Long-term outcome of infrapopliteal catheter-based intervention for critical limb ischemia

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CONTEXT: Percutaneous treatment of tibioperoneal occlusive disease is associated with decreased morbidity compared with bypass surgery. The long-term patency and limb salvage rates are not well documented.

AIMS: To evaluate the long-term outcome of endoluminal interventions for tibioperoneal lesions.

METHODS: A retrospective study was performed to determine the outcomes of patients undergoing infrapopliteal catheter-based intervention for critical limb ischemia. Collected data included demographics, comorbidities, clinical presentation, pre- and postintervention noninvasive vascular measurements (segmental pressure and waveforms, and ankle-brachial index [ABI]), type of intervention, limb loss rate, patient follow-up and need for surgical revascularization. Statistical analysis was performed with the two-tailed *t* test. $P < 0.05$

was considered significant; results were reported as mean $\pm$ SD. Cox regression analysis and Kaplan-Meier limb survival analysis were performed to demonstrate freedom from amputation over time.

RESULTS: Thirty-five patients underwent intervention from 2003 to 2008; technical success was achieved in 26 patients (75%). Arterial segmental pressure studies revealed a significant increase in ABI – preprocedure ABI was 0.62 ± 0.24 versus a postintervention ABI of 0.81 ± 0.29 ($P = 0.02$). The limb salvage rate was 63% during the follow-up period. Limb salvage was better for patients who underwent isolated infrapopliteal intervention versus combined above and below the knee intervention.

CONCLUSION: Percutaneous interventions for tibioperoneal occlusive disease offer an acceptable limb salvage rate and may be the preferred initial treatment for critical limb ischemia.

Key Words: *Atherectomy; Critical limb ischemia; Tibioperoneal angioplasty*

Endovascular therapy has changed the paradigm of arterial occlusive disease treatment. Percutaneous transluminal angioplasty (PTA) and stenting is increasingly used to treat infrainguinal occlusive disease. PTA for superficial femoral lesions is frequently performed as an alternative to bypass. Catheter-based interventions for infrapopliteal disease have been used less often, and outcome data are still under evaluation. We reviewed our five-year experience with infrapopliteal endoluminal interventions, including angioplasty with or without stenting and/or atherectomy in patients with critical limb ischemia (CLI).

METHODS

A retrospective study was performed to determine the outcomes of patients undergoing infrapopliteal catheter-based intervention for CLI. Institutional review board approval was obtained. All patients who presented to the University of Kentucky Chandler Hospital and the Veterans Affairs Hospital (Lexington, Kentucky, USA) with rest pain or tissue loss, and who underwent infrapopliteal angioplasty, stenting and/or atherectomy from 2003 to 2008 were identified. Collected data included demographics, comorbidities, clinical presentation, pre- and postintervention noninvasive vascular measurements (segmental pressure and waveforms,

and ankle-brachial index [ABI]), type of intervention, limb loss rate, patient follow-up and need for surgical revascularization.

All patients had interventions for CLI; symptoms of CLI included tissue loss and rest pain. Preoperative diagnostic evaluation was performed with computed tomography angiography and/or digital subtraction angiography. The decision to undergo percutaneous intervention was based on the patient's comorbidities, extent of vascular disease and anticipated life expectancy as well as availability of a venous conduit for tibial or peroneal bypass. Technical success was determined by the operating surgeon based on residual stenosis of less than 30% of the flow channel. Failure was defined as either immediate arterial occlusion following angioplasty or inability to cross the lesion. The end point of primary patency was determined by subsequent imaging studies, noninvasive vascular testing or requirement for further intervention including amputation or bypass. Limb loss was defined as amputation either above or below the knee. Ray or transmetatarsal amputation was not considered limb loss. Statistical analysis was performed with the two-tailed *t* test. $P < 0.05$ was considered significant; results are reported as mean $\pm$ SD. Cox regression analysis and Kaplan-Meier limb survival analysis were performed to demonstrate freedom from amputation over time.

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TABLE 1
Patient demographics

Patients, n	Male sex	Age, years	Diabetes	Hypertension	Smoking	Coronary disease	Renal failure	Tissue loss	Rest pain
35	88	67.2±11.3	63	65	49	69	22.8	85	15

Mean variables expressed in percentages unless otherwise indicated. Age reported as mean ± SD

TABLE 2
Intervention results

Isolated infrageniculate intervention, %	Combined with femoral/iliac intervention, %	Preoperative ABI	Postoperative ABI	Technical success at time of intervention, %	Limb salvage rate, %	30-day mortality, %	30-day primary patency, %
37	63	0.62±0.24	0.81±0.29	75	63	2.9	74

Ankle-brachial indexes (ABIs) expressed as mean ± SD

Figure 1 Kaplan-Meier curve of limb salvage over follow-up period for the entire patient population

RESULTS

Thirty-five patients underwent intervention for infrapopliteal lesions. Most patients demonstrated multilevel disease and thus combined endoluminal iliac and femoral intervention with the infrapopliteal intervention; this was performed in 22 patients, most under conscious sedation. Over two-thirds of the interventions were performed from the contralateral femoral access site. There were 31 men and four women; 22 were diabetic, 23 were hypertensive, 17 were smokers and 24 had significant coronary artery disease. A total of 22.8% of patients were on hemodialysis (Table 1). Interventions performed included four atherectomies in three patients and two cryoplasty angioplasties; the remainder were conventional angioplasties. The decision to perform angioplasty with subsequent stenting versus angioplasty alone was made at the time of the intervention. Tibioperoneal trunk stenting was performed in five patients. Endovascular therapy was deemed successful following intervention in 26 patients. Arterial segmental pressure studies revealed a significant increase in the ABI – preprocedure ABI was 0.62 ± 0.24 versus a postintervention ABI of 0.81 ± 0.29 ($P=0.02$; Table 2). Thirty-day mortality was 2.9% (two patients). After the procedure, all patients received acetylsalicylic acid indefinitely and 14 patients received clopidogrel 75 mg daily for at least one month. There was a 63% limb salvage rate overall during a mean follow-up of

Figure 2 Kaplan-Meier survival curve demonstrating limb salvage over time for two groups – isolated infrapopliteal intervention and combined iliofemoral and infrapopliteal intervention

43±18 months (Figure 1). Limb salvage was better for patients who underwent isolated infrapopliteal intervention versus combined above and below the knee intervention (Figure 2). Diabetes, sex, hypertension and smoking were not found to influence the limb salvage rate by Cox regression analysis.

DISCUSSION

Our experience with endoluminal lower extremity revascularization for CLI suggests that this approach is associated with low morbidity and good limb salvage rates in a patient population with multiple comorbid conditions. Open surgical bypass has been considered the gold standard for CLI patients (1) with an excellent long-term patency and limb salvage rate (1,2). However, patients with unfavourable anatomy or without an autologous vein conduit may require bypass with a cryopreserved vein or prosthetic; these procedures do not have as good results (3). Klinkert et al (4) demonstrated 64% primary patency after six weeks and only an 18% primary patency rate at five years with prosthetic grafts. As a result, endovascular approaches to revascularization may be attractive. Our study demonstrates acceptable long-term limb salvage in high-risk patients with multiple medical comorbidities who are not candidates for tibial bypass, with follow-up that was more

extensive than in other recently published reports (5-7). It is interesting that after 13 months no limb loss was observed, and the majority of the secondary interventions or amputations occurred within three months after initial intervention. This suggests that failure from catheter-based procedures often presents early, and those with initial success enjoy long-term limb salvage.

Another observation in the current study was the accelerated rate of limb loss in patients requiring both femoral and infrapopliteal interventions. This may be expected because those with more aggressive disease should be expected to have higher rates of limb loss, and would require more extensive intervention at both femoral and infrapopliteal levels. Our early mortality rate of 2.9% is similar to that published by Haider et al (8), observed after infrainguinal PTA. The mortality rate of amputation above the knee has been demonstrated to be as high as 16% in large retrospective studies (9). Because the mortality rate of amputation above the knee is so high, limb salvage and prevention of such an event in 63% of unfit surgical candidates was substantial.

No significant risk factor differences were observed for diabetes, sex, and hypertension or smoking by Cox regression analysis. There was improvement in the ABIs following endovascular intervention, and limb salvage was achieved in

approximately two-thirds of our patients. Our follow-up range, extending to 75 months, is relatively unique among this group of patients with advanced pathology.

A limitation of our study is that it represents a retrospective review of a relatively small number of patients. In addition, the lesions were not classified according to the TransAtlantic InterSociety Consensus (TASC). Giles et al (5) demonstrated that TASC A, B and C lesions displayed significant differences in outcome compared with TASC D lesions. Patients with TASC D lesions below the knee were more likely to require an amputation and have a higher mortality rate. Another potential outcome predictor is the level of run-off and extent of distant disease. Multiple reports have demonstrated the importance of run-off to achieve acceptable results from PTA below the inguinal ligament (10-12).

CONCLUSION

Endoluminal intervention for patients with CLI is associated with low mortality, good long-term limb salvage and is a valuable therapeutic option for selected patients with infrapopliteal disease (6). It is associated with low mortality. Prospective randomized controlled trials should address whether a catheter-based intervention should be the initial approach for all patients at risk for limb loss.

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