

The CLASE Study: Endovascular Management of the Superficial Femoral Artery

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ABSTRACT

- **Objective** – The purpose of this study was to compare endovascular treatment modalities for peripheral vascular disease in the femoropopliteal arteries with respect to technical success, efficacy, and patency at mid-term follow up.
- **Methods** – A retrospective review of patients that underwent endovascular management of the femoropopliteal segment was conducted to evaluate patency. The CLASE study included 5 treatment arms: cryoplasty, laser, angioplasty/stent, silverhawk atherectomy, and viabahn endoluminal graft.
- **Results** – Between November 2004 and May 2009, 306 patients met inclusion criteria. There was a statistically significant difference in patencies among treatment groups ($p=0.016$), driven by laser having a significantly lower patency than the angioplasty/stent, silverhawk atherectomy, and viabahn endoluminal graft groups.
- **Conclusions** – Many of the expensive endovascular devices have poor patencies lasting less than 6 months. Angioplasty/stent is not inferior to these new devices, and may remain the standard of care.

INTRODUCTION

Peripheral vascular occlusive disease is a progressive and often debilitating form of atherosclerosis affecting the vessels of the upper and lower extremities. Patients typically present with complaints of pain in the involved extremity and claudication. Others present with numbness, heaviness, or fatigue in the affected limb. Up to 10% of patients with intermittent claudication may progress to limb loss over the course of 5 years.

The superficial femoral artery (SFA) has been the region most difficult to treat and maintain patency. Stenosis and/or occlusion can often occur by 6 months. Results of balloon angioplasty and stenting in the femoropopliteal segment have been for the most part variable and often without consistent results. The SFA and popliteal arteries are extremely difficult to treat because of the diffuse nature of disease, high degree of recoil, large number of occlusions, calcification, and the impact of inflow and run-off.

Percutaneous revascularization has become an option for many patients due to its minimally invasive nature. Newer modalities, such as cryoplasty, laser, silverhawk atherectomy, and viabahn endoluminal grafts, have been used in an attempt to obtain better long-lasting results than the standard angioplasty/stent. At present, few studies have compared the use of these devices to angioplasty/stent based on similar types and characteristics of femoropopliteal lesions. There are, however, several reports on the use of these new devices that indicate that perhaps a better patency and lasting result can be obtained.

METHODS

A retrospective review of patients that underwent endovascular management of the SFA at Arizona Heart Institute/Hospital between November 2004 and May 2009 was performed. The CLASE study looked at 5 treatment arms: cryoplasty, laser, angioplasty/stent, silverhawk atherectomy, and viabahn endoluminal graft.

Inclusion criteria were: (a) >70% stenosis or total occlusion of the femoropopliteal segment, not including the common femoral artery, (b) SFA and popliteal >4mm in diameter, (c) at least one vessel run-off, and (d) de novo cases with no previous SFA/popliteal intervention or bypass. Exclusion criteria were: (a) total occlusion of the femoral artery with non-visualization of the origin of the SFA and (b) acute ischemia or acute thrombosis of the femoropopliteal segment.

Demographics, procedure indication, lesion characteristics, concomitant procedures, complications, reintervention, and mortality were noted.

Follow up evaluation included clinical symptoms, physical exam, and duplex ultrasound. If duplex ultrasound was inconclusive, CT angiogram or angiogram may have been done. Failure of patency was defined as >70% stenosis or total occlusion of the femoropopliteal segment by duplex ultrasound, or worsening of the clinical symptoms.

RESULTS

During the study period of November 2004 to May 2009, 828 patients with femoropopliteal lesions were treated with endovascular technique. 522 of these were excluded because they did not meet inclusion criteria. 306 patients were included in the study: cryoplasty (61 patients, 20%), laser (55, 18%), angioplasty/stent (63, 21%), silverhawk atherectomy (65, 21%), and viabahn endoluminal graft (62, 20%).

The average age of the patients was 72 years (35-90 years). There were 187 (61%) male patients and 119 (39%) female patients. Comorbidities were HTN (278 patients, 91%), CAD (196, 64%), COPD (60, 20%), renal insufficiency (101, 33%), hyperlipidemia (227, 74%), DM (155, 51%), and tobacco use (227, 74%), with no statistically significant differences among groups. Indications were severe claudication (225 patients, 74%), rest pain (28, 9%), and tissue loss (53, 17%), with no differences among groups. TASC II classifications were A (83 patients, 27%), B (85, 28%), C (71, 23%), and D (67, 22%), with significant differences $p<0.05$ across treatment groups for A and D. Lesions were stenosis (125 patients, 41%), occlusion (129, 42%), and tandem (52, 17%), with significant differences $p<0.05$ across treatment groups for stenosis and occlusion. Distal runoff vessels were 1 (85 patients, 28%), 2 (119, 39%), and 3 (102, 33%), with no differences among groups.

Concomitant procedures were classified as inflow (52 patients, 17%) or outflow (48, 16%), with significant differences $p<0.05$ across treatment groups for outflow. Complications were dissection (64 patients, 21%), perforation (23, 8%), hematoma (17, 6%), thrombosis (1, 0.3%), bleeding (1, 0.3%), pseudoaneurysm (3, 0.9%), and groin infection (2, 0.6%). There were significant differences $p<0.05$ across treatment groups for dissection and perforation, with higher rates in laser and viabahn endoluminal graft groups. Reinterventions occurred in 129 (42%) patients, with no differences among groups. There were no <30 day mortalities and a 7% (21 patients) >30 day mortality rate, with no differences among groups.

The average length of follow up was 9.14 months with a range of 0 to 60 months. 180 patients were followed until the intervention failed. The other 126 were either lost to follow up or died from other causes.

The overall mean patency was 8.35 ± 9.38 months. ANOVA indicated no overall statistical differences ($p=0.28$) in mean patency across the five groups. On pairwise comparison, laser had a lower mean patency than angioplasty/stent ($p=0.029$).

Table 1 shows the overall patencies and patencies by treatment at various timepoints. Figure 1 shows the associated Kaplan-Meier survival curve. The log rank test showed a statistically significant difference among treatment groups ($p=0.016$). Upon pairwise examination, this difference was driven by laser having significantly lower patency than the angioplasty/stent, silverhawk atherectomy, and viabahn endoluminal graft groups. Other pairwise comparisons didn't reach statistical significance.

	Overall	Cryoplasty	Laser	PTA/Stent	Silverhawk	Viabahn
0mos	99%	100%	93%	100%	100%	100%
3mos	76%	71%	59%	80%	71%	83%
6mos	54%	50%	36%	62%	51%	70%
9mos	44%	39%	24%	57%	45%	55%
12mos	37%	34%	16%	49%	40%	44%
18mos	33%	34%	16%	41%	34%	36%
24mos	26%	30%	12%	30%	24%	31%

Table 1: Patencies

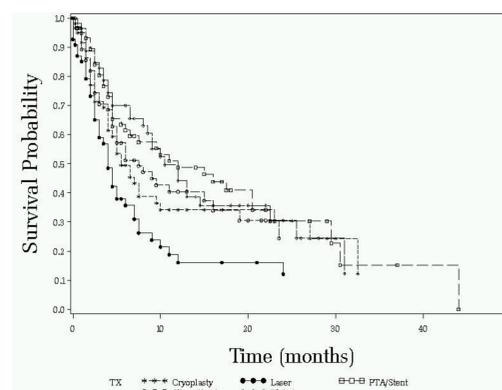


Figure 1: Kaplan-Meier Curve

DISCUSSION

With the growth of endovascular treatment of peripheral vascular disease, there has been rapid development of new devices that claim to result in improved patencies and patient outcomes. These new technologies have considerably higher costs than the traditional angioplasty/stent technique. Current literature is limited in the evaluation and comparison of these newer devices against angioplasty/stent. We present a retrospective review of patients with similar femoropopliteal lesions treated with 5 endovascular modalities, and show that there is a statistically significant difference among treatment groups. The laser group had significantly lower patency than the angioplasty/stent, silverhawk atherectomy, and viabahn endoluminal graft groups, but other pairwise comparisons didn't reach statistical significance. It is notable that all of the endovascular treatment modalities had patencies <50% at one year. The laser group had the worst patency, falling to 36% at 6 months.

For many patients with multiple comorbidities and threatened limb salvage, there are advantages to endovascular technique over open surgery. In this study, we treated 53 patients with rest pain or tissue loss. All of the treatments achieved limb salvage, and have a role in treating patients with critical limb ischemia.

Randomized studies need to be done to better evaluate whether the newer endovascular devices truly result in a better patency than the standard angioplasty/stent.

CONCLUSION

In patients with femoropopliteal lesions treated with 5 endovascular modalities, there was a statistically significant difference in patencies, driven by laser having significantly lower patency than the angioplasty/stent, silverhawk atherectomy, and viabahn endoluminal graft groups. All therapies are useful in limb salvage for patients with critical limb ischemia. Many of the expensive technologies used in the femoropopliteal arteries have poor patencies lasting less than 6 months, suggesting that angioplasty/stent is not inferior to these new devices and remains the standard of care.