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CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

Endovascular Recanalization of Thromboangiitis Obliterans (Buerger's Disease) in Twenty-Eight Consecutive Patients and Combined Antegrade–Retrograde Intervention in Eight Patients

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Abstract

Purpose The aim of the study was to evaluate the technical success of the procedure and the clinical efficacy of treatment in patients with thromboangiitis obliterans (TAO) (Buerger's disease) based on a change in the Rutherford classification.

Materials and Methods A total of 28 consecutive patients (26 males, 2 females, mean age 43.3 ± 5.32 years) underwent endovascular recanalization with a diagnosis of TAO, between April 2015 and July 2018. After unsuccessful attempts using the antegrade approach, retrograde approaches were used in 8 patients under ultrasound guidance. Clinical follow-up was routinely performed at 1-month, 3-month, 6-month, and 1-year intervals.

Results A total of 28 TAO patients underwent 40 procedures in 32 limbs. Technical success was achieved in 28 of the 32 limbs (87.5%). In total, 45 of 59 (76.2%) below the knee arteries were treated successfully. One major amputation was performed, providing a 96.8% rate for limb salvage both at 12 and 24 months. Amputation-free survival estimated by Kaplan–Meier analysis was 84% at 12 and 24 months. Primary patency rates at 12, 24, and 36 months were 84%, 78%, and 75%, respectively. Secondary patency rates were 87.5% both at 12 and 24 months.

Conclusion Endovascular treatment is a technically feasible and potentially effective treatment modality for Buerger's disease. Combined antegrade and retrograde interventions in TAO patients may improve technical success and clinical recovery, especially in cases where the antegrade approach has failed.

Keywords Buerger's disease · Thromboangiitis obliterans · Angioplasty · Endovascular · Limb ischemia

Introduction

Thromboangiitis obliterans (TAO) or Buerger's disease is a non-atherosclerotic peripheral vascular disease, which affects mainly young male smokers before the age of 45, especially in low socioeconomic regions [1, 2]. The patients usually suffer from claudication of the affected extremities, ischemic pain, and ulcerations of the legs, arms, feet, and hands [3]. The prognosis of limb loss in patients with Buerger's disease is worse than in patients with atherosclerosis and various forms of necrotizing immune arteritis [1, 4]. Angiography images show typical corkscrew collaterals which may represent compensatory changes in the vasa vasorum [5–8]. Although there is no clinical guideline for the treatment of TAO, medical, surgical, or endovascular treatment options can be applied separately or together for limb salvage. Cessation of smoking is the only proven strategy to prevent progression of the disease [9, 10]. Although arterial bypass with autogenous vein operations is considered to be an ideal strategy for patients with advanced lower limb occlusions, as a result of procedural difficulties, endovascular

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recanalization has become an alternative treatment method for TAO in the last two decades [11, 12]. The aim of this study was to present our experience of 40 endovascular procedures in 28 patients and to demonstrate the effectiveness of these procedures in patients with TAO.

Material and Method

Patient Population

This was a retrospective study of 28 consecutive patients (26 males, 2 females, mean age 43.3 ± 5.32 years) who underwent endovascular recanalization with a diagnosis of TAO based on the Shionoya criteria (Table 1) and arteriographic findings at our center, between April 2015 and July 2018. All patients presented with peripheral arterial disease findings such as intermittent claudication, rest pain, non-healing foot wound, or skin discoloration. Typical angiographic findings in all cases showed non-calcified long occlusions and corkscrew collaterals compatible with Buerger's disease. All patients had a history of smoking in the past (*n* 18) or at the time of the procedure (*n* 10) and had no serious cardiopulmonary comorbidities. All patients were informed about the harmful effects of smoking on their disease. The demographic data, indications, and comorbidities are outlined in Table 2. This study was approved by the institutional review board, and written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Endovascular Treatment

All patients were evaluated preoperatively with duplex ultrasonography (DUS) scanning before the angiography procedure, and all endovascular interventions were performed in a dedicated angiographic room equipped with a C-Arm (Axiom Artis C-arm imaging system, Siemens, Germany) and a DUS scanner (Acuson Antares, Siemens, Germany). All patients were taking aspirin (100 mg/d), while 24 patients were taking clopidogrel (75 mg) before treatment. The other 4 patients received a loading dose of

Table 1 Shionoya clinical criteria

- Smoking history
- Onset before the age of 50 years
- Infrapopliteal arterial occlusions
- Either upper limb involvement or phlebitis migrans
- Absence of atherosclerotic risk factors other than smoking

Table 2 Demographic characteristics of patients

Number of patients/limbs	28/32
Age (years)	43.3 ± 5.32
Gender *n* (%)	
Men	26 (92.8%)
Women	2 (7.2%)
Hypertension *n* (%)	1 (3.5%)
Dyslipidemia *n* (%)	5 (17.8%)
Smoking *n* (%)	
Current	10 (35.8%)
Former	18 (64.2%)
Diabetes *n* (%)	0 (0%)
Coronary artery disease *n* (%)	0 (0%)
Chronic kidney disease *n* (%)	0 (0%)
Rutherford classification *n* (%)	
Class 1	0 (0%)
Class 2	0 (0%)
Class 3	4 (12.5%)
Class 4	15 (46.9%)
Class 5	13 (40.6%)
Class 6	0 (0%)

300 mg clopidogrel 12 h before the planned intervention. With the patient under local anesthesia, common femoral artery access was obtained under ultrasound guidance (7.5-MHz linear probe), and a 6-F sheath was deployed. Femoral access was obtained in 29 procedures with ipsilateral antegrade puncture and in 11 procedures with contralateral retrograde puncture. Unfractionated heparin at a dose of 5000 units was administered after the sheath was deployed, and an additional 1000–2000 U was given for interventions that lasted > 1 h. Prior to the endovascular treatment, diagnostic angiography was performed to document arterial disease. Antegrade recanalization was first attempted in all patients using multiple wiring techniques. When guidewire passage of the occlusion failed, retrograde approaches were used under ultrasound guidance. In 40 procedures, a total of 13/80 (16.2%) target arteries (9 dorsalis pedis artery-distal segment of ATA and 4 plantar artery-distal segment of PTA) in 11/28 patients (39.2%) were partially or totally filled with collateral arteries angiographically (Figs. 1B, 2B). Ipsilateral retrograde access was attempted in 2 patients with PTA (posterior tibial artery), in 2 patients with PEA (peroneal artery) and in 5 patients with ATA (anterior tibial artery). Retrograde access to the peroneal arteries was obtained with puncture to the plantar artery. In this approach, local anesthesia was administered percutaneously into the subcutaneous tissue close to the target area. Direct puncture was applied using a micropuncture introducer set (Cook Medical, Bloomington,

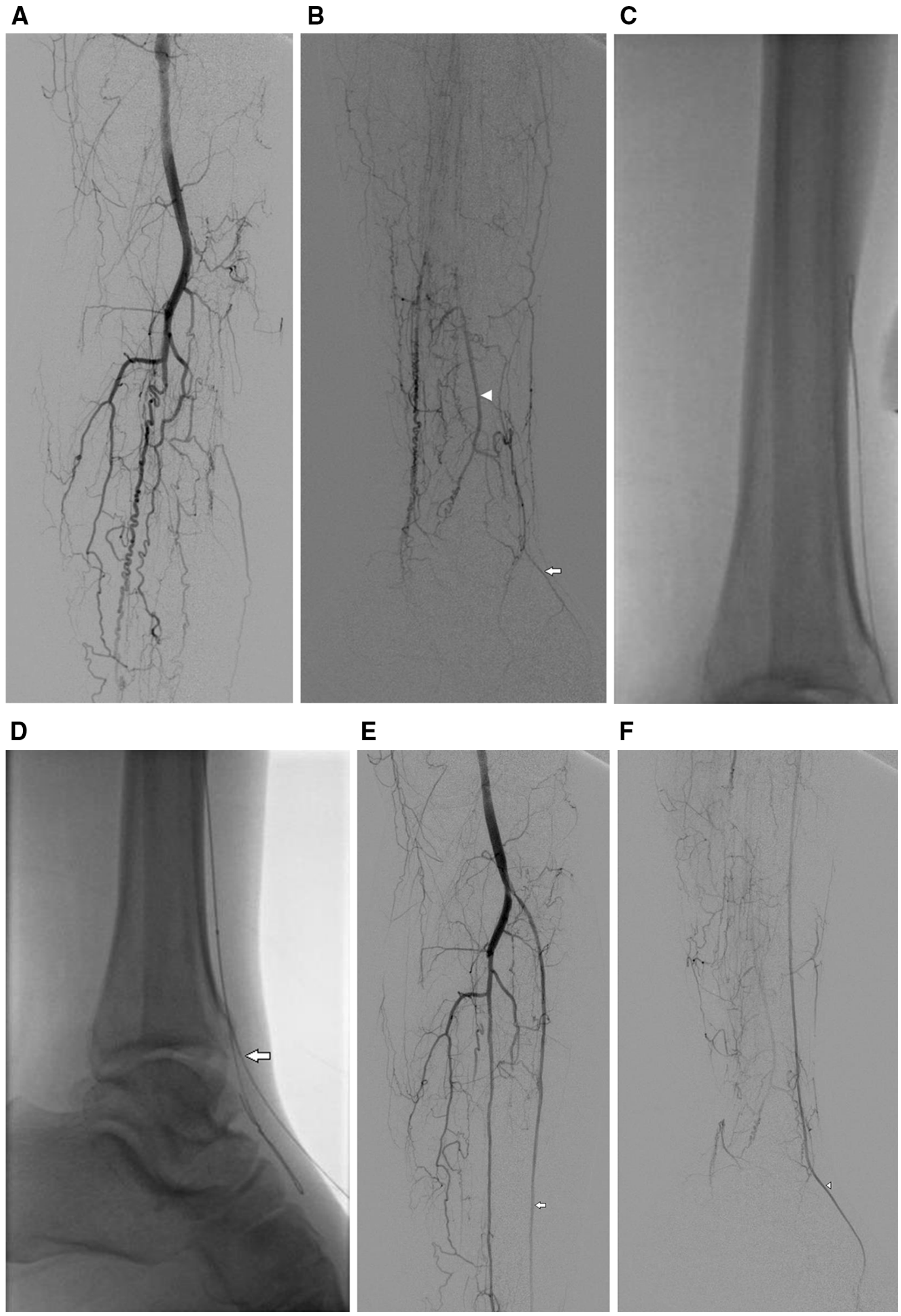

Fig. 1 **A**, **B** Diagnostic angiography showing total occlusion of anterior tibial artery and posterior tibial artery. The dorsalis pedis artery (arrow) and the distal segment of the peroneal artery (arrowhead) were filled via collateral arteries. Angiographic images show multiple corkscrew collaterals typical of TAO. **C**, **D** The anterior tibial artery was punctured (arrow) under ultrasonography and the guide wire advanced to the popliteal artery, while the other guide wire was placed into the target artery with the aid of a support catheter. **E**, **F** Recanalization of the anterior tibial artery (arrow) to the dorsalis pedis artery (arrowhead), providing direct flow to the foot

IN, USA) under ultrasound guidance (7.5 MHz linear probe) with the retrograde approach. After access to the artery was confirmed on ultrasound, a 0.014-inch or 0.018-inch guide wire (V Control, Boston Scientific) was passed through the needle into the vessel under fluoroscopic guidance. The needle was removed and a balloon or 4F support catheter (NaviCross, Terumo Medical Corp, Tokyo, Japan) was passed over the wire to access the patent artery, after which balloon dilatation was performed to the proximal segment of the occluded arteries. Once the target artery was crossed from an antegrade approach, balloon dilatation was performed along the length of the occluded artery. The procedure was then completed from an antegrade approach (Figs. 1, 2). After the procedure, IV heparin was administered 1000 U/h for 12 h, and antiplatelet therapy with aspirin and clopidogrel was provided as long-term treatment. As ankle/brachial pressure index (ABI) measurement is not a good indicator in Buerger's disease

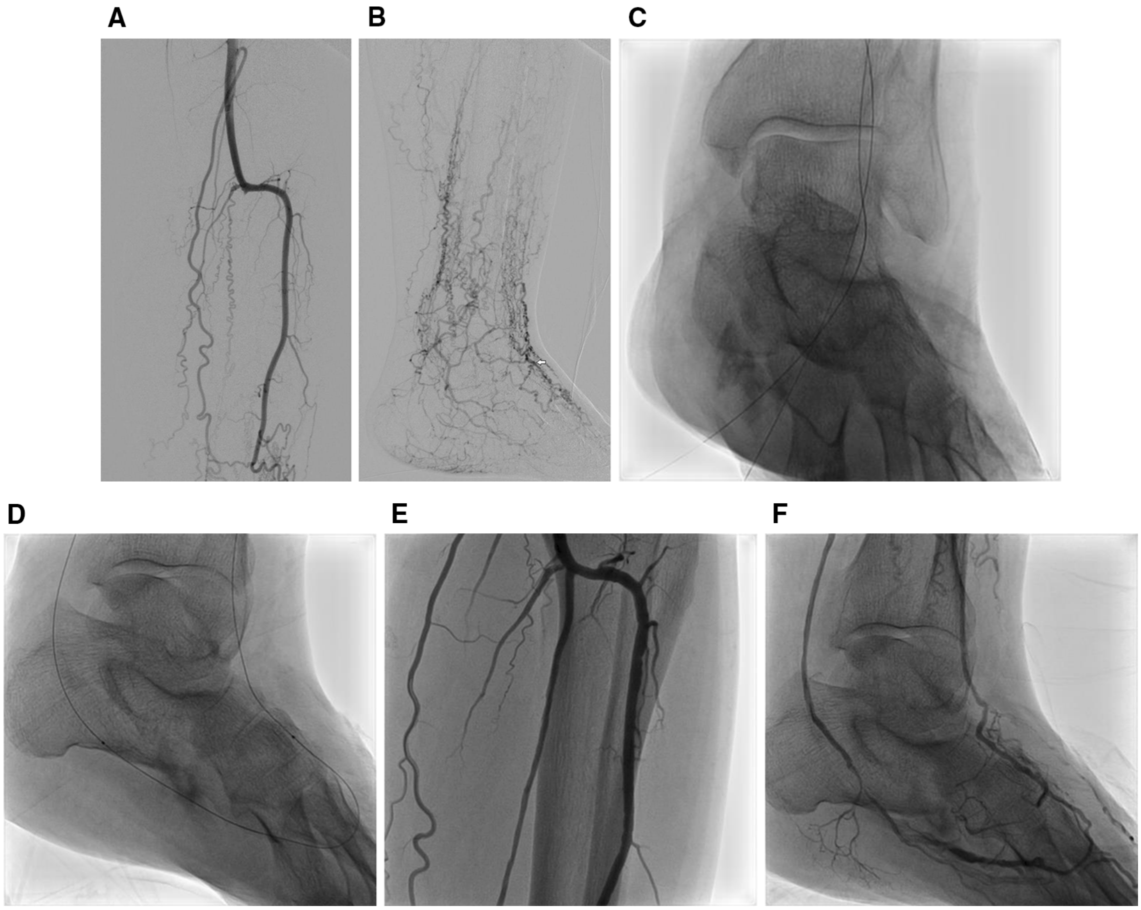

Fig. 2 **A**, **B** Diagnostic angiography showing peripheral arterial disease and corkscrew collaterals typical of TAO. The posterior tibial artery, peroneal artery and the distal segment of the anterior tibial artery are totaly occluded. The proksimal segment of the dorsalis pedis artery (arrow) filled by collateral arteries. **C**, **D** After the retrograde direct puncture of anterior tibial artery under ultrasonography, the guide wire advanced to the popliteal artery and the other guide wire was placed into the target arteries using the antegrade approach. **E**, **F** Recanalization of anterior and posterior tibial artery

because of the distal occlusion [13], it was decided to use clinical examination, Rutherford classification and Doppler ultrasound scanning at 1 month, 3 months, 6 months, and 1 year for clinical follow-up.

Study Outcome Measurements

The primary outcome measurement of the study was to evaluate the technical success of the procedure in obtaining the ability to pass the wire across the target artery and provide blood flow to the pedal arteries with residual stenosis of $< 30\%$. The secondary outcome measurement of the study was to evaluate the clinical effectiveness of the procedure, based on the change in the Rutherford classification (improvement of $\geq$ 1 Rutherford category) and limb salvage of the patients.

Statistical Analysis

Statistical analysis was performed using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2013) and IBM SPSS statistics version 23 (IBM Corp, USA). The normality of continuous variables was evaluated using the Shapiro–Wilk's test. Descriptive statistics were presented as mean and standard deviation values for normally distributed variables and median (minimum–maximum) values for non-normally distributed variables. The Wilcoxon signed-rank test was used in the comparison of two non-normally distributed dependent groups. A two-sided p value of < 0.05 was accepted as statistically significant. The time to limb salvage, amputation-free survival rate, and primary and secondary patencies were studied by applying Kaplan–Meier analysis.

Table 3 Procedure details

	SFA	PA	ATA	PTA	PEA	Ark
Occluded artery	13	18	34	35	31	36
Intervention	13	18	24	13	15	7
Angioplasty	10	17	24	13	15	7
Stent	3	1	–	–	–	–
Responsive/unresponsive	12/1	17/1	18/6	9/4	12/3	6/1
Success rate (%)	92.3	94.4	75	69.2	80	85.7

Table 4 Length of occlusions treated

Length of occlusion (cm) (mean ± SD)	
Superficial femoral artery	23.4 ± 12.4
Popliteal artery	14.2 ± 4.7
Anterior tibial artery	26 ± 10.2
Posterior tibial artery	29.5 ± 11.9
Peroneal artery	24.7 ± 12.4
Plantar arc arteries	17.4 ± 6.4

Results

Analysis was made of a total of 28 consecutive patients with a diagnosis of TAO who underwent an endovascular procedure, with 40 procedures applied to 32 limbs. Technical success was achieved in 28 of the 32 limbs (87.5%). In total, 45 out of 59 (76.2%) below the knee (BTK) arteries were treated successfully, but 14 BTK vessels did not respond to angioplasty. It was thought that the cause of failed angioplasties could be due to elastic recoil or occlusive dissection. Re-intervention was required by 8 patients in the same limb and the procedures were attempted in two separate limbs in 4 patients. In 1 patient, two interventions were performed on the right limb, while one intervention was performed on the left limb. All lesions were occlusions (13 SFA (superficial femoral artery), 18 PA (popliteal artery), 34 ATA, 35 PTA, 31 PEA, and 36 PAA (plantar arch arteries)) in 40 procedures. A successful response to endovascular treatment was obtained in 12/13 SFA (92.3%), 17/18 PA (94.4%), 18/24 ATA (75%), 9/13 PTA (69.2%), 12/15 PEA (80%) and 6/7 PAA (85.7%) (Table 3). After failed antegrade attempts, ipsilateral retrograde access was attempted in a total of nine arteries (2 PTA, 2 PEA and 5 ATA) of 8 patients. In all of these patients, the guidewire was passed through the occlusive artery and access to the patent lumen was provided. In 1 of these patients, SFA and PA did not respond to angioplasty despite retrograde passage through ATA. Except for this case, endovascular treatment was successfully performed in all patients with retrograde access. The length of the treated occlusions is shown in Table 4. The interventional procedure was applied to the right side in 20 patients and to the left side in 20 patients. A stent (Ev3 Inc., Plymouth, MN, USA) was deployed in 3 patients with occluded SFA and in 1 patient with occluded popliteal artery. With the exception of these 4 patients, the balloon angioplasty procedure was performed in all other patients. There was no occlusion of the stents during the follow-up period. In 1 patient who did not respond to angioplasty due to SFA, PA, PTA, and PEA occlusion and the presence of immediate thrombus of the arteries, tPA (rate of 1 mg/h for 16 h) was administered and the re-intervention was performed the next day. In this patient, SFA and popliteal artery were treated using angioplasty stent procedures, PTA and PEA were treated by angioplasty procedures, and there was no occlusion of the treated arteries during the follow-up period. Minor complications occurred in 4/28 (14.2%) procedures, including hematomas that did not require treatment. There were no major complications in any of the cases.

At the 1-month follow-up examination, angioplasty was performed for the second time in a patient who had no previous response to angioplasty in ATA and PTA occlusion, but no response was obtained in the second procedure. The procedure was repeated in a patient with PA, ATA, and PEA occlusion in the first 3 months of follow-up, and good results were obtained again in the second procedure. In one case, major amputation was required due to progression of the established necrosis after 2 months of endovascular procedure. At the 6-month follow-up examination, angioplasty was successfully performed again on the same vessels during the second procedure in a patient who had undergone PA and ATA angioplasty. At the 12-month follow-up examination, a patient who had previously been successfully treated with SFA occlusion was treated successfully again. The median follow-up was 25.5 ± 13.3 months. A patient who had previously undergone successful angioplasty with PTA and PAA was subjected to re-intervention in the same occluded vessels in the 14th month, but no response was obtained (Fig. 3). A patient who had undergone successful angioplasty due to occlusion in the PA and PTA vessels had recurrence at the 16th month and was treated successfully again. A total of 13 limbs had ischemic foot ulcers. Minor amputation was applied to 4 limbs during the follow-up period. Amputation-free survival estimated by Kaplan–Meier analysis was 84% at 12 and 24 months, respectively (Fig. 4). Primary patency rates at 12, 24 and 36 months were 84%, 78%, and 75%, respectively (Fig. 5). The secondary patency rate was 87.5% both at 12 and 24 months (Fig. 6).

In addition to recanalization procedures, the remaining 9 limbs underwent conservative treatment such as wound

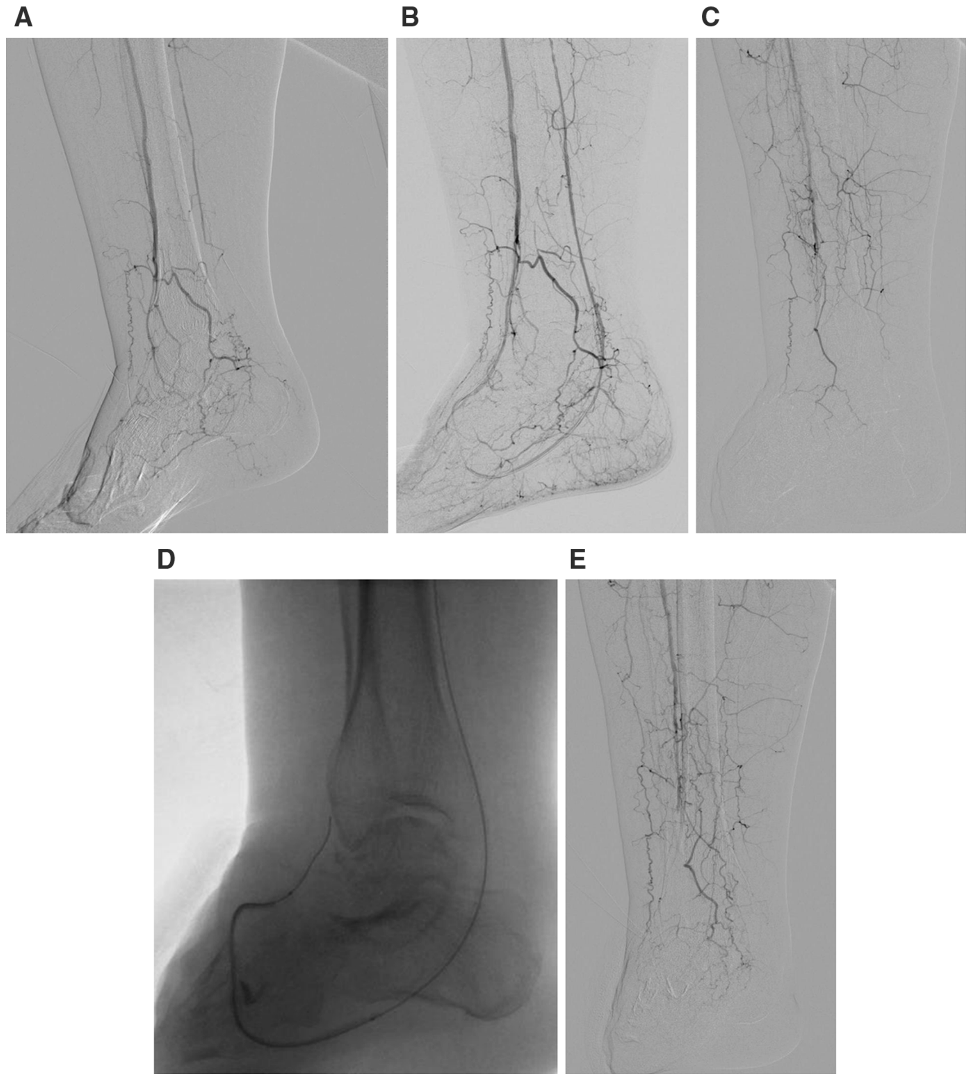

Fig. 3 **A**, **B** A patient who had previously undergone successful angioplasty with posterior tibial artery and plantar arc arteries. **C** In the follow-up examination, angiography and angioplasty were repeated after the occlusion was detected in the same arteries on the control Doppler examination. Angioplasty was performed using the pedal plantar loop technique with the antegrade approach. **D**, **E** There was no response despite recurrent angioplasties

care, hyperbaric oxygen therapy, exercise therapy, and double antiplatelet therapy, and the wounds were treated successfully at follow-up. At baseline, 6/9 limbs (67%) had no patent BTK artery and 3/9 limbs (33%) had 1 patent BTK artery. On completion of the procedure 8/9 had 2 (89%) and 1/9 (11%) had 3 patent BTK arteries. In 3 of these patients, pedal arch patency was achieved. One major amputation was performed, providing a 96.8% rate for limb salvage both at 12 and 24 months (Fig. 7). The mean Rutherford pre-score was 4.2 ± 0.7, and the mean Rutherford post-score was 1.5 ± 1.1. The change between pre- and post-Rutherford scores was found to be statistically significant (Wilcoxon signed-rank test). The group with surgical success showed a statistically significant difference from pre- to post-Rutherford scores (Wilcoxon signed-rank test $p < 0.001$), whereas the other group did not (Wilcoxon signed-rank test $p = 0.180$) (Table 5 and 6).

Discussion

Buerger's disease is characterized by a high rate of cellular and inflammatory occlusive thrombus within the blood vessels. Increased levels of anti-endothelial cell antibodies and impairment of endothelium-dependent vasodilation are the two important pathophysiological mechanisms involved in this disease [14]. To date, no precise diagnostic criteria have been defined for TAO. One of the most important criteria in the diagnosis of the disease is the exclusion of risk factors for arteriosclerosis or other occlusive vasculopathies [15]. Diagnosis is mainly based on clinical and angiographic findings [1, 2]. The most frequently used diagnostic criteria are the Shionoya criteria [2]. Cessation of smoking, calcium channel blockers, hyperbaric oxygen treatment, anticoagulants, thrombolytics, prostaglandin analogues, sympathectomy,

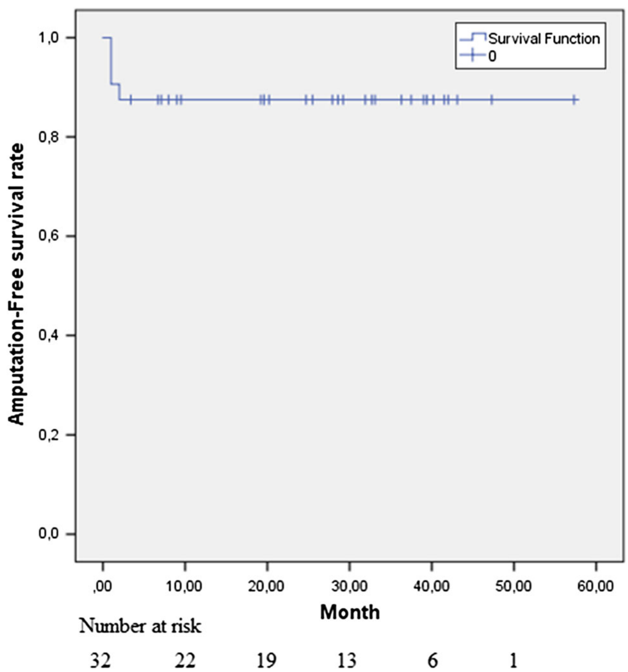

Fig. 4 Kaplan–Meier curve showing amputation-free survival rates

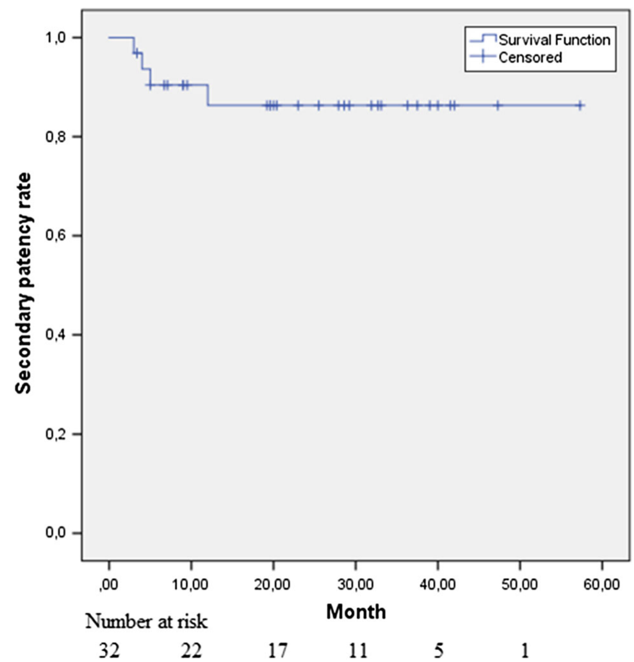

Fig. 6 Kaplan–Meier curve showing secondary patency

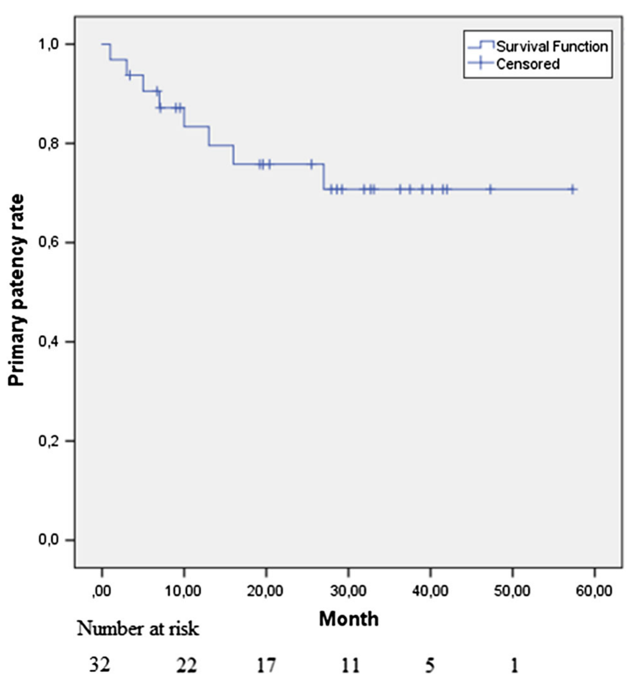

Fig. 5 Kaplan–Meier curve showing primary patency

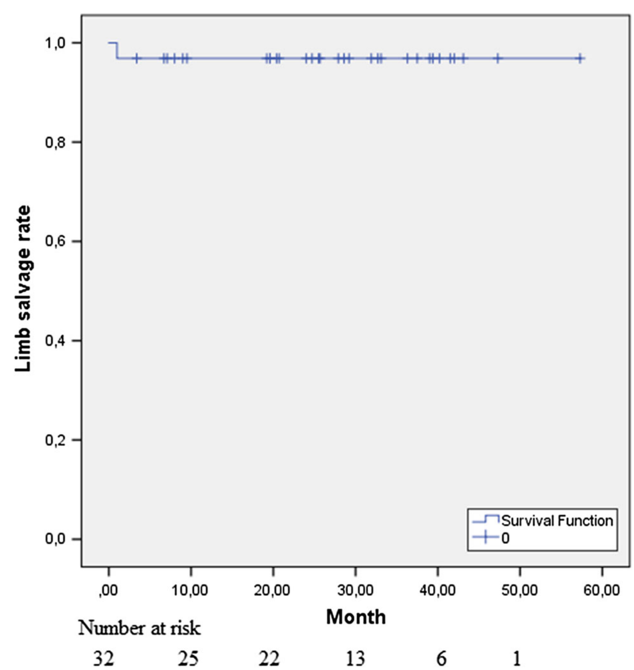

Fig. 7 Kaplan–Meier curve showing limb salvage rates

adrenalectomy, spinal cord stimulants, omental transfers, stem cell therapy, surgical treatment, and endovascular revascularization options can be used to relieve the symptoms of the disease [16–23]. Surgical and interventional methods are invasive procedures that are applied to increase blood flow to the extremity.

While cessation of smoking has a significant effect on the dramatic improvement in disease-related symptoms and protection from amputation, a reduction in the number of daily cigarettes does not significantly affect the outcome of the disease [16]. In a study comparing intravenous iloprost with lumbar sympathectomy (LS), it was found that iloprost use improved ischemic symptoms better than LS [20]. In another study, autologous bone marrow-derived

Table 5 Rutherford scoring

	Mean ± SD	Med (min–max)
Rutherford (pre)	4.2 ± 0.7	4 (3–5)
Rutherford (post)	1.5 ± 1.1	1 (1–6)
*p**	**< 0.001**	

Bold value is statistically significant $p < 0.05$

*Wilcoxon signed-rank test

Table 6 Change in Rutherford scores due to technical success

	Unsuccessful	Successful
Rutherford (pre)		
Mean ± SD	4.3 ± 0.6	4.2 ± 0.8
Med (min–max)	4 (4-5)	4 (3–5)
Rutherford (post)		
Mean ± SD	2.7 ± 1.2	1.4 ± 1.0
Med (min–max)	2 (2–4)	1 (1–6)
*p**	0.180	**< 0.001**

Bold value is statistically significant $p < 0.05$

*Wilcoxon signed-rank test

mononuclear cell (ABMMNC) therapy treatment was seen to significantly improve amputation-free survival, ulcer healing, and pain, and the 10-year amputation-free survival rate in patients treated with ABMMNC was 85.3% [21]. Surgical treatment is generally considered ineffective in TAO disease because small and medium-sized vessels of the extremities are affected [24]. However, in a study comparing endovascular treatment with bypass surgery, similar extremity salvage and graft patency rates were found [25].

The primary purpose of endovascular treatment is to increase the blood flow to the distal extremity and to provide wound healing, thereby preventing amputation of the leg. In previous studies, the success rate for endovascular treatment was 80–96% and the rate of limb salvage was 86–100% [12, 23, 26, 27]. In this study, the technical success rate was 87.5% and the limb salvage rate was 96.8%.

The most important stage of the angioplasty procedure is to be able to pass the guiding wire through the occluded artery [28]. Although the ipsilateral antegrade approach is the most preferred method of crossing the occlusion, it has a failure rate of 10–40% [29, 30]. Proximal artery disease and morbid obesity are limitations for the antegrade approach [31]. With the development of new techniques, the success rates of endovascular recanalization are increasing in peripheral arterial diseases. If the antegrade approach is not successful or not possible, the retrograde approach under ultrasound guidance may be considered for these patients. A review of previous studies showed that retrograde approaches are frequently used in atherosclerotic occlusive diseases. The technical success rate has been reported as between 67 and 100% in different series [32–34]. In one case report about TAO where the antegrade approach was not successful, ADP was passed through the retrograde approach and mechanical thrombectomy was performed [35]. In the current study, retrograde access under ultrasonography was used after unsuccessful interventions using the antegrade pathway in a total of nine arteries of 8 patients. In all these patients, it was technically possible to advance the guide wire to the target artery. As additional information to previous studies, it was concluded that in patients with Buerger's disease where antegrade intervention was unsuccessful, retrograde intervention could also be used when collateral filling was observed in the foot arteries.

Conclusions

Endovascular treatment is a technically feasible and potentially effective treatment modality for Buerger's disease and may be considered in the treatment of limb salvage with other treatment options. The use of retrograde interventions in TAO patients can be considered to improve technical success and clinical improvement, especially in cases where the antegrade approach is unsuccessful.

Compliance with Ethical Standards

Conflict of interest The author declares that he has no conflict of interest.

Ethical Approval The ethical committee approval is not required since the study is retrospective.

Informed Consent Informed consent was obtained from all participants.

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