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PII: S0890-5096(22)00504-0
DOI: https://doi.org/10.1016/j.avsg.2022.08.004
Reference: AVSG 6463


Received Date: 13 June 2022
Revised Date: 17 July 2022
Accepted Date: 7 August 2022

Please cite this article as: Liu P, Zheng Lh, He Xq, Yang Y, Zhang Lk, Zhang L, Zhang F, Mid-Term Outcomes of Endovascular Therapy for TASC II D Femoropopliteal Lesions with Critical Limb Ischaemia: A Retrospective Analysis, Annals of Vascular Surgery (2022), doi: https://doi.org/10.1016/j.avsg.2022.08.004.

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Mid-Term Outcomes of Endovascular Therapy for TASC II D Femoropopliteal Lesions with Critical Limb Ischaemia: A Retrospective Analysis

Short Title: TASC II D femoropopliteal lesions EVT

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Abstract

Objective:
This study evaluated the mid-term results of endovascular therapy (EVT) for Trans-Atlantic Inter-Society (TASC) II D femoropopliteal lesions in patients with critical limb ischaemia (CLI).

Methods:
Fifty-seven limbs of 54 patients with CLI due to TASC II D femoropopliteal lesions who underwent EVT at the First Hospital of Hebei Medical University were retrospectively analysed in single-centre, observational study. The patient characteristics, endovascular procedural details, freedom from target lesion revascularisation (TLR), patency rates, ulcer healing rate, and limb salvage rate were accessed.

Results:
The patients’ mean age was 68.2 ± 8.2 years. All patients were treated by EVT. The final technical success rate was 98.2% (56/57). There were 23 cases of pain at rest, 18 cases of ulcer, and 15 cases of gangrene. The median length of the treated segment was 286 ± 42 mm (56/56) and the mean number of stents placed per patient was 2.0 ± 0.8 (49/56). The postoperative ankle-brachial index (ABI) was significantly higher than that of the preoperative ABI (P < 0.05). The perioperative complication rate was 10.7% (6/56). The re-stenosis or occlusion rate was 44.6% (25/56). The estimated rates of freedom from TLR at 1 year, 2 years, and 3 years were 86.8%, 67.0%, and 62.5%, respectively. Univariate analysis showed that predictors of freedom from TLR were the number of runoff vessels, length of the lesion, and complexity of the lesion, while predictors for re-stenosis or occlusion were the length and the complexity of the lesion. The ulcer healing rate was 93.8%. The limb salvage rates were 76.4%, 74.4%, and 70.9% at 1, 2, and 3 years after treatment, respectively.

Conclusions:
The mid-term outcomes of EVT for TASC II D femoropopliteal lesions in patients with CLI indicated that this treatment approach is safe and effective, and is clinically applicable.

Keywords:
Critical limb ischaemia; Endovascular therapy; Patency rate; Peripheral artery disease; TASC II D lesions

Glossary of abbreviations:
PAD: Peripheral artery disease
CLI: Critical limb ischaemia
TASC: Trans-Atlantic Inter-Society Consensus
CTO: Chronic total occlusion
CFA: Common femoral artery
SFA: Superficial femoral artery
EVT: Endovascular therapy
ABI: Ankle brachial index
TLR: Target lesion revascularisation
PTA: Percutaneous transluminal angioplasty
Introduction
Peripheral artery disease (PAD) comprises different stages from asymptomatic stenosis to ischaemic amputation\textsuperscript{1,2} with higher incidence rate in older people.\textsuperscript{3} To facilitate the choice of best method of treatment for symptomatic PAD, the Trans-Atlantic Inter-Society Consensus (TASC) II re-defined class D femoropopliteal lesions as long, chronic total occlusion (CTO) suggesting the need for open surgical revascularisation.\textsuperscript{4,5} However, patients presenting CLI usually have poor physical fitness and are at high-risk for open surgery. Additionally in recent years, with the accumulation of clinicians’ experience and technical and material advances, endovascular therapy (EVT) of complex, longer lesions of the lower limbs has become commonplace,\textsuperscript{6} and have achieved good clinical results with TASC II D femoropopliteal lesions.\textsuperscript{7-9} The aim of this study was to evaluate the mid-term safety and performance outcomes of the EVT, for the treatment of TASC II D femoropopliteal lesions in patients with CLI.

Patients and Methods
Patients
From September 2016 to October 2020, 57 limbs of 54 patients referred for EVT of TASC II D femoropopliteal lesions with CLI were included in this observational, single-arm, single-institution, prospective study. Ankle brachial index (ABI) measurement, Doppler ultrasound, and angiography-computed tomography (angio-CT) were performed before and after each scheduled endovascular procedure in all patients.
PAD was clinically determined according to Rutherford stages. The inclusion criteria were as follows: age > 40 years, symptomatic (Rutherford 4, 5, 6), TASC II D lesion [CTO length of common femoral artery (CFA) and superficial femoral artery (SFA) > 20 cm, involving the popliteal artery],\textsuperscript{5} at least one run-off vessel continuous with the femoropopliteal segment, and informed consent given by the patient. Exclusion criteria were acute ischaemia or acute thrombosis, known allergy to antiplatelet and contrast agent, pregnancy, previous endovascular and bypass surgery of target vessels, Buerger disease, and life expectancy < 1 year.
This research was approved by the Medical Ethics Committee of The First Hospital of Hebei Medical University (20200345). All patients provided informed consent.
Definitions

Definitions are listed in Table 1. The indication for stent implantation was residual stenosis > 30% or limited dissection. The area method was used to calculate the size of the foot ulcer. Calculation of the healing time was from the operation date to the last follow-up or day by which the foot ulcer had healed.\(^\text{10}\) The length of the arterial lesion was evaluated by using a radiopaque ruler during digital subtraction angiography.

Procedures

All the affected limbs underwent EVT. Procedures were performed under local or general anaesthesia by the same group of vascular surgeons. Access to the target lesion was determined using a 6 F 45-cm-long sheath (Fortress, Biotronik, Dresden, Germany), crossing over the aortic bifurcation, or using a 6 F 16-cm-long sheath (Radifocus\(^\text{®}\), Terumo Corporation, Hanoi, Vietnam) via an antegrade approach. After sheath placement, unfractionated 100 IU/kg heparin was administered by injection. A 0.035-inch hydrophilic guidewire (150 cm, RADIFOCUS\(^\text{®}\), Terumo Corporation) crossed through the culprit lesions. The target vessel was first opened in the true lumen, and a subintimal technique was used if this failed. To reduce damage, a balloon with a diameter 1 mm narrower than the target vessel was chosen. Pre-dilation with small balloon catheter was performed for ≥ 2 minutes to limit the risk of dissection. Using a stent sizing selected to a 1:1 ratio to the normal artery segment diameter and extending at least 10 mm past the lesion proximally and distally. Adjacent stents were overlapped by 1-cm maximum. A radiopaque ruler was used to measure the length of the stented segment. Four types of nitinol self-expanding stents were implanted: Protégé Everflex (ev3, Plymouth, MN, USA), Aston Pulsar (Biotronik, Berlin, Germany), Lifestent (Bard peripheral vascular, Tempe, AZ, USA), Zilver Flex (COOK, Limerick, Ireland). The routinely post-dilated balloon after stenting was performed within the stented segment. In case of percutaneous approach, groin closure was accomplished by manual compression or by using a vascular closure device (2 mm Perclose Proglide, Abbott Vascular, Diegem, Belgium).

Drug administration and follow-up
Aspirin (100 mg/d) and clopidogrel (75 mg/d) were administered in the absence of contraindications at least 3 days before operation, after which only aspirin (100 mg/day) was continued. Follow-up visits of outpatient administration were commonly scheduled at 1, 3, 6, and 12 months after the procedure; thereafter, they were evaluated at 6-monthly intervals. Follow-up included an interview, health education with correction of cardiovascular risk factors, ABI, ultrasound imaging, and clinical examination.

Statistical analysis
Data were analysed using SPSS 26.0 software. Continuous variables are presented as mean ± SD. Categorical variables are presented as counts and percentages. Kaplan–Meier analysis with log-rank testing was used to analyse primary patency, assisted-primary patency, and secondary patency rates. A univariate Cox regression model was fitted to investigate risk factors for freedom from TLR and re-stenosis or occlusion. The estimated effect of each variable was calculated as the hazard ratio (HR) with 95% confidence interval (CI). A P-value < 0.05 was considered significant.

Results
Characteristics of the patients
The technical success rate was 98.2% (56/57) (Figure 1). In one patient, the guidewire did not cross the target lesion, and surgical revascularisation with bypass was required. This limb was excluded from analysis. Thus, 56 limbs of 54 patients were enrolled. The baseline demographic and clinical characteristics are described in Table 2. The most common cardiovascular risk factors were hypertension and hypercholesterolemia, which were present in almost 80% of all patients. About half of patients were past or current smokers.

Outcomes of perioperative course
The average baseline Rutherford class was 4.9 ± 0.8. This decreased to 1.3 ±1.4 at 12 months (54 limbs, P < 0.001) after the intervention. The baseline ABI was 0.17 ± 0.1 and increased to 0.89 ± 0.1 at 1 month (55 limbs, P < 0.001), and remained at 0.85 ± 0.1 at 12 months (49 limbs). No clinical worsening was found. Of the 56 limbs in this group, 49 (87.5%) required a
secondary stenting procedure because of an inadequate percutaneous transluminal angioplasty (PTA) result. Stented lesions were significantly longer (28.7 ± 4.5 cm versus 23.0 ± 1.7 cm; *P = 0.001*) than those that underwent PTA only.

The endovascular procedural details are described in Supplementary Table S1. During the perioperative period, six limbs developed procedure-related complications: two cases of myocardial infarction with one procedure-related death; one case of ischaemic stroke, one case of in-stent acute thrombosis and one case of distal embolisation, both of which were treated successfully with thrombolytic therapy; one case of pseudoaneurysm that required open surgery; and one case of local bleeding at the site of vascular access, requiring blood transfusion without surgery. Except for the cases of reoperation and death, other complications were conservatively treated, with good results before discharge. Complete follow-up data were obtained from 94.6% (53/56) patients. The mean time of follow-up was 31.7 ± 12.0 months (range: 1–61 months).

**Vascular patency and TLR**

According to Kaplan–Meier analysis, the primary patency rates at 1 year, 2 years, and 3 years were 84.9%, 34.7% and 20.2%, respectively, with a median time of 19 months. The assisted-primary patency rates at 1 year, 2 years, and 3 years were 88.7%, 44.4%, and 21.8%, respectively, with a median time of 22 months. The secondary patency rates were 98.1%, 55.8%, and 31.5%, respectively, with a median time of 24.5 months (Figure 2).

During the follow-up period, 17 lesions (4 with rest pain, 5 with ulceration, and 8 with gangrene) required TLR. The estimated rates of freedom from TLR at 1 year, 2 years, and 3 years were 86.8%, 67.0%, and 62.5%, respectively. Univariate analysis showed that predictors of freedom from TLR were greater number of runoff vessels (*P = 0.004*), shorter length of lesions (*P = 0.038*), and the absence of complex lesions (*P = 0.036*) (Supplementary Table S2).

**Risk factors for re-stenosis or occlusion**

Overall, 8 of 12 (66.7%) symptomatic re-stenosis and 10 of 13 (76.9%) symptomatic re-occlusion cases successfully underwent reintervention by EVT during the follow-up period. However, in one limb of a patient with technical failure, surgical bypass was required. Five
limbs were treated with rotational atherectomy, covered stents were implanted in six limbs, while a paclitaxel-coated balloon was used in ten limbs at the site of re-stenosis or occlusion. Univariate analysis revealed that predictors of re-stenosis or occlusion were the longer lesion \((P = 0.049)\) and the presence of more complex lesions \((P = 0.025)\) (Supplementary Table S3).

**Ulcer healing**

The ulcer area was determined in 16 patients as 1.0–5.3 cm\(^2\), with an average of 2.3 ± 1.3 cm\(^2\). The ulcer healing rate was 93.8\% (15/16). In 15 cases, wound healing was achieved rapidly after intervention (8–28 days), with an average of 13.4 ± 5.9 days (Supplementary Fig. S1). One patient with ulcer progression, who did not achieve complete healing, required minor amputation due to the gangrene in the toes.

**Limb salvage rate**

The limb salvage rates in the 56 limbs were 76.4\%, 74.4\%, and 70.9\% at 1 year, 2 years, and 3 years, respectively. At the end of follow-up, 15 amputations had been performed, including 4.3\% (1/23) in the rest pain group, 5.6\% (1/18) in the ulceration group, and 86.7\% (13/15) in the gangrene group. These included six cases of major amputation (Figure 3) and nine cases of minor amputation. The other two cases of gangrene were successfully salvaged by skin flap transplantation and other techniques (Figure 4). Complete healing of skin lesions occurred in 14 of 15 limbs, while the remaining patient required reoperation due to the re-occlusion of the treated lesion, and had not undergone surgery by the time of the last follow-up.

**Discussion**

Surgery remained the primary treatment choice for TASC II D lesions. However, advances in endovascular techniques and products for interventional therapy have been reported to have improved the efficacy of EVT for longer lesions,\(^1\) particularly for older and fragile patients in whom open surgical revascularisation under general anaesthesia is contraindicated, as well as for patients undergoing dialysis, and those with coronary artery disease and cerebrovascular disease.\(^12,13\) This study reported the mid-term (3-year) outcomes of EVT, with vessel preparation by PTA, with or without the implantation of one or several self-
expansible bare-metal stents, in TASC II D femoropopliteal lesions with CLI. The overall technical success rate was high (98.2%). Using EVT for TASC II D femoropopliteal lesions yielded acceptable results at 1, 2, and 3 years with satisfactory patency.

However, our results were somewhat discouraging in that the patency rates detected were lower than those previous reported.\textsuperscript{6,14} This outcome can be attributed to the following: first, we analysed only limbs with TASC II D lesions to reduce bias, and the treated lesions were longer (mean length: 286 ± 42 mm) than those in other studies.\textsuperscript{14,15} Secondly, implantation of different types of nitinol self-expandable metal-bare stents played an important role in the low patency rate. Lastly, the primary patency rates of patients suffering from claudication appear to be higher than that of patients with CLI,\textsuperscript{16} and the latter were predominant in our study.

A previous study demonstrated that using primary stents as the first treatment option in femoropopliteal lesions yielded superior outcomes as compared to PTA alone, because of the elastic recoil, residual stenosis, and dissection that occurs in moderate/long-length lesions.\textsuperscript{17,18} In our context, which involved only TASC II D femoropopliteal lesions, there was no significant difference in TLR and primary patency between groups who underwent PTA only and those who received stents. This may be related to the shorter length lesions in the PTA group (23.2 ± 2.6) than in the stent group (28.3 ± 4.3, \(P = 0.004\)). Additionally, the small sample size \((n = 7)\) in the PTA-only group was insufficient for accurate estimation of clinical outcomes. In the early stages of this study, a PTA-only strategy provided less satisfactory results for long femoropopliteal lesions than did angioplasty and stent implantation.

The length of the lesion could determine the patency outcomes after revascularisation, particularly EVT.\textsuperscript{3,19} Primary patency rates appear to be higher in patients suffering from claudication rather than those with CLI, and fall substantially with the increase in the mean treated lesion length.\textsuperscript{15} In our study, longer femoropopliteal lesions had a lower freedom from TLR rate and a higher rate of re-stenosis or occlusion. Moreover, the freedom from TLR rate was significantly lower in complex femoropopliteal TASC II D lesions involving the CFA, and the incidence of re-stenosis or occlusion was significantly higher in these lesions.\textsuperscript{18} The patency rate for lesions involving the CFA may be considered a contraindication to the use of EVT,\textsuperscript{20} as this rate was lower than that in the group of simple femoral popliteal artery lesions.
From a technical standpoint, femoral artery bifurcation near the joint involves a large range of motion and complex haemodynamics. Furthermore, PTA and stenting at the SFA origin is likely to damage the ostium of the profound femoral artery. Lastly, considering the risk of stent fracture and occlusion, the implantation of a stent at the groin is usually not advisable.

Several previous studies have defined a hybrid operation as a combination of proximal SFA open surgery with distal EVT, and have suggested that this is an effective alternative to EVT only for the treatment of femoropopliteal lesions involving bifurcation of the femoral artery.\(^\text{21,22}\) Moreover, these studies have reported that use of an autogenous vein and artificial vessel would likely achieve better clinical outcomes and superior long-term patency, but with longer hospital stay and slow recovery. Unfortunately, there have been no specific guidelines for hybrid therapy for PAD, and this will require further investigation.

The main findings of previous studies were that the number of infra-popliteal arterial runoff vessels is crucial in determining the clinical outcomes after the recanalisation of CTO.\(^\text{23,24}\) Therefore, we attempted to enrol patients with more runoff vessels below the knee, in order to obtain a good long-term clinical result. We found that interventions in cases with two or three run-off vessels had a better outcome than in cases with one runoff vessel, similar to the findings of previous studies.\(^\text{14,25}\) However, few studies have investigated whether the number of run-off vessels is a risk factor for re-stenosis or occlusion, and we only included 25 such cases in our study.

No covered stents were used in the primary EVT in our study, as we consider that these should only be used in patients with in-stent re-stenosis or occlusion due to myo-intimal hyperplasia. It has been reported that in-stent re-stenosis or occlusion was the main drawback after EVT, with an incidence of 40–50%, and that the most common site is in the femoral popliteal artery.\(^\text{26}\) In this study, 23.2% (13/56) patients developed in-stent re-occlusion. Furthermore, our study confirmed that a longer lesion could increase the occurrence rate of re-stenosis or occlusion.

In this study, most of the patients were over 60 years old (87.0%, 47/54) with poly-vascular disease, and the incidence of cardiovascular and cerebrovascular events during the perioperative period was high (5.6%; 3/54). The ulcer healing rate was 93.8% (15/16) after EVT. CLI was a risk factor for amputation and fatal vascular events. During the follow-up in this study, 15 amputations were performed. The patients included in this study had similar
demographics and atherosclerotic risk factors with CLI, while other studies included a significant number of patients suffering from intermittent claudication and rest pain. This difference in the indication for EVT likely had a detrimental effect on the limb salvage rates. The amputation rate in patients with gangrene in this study was 86.7% (13/15). Due to the small number of cases in this group, the risk factors affecting the ulcer healing rate and limb salvage rate were not statistically analysed, and the relevant literature also did not draw a firm conclusion.

**Study limitations**

Our study had important limitations. Firstly, this was a retrospective observational study involving a small cohort and the risk of all sorts of bias and confounding is substantial, which limited external validity of any finding or conclusion. Second, we were unable to account for the effectiveness of endovascular or surgical revascularisation procedures since there was no comparison with surgical bypass in our study. Future studies are required to establish if the good results achieved by EVT last in the long-term.

**Conclusion**

In this single-centre, retrospective study, the mid-term follow-up outcomes of EVT for TASC II D femoropopliteal lesions with CLI were safe and satisfactory. These results strengthened those of other already published studies in confirming that this patient subset would benefit from a minimally invasive EVT. We consider that EVT could be the main treatment for femoropopliteal TASC II D lesions. Our study showed that this approach can result in clinical improvement with abolition of rest pain and wound healing for ulcers and gangrene, with quite impressive results. However, further prospective randomised trials providing a higher level of evidence are needed to determine whether EVT should be considered as first-choice treatment for TASC II D femoropopliteal lesions.

**Declaration of conflicting interests**

None.

**Funding**
The study was a government sponsored program and funded by the Medical Science Research Project of the Key Research and Development Program of Hebei Province, China (No:20377732D).

**Contribution**

PL and FZ participated in the design of this study and they both performed the statistical analysis. XQH and LZ collected clinical and demographic data. LKZ and YY drafted the manuscript. LHZ provide patients to the study. All authors read and approved the final manuscript.

**Appendix A. Supplementary data**

The following is the Supplementary data to this article: Supplementary Table S1-3 and Figures S1.

**References**


<table>
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<tr>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>Residual stenosis &lt; 30% and positive blood flow as assessed by angiography</td>
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<td>Clinical success</td>
<td>Attained at least a level of claudication</td>
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<td>Target lesion revascularisation (TLR)</td>
<td>Revascularisation of a treated arterial segment, performed on a patient who returned due to symptomatic recurrence and re-stenosis or occlusion as determined by duplex ultrasound, following EVT of femoropopliteal PAD</td>
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<td>Coronary artery disease</td>
<td>History of angina, myocardial infarction, or prior coronary artery revascularisation</td>
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<td>Cerebrovascular disease</td>
<td>History of ischaemic stroke, cerebral haemorrhage, and transient ischaemic attack</td>
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<td>Complex lesions</td>
<td>Involving femoral trifurcation including the CFA, the origin of the profound femoral artery (PFA), or flush occlusion of the SFA</td>
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<td>Major amputation</td>
<td>Amputation above the level of the ankle joint</td>
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<td>Minor amputation</td>
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<td>Primary patency</td>
<td>Persistent patency without any other revascularisation in the treated arterial segment</td>
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<tr>
<td>Assisted-primary patency</td>
<td>Persistent patency through new EVT in stenotic segment</td>
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<td>Secondary patency</td>
<td>Duration of patent revascularization after new intervention for occlusion</td>
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<td>Re-stenosis</td>
<td>Stenosis &gt; 50% in the intervened vessel or a peak systolic velocity ratio &gt; 2.4 on duplex ultrasound</td>
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<td>Variables</td>
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<td>Rutherford Classification, n (4/5/6)</td>
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<tr>
<td>Follow-up time (months, mean ± SD)</td>
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Figure table legends

Mid-Term Outcomes of Endovascular Therapy for TASC II D Femoropopliteal Lesions with Critical Limb Ischaemia: A Retrospective Analysis

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Content list:
**Figure 1.** A, B Angiogram illustrates femoropopliteal occlusion. C, D, E, F Angiogram shows the patent femoropopliteal segment after the percutaneous transluminal angioplasty and stenting.

**Figure 2.** Kaplan–Meier curves for primary patency, primary-assisted patency, and secondary patency.

**Figure 3.** Rutherford 6, Gangrene patient; 76-year-old male underwent major amputation because of in-stent re-occlusion.

**Figure 4.** Rutherford 6, Gangrene patient; a 78-year-old male underwent surgical debridement, negative pressure wound therapy, and skin grafting after endovascular therapy.
ARTICLE HIGHLIGHTS

Type of Research: Single-centre retrospective observational study.

Key Findings: EVT of TASC II D femoropopliteal lesions with CLI during EVT using or not stent in 54 patients followed up for 3 years results in 98.2% technical success rate, higher postoperative ABI, in 86.8% 1 year freedom from TLR, 93.8% ulcer healing and 76.4% 1 year limb salvage.

Take home Message: Using EVT to revascularize TASC II D femoropopliteal lesions with CLI is feasible with favorable perioperative outcomes.

Table of Contents Summary

The mid-term outcomes of EVT for TASC II D femoropopliteal lesions with CLI in this retrospective study of 54 patients was significantly acceptable. EVT for TASC II D femoropopliteal lesions appear justified.