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Laser in Infrapopliteal and Popliteal Stenosis 2 Study (LIPS2): Long-Term Outcomes of Laser-Assisted Balloon Angioplasty Versus Balloon Angioplasty for Below Knee Peripheral Arterial Disease

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Abstract

Background—Laser-assisted balloon angioplasty (LABA) has been shown to be more effective in achieving angiographic success for treatment for below knee peripheral artery disease (PAD) compared with balloon angioplasty alone (BA). However, long-term outcomes of LABA compared with BA for popliteal and infrapopliteal PAD are unknown.

Methods—We evaluated data on 726 patients undergoing LABA ($n = 395$) and BA ($n = 331$) for popliteal and infrapopliteal PAD retrospectively at a single center (2007–2012). Outcomes included long-term ipsilateral major limb amputation, revascularization and mortality (median follow-up = 36 months).

Results—Baseline features were similar in two groups with the exception of more TASC-D lesions (92.4 vs. 66.5%; $P < 0.0001$) and chronic total occlusions (86.4 vs. 49.5%; $P < 0.0001$) in LABA group. Angiographic success was higher in LABA compared with BA (97.7 vs. 89.2%; $P < 0.0001$). Ipsilateral major limb amputation (4.1 vs. 5.1%, $P = 0.48$) and repeat revascularization (25.1 vs. 23.3%, $P = 0.47$) were similar in LABA and BA patients despite unfavorable baseline angiographic characteristics in the former. Compared with BA, death was more frequently in LABA group (35.2 and 26.3%, $P = 0.01$), a reflection of higher comorbid conditions in this group (adjusted HR 1.05, 95% CI 0.79–1.39).

Conclusion—Despite worse baseline angiographic characteristics compared with BA, LABA was associated with higher angiographic success and similar ipsilateral major amputation, repeat revascularization, and long-term mortality. Future randomized clinical trial should evaluate the efficacy of LABA compared with BA (particularly drug-eluting) in improving limb salvage and reducing repeat revascularization in these high-risk PAD patients.

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Keywords

balloon angioplasty; laser; peripheral arterial disease

INTRODUCTION

Popliteal and infrapopliteal peripheral arterial disease (PAD) often manifest as claudication but more commonly as severe critical limb ischemia (CLI) that includes rest pain in the leg or foot, nonhealing ischemic ulcers, and/or gangrene. CLI when untreated has a high likelihood of resulting in to major limb amputation within 6 months [1,2]. In 2005, 1.6 million people suffered limb loss in the United States due to PAD. It is projected that this number will more than double by the year 2050 [3,4]. Prompt revascularization by endovascular approach or surgical bypass, in addition to optimal medical therapy and local wound care, has potential for improving symptoms, limb salvage, decreasing the extent of limb loss and promoting healing after surgery [5]. Excimer laser-assisted balloon angioplasty (LABA) has emerged as an available treatment option for endovascular treatment of CLI and has the potential for improving short and long-term outcomes. The 2013 ACCF/AHA practice guidelines endorses lasers (and other adjunctive techniques) as being useful in the femoral, popliteal, and tibial arteries for salvage therapy after suboptimal or failed balloon dilation [6]. This recommendation is based on the results of small case series that have reported high angiographic success and intermediate term limb salvage rates with LABA [7,8]. The Laser in Infrapopliteal and Popliteal Stenosis (LIPS) showed that the use of LABA was safe and was associated with better procedural success compared with BA in the treatment of CLI from complex popliteal and infrapopliteal PAD [5]. However, the long-term clinical outcomes of LABA compared with BA in these patients beyond index procedure are not known.

Accordingly, we evaluated the long-term outcomes (beyond hospitalization for index procedure) of patients with CLI who underwent endovascular revascularization with LABA versus BA for popliteal or infrapopliteal PAD.

METHODS**Study Population**

We evaluated all patients enrolled in the LIPS study and treated at a single tertiary hospital. Details of this study have been previously published [5]. In brief, 726 patients undergoing LABA with or without BA ($n = 395$) or BA alone ($n = 331$) for CLI due to popliteal or infrapopliteal occlusive disease between 2007 and 2012 were included in the study. The use of LABA or BA was not specified in the study but left to the discretion of the operator. Commonly used laser devices in LABA group included Turbo Elite 0.9 to 2.3 mm and Turbo Tandem 2.0 (Spectranetics Corporation) whereas BA was performed using a variety of balloon catheters. Heparin was used to achieve a target an ACT of >250 s. All patients received 325 mg of aspirin before procedure that was expected to be life-long and received a loading dose of a thienopyridine followed by a maintenance dose that was mandated for at least 30 days after the procedure. All secondary prevention medications (statins and

antihypertensive medications for hypertensive patients) and life style changes (exercise and smoking cessation) were expected to be in compliance with national guidelines [6]. Patients were encouraged to join structured rehabilitation program.

Data Collection

We conducted a retrospective chart review using hospital's and outpatient offices' electronic medical record (EMR). Furthermore, we performed telephone interview of patients or their close relatives to obtain follow-up information. Data collected included the occurrence as well as the time to ipsilateral amputation, endovascular revascularization or peripheral bypass surgery and mortality. In few patients, mortality data was also obtained from online public database (social security death index) using patients' names and social security numbers (<http://www.genealogybank.com/gbnk/ssdi>). This study and follow-up were approved by the institutional review board.

Definitions

Major amputation was defined as any amputation above ankle, which includes above knee, below knee and ankle amputation. Minor amputation is defined as any amputation below ankle, which includes mid foot or toe amputation. Total pre- and postprocedure Yamasaki classification score were used to define disease severity and burden [5].

Outcomes

The primary outcome of interest was survival free of ipsilateral major limb amputation (above ankle amputation). Secondary outcomes include all ipsilateral limb amputations (including minor toe amputations), need for repeat revascularization either by endovascular approach or bypass surgery of ipsilateral limb and all-cause mortality.

Statistical Analysis

Continuous data were presented as mean and standard deviation, median, and interquartile range for non-normal distribution, and categorical data as frequency counts and percentages. Missing data were not defaulted to negative and denominators reflect cases reported. Differences in baseline characteristics between patient groups were evaluated by χ^2 tests or by Kruskal–Wallis tests as appropriate. Multivariate analyses were performed using Cox proportional hazard model to estimate the association of the two strategies on individual patient outcomes. hazards ratio (HR) and 95% confidence intervals (CI) were generated to provide an estimate of these associations. All *P* values were two-sided with values <0.05 considered statistically significant. All data were analyzed using SPSS v. 22.0.

RESULTS

Patient Demographics, Clinical, and Angiographic Features

Patient demographics and characteristics were similar in both groups except for higher percentage of African American (42.5 vs. 28.7%, *P* = 0.001) in LABA group and higher prevalence of prior contralateral limb amputation (7.2 vs. 12.2%; *P* = 0.02) and history of smoking (63.0 vs. 71.8%; *P* = 0.02) in BA group (Table I). Baseline lesion characteristics and

procedural outcomes/angiographic are shown in Table II. Despite having more TASC-D lesions in LABA group (92.4 vs. 66.5%, $P < 0.0001$), the rate of angiographic success (residual stenosis $< 50\%$, 97.7 vs. 89.2%, $P < 0.001$) were higher in LABA compared to BA. Complication rates during index procedure were similar except for lower incidence of distal embolization in LABA group (0.5 vs. 3.3%, $P = 0.004$) [5].

Primary Outcome

Major ipsilateral amputation was required in 33 of 726 patients (4.5%) and was similar in LABA and BA group (Table III). Kaplan–Meier curve for major amputation-free survival is shown in Fig. 1. This adverse event was higher in patients with diabetes (6.7 vs. 1.4%, $P < 0.001$), end-stage renal disease (ESRD) (9.0 vs. 3.9%, $P = 0.04$), prior contralateral limb amputation (13.2 vs. 3.6%, $P < 0.001$) and in those with a history of congestive heart failure (CHF) (6.8 vs. 3.6%, $P = 0.07$). Multivariate Cox regression analysis showing independent predictors of increased risk of major limb amputation are shown in Table IV. Procedure type (LABA vs. BA) was not associated with increased risk of this event. The median time to major amputation was similar in the two groups.

Secondary Outcomes

Among 726 patients, eighty-seven patients (12.0%) had major and/or minor amputations. Surgical bypass was performed in 7 (1.8%) and 5 (1.5%) patients in LABA and BA group, respectively ($P = 0.89$). Repeat endovascular revascularization was needed in 95 and 74 patients in LABA and BA group, respectively, (24.1 vs. 22.4%, $P = 0.56$). Repeat revascularization (endovascular and/or bypass surgery) were significantly higher in blacks vs. white (27.3 vs. 20.5%, $P = 0.05$), and in those with prior stroke (30.1 vs. 22.2%, $P = 0.03$), diabetes (27.0 vs. 20.3%, $P = 0.04$), and prior peripheral bypass surgery (40 vs. 23.1%, $P = 0.01$). Independent predictors of repeat revascularization are shown in Table V. Procedure type was not associated with increased risk of repeat revascularization. Median time to repeat revascularization was similar in the two groups.

Long-term deaths occurred in 139 (35.2%) and 87 (26.4%) patients in LABA and BA respectively ($P = 0.01$). Fig. 2 shows the Kaplan–Meier curve for long-term death. Factors associated with higher mortality were prior stroke (37.7 vs. 28.8%, $P = 0.02$), coronary artery disease (CAD, 34.3 vs. 23.7%, $P = 0.01$), CHF (42.1 vs. 27.0%, $P < 0.001$), atrial fibrillation (AF) (47.8 vs. 27.0%, $P < 0.001$), diabetes (36.4 vs. 23.6%, $P < 0.001$), ESRD (48.7 vs. 28.9, $P < 0.001$), prior contralateral limb amputation (44.1 vs. 29.7, $P = 0.01$), procedure type (LABA vs. BA, 35.2 vs. 26.3, $P = 0.01$), and periprocedural dissection (39.8 vs. 29.9, $P = 0.05$). Multivariate Cox regression analysis results showing independent predictors of death are shown in Tables VI and VII. Despite higher observed long-term mortality, LABA was not associated with increased risk of death once adjusted for baseline confounders (HR 1.05, 95% CI 0.79–1.39).

DISCUSSION

Our Study Findings

To the best of our knowledge, this study was the largest to evaluate long-term outcomes of patients with popliteal and infrapopliteal peripheral artery disease undergoing LABA and BA. While LABA was associated with better procedural angiographic success and improving lesion severity score, despite having worse baseline angiographic characteristics (more chronic total occlusion and TASC C/D lesions) as reported before [5], this was associated with similar rate of major ipsilateral limb amputations, any ipsilateral (major and/or minor) amputations and repeat revascularizations compared with BA at median follow up time of 36 months. Periprocedural complication rates were similar, except for less distal embolization in LABA. However, the length of stay for index procedure was slightly longer in LABA group, possibly due to more severe disease burden. Additionally, even though the observed long-term mortality was higher in the LABA group, this adverse event did not differ significantly after risk adjustment in the two groups suggesting that the difference was accounted for by baseline confounding factors.

Comparisons with Prior Studies

Trials of pharmacotherapy for CLI in patients in whom revascularization was not possible or had failed have showed that approximately 40% of these patients lose their leg within 6 months [7]. In current practice, it is no longer possible to describe natural history of advanced PAD and CLI because most patients receive some form of active invasive treatments. However, it is estimated that 30% of CLI patients will be alive and have amputation at 1 year, 20% of patients will continue to have CLI and 25% of patient will die at 1 year [7]. In Framingham study, major amputation was required in 1–3.3% in patients with intermittent claudication over 5-year period, whereas incidence was thought to be much higher in patients with CLI [8]. Rabellino et al. reported major amputation rate of 3 versus 23.3% at a median follow-up of 14 months following endovascular treatment of TASC C and D lesions, respectively, within femoropopliteal segment [9]. More recently, Tewksbury et al. reported 77.7% limb salvage rate in 74 patients [10]. In our study population, with vast majority of patients with TASC D popliteal and below popliteal lesions, major amputation rate at 3 years was similar or better when compared with previously reported rate, but did not differ significantly with procedure type [8–10].

Small single-center studies have reported limb salvage rate ranging from 33 to 95% for BA [11,12]. LACI Multicenter Trial reported procedural success of 86% and 6-month limb-salvage rates of 93% with Excimer LABA with or without adjunctive stenting [13]. These results were replicated in the subsequent small LACI Belgium study that enrolled 48 patients, with 51 critically ischemic limbs showing 90.5% 6-month limb-salvage rates with the use of this strategy [14]. No comparison was made between LABA and BA in these two studies. No data exist from large-scale randomize clinical trial on the efficacy of LABA compared with other revascularization strategies (BA with or without stenting or peripheral bypass surgery). We have previously reported the findings of nonrandomized retrospective Laser in Infrapopliteal and Popliteal Stenosis (LIPS) study that compared LABA with BA alone for popliteal and infrapopliteal PAD, and showed that the use of LABA was safe and

resulted in better procedural success compared to BA for treatment of CLI from complex popliteal and infrapopliteal vascular disease [5]. The current study provided further insights into the long-term outcomes of these patients and suggested that despite higher initial angiographic success rate in LABA group, long-term limb loss was similar in the two groups. Thus, at least based on this nonrandomized data, these findings potentially suggested that the baseline angiographic features perhaps accounted for long-term limb loss rather than initial success. Alternatively, it is also plausible that the higher initial angiographic success with laser in those with adverse baseline angiographic features may have delayed or lead to similar amputation rate at long-term compared with BA in the lower risk baseline angiographic features.

Restenosis is common and considered Achilles' heel following peripheral artery intervention. Steinkemp et al. reported overall vessel patency of 42.2 vs. 29.6% following LABA and BA of popliteal artery at 12 months [15]. While we did not evaluate angiographic restenosis in our investigation, clinically driven repeat revascularization of ipsilateral limb (of index and/or nonindex vessels) was needed in about a quarter of patients and was similar in the two groups. History of stroke, diabetes, prior contralateral bypass surgery, and higher pre-Yamasaki score, all of which were surrogates of more atherosclerosis, were found to be predictors of repeat revascularization. White patients were less likely to have a repeat procedure. Prior studies have reported higher adverse outcomes in black patients undergoing below knee bypass surgery [16,17].

Observed death rate was significant higher in LABA than BA patients. This was likely because LABA patients were sicker and had more complex disease as once adjusted for baseline confounders, there was no significant difference between the two groups in long-term mortality. This suggested that even though the type of endovascular treatment may have the potential for angiographic success (and potentially for limb salvage) and symptom relief, long-term mortality is likely to be unaffected by these strategies. Life style and risk factors modification, and measures of secondary prevention perhaps have the greatest likelihood of influencing this outcome.

Clinical Implications

Excimer laser was invented in 1970s and ultraviolet laser light energy emitted by it is found to be well suited to ablate biological tissue cleanly in precision without damaging the adjacent tissue or creating heat. Because of this special property, excimer laser is adopted widely in delicate microscopic medical procedures such as LASIK eye surgeries and endovascular atherectomy procedures. Unlike other atherectomy devices which use various mechanical blades or grinders, excimer laser exerts nonthermal, microscopic, photochemical precision cut, thus it has a theoretical advantage of making clean cuts without risk of adjacent tissue damage or tissue disruption resulting distal embolization. Infrapopliteal arteries are smaller caliber vessels compared to the iliofemoral arteries and they tend to have long diffuse lesions with high frequency of occurrence of chronic total occlusions. This situation appears to be ideal for laser atherectomy. Prior LIPS study showed better short-term outcomes of the laser compared to balloon angioplasty in a retrospective single center large cohort analysis. In this study with same cohort with longer duration of follow-up, we

showed similar risk adjusted mortality and amputation free survival despite original adverse lesion characteristics in laser treated patients compared to the balloon only treated patients. This is the largest study of this patient population so far in the literature we know of and if our finding is confirmed by prospective study, there will be a significant clinical implication adding a useful tool in the improvement of treatment of below the knee peripheral arterial disease, which many times turn out to be extremely challenging.

Study Limitations

Our study was a retrospective evaluation of non-randomized data of patients with popliteal and infrapopliteal PAD treated with LABA versus BA and is subject to missing information. We are only able to adjust for measured confounders and influence of unmeasured factors on our study findings cannot be ascertained. We did not evaluate if BA or LABA resulted in any better outcomes over optimal medical therapy along with lifestyle changes in these patients. Given retrospective and observational nature of our analysis, caution needs to be exerted while inferring causation. Our findings should be regarded as hypothesis generating and require confirmation in future study.

CONCLUSIONS

In contemporary practice, LABA has been used in patients with advanced popliteal and infrapopliteal PAD. Despite worse baseline angiographic characteristics compared with BA, LABA was associated with higher angiographic success and similar ipsilateral major amputation, repeat revascularization, and long-term mortality. Future randomized clinical trial should evaluate the efficacy of LABA compared with BA (particularly drug-eluting) in improving limb salvage and reducing repeat revascularization in these high-risk PAD patients.

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References

1. Elsayed S, Clavijo LC. Critical limb ischemia. *Cardiol Clin.* 2015; 33:37–47. [PubMed: 25439329]
2. Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MW, Halperin JL, Hiratzka LF, Murphy WC, Olin JW, Puschett JB, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease); endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. *Circulation.* 2006; 113:e463–654. [PubMed: 16549646]

3. Fisher, RK., Harris, PL. Critical Limb Ischemia. Armonk, NY: Futura Publishing Company; 1999. Epidemiological and economic considerations in the critically ischemic limb; p. 19-25.
4. Ziegler-Graham K, et al. Estimating the prevalence of limb loss in the United States: 2005–2050. *Arch Phys Med Rehabil.* 2008; 89:422–429. [PubMed: 18295618]
5. Singh T, et al. Laser in infra-popliteal and popliteal stenosis (LIPS): Retrospective review of laser-assisted balloon angioplasty versus balloon angioplasty alone for below knee peripheral arterial disease. *Cardiovasc Interv Ther.* 2014; 29:109–116. [PubMed: 24155171]
6. Anderson JL, et al. Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2013; 61:1555–1570. [PubMed: 23473760]
7. Norgren L, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *Eur J Vasc Endovasc Surg.* 2007; 33:S1–S75. [PubMed: 17140820]
8. Kannel WB, et al. Intermittent claudication. Incidence in the Framingham Study. *Circulation.* 1970; 41:875–883. [PubMed: 5444530]
9. Rabellino M, et al. Clinical follow-up in endovascular treatment for TASC C-D lesions in femoro-popliteal segment. *Catheter Cardiovasc Interv.* 2009; 73:701–705. [PubMed: 19309709]
10. Tewksbury R, et al. Outcomes of infrapopliteal endoluminal intervention for transatlantic intersociety consensus C and D lesions in patients with critical limb ischemia. *ANZ J Surg.* 2014; 84:866–870. [PubMed: 24286673]
11. Brown KT, et al. Infrapopliteal angioplasty: Long-term follow-up. *J Vasc Interv Radiol.* 1993; 4:139–144. [PubMed: 8425091]
12. Molloy KJ, et al. Percutaneous transluminal angioplasty in the treatment of critical limb ischemia. *J Endovasc Ther.* 2003; 10:298–303. [PubMed: 12877613]
13. Laird JR, et al. Limb salvage following laser-assisted angioplasty for critical limb ischemia: Results of the LACI multicenter trial. *J Endovasc Ther.* 2006; 13:1–11. [PubMed: 16445313]
14. Bosiers M, et al. Excimer laser assisted angioplasty for critical limb ischemia: Results of the LACI Belgium Study. *Eur J Vasc Endovasc Surg.* 2005; 29:613–619. [PubMed: 15878540]
15. Steinkamp HJ, et al. Percutaneous transluminal laser angioplasty versus balloon dilation for treatment of popliteal artery occlusions. *J Endovasc Ther.* 2002; 9:882–888. [PubMed: 12546591]
16. Nguyen LL, et al. Disparity in outcomes of surgical revascularization for limb salvage: Race and gender are synergistic determinants of vein graft failure and limb loss. *Circulation.* 2009; 119:123–130. [PubMed: 19103988]
17. Rowe VL, et al. Race independently impacts outcome of infrapopliteal bypass for symptomatic arterial insufficiency. *Vasc Endovascular Surg.* 2007; 41:397–401. [PubMed: 17942854]

Assessment of severity of disease across 4 arterial segments by Yamasaki Score.***Inflow: (Any CIA, EIA, CFA or SFA)***

< 50% stenosis from aortic bifurcation to popliteal - Score -0

≥ 50% stenosis from aortic bifurcation to popliteal - Score -1

Min score possible - 0. Max score possible - 1

Popliteal Artery:

< 50% stenosis - Score - 0

50% ≤ but < 100% stenosis - 1

100% stenosis/Total occlusion - 2

Min score - 0. Max score - 2

Infra-popliteal vessels: (TP Trunk, AT, PT and Peroneal)

< 50% stenosis in all vessels - Score - 0

50% ≤ but < 100% stenosis in each vessel - Score - 1

Each vessel that is occluded - Score - 2

Minimum score is 0 if all vessels are <50% stenotic

Max score is 8 if all vessels are occluded.

Outflow:

Any inframalleolar vessel with straight line flow present - Score - 0

No inframalleolar vessels with straight line flow present - Score - 1

Min score - 0. Max score - 1

Fig. 1.

Yamasaki classification for popliteal and infrapopliteal peripheral arterial disease. The end score is added up from four categories. Patient could have a minimum score of 0 to maximum score of 1. CIA, common iliac artery; EIA, external iliac artery; CFA, common femoral artery; SFA, superficial femoral artery; TP, trunk; tibioperoneal trunk; AT, anterior tibial artery; PT, posterior tibial artery.

Fig. 2. Kaplan–Meier curve for survival (top) and major amputation-free survival (bottom). LABA, laser-assisted balloon angioplasty; BA, balloon angioplasty. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

TABLE I

Baseline Characteristics and Patient Demographics

	LABA <i>n</i> = 395 (%)	BA <i>n</i> = 331 (%)	<i>P</i> value
Male	211 (53.4)	182 (55.0)	0.673
Age (years) Mean $\pm$ SD	71.59 $\pm$ 11.117	71.14 $\pm$ 11.705	0.543
BMI Mean $\pm$ SD	28.6 $\pm$ 6.4	28.2 $\pm$ 6.0	0.313
Caucasian	211 (53.4)	222 (67.1)	0.001 ^a
African-Americans	168 (42.5)	95 (28.7)	
Race other	16 (4.1)	14 (4.2)	
Stroke	95 (24.5)	88 (26.8)	0.486
CAD	273 (70.5)	223 (68.0)	0.460
Hypertension	372 (96.1)	320 (97.6)	0.278
CHF	101 (26.1)	89 (27.1)	0.755
Atrial fibrillation	78 (20.2)	60 (18.3)	0.530
CABG	112 (28.9)	85 (25.9)	0.367
Hyperlipidemia	368 (95.1)	314 (95.7)	0.684
Diabetes	230 (59.6)	188 (57.3)	0.540
ESRD	44 (11.4)	34 (10.4)	0.668
Creatinine >2 mg/dl	47 (12.1)	39 (11.9)	0.917
Prior peripheral bypass	24 (6.2)	21 (6.4)	0.912
Prior contralateral limb amputation	28 (7.2)	40 (12.2)	0.024 ^a
Tobacco use (current or prior)	244 (63.0)	235 (71.6)	0.015 ^a

Values are mean $\pm$ SD or %.

LABA, laser-assisted balloon angioplasty; BA, balloon angioplasty; CAD, coronary artery disease; CHF, congestive heart failure; CABG, coronary artery bypass grafting; ESRD, end-stage renal disease.

^aStatistically significant.

TABLE II

Baseline Lesion Characteristics and Procedural Outcomes/Angiographic Endpoints

	LABA <i>n</i> = 395 (%)	BA <i>n</i> = 331 (%)	<i>P</i> value
Mean LOS days Mean $\pm$ SD	2.4 $\pm$ 3.7	1.8 $\pm$ 2.3	0.008 ^a
Heparin used	347 (87.8)	316 (95.5)	<0.0001 ^a
Bivalirudin used	48 (12.2)	15 (4.5)	
Femoral access	386 (97.7)	320 (96.7)	0.392
Other access	9 (2.3)	11 (3.3)	
TASC D lesion	365 (92.4)	220 (66.5)	<0.0001 ^a
TASC C lesion	26 (6.6)	111 (33.5)	
TASC A/B lesion	4 (1)	0 (0)	
Vessel 1			
Primary target vessel			
Popliteal	120 (30.4)	53 (16)	<0.0001 ^a
Tibioperoneal trunk	46 (11.6)	33 (9.9)	
Anterior tibial	125 (31.6)	117 (35.3)	
Posterior tibial	71 (17.8)	74 (22.2)	
Peroneal	33 (8.4)	54 (16.3)	
Chronic total occlusions	344 (86.4)	165 (49.5)	<0.0001 ^a
Initial % stenosis	98.4 $\pm$ 5.0	92.9 $\pm$ 9.7	<0.0001 ^a
Mean $\pm$ SD			
Residual % stenosis	16.3 $\pm$ 14.9	22.2 $\pm$ 25.3	<0.0001 ^a
Mean $\pm$ SD			
Angiographic success (<50% residual stenosis)	389 (97.7)	297 (89.2)	<0.0001 ^a
Vessel 2			
Primary target vessel			
Popliteal	64 (45.7)	32 (27.8)	0.001 ^a
Tibioperoneal trunk	8 (5.7)	21 (18.3)	
Anterior tibial	8 (5.7)	12 (10.4)	
Posterior tibial	30 (21.4)	32 (27.8)	
Peroneal	30 (21.4)	18 (15.7)	
Chronic total occlusions	110 (78.6)	55 (47.8)	<0.0001 ^a
Initial % stenosis	98.35 $\pm$ 5.014	92.81 $\pm$ 9.745	<0.0001 ^a
Mean $\pm$ SD			
Residual % stenosis	16.3 $\pm$ 16.7	26.2 $\pm$ 30.1	0.002 ^a
Mean $\pm$ SD			
Angiographic success (<50% residual stenosis)	136 (97.1)	97 (84.3)	<0.0001 ^a

Values are mean $\pm$ SD or %.

LABA, laser-assisted balloon angioplasty; BA, balloon angioplasty; LOS, length of stay; TASC, Trans-Atlantic Intersociety Consensus classification.

^aStatistically significant.

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TABLE III**Primary and Secondary Outcomes**

Outcomes	LABA <i>n</i> (%)	BA <i>n</i> (%)	<i>P</i> value
Ipsilateral major limb amputation	16 (4.1)	17 (5.1)	0.48
Median time to ipsilateral major limb amputation (interquartile range)	2.1 (11.0)	3.0 (8.2)	1.0
Any ipsilateral amputation (major or minor)	42 (10.6)	45 (13.6)	0.22
Median time to any ipsilateral amputation (interquartile range)	1.5 (3.9)	3.0 (9.5)	0.47
Ipsilateral repeat revascularization	99 (25.1)	77 (23.3)	0.57
Endovascular	95	74	
Surgical bypass	7	5	
Median time to ipsilateral repeat revascularization (interquartile range)	5.2 (12)	5.4 (7.9)	0.77
Death	139 (35.2)	87 (26.3)	0.01
Mean time to death	21.3 ± 18.9	17.7 ± 15.0	0.12

Median time was reported in months with interquartile range.

Mean time was reported in month ± standard deviations.

LABA, laser-assisted balloon angioplasty; BA, balloon angioplasty.

TABLE IV

Multivariate Cox Regression Analysis of Independent Predictors of Major Limb Amputation

Variables	HR	95% CI		P value
		Upper	Lower	
Age	0.97	0.94	1.00	0.053
BMI	0.89	0.83	0.96	0.002
Total prescore	1.22	1.06	1.39	0.004
DM	5.52	1.82	16.71	0.003
ESRD	1.47	0.61	3.53	0.39
Prior contralateral limb amputation	2.24	1.00	5.02	0.05
CHF	1.75	0.85	3.58	0.13
Procedure type (LABA)	0.72	0.35	1.49	0.72

LABA, laser-assisted balloon angioplasty; BMI, body mass index; DM, diabetes mellitus; ESRD, end-stage renal disease; CHF, congestive heart failure; Total Prescore, total preindex procedure Yamasaki score.

TABLE V**Multivariate Cox Regression Analysis of Repeat Revascularization**

Variables	HR	95% CI		P value
		Upper	Lower	
White race	0.64	0.46	0.89	0.008
Stroke	1.44	1.04	1.99	0.03
DM	1.42	1.04	1.94	0.03
Prior contralateral bypass surgery	1.64	1.00	2.68	0.05
Lesion length	1.41	0.87	2.29	0.16
Total prescore	1.14	1.07	1.20	<0.001
Procedure (LABA)	0.95	0.69	1.31	0.76

DM, diabetes mellitus; LABA, laser-assisted balloon angioplasty; total prescore, total preindex procedure Yamasaki score.

TABLE VI

Multivariate Cox Regression Analysis of All-Cause Mortality

Variables	HR	95% CI		P value
		Upper	Lower	
Age	1.04	1.03	1.05	<0.001
BMI	0.96	0.94	0.99	0.002
Total prescore	1.00	0.95	1.06	0.91
Procedure type (LABA)	1.05	0.79	1.39	0.73
Stroke	1.33	1.00	1.78	0.05
CAD	1.19	0.86	1.64	0.30
CHF	1.56	1.18	2.07	0.002
AF	1.29	0.95	1.76	0.11
DM	1.83	1.33	2.52	<0.001
ESRD	1.66	1.14	2.42	0.009
Prior contralateral limb amputation	1.62	1.06	2.47	0.03

BMI, body mass index; LABA, laser-assisted balloon angioplasty; Total Prescore, total preindex procedure Yamasaki score; CAD, coronary artery disease; CHF, congestive heart failure; AF, atrial fibrillation; DM, diabetes mellitus; ESRD, end-stage renal disease.

TABLE VII
Comparisons with Other Studies for Angiographic Success, Limb Salvage Rate in Below Knee Interventions

Authors [reference]	Modality	Number of patients	Angiographic success (%)	Limb salvage rate (%)	Length of follow-up (months)
Piyaskulkaew et al.	LABA	395	97.9	95.9	36
Bosiers et al. [14]	LABA (single arm)	48 (56% of lesions were below knee)	100	90.5	6
Steinkamp et al. [15]	LABA in popliteal artery	94	81	N/A	36

LABA, laser-assisted balloon angioplasty; BA, balloon angioplasty.