Outcomes of Patients Treated For Critical Limb Ischemia in an Outpatient Endovascular Center

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Abstract: Purpose: Patients with critical limb ischemia (CLI) have a high incidence of limb amputation and mortality. One factor believed to impact outcome is access to the specialized care required. Endovascular therapy is typically performed in the hospital setting as a result of disease complexity and high risk of complications. This study strives to evaluate the safety and efficacy of endovascular therapy for CLI performed in an outpatient clinic. Methods: Data were obtained using retrospective electronic chart review of 219 consecutive patients presenting to our center with CLI over a 3-year period from October 28, 2013 through October 28, 2016. All patients presenting to the clinic with CLI and receiving endovascular therapy were included. Demographic and risk factors were reported. Clinical outcomes including mortality, major and minor amputation, wound healing, and the need for repeat intervention were correlated with Rutherford class (RC). Procedure-related variables, including access sites, vessels treated, incidence of chronic total occlusion, and complications were noted. The follow-up period was 12 months. Results: In total, 377 endovascular interventions were performed on 219 patients (1.72 interventions/patient) presenting with CLI. There were 119 men and 100 women included, and patients had a mean age of 74.1±11.9 years (range 40 to 96 years), representing 275 limbs (1.26 limbs/patient; 1.37 interventions/limb). The interventions were performed by a single experienced operator over a 3-year period, during which 996 vessels, 618 of which were chronic total occlusions (CTO) (62.0%), were treated. All patients were discharged home the same day. RC included 106 patients presenting with RC-4 (48.4%), 73 patients with RC-5 (33.3%), and 40 patients with RC-6 (18.3%). Two-hundred and two patients had complete 12-month follow-up. Major amputation-free survival was 83.1% at 12 months (82.6% in women and 83.4% in men). Conclusion: The safety and efficacy of treating patients with CLI in an outpatient endovascular center is comparable to published results obtained at hospital centers.

Critical limb ischemia is present in only about 1% to 2% of all patients with peripheral arterial disease (PAD), but it is the most severe form of PAD and is responsible for 185,000 amputations in the United States each year. Many CLI patients do not receive a vascular evaluation prior to amputation, despite efforts to educate the medical community and the public about PAD. The problem is believed to be, in part, a result of lack of access to the specialized medical care needed for limb salvage. However, the ability to improve this access may be within our grasp.

Endovascular treatment of the more complex patients with CLI has been the purview of hospitals, but there has recently been a burgeoning growth of outpatient facilities around the country (often referred to as Office Based Labs or OBLs) that appear to be able to treat PAD safely and cost effectively, including higher risk patients. The ability to treat in an outpatient setting is largely a result of better training and education for physicians, improved interventional tools, and advancements in technique.

Our center opened about 4 years ago and was established mainly to treat patients with advanced PAD at high risk for limb amputation. To that end, we integrated a wound center within the clinic to enable us to follow our CLI patients more closely and intervene more promptly when arterial insufficiency becomes a factor in wound healing.

In this study, we present data on outcomes from our center on 219 consecutive patients who presented with CLI and received interventional treatment during the first 3 years of operation. It is our belief that by demonstrating the safety and effectiveness of such centers, we can ultimately expand access to the specialized care needed to salvage the limbs and improve the quality, and quantity, of life in patients with CLI.

METHODS
Two-hundred and nineteen patients with critical limb ischemia (CLI) presented to the clinic during the first 3 years of operation, from October 28, 2013 through October 28, 2016. Retrospective identification of these patients, as well as all the data reported upon in this paper, was accomplished through electronic chart review. Our Institutional Review Board ruled the study exempt under 45 CRF 46.

All patients who presented with symptoms of Rutherford class (RC) 4-6 and underwent endovascular intervention during the
time period indicated were included in the study. No patients presenting with CLI were referred to another institution for endovascular therapy (ie, the patients were not “cherry picked”). Information collected included certain demographics, cardiovascular risk factors and comorbidities, and angiographic and procedural variables, including vessels treated, finding of chronic total occlusion, interventional treatment modality, need for repeat intervention, access site, and procedure-related complications.

Patient outcomes were followed up to 12 months. Clinical outcomes were recorded during the follow-up period and included death, major amputation (above the foot), minor amputation, and wound healing. In patients who had bilateral limb involvement, both patient and limb outcomes were reported separately where appropriate. Continuous variables are reported as mean ± standard deviation and range (minimum-maximum) depending on normality assumptions. Categorical variables are presented as numbers with percentages. Amputation-free survival (AFS) was analyzed using patients with either complete follow-up of 12 months or satisfying the endpoints of major amputation or death prior to 12 months.

**RESULTS**

From October 28, 2013 through October 28, 2016, 219 patients (119 men and 100 women) who presented with CLI RC 4 to 6 were identified. Thirty-three patients presenting with bilateral CLI and another 23 patients developed contralateral CLI during the follow-up period of 12 months per patient. A total of 275 limbs were represented. A majority of patients had a history of hypertension, cigarette smoking, and diabetes (Table 1). A total of 17 patients representing 17 limbs were lost to follow-up prior to 12 months; 10 of these patients had follow-up to 6 months. Of the 219 total patients, 48.4% presented as RC-4, 33.3% as RC-5, and 18.3% as RC-6 (Figure 1). The 219 patients, representing 275 limbs, underwent 377 interventions (mean 1.72 intervention/patient; 1.37 intervention/limb).

**Table 1. Demographics and Comorbidities.**

<table>
<thead>
<tr>
<th>Age</th>
<th>74.1±11.9 (range 40 – 96)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>119 (54.3%)</td>
</tr>
<tr>
<td>Female</td>
<td>100 (45.7%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>199 (90.9%)</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>111 (50.7%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>153 (69.9%)</td>
</tr>
<tr>
<td>Cigarette Smoking (current or former)</td>
<td>149 (68.0%)</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>85 (38.8%)</td>
</tr>
<tr>
<td>Dialysis</td>
<td>8 (3.7%)</td>
</tr>
</tbody>
</table>

**Figure 1.** Clinical classification. Note: Thirty-three patients presenting with bilateral CLI were classified according to the more severe limb.

**Figure 2.** Vessels treated.

Abbreviations: AT, anterior tibial; CTO, chronic total occlusion; PT, posterior tibial; TPT, tibio-peroneal trunk.
In total, 996 vessels were treated (mean 2.6 vessels/intervention), and 62% were chronic total occlusions (CTO). Sixty-three patients (28.8%) required repeat intervention to resolve the CLI limb during follow-up (absence of ischemic rest pain or healing of ulcers). No patients presenting with CLI had any procedures performed in a hospital setting.

The frequency of specific vessels treated is noted in Figure 2 with tibio-peroneal being most frequently treated as a group (61%). Most patients were treated with atherectomy and balloon angioplasty followed closely by atherectomy, balloon angioplasty, and stenting (Figure 3). The mortality in the entire cohort was 11.4%. The major amputation rate was 5.4%, while 6.4% had minor amputations (Figure 4). Among the patients not lost to follow-up, amputation, or death prior to 12 months, 76% of RC-5 and 48% of RC-6 limb wounds healed by 1 year (Figures 4-6). Hemostasis was achieved using closure devices in 97.8% of femoral artery access sites. There were 42 tibio-pedal access sites (Figure 7).

Overall, AFS was 83.1% (82.6% in women and 83.4% in men). Only 4 procedure-related complications occurred (1.1%), including 1 common femoral artery (CFA) pseudoaneurysm treated with ultrasound-guided thrombin injection, 2 acute CFA occlusions after closure device deployment that were treated with prompt endovascular intervention, and 1 iliac artery perforation treated with a covered stent. There were no clinically apparent access site hematomas. No patients required acute hospitalization, and all patients were discharged to home the same day.

**DISCUSSION**

CLI is associated with high rates of limb amputation and mortality, though revascularization has been shown to decrease these complications. Endovascular therapy has become the predominant method of revascularization, but these procedures are typically performed in the hospital setting due to higher risk associated with sicker patients with greater comorbidities.

The purpose of this study was to determine whether endovascular therapy for CLI can be performed in an outpatient center (office-based lab, OBL) with comparable outcomes and safety to those achieved in the hospital setting. We believe this is the first report focused on endovascular outcomes in CLI patients in an outpatient, stand-alone facility.

Of note, due to the presence of a wound clinic within the center, we were able to achieve a high rate of follow-up on patients as well as document wound healing in the vast majority of patients with wounds. Wound healing was found to be in line with results reported in other studies of CLI patients. Perhaps most surprising was the relatively low mortality rate of 13% and the 21% major amputation rate in RC-6 patients at 1 year, although the numbers are small.

In addition, there was a very low access site complication rate. It was recognized at the outset that access site complications comprise a large portion of procedure-related complications. Our compulsive protocol for recognizing these complications (usually while still in the angiographic laboratory) and prompt amelioration when they occur is critical to mitigating potential complications after discharge. It is likely that the low complication rate reported is related to this approach, as well as to liberal use of ultrasound-guided access and use of closure devices whenever feasible.

Limitations of the study include a relatively small sample size, retrospective rather than prospective analysis, and deriving the...
data from a single operator. Nevertheless, an AFS rate of 83.1% is in line with that reported in hospital-based, multicenter studies, and complication rates in our study are below average. An interim report from the PRIME Registry reported an AFS rate of 84%, while the OLIVE registry reported a 74% rate of AFS.

CONCLUSION

Treatment of CLI patients requiring an endovascular procedure in an outpatient, office-based clinic may have similar outcomes to treatment of patients in a hospital setting. Expanding access to this therapy with similar centers may allow more patients with CLI to achieve optimal results. More data collected in a prospective manner from multiple centers and operators on a greater number of patients are required before these results can be generalized.

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest and report no conflicts of interest regarding the content therein.

Manuscript submitted on April 23, 2018; Accepted on May 22, 2018.
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