Reducing Amputation Rates in Critical Limb Ischemia Patients Via a Limb Salvage Program: A Retrospective Analysis

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ABSTRACT: Objectives: Peripheral artery disease (PAD) is a prevalent disorder that affects approximately 18 million Americans. Left untreated, PAD can lead to critical limb ischemia (CLI), which in turn leads to amputation. The number of amputations performed annually in the United States is estimated to be 160,000 to 180,000, and more than 50% of these patients had no diagnostic/therapeutic endovascular intervention performed in the year before an amputation. The objective of this retrospective analysis is to describe and evaluate the recently implemented limb salvage program (LSP) at Martin Health Systems (MHS) in Stuart, Florida. Methods: This retrospective, observational, single-center study of high-risk patients with CLI, treated between 2010 and 2014, was completed to determine the impact of a LSP on angiography usage and the incidence of major amputations. Results: The implementation of a LSP at MHS led to a multidisciplinary algorithm of patient screening, diagnosis, treatment, and subsequent intensive wound care follow-up. As a result, from 2010 to 2014, the number of CLI patients at MHS who received an angiographic assessment increased from 84 to 500, while the number of major amputations decreased from 24 to 5. Thus, during a 5-year period, the MHS multidisciplinary LSP lowered the amputation rate from 29% to 1%. Conclusions: This retrospective analysis demonstrates that the implementation of a comprehensive LSP can lead to increased angiographic assessment and endovascular treatment of high-risk CLI patients, preventing unnecessary major amputations within a community hospital.

Key words: peripheral vascular disease, critical limb ischemia, amputation, angiography, limb salvage program

Approximately 18 million US citizens have peripheral artery disease (PAD), and of these patients 2 million suffer from critical limb ischemia (CLI), the most severe and deadly form of the disease. Critical limb ischemia increases the risks of limb loss and mortality. Patients with CLI have a major amputation rate as high as 40% at 6 months and a mortality rate of 20% to 25% in the first year after presentation. At 5 years, the all-cause mortality rate of 70% exceeds that of colorectal cancer, breast cancer, stroke, and coronary ar-

VASCULAR DISEASE MANAGEMENT 2016;13(5):E112-E119
tery disease. Patients with CLI are typically elderly and have a high prevalence of multiple severe comorbidities including diabetes, cardiovascular or cerebrovascular disease, histories of hypertension, renal insufficiency, and transient ischemic attack.

Over the last 15 years, the interventional treatment of PAD and CLI has changed significantly with endovascular revascularization replacing surgical bypass as the dominant therapy. Major amputations have also declined. However, major amputation continues to be the first therapy in 60%-70% of CLI patients and about half of major amputations occur without any prior diagnostic evaluation. Major amputation is associated with high perioperative mortality and morbidity as well as high revision rates. These complications increase length of stay and add to the costs of the overall treatment. Five percent to 10% of below-knee amputees and 15% to 20% of above-knee amputees die in the hospital. In comparison, perioperative mortality for infrainguinal bypass and endovascular revascularization is 2% to 8% and 1% to 3%, respectively. Review of the literature demonstrates that primary amputation is considered the appropriate procedure in only 15% of CLI cases whereas revascularization is considered appropriate in 70%, with the other 15% recommended to undergo palliative care/wound care. The 20% to 37% major complication rate associated with amputation is considerably higher than the 16% to 17% average for vascular surgery and the 5% to 9% for endovascular revascularization. Wound infection, the most frequent complication, occurs at a rate of 10% to 30%, and if not resolved it can lead to reamputation at a higher level. Other serious complications include high rates of deep vein thrombosis (13%-26%), cardiac complications (9%-10%), sepsis (9%), bleeding (8%), and renal failure (2%-3%).

In a recent study, the rates of preamputation arterial testing, including ABI measurement, duplex ultrasound, invasive angiography, computed tomographic angiography, and magnetic resonance angiography were reported in Medicare beneficiaries undergoing lower extremity amputation from 2000 to 2010. Strikingly, of the 17,463 patients, 31.6% did not undergo arterial testing in the 12 months preceding amputation. Another recent study found similar low utilization with only 27% of Medicare CLI patients undergoing an angiogram prior to amputation.

Arterial testing should be offered to patients referred for major amputation, given the benefit of revascularization in improving amputation-free survival and quality of life (QOL). In addition, CLI patients undergoing diagnostic angiography have a 90% lower odds of having an amputation. Previous research also supports the necessity of multidisciplinary approaches to limb salvage. The evaluation, diagnosis, and management of lower-extremity wounds by general physicians, vascular surgeons, interventionalists, podiatrists, and wound care specialists is critical. The multidisciplinary approach provides a comprehensive treatment protocol and significantly increases the chances of successfully healing an ulcer, subsequently preventing wound recurrence or amputation. For example, the implementation of a limb preservation service at a military medical center resulted in an 82% decrease in lower-extremity amputations over a 5-year period. In addition, a prospective study in the United Kingdom reported a 62% reduction in
major amputations over an 11-year period following the implementation of multidisciplinary foot care service consisting of improved vascular, radiologic, and microbiologic services. Unfortunately, similar multidisciplinary programs have not been widely adopted at a national level.

The purpose of this study is to provide evidence that a community hospital can reduce major amputation rates by following a dedicated focus on (1) PAD awareness programs, (2) the implementation of advanced endovascular therapies, and (3) multidisciplinary wound care protocols. This article describes and evaluates the Martin Health Systems (MHS) limb salvage program (LSP) for reduction of incidence of major amputations between 2010 and 2014.

METHODS

Key Components of a Limb Salvage Program
In 2010, MHS instituted an evidence-based amputation prevention approach that has evolved into a multidisciplinary LSP. One of the main initiatives of the program was to identify the need for PAD and CLI patient care within the surrounding communities and reduce the rate of major amputation. Martin Health Systems accomplished this by establishing four focus areas: (1) physician, staff, and patient education; (2) community PAD and CLI awareness programs; (3) a multidisciplinary approach to amputation prevention; and (4) hyper-focused wound care of intractable ulcers via hyperbaric oxygen therapy.

RESULTS

Education of Professionals and Patients
Educating physicians who treat patients who are elderly, are diabetic, and/or have renal insufficiency was one of the key focus areas because these comorbidities are common in CLI. In addition, physician awareness of PAD, CLI, and minimally invasive endovascular treatment options would likely result in earlier diagnosis, referral, and treatment of CLI, which is essential for limb preservation. Rogers and Chopra previously had found that only 42% of the primary care physicians and nephrologists were aware of certain risk factors of PAD, 60% did not refer patients with lower extremity wounds to PAD specialists, and 72% did not refer patients with diabetes to specialists for vascular assessment.

Therefore, the lead interventionalist at MHS attended training programs and CLI courses to learn the most advanced techniques in the rapidly evolving field of peripheral intervention from the best CLI experts in the United States. These programs focused on the latest advances in atherectomy treatment of calcified plaque, angiosome-guided therapy, chronic total oc-
clusion crossing techniques, and tibiopedal access. That information was then used to educate MHS diagnosing physicians, nurses, physician assistants, and nurse practitioners on what to look for and how they can work together to save patients from amputation. Raising staff awareness of high-risk patients and educating them on mission, program goals, recognition of CLI, and the latest advances in peripheral CLI intervention techniques played an important role in implementing the LSP.

Patient education on PAD risk factors was also a high priority, because the benefit of patient education in reducing diabetic foot ulcers and lower-extremity amputations is well documented. However, it has been shown that most PAD and CLI patients do not ask for proper treatment and often seek medical care after it is too late to salvage the limb. Therefore, at
MHS clinicians educated patients on PAD risk factors and the importance of proper diabetes management during patient examinations. In addition, patients were also advised to avoid foot trauma by following proper foot hygiene, proper shoe selection, and completion of daily foot inspections.

**Multidisciplinary Team Approach**

The LSP consisted of a multidisciplinary team (Figures 1 and 2) that included a lead CLI interventionalist, a noninvasive imaging specialist, a podiatrist, an infectious disease and wound care specialist, and a nurse practitioner. In addition, hospitalists and emergency department professionals were essential to the multidisciplinary approach.

The MHS lead CLI interventionalist worked with the David L. Smythe Wound Care Center to develop protocols (Figure 3) and treatments to improve wound healing, subsequently preventing amputations. The implementation of a multidisciplinary team-based approach led to a systematic process for patient screening, evaluation, treatment, and follow-up, with the collective goal of achieving the best patient outcomes (Figure 4).

Each year, significantly more MHS patients were evaluated for PAD/CLI, while at the same time the number of amputations decreased (Figure 5) as a result of implementing the LSP. In 2010, 24 of the 84 patients (29%) who were evaluated had amputations; in 2011, 18 of 146 patients (12%) who were evaluated...
had amputations; in 2012, 10 of 228 patients who were evaluated had amputations (4%); and in 2013, 6 of 249 patients (2%) had amputations. Finally in 2014, 500 patients were evaluated, and five (1%) had amputations. As a result, the rate of major amputations fell from 29% in 2010 to only 1% in 2014, while the use of angiography increased. In comparison, 25% to 33% of Medicare CLI patients undergo primary amputation.33,41

**DISCUSSION**

The rate of amputations at MHS decreased from 29% to only 1% over a 5-year period after the center implemented the LSP that ensured each PAD/CLI patient received an angiographic assessment. In addition, significantly more patients were evaluated because of a program to increase awareness regarding PAD and potential treatment options among patients and physicians.

It is also important to note that PAD is not curable; symptoms are treated so patients can improve their quality of life and avoid amputations. Once a patient is diagnosed with PAD it is critical to monitor them for the rest of their lives with an aggressive surveillance program (Figure 4). This is the best way to address problems before they become more complex. Therefore, it is recommended that patients are evaluated at 3, 6, 9, and 12 months post intervention via duplex ultrasound and then once a year thereafter.
CONCLUSIONS

During a 5-year period, after the implementation of a LSP, MHS lowered its amputation rate from 29% to 1%. These results demonstrate the benefits of a multi-disciplinary approach to treat CLI that includes PAD awareness programs, CLI interventionalists, vascular surgeons, podiatrists, infectious disease specialists, and wound care specialists. At MHS, the successful LSP has resulted in the treatment of significantly more patients each year with significantly fewer major amputations.

Editor’s note: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. Drs. Sanguily and Pham report employment with Martin Health System. Dr. Sanguily reports consultancy to and honoraria and travel reimbursements from Cardiovascular Systems, Inc. Drs. Martinsen and Igyarto report employment and stock options with Cardiovascular Systems, Inc.

Manuscript received November 30, 2015; provisional acceptance given December 16, 2015; manuscript accepted February 9, 2016.

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