and periprocedural cardiac, respiratory,

stroke, bleeding, and infection complications are significantly reduced for endovascular procedures compared to open surgical bypass in national database registries. In 2009, the number of endovascular interventions was two to three times more common than that of lower extremity bypass, while the incidence of major lower extremity amputation is continuing to decrease.

Most institutions do not currently have a dedicated multidisciplinary team for managing CLI patients. Patients with CLI are primarily directed toward individual physicians and wound centers or to orthopedic surgeons for amputation. Managing patients with CLI is, in fact, a multifactorial process, and as such, optimal care is generally received in a multidisciplinary program.

ANATOMY OF A MULTIDISCIPLINARY CLI TEAM

The CLI team should consist of multiple individuals with specialization in vascular interventions (vascular surgeon, interventional cardiologist, or interventional radiologist), operative podiatrists, podiatrists specializing in wound pressure offloading, wound specialists, plastic surgeons, endocrinologists, cardiologists, vascular imaging specialists, orthopedics, and a patient management team (physician assistants, social workers, dieticians, and discharge coordinators).

Endovascular and Surgical Responsibilities

The CLI team at Columbia University of New York Presbyterian Hospital System is a multidisciplinary effort directed by the vascular surgery division. The vascular surgery division coordinates state-of-the-art endovascular procedures as well as open surgical bypass or hybrid endovascular/open surgical procedures as appropriate to optimize the restoration of lower extremity arterial perfusion aimed at wound healing or control of ischemic rest pain. Endovascular interventions are also performed by interventional cardiologists and interventional radiologists, with open surgical repair performed by vascular surgeons. Other multidisciplinary teams in the United States have endovascular interventions performed by interventional radiologists or interventional cardiologists, while vascular surgeons specializing in surgical bypass handle the open repairs. In some centers,

COVER STORY

the programs are directed by a podiatrist or wound specialist.

Podiatry

There is a close relationship with our podiatric specialists for treating complex lower extremity wounds, the appropriate management of bony deformities, and offloading prostheses and casts. This close relationship exists not only with the in-house podiatrists but also with podiatrists in the tristate area (New York, New Jersey, and Connecticut) to assist in identifying patients with CLI. There is an active outreach program to the clinical podiatrists to assist with postgraduate educational programs for new and innovative technology and wound management strategies. In addition to providing the in-house podiatric management of these complex patients, the inpatient podiatry service acts as a liaison to the community podiatrists. There is a potential added benefit in collaborating with a prosthesis specialist for midfoot amputation prostheses.

Endocrinology

Due to the high incidence of diabetes in patients with CLI, close collaboration with endocrinology is imperative for the success of the CLI program. An active consultation service assists with inpatient management of patients with diabetes and CLI, which will also serve to coordinate the continuing long-term diabetic management with the patient's primary care physician or outpatient endocrinologist.

Cardiology

Patients with CLI and diabetes also have a significant incidence of coronary artery disease.¹ Preprocedural cardiac evaluation and periprocedural cardiac management is often required in these complex patients, and continued interaction throughout their treatment plan with a cardiologist is certainly beneficial. The long-term management of a patient's lipid profiles and the use of cholesterol-lowering medications should be coordinated through either a cardiologist or an internal medicine specialist with specific interest in hypercholesterolemia and lipid management.

Imaging Specialists

Noninvasive imaging of the CLI patient has become much more common compared to invasive angiography. Radiology and vascular surgery specialists interested in high-quality duplex and CTA/MRA imaging are essential for the evaluation of the patient with lower extremity ischemia. New imaging methods are continually being developed, and collaboration with imaging specialists is recommended.

Orthopedic Surgery

Orthopedic surgeons may be required for bony issues

above the level of the ankle. In some institutions, they work independently or in conjunction with podiatry for the care of patients with foot and ankle disease.

Patient Management

Additional members of the CLI program include physician assistants as well as social workers and discharge coordinators. The needs of these complex patients are extensive, and a dedicated team is truly required to effectively manage their preadmission, hospitalization, and postoperative course. Failure to adequately follow patients who have CLI can result in recurrent ulcerations and gangrene. Preventing a wound from recurring is certainly less stressful on the patient than treating a recurrent ulcer or gangrene.

IMPROVING OUTCOMES IN A DEMANDING HEALTH CARE ENVIRONMENT

Driver et al studied the multidisciplinary team at Boston University and found that the implementation of the team approach to the management of the diabetic foot ulcer resulted in a reduced long-term amputation rate from 82% to 62%. They hypothesize that with better screening and prevention programs, as well as earlier intervention, reducing long-term costs may be possible, especially when the added cost of the support and management of the patient with a major amputation are added. These results have been duplicated by a United Kingdom-based study showing a 62% reduction in major amputations, and a 40% decrease in all amputations over a more than 10-year period. 9

Another aspect of CLI patient management is the assessment of outcomes and quality assurance. In order to have optimal outcomes, careful analysis of individual institutional results is required. The choice of appropriate treatment options for patients with CLI must be evaluated based on institutional outcomes. Also, as the cost of endovascular interventions to the hospital has shifted to a lump sum payment per ICD-9 code with the potential inclusion of the postintervention period, there will be added emphasis for the hospital to ensure the most effective therapy is utilized first. With changes in the overall health care system, there will be increased focus on the safety and longevity of the management strategies for patients with CLI because this may be tied to reimbursement (pay for performance).

It is extremely complicated and cumbersome for any one group to coordinate the collaboration of this multispecialty group. Coordinating an optimal CLI program requires the resources and focus of a hospital system. The resources required include a dedicated area to see patients in a multi-disciplinary fashion, high-quality vascular imaging with duplex scanning, noninvasive flow studies, magnetic resonance and computed tomography angiography, and invasive endovascular and surgical bypass. Physician and patient

education programs as well as screening programs for patients at risk for PAD can dramatically increase the number of patients being treated in a CLI program. Certainly, hospital resources and use of affiliate hospitals can promote these screening and education programs. Programs dedicated to the management of patients with CLI will not only facilitate increased numbers of hospital dis-

charges, but also ancillary services such as radiographic evaluations, hematologic and other laboratory evaluation, hyperbaric oxygen, visiting outpatient nurse association visits, outpatient intravenous antibiotic administration, noninvasive vascular laboratory, cardiac assessment and potential cardiac catheterization procedures, and coronary artery bypass procedures can all result from the development of a CLI program. Outpatient consultations in the pre- and postoperative evaluation phase as well as periprocedural consultations will help support not only the hospital but also the CLI program physicians.

CASE STUDY

Patients often present to outside podiatrists and are then referred into the CLI program for evaluation and revascularization. Figure 1A shows a severely ischemic foot of the patient who presented to an outside podiatrist with severe cellulitis requiring major forefoot amputation. The patient had been seen by a local vascular specialist, and a belowknee amputation was recommended. The patient was referred to the Columbia University vascular program for consideration of revascularization options. The outside angiogram revealed no tibial runoff (Figure 1B). The patient underwent a repeat angiogram at Columbia, which again confirmed only a below-knee popliteal artery segment and no tibial vessel runoff. The outflow vessels were probed with a catheter and a hydrophilic wire, and a distal reconstitution of the peroneal artery was identified. Atherectomy was then performed using the SilverHawk device (Covidien, Mansfield, MA), resulting in reconstitution of flow down the ankle (Figure 1C). The patient returned to his community operative podiatrists, who performed further debridement followed by hyperbaric oxygen and skin grafting with complete wound healing, which has persisted now for more than 5 years (Figure 1D).

CONCLUSION

A hospital-based multispecialty program dedicated to the management of CLI can supply high-quality care for patients with ischemic limbs. A comprehensive CLI program can also serve as an important component of a hospital, resulting in increased benefit to the center by appropriately

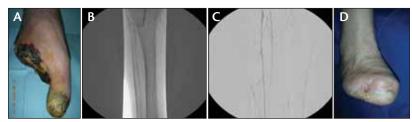


Figure 1. Severely ischemic foot (A). Angiogram showing no tibial runoff (B). Reconstitution of flow to the ankle after atherectomy (C). Five-year follow-up (D).

increasing ancillary testing and radiographic studies and supporting physician consultation services. There is also a significant advantage to the hospital in marketing itself as a center of excellence capable of managing these complex patients and obtaining excellent results. Most importantly, the patients will benefit by minimizing procedures, optimizing care, and most importantly, preventing amputation in this already compromised patient subset.

James F. McKinsey, MD, FACS, is Chief of Vascular Surgery and Endovascular Interventions, Director of the New York Presbyterian Vascular Fellowship of Columbia and Cornell, and Co-Executive Director of the Vascular Service Line New York Presbyterian Hospital System in New York. He has disclosed that he has educational/speaker's relationships with C.R. Bard, ev3 Covidien, Cook Medical, Medtronic, W. L. Gore & Associates, Cordis, Pathway Medical, and Avinger. Dr. McKinsey may be reached at (212) 342-3255; jfm2111@columbia.edu.

Thomas P. Davis, MD, is Medical Director of the Cardiac Cath Lab and Medical Director of Peripheral Interventions and Disease at St. John Hospital and Medical Center in Detroit, Michigan. He has disclosed that he has educational/consulting relationships with Cardiovascular Systems Inc., Pathway Medical Technologies, Inc., Covidien, Bard Peripheral Vascular, Abbott Vascular, and Avinger, and that he has stock ownership in AccessClosure, Avinger, and Ostial Solutions.

Gautam V. Shrikhande, MD, is Assistant Professor of Surgery, Director of the Vascular Laboratories for the Division of Vascular Surgery at Columbia University in New York. He has disclosed that he has no financial interests related to this article.

- Shammas NW. Epidemiology, classification, and modifiable risk factors of peripheral arterial disease. Vasc Health Risk Manag. 2007;3:229-234.
 Dillingham T, Pezzin L, MacKenzie E. Limb amputation and limb efficiency: epidemiology and recent trends in the United States. South Med J. 2002;95: 875-883.
 Aulivola B, Hile CN, Hamdan AD, et al. Major lower extremity amputation: outcome of a modern section. Act 6: 00004402051 2003.
- series. Arch Surg. 2004;139:395-399
- 4. Estimated Diabetes Costs in the United States, 2007. http://diabetes.niddk.nih.gov/dm/pubs/sta-
- tistics/#Estimated. Accessed August 7, 2011.

 5. Sanders LJ, Robbins JM, Edmonds ME. History of the team approach to amputation prevention: pioneers and milestones. J Vasc Surg. 2010;52(3 suppl):3S-16S.

 6. Egorova NN, Guillerme S, Gelijins A, et al. An analysis of the outcomes of a decade of experience
- with Tower extremity revascularization including limb salvage, lengths of stay, and safety. J Vasc Surg. 2010; 51:878-885.
- 7. Goodney PP, Beck AW, Nagle J, et al. National trends in lower extremity bypass surgery, endovascular interventions, and major amputations. J Vasc Surg. 2009; 50:54-60.

 8. Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the
- More with radio with Carego year, Chibosha and Salaman Sa Care. 2008;31:99-101.