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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Endovascular recanalization of infra-popliteal TASC C and TASC D lesions in patients with critical limb-threatening ischemia: a single-center experience

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PURPOSE

The present study aims to (1) assess the technical success and limb salvage rates of endovascular therapy in patients with critical limb-threatening ischemia (CLTI) and infra-popliteal Trans-Atlantic Inter-Society Consensus (TASC) C/D lesions according to the updated 2015 TASC II classification and (2) to present our institutional experience.

METHODS

A single-center retrospective study was conducted on patients with TASC C/D CLTI who underwent endovascular treatment between 2012 and 2017. The follow-up protocol consisted of Doppler ultrasound conduction every 3 months for the first year unless patients showed symptoms of CLTI. Patients with at least 1 year of follow-up data were included in the study, and if applicable their 3-year results were evaluated in terms of primary patency, absence of amputation, amputation-free survival, and overall survival.

RESULTS

A total of 248 patients and 287 limbs (238 TASC D lesions and 49 TASC C lesions) were treated via infra-popliteal percutaneous transluminal angioplasty. The overall technical success was 87%, the primary patency rate was 41.5% in the first year, and the freedom from amputation rates were 80.8% in 1 year and 67.7% in 3 years.

CONCLUSION

In patients with infra-popliteal arterial occlusive diseases, endovascular treatment methods demonstrate a high rate of technical success and favorable outcomes in limb preservation.

KEYWORDS

Percutaneous angioplasty, infra-popliteal arteries, critical limb ischemia, TASC

Infra-popliteal arterial disease constitutes a substantial contributor to critical limb-threatening ischemia (CLTI); it is also closely associated with elevated rates of limb amputation and mortality. CLTI is marked by (1) a presence of persistent ischemic pain at rest or (2) tissue loss, typically occurring in the distal parts of the lower extremities.[1-4] Surgical revascularization of CLTI for limb salvage is a known traditional treatment option; however, an increasing number of centers are treating patients with CLTI via endovascular procedures as the first approach. With the development of small-size stents, low profile balloon catheters, hydrophilic guidewires, support catheters, recanalization devices, and vasodilators, the endovascular approach for infra-popliteal arterial occlusive disease is becoming increasingly common.[5-7] Surgical methods carry an elevated risk of systemic and local complications attributable to the presence of multiple comorbidities.[8]

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CLTI is defined as a Rutherford 4, 5 and 6 disease (ischemic rest pain; nonhealing ulcer/gangrene with minor tissue loss and major tissue loss),[9] and Trans-Atlantic Inter-Society Consensus (TASC) D lesions are characterized as occlusions within the target tibial artery, with a total lesion length of >10 cm, substantial lesion calcification, or a lack of collateral visualization. Additionally, it includes cases where the other tibial arteries are occluded or densely calcified. The TASC C lesions, on the other hand, are defined as stenoses within the target tibial artery or an occlusion with a total lesion length of 10 cm. They also encompass occlusion or stenosis of a comparable or relatively severe degree in the other tibial arteries.[10]

In the literature, significant heterogeneity is evident in studies investigating endovascular treatment outcomes of infra-popliteal artery occlusions.[11] The present study aims to share its authors' institutional experience regarding the endovascular treatment of infra-popliteal arterial occlusive disease in patients with CLTI, as per the revised TASC II classification. Furthermore, it seeks to assess the technical success and limb salvage rates specifically for TASC C and D lesions in endovascular treatment.

Methods

The present study was conducted with adherence to the principles outlined in the Declaration of Helsinki Good Clinical Practice guidelines and was approved by the Gazi University Ethical Committee (date: 12/2019, reference number: 286). Patient consent was waived.

A retrospective analysis was conducted on all consecutive patients diagnosed with CLTI who underwent an endovascular intervention for revascularization of TASC C/D infra-popliteal lesions between January 2012 and September 2017. Patients with at least 1 year of follow-up data were enrolled in the study, and if applicable the 3-year outcomes of these patients were evaluated. Demographic details and follow-up data were collected from Gazi University digital medical records database.Technical success was defined as the achievement of successful revascularization, characterized by <50% residual stenosis following angioplasty and the absence of flow-limiting dissection. Baseline angiograms of the whole limb were obtained for comparison purposes.

In all patients, the preferred initial approach involved ipsilateral antegrade access through the common femoral artery and subsequent revascularization. Following the ultrasound-guided puncture of the common femoral artery, a 6-Fr peripheral guiding sheath (Destination, Terumo) was placed in the distal superficial femoral or popliteal artery to reduce contrast media administration and for better catheter support and guidewire control. The study authors tried to cross all the occluded segments with a 0.014-inch hydrophilic-tipped guide wire (V14, Boston Scientific Corporation) with a compatible support catheter (Seeker, Bard; TrailBlazer, eV3). If these methods failed, the authors tried to cross the arterial occlusion with more supportive 0,018-inch guide wires (V18, Boston Scientific Corporation) and a compatible support catheter (Seeker, Bard; TrailBlazer, eV3). In cases with failed antegrade crossing attempts, retrograde pedal artery access under ultrasound guidance with a pedal access kit (Cook Medical Inc.) or atherectomy catheter (Crosser, Bard) were used. After crossing the occlusion from retrograde pedal access, the wire was snared from or inserted into the femoral access sheath, and the procedure continued from the antegrade approach. The occluded segments crossed with a guidewire and a support catheter, and these segments were dilated with an appropriately sized low-profile balloon catheter. Balloon catheters with a diameter of 2–4.5 mm were inflated for 60 s at 6–8 atm. If there was a suboptimal result or flow-limiting dissections, further dilatation was performed for an additional 2 min or the occluded segment was dilated with a balloon 0.5 mm larger in diameter. Bail-out stenting (Ephesos II, Alvimedica) was performed in lesions due to persistent flow-limiting dissections or immediate post-angioplasty recoiling. A final angiogram was performed to reveal the result, including the pedal arteries (Figure 1).

During the procedure, 5000 IU intravenous heparin was administered to all patients except those with renal failure, who received 2500 IU heparin following the insertion of the arterial sheath. Dual antiplatelet therapy of clopidogrel (75 mg/day) and acetylsalicylic acid (ASA) (100 mg/day) were recommended 3 days before the procedure and resumed for 6 months. Lifelong treatment with ASA was continued. After the intervention, 4000 anti-Xa units of low-molecular-weight heparin were recommended twice daily for 5 days.

The authors' follow-up protocol included Doppler ultrasound (DUS) imaging at discharge at the first month and every 3 months thereafter for the first year. The first-year control interval then increased to every 6 months unless patients presented with symptoms of CLTI. Follow-up angiography and/or re-intervention was considered when the DUS findings suggested restenosis of >50% (with a Rutherford score of >4 and no wound healing).

Statistical analysis

Data analysis was performed using the Statistical Package for the Social Sciences (IBM, SPSS Statistics for Macintosh, Version 25.0, Armonk, New York). Continuous variables were represented as mean ± standard deviation, and categorical variables were de-

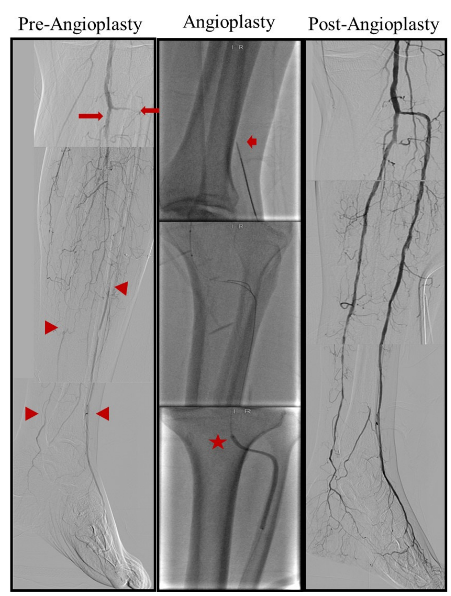

Figure 1. Pre-angioplasty images show occlusion of all crural arteries (arrows). Reconstitution of the tibial arteries are visible distally (arrowheads). The anterograde approach was performed, and recanalization was achieved in the posterior tibial artery (PTA) but not in the anterior tibial artery (ATA). The distal ATA was punctured, and retrograde access was gained (small arrow). Next, anterograde access was gained using the rendezvous technique, and successful recanalization and balloon angioplasty of the ATA was accomplished (star). The final angiogram shows successful recanalization and patency of both ATA and PTA.

Main points

- Infra-popliteal arterial disease is a major cause of critical limb-threatening ischemia (CLTI) and it is associated with high rates of limb loss and mortality.
- Challenging infra-popliteal arterial lesions can be treated via endovascular approaches with low complication rates.
- Endovascular treatment methods are effective and reliable in alleviating symptoms associated with CLTI and in preventing limb loss in cases involving challenging infra-popliteal arterial lesions.

picted as values along with their respective percentages. Each patient's demographic and comorbidity details were recorded, and patency data were calculated for each individual. Outcomes regarding major amputation and mortality rates in the patient cohort were visualized via Kaplan–Meier analysis.

Results

Between 2012 and 2017, 1,244 patients were treated at Gazi University Hospital for peripheral arterial disease. Patients with isolated infra-popliteal lesions were included in the study; among them, 380 had infra-popliteal TASC C/D lesions, and only 248 patients had complete 1-year follow-up data and were enrolled in the study.

A total of 238 TASC D and 49 TASC C lesions were treated in the 248 patients. In 95 of the patients, more than one infra-popliteal artery was treated. A total of 190 patients were men (76.6%), and the mean age was 65.3 years. Patient characteristics are given in Table 1. A total of 190 patients (76.6%) had diabetes mellitus, 183 (73.7%) had hypertension, and 39.9% had coronary artery disease.

Table 1. Baseline characteristics

Characteristic	Value
Patients (n)	248
Limbs (n)	287
Male gender	190/248 (76.6%)
Diabetes mellitus	190/248 (76.6%)
Hypertension	183/248 (73.7%)
Smoking	184/248 (74.6%)
Hyperlipidemia	102/248 (41.1%)
CAD	99/248 (39.9%)
ESRD	21/248 (8.5%)

CAD, coronary artery disease; ESRD, end-stage renal disease.

Risk factors are also noted in Table 1. According to the Rutherford classification, 38 of the patients (13.2%) fell into category 4, 172 (59.9%) fell into category 5, and 77 (26.8%) fell into category 6. Treated occlusions were 10–30 cm long, and the average occlusion length was 15.7 ± 0.2 cm. Detailed lesion characteristics are given in Table 2.

In 203 of the lesions (71%), recanalization was successful with standard guidewires and support catheters via anterograde access. In the remaining 48 (16%) lesions, retrograde pedal access was needed to cross the occluded segment. In 29 (10%) lesions, atherectomy devices were used. A total of 7 (3%) lesions required use of both pedal access and atherectomy devices. In 33 and 23 patients, the anterior tibial artery and posterior tibial artery, respectfully, were punctured under ultrasound guidance with a pedal access set. However, in 6 of the lesions, all attempts at recanalization were unsuccessful. The overall occlusion crossing success rate was 97.9%. After balloon dilatation, a result of suboptimal angioplasty or flow-limiting dissection was seen in 57 (19.8%) lesions. In 20 (6.9%) additional lesions, successful revascularization was achieved after repeated balloon dilatations for an additional 2 min at nominal pressure. In 6 lesions (2%) a persistent flow-limiting dissection was noticed, and bail-out stenting was performed. Despite all attempts, adequate vessel patency was not achieved in 37 (12.8%) of the lesions.

The procedure was technically successful in 87.2% of lesions. In the follow up, the Rutherford score improved to 3.3 ± 0.4 in the first year. The primary patency rate was 65.2% at 3 months and declined to 41.5% at 12 months (Figure 2). At 1 year, a total of 67 (23.3%) limbs required re-intervention; among them, 12 (4.8%) were referred for bypass surgery. Amputations above the ankle level were accepted as major amputation,

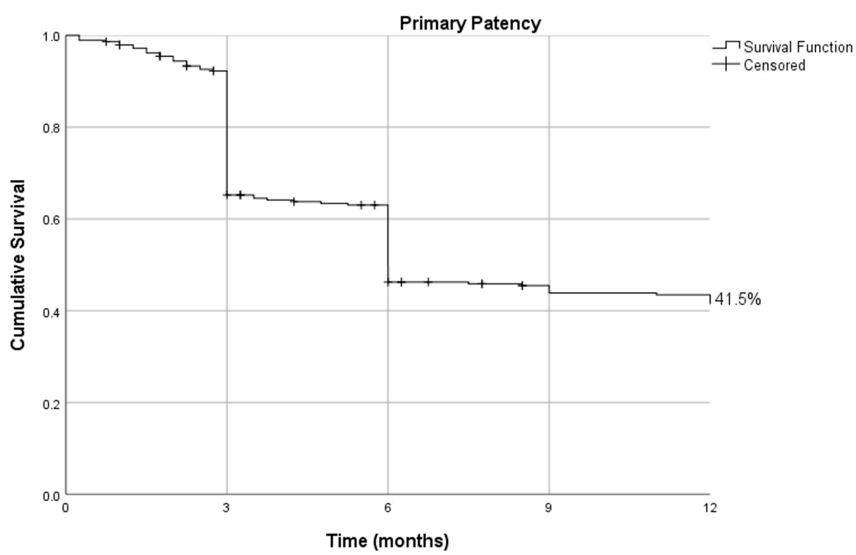

Figure 2. Kaplan–Meier curve for primary patency.

Table 2. Lesion characteristics

		Rutherford			
		4	5	6	Total
TASC	C	28	16	5	49 (17.1%)
	D	10	156	72	238 (82.9%)
Total		38 (13.2%)	172 (59.9%)	77 (26.8%)	
Lesion length			15.7 ± 0.2		
Vessel diameter			2.92 ± 0.3		
Lesion location					
Anterior tibial artery			191		
Posterior tibial artery			130		
Peroneal artery			62		

TASC, Trans-Atlantic Inter-Society Consensus.

and at 12 months, 25 (8.6%) limbs had undergone major amputation, and 32 (11.1%) limbs had undergone minor amputation. Over the 3-year follow-up period, 40 (13.9%) limbs had undergone major amputation, and 40 (13.9%) limbs had undergone minor amputation. The amputation-free survival rates were 70.7% at the first year and 32.9% at the third year (Figure 3). A total of 30 patients (12%) died during 12 months of the follow up, and 117 (47.1%) died over 3 years (Figure 4). Freedom from amputation was 80.8% at the first year and 67.7% at 3 years (Figure 5).

There were no procedure-related deaths in the first month after the procedure. There were 9 major complications (3.6%), including 4 pseudoaneurysms and 5 persistent flow-limiting dissections at the puncture site, which were treated accordingly. There were 21 minor complications, such as a small hematoma at the puncture site.

Discussion

This study presents the 3-year outcomes of patients diagnosed with CLTI who received endovascular interventions to address infra-popliteal lesions categorized as TASC C and TASC D. Percutaneous revascularization of infra-popliteal lesions was performed with an 87.2% technical success rate and a low major adverse events rate (3.6%).

The success of the revascularization procedure was assessed by evaluating the patency rates and clinical endpoints, including amputation-free survival. The occurrence of restenosis (>50%) poses a significant challenge. The present authors' primary approach always centered on reducing rest pain and amputation rates, coupled with vigilant post-intervention follow up to achieve these goals.

The effectiveness of the endovascular approach for treating infra-popliteal arterial lesions remains uncertain and not yet firmly established.[12] For the treatment of CLTI, both bypass surgery and endovascular revascularization are viable options, each demonstrating favorable limb salvage rates.[13] Although venous bypass surgery seems to have a higher durability, many patients with CLTI are not suitable for surgery due to comorbidities. Endovascular treatment stands as a less invasive, efficient, and secure therapeutic choice that can be carried out under local anesthesia.[14] Despite a general trend toward initially adopting the endovascular approach for all patients with CLTI, surgical revascularization for infra-popliteal lesions in CLTI cases is still commonly observed.[15]

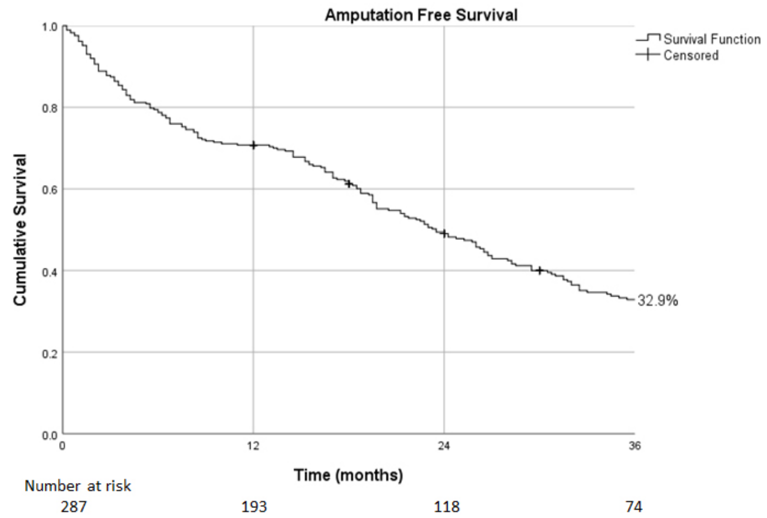

Figure 3. Kaplan–Meier curve for amputation-free survival.

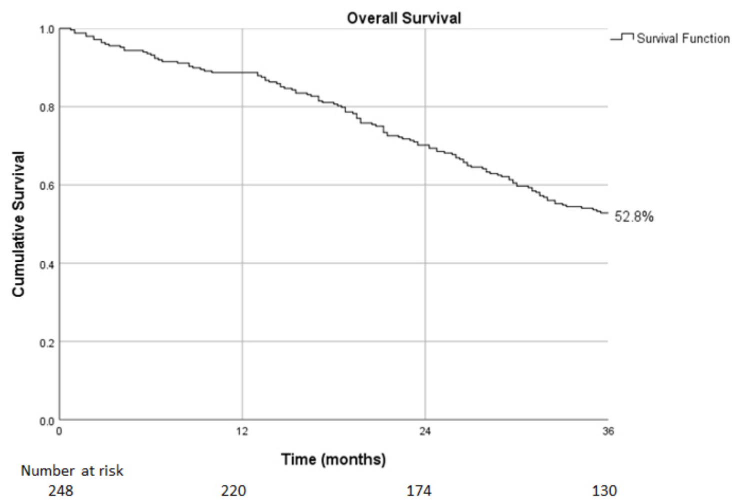

Figure 4. Kaplan–Meier curve for overall survival.

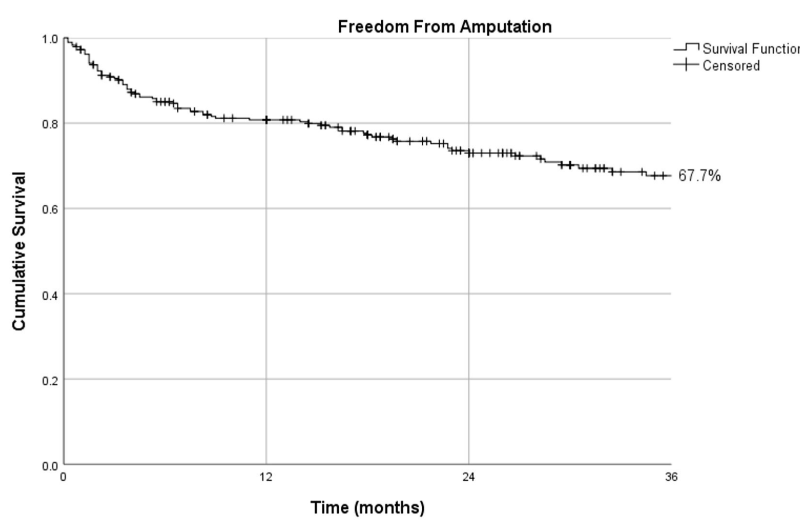

Figure 5. Kaplan–Meier curve for freedom from amputation.

Table 3. Published endovascular treatment reports of infra-popliteal arterial disease in patients with CLI or TASC C/D lesions in the literature

Author	Number of patients	Technical success	Primary patency rate at 1 year	Limb salvage rates at 1 year	Amputation-free survival at 1 year
Present study	248	87.2%	41.5%	80.8%	70.7%
Singh et al.[17]	94	80%	51%	74%	57%
Pavé et al.[18]	139	87.9%	55%	81%	NA
Nakano et al.[19]	449	71%	NA	77%	51%
Kok et al.[20]	112	75%	NA	77%	NA

CLI, critical limb ischemia; TASC, Trans-Atlantic Inter-Society Consensus; NA, not available.

In a single-center study, complex infra-popliteal lesions had poorer outcomes compared with moderate lesions over long-term outcomes.[16] In a separate study, the TASC C/D lesions were linked with a lower rate of procedural success, higher incidence of major amputations, and poorer primary patency. This was attributed to the fact that these small vessel lesions tend to be significantly longer and are more frequently characterized as chronic occlusions.[17] While the present technical success rate of 87.2% appears comparable with the mentioned study, it is important to note that in the present study, all the lesions were occlusions with a length of >10 cm.

Recent reports for endovascular treatment of CLTI have high limb salvage rates of,[18-20] which is similar to the results of the present study. The present findings revealed high technical success rates in the treatment of infra-popliteal occlusions via balloon angioplasty following crossing with a guidewire and a compatible support catheter via the antegrade access. Furthermore, the use of pedal access safely increases the recanalization rates in infra-popliteal occlusions when the traditional antegrade approach fails.[21]

In the endovascular treatment of infra-popliteal lesions, a high rate of restenosis is expected, especially if the lesions are long-segment occlusions.[22,23] In a series of 139 patients with CLTI treated via angioplasty, the restenosis rate reached 45.3% at 1 year.[22] In another study, Schmidt et al.[23] reported 77 infra-popliteal arterial interventions with long-segment disease, where 65% of the lesions were occlusions. The 3-month angiography follow up showed >50% restenosis or re-occlusion, and despite these rates, clinical findings in 76% of the patients with CLTI had improved. In another infra-popliteal interventional revascularization study, Nakano et al.[19] investigated 449 patients with CLTI who also had end-stage renal disease, demonstrating a 77% limb salvage rate (Table 3).[24]

In the present study, the endovascular approach was used as the first-line treatment. The majority of the patients were not eligible for surgical treatment due to comorbidities or unavailability of distal vessels for bypass surgery. In the follow up, 13.9% limbs had undergone major amputation and 13.9% had undergone minor amputation. Although the prognosis for TASC C and D lesions is poor, the mean Rutherford score improved from 5.13 ± 0.6 to 3.3 ± 0.4 at the 12th month after endovascular treatment.

An improved Rutherford score and wound healing in some patients were observed even after restenosis and re-occlusion in target arteries. Infra-popliteal interventions have high rates of restenosis in patients with CLTI but less clinical importance in wound healing and rest pain, as the aim of these interventions is to provide more arterial perfusion pressure for the non-healing tissue at least for a certain time.[25] To obtain better perfusion pressure, multilevel interventions are thought to be more beneficial than only treating a target vessel or isolated lesion.[26] Thus, the authors aimed to revascularize as many vessels as possible.

The present study has some limitations. First, due to the lack of a surgical counterpart in this study, it is difficult to draw firm conclusions regarding the role of endovascular therapies in the treatment strategies of patients with CLTI. Second, given that the present paper is a retrospective study from a single center targeting only selected patients, it might not reflect the patient characteristics of the whole target population.

In conclusion, this study has shown that endovascular treatment of TASC C/D lesions can be accomplished with a high rate of technical success and a low incidence of complications. Based on this data, the authors believe that endovascular treatment can be used as a first-line treatment with high limb salvage and primary patency rates in the treatment of infra-popliteal occlusion. Further randomized cohort studies should be performed to promote the success rates of endovascular treatment in infra-popliteal TASC C and D lesions.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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