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Endovascular treatment of chronic total occlusion of iliac/femoral arteries: Mid-term follow-up

Görkem Yiğit, Mehmet Cahit Sarıcaoğlu, Ferit Çetinkaya, Anıl Özen, Hakkı Zafer İşcan

Department of Cardiovascular Surgery, Ankara City Hospital, Ankara, Turkey

ABSTRACT

Objectives: This study aims to present our mid-term experience of treating chronic iliac or femoral total occlusions via percutaneous transluminal angioplasty (PTA).

Patients and methods: Between January 2017 and August 2019, this single-center, retrospective study included 45 patients (40 males, 5 females; median age 60 years; range, 33 to 81 years) who underwent PTA due to chronic total occlusion.

Results: Of the patients, eight had iliac and 37 had superficial femoral artery occlusion. The technical success rate was 95.5% with a mean follow-up period 17.2±0.4 months. Bail-out stenting was required in 10 (22.2%) of the lesions and only seven patients (15.5%) needed percutaneous reintervention at the end of follow-up. Following endovascular interventions, one patient (2.2%) developed seroma, while two (4.4%) developed infections and one (2.2.%) developed a pseudoaneurysm of the femoral artery. Three patients (6.6%) underwent femoro-popliteal bypass. A total of 42 patients completed the follow-up. The Kaplan-Meier analysis revealed a primary patency rate of 83.3% and freedom from reintervention of 95.2% during 17-month follow-up.

Conclusion: The endovascular treatment strategy of chronic total occlusions of the iliac and femoral arteries is acceptable with less morbidity and good patency rates. Cardiovascular surgeons should be encouraged in the field of endovascular treatment of peripheral arterial disease including chronic total occlusions.

Keywords: Endovascular treatment, iliac artery, occlusion, peripheral arterial disease.

Occlusions of iliac or femoral arteries contributes substantially to limb ischemia in patients with peripheral arterial disease (PAD). Conventional methods include surgical arterial reconstructions such as aortoiliac bypass, axillofemoral bypass, cross-over femoral bypass, and femoropopliteal bypass.[1] The rates of mortality and complications following bypass surgery are about 3 to 5% and 8 to 13%, respectively.[2]

Endovascular methods have been increasingly used in the field of vascular surgery with durable results.[3] These methods are less invasive with a shorter length of hospital stay and early recovery and can be performed under local anesthesia.

The Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease II (TASC II) guidelines still recommend conventional surgical bypass surgery for the type D iliac artery lesions owing to its curative effect.[4] On the contrary, according to the 2016 American Heart Association (AHA) guidelines, treatment of iliac and femoral occlusions with percutaneous transluminal angioplasty (PTA) and stenting are considered effective (COR I/LOE A) and reasonable (COR IIa/LOE B-R), respectively in terms of revascularization option for patients with lifestyle-limiting claudication and hemodynamically significant occlusive disease.[5] However, long-term

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Correspondence: Görkem Yiğit, MD. Ankara Şehir Hastanesi Kalp ve Damar Cerrahisi Kliniği, 06800 Çankaya, Ankara, Türkiye.
e-mail: drgorkemyigit@gmail.com

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data for procedures used for treating iliac and femoral occlusions are still limited.

In the current study, we present our mid-term experience of treating chronic iliac or femoral total occlusions via PTA.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at Ankara City Hospital between January 2017 and August 2019. Mid-term results of a total of 45 patients (40 males, 5 females; median age 60 years; range, 33 to 81 years) who underwent PTA due to chronic total occlusion of iliac or femoral arteries were retrospectively analyzed. All patients underwent PTA through Luminor® paclitaxel-coated drug-eluting balloon (PCB) catheter (iVascular, S.L.U., Barcelona, Spain) and bail-out therapy with iVolution® self-expanding nitinol stent (iVascular, S.L.U., Barcelona, Spain) for total iliac and femoropopliteal lesions. Eligible patients were those having atherosclerotic disease of iliac or femoral arteries with symptoms of moderate intermittant claudication to diffuse pedal ischemia according to the Rutherford classification[6] (Class 2 to 5) and those who were either not eligible for surgery due to comorbidities or refused open surgery. A written informed consent was obtained from each patient. The study protocol was approved by the Türkiye Yüksek İhtisas Training and Research Hospital Ethics Committee (Date: 31.01.2017, No: 29620911-929). The study was conducted in accordance with the principles of the Declaration of Helsinki.

All clinical, perioperative, and demographic data were obtained through review of original hospital and physician records, including data collected prospectively in a departmental registry.

Demographic and clinical data including age, sex, hypertension, dyslipidemia, chronic obstructive pulmonary disease, and presence of coronary artery disease, chronic kidney disease, previous coronary artery bypass grafting, cigarette smoking, and previous percutaneous intervention were recorded.

Prior to PTA, all patients were evaluated with Duplex ultrasound and digital subtraction angiography (DSA). In the clinical practice of our department, PTAs are performed under local anesthesia with monitorization by cardiovascular surgeons in the hybrid operating theater. We usually prefer antegrade femoral or contralateral retrograde femoral access. Following the insertion of a 7-Fr single lumen sheath, intravenous heparin is administered according to an activated clotting time (ACT) of 180 to 200 sec. None of the lesions are predilated. All lesions are dilated with PCB (at a vessel/balloon ratio of 1:1 on the basis of visual estimate) for a total inflation time of 3 min at 6 to 14 atm. Balloons are inflated only once. However, when control angiography reveals a residual lesion (>50% stenosis), flow-limiting dissection or atherosclerotic plaque deformation, a second PCB is carried out and dilatation is maintained for a longer period (≥3 min). In such cases in which residual stenosis or flow-limiting dissection persists after repeated dilatation, self-expanding nitinol stents are implanted as bail-out therapy.

Statistical analysis

Statistical analysis was performed using the SPSS version 16.0 software (SPSS Inc., Chicago, IL, USA).

Table 1. Demographic and clinical characteristics of patients

Variable	n	%	Median	Range
Age (year)			60	33-81
Gender				
Male	40	88.8		
Female	5	11		
Hypertension	22	48.8		
Dyslipidemia	32	71		
Chronic obstructive pulmonary disease	11	24.4		
Coronary artery disease	9	20		
Chronic kidney disease	2	4.4		
Coronary artery bypass grafting	2	4.4		
Current smoker	39	86.6		

Table 2. Post-procedural data

	n	%	Mean±SD
Clopidogrel medication	45	100	
Cilostazol medication	9	20	
Statin medication	23	51	
Hospitalization period (day)			1.8±1.6
Claudication at control (Rutherford class ≥2)	10	22.2	
Follow-up period (month)			17.2±0.4
Decision after control examination			
Medical follow-up	35	77.7	
Surgical intervention	3	6.6	
Percutaneous reintervention	7	15.5	

SD: Standard deviation.

Table 3. Procedural data

	n	%	Mean±SD
Complications	4	8.8	
Seroma	1	2.2	
Pseudoaneurysm	1	2.2	
Infection	2	4.4	
Femoropopliteal bypass	3	6.6	
Preprocedural creatinine level			1.2±0.9
Postprocedural creatinine level			1.31±1.1

SD: Standard deviation.

Descriptive data were expressed in mean ± standard deviation (SD) or median (min-max) for continuous variables and in number and frequency for nominal variables. The Shapiro-Wilk test was used to check the normal distribution of continuous variables. Dependent intra-group variables were compared using the Wilcoxon test. A p value of <0.05 was considered statistically significant.

RESULTS

Of the patients, eight had iliac and 37 had superficial femoral artery occlusion. Baseline demographic and clinical characteristics of the patients are shown in Table 1.

The technical success rate was 95.5% with a mean follow-up period 17.2±0.4 (range, 15 to 19) months. Bail-out stenting was required in 10 (22.2%) of the lesions and only seven patients (15.5%) needed percutaneous reintervention at the end of follow-up. Clopidogrel was prescribed to all patients (Table 2). However, cilostazol was prescribed only for patients with a poor distal vasculature (Table 2). Blood glucose regulation was achieved in all patients.

Although all patients were preoperatively symptomatic and had claudication, 77.7% of them had mild symptoms or were asymptomatic at the end of follow-up. The ankle-brachial index (ABI) was improved significantly after the procedure (p<0.001). Following endovascular interventions, one patient

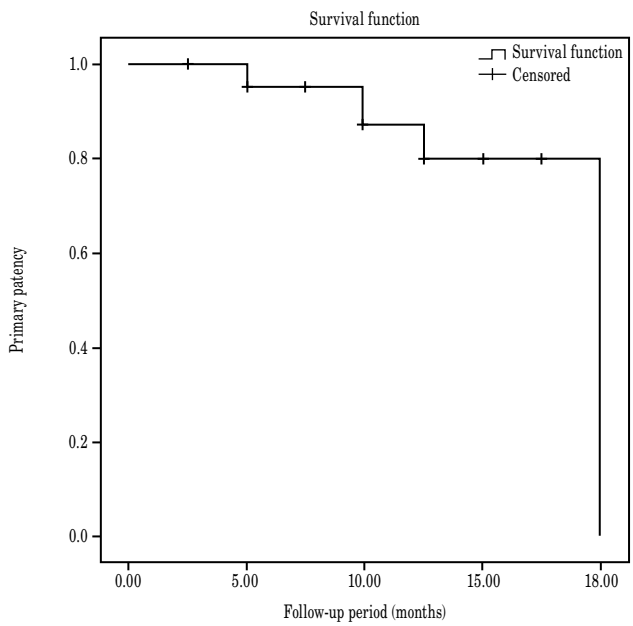

Figure 1. Kaplan-Meier plot analysis showing primary patency rate at eight months.

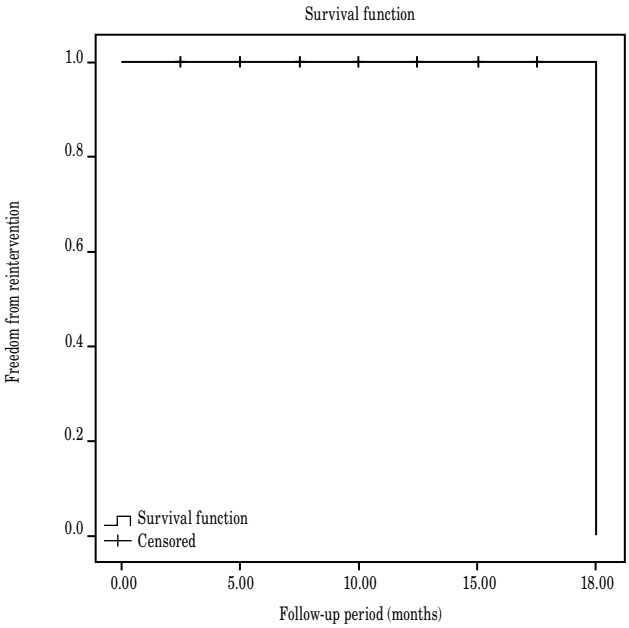

Figure 2. Kaplan-Meier plot analysis showing freedom from reintervention rate at eight months.

(2.2%) developed seroma, while two (4.4%) developed infections and one (2.2.%) developed a pseudoaneurysm of the femoral artery (Table 3). Three patients (6.6%) underwent femoropopliteal bypass.

During follow-up, none of the patients died or had amputation. The Kaplan-Meier analysis revealed a primary patency rate of 83.3% and a freedom from reintervention rate of 95.2% during an eight-month follow-up period (Figures 1 and 2).

DISCUSSION

In the present study, we evaluated the patients according to the guidelines for PAD, recent clinical trials, and patients' preferences. In our clinic, we have been performing endovascular procedures for five years as cardiovascular surgeons. Initially, endovascular intervention rates of aortoiliac and femoral occlusive lesions were low. However, through increased experience and success rates, we have begun to perform these techniques for more challenging issues with relatively low complication rates.

The main goals of PAD treatment are to improve quality of life of patients, to relieve symptoms, and to provide limb salvage. Traditional and endovascular treatment methods can be used for the treatment of PAD. However, the TASC II guidelines[4] recommend conventional surgical bypass surgery for type D iliac artery lesions owing to its curative effect. On the contrary, due to the traumatic nature of the surgical treatment, existing comorbidities, complications, and higher mortality rates, endovascular approaches have become prominent by cardiovascular surgeons in recent years.[7]

Minimally invasive nature of endovascular treatment is more acceptable in recent years, as it is a simple, rapid, and reproducible technique. Also, it can be performed under local anesthesia with low complication rates.[8] In this study, we evaluated our clinical experience in patients with chronic total occlusions of the iliac and femoral arteries treated by the cardiovascular surgeons.

On the other hand, endovascular intervention for the treatment of such chronic total occlusions is quite challenging due to their complexity and initial embolic complications. Nevertheless, there are endovascular studies with high technical success rates for totally occluded iliac and femoral arteries in the literature. Colapinto et al.[9] reported a four-year patency rate of 78%, including both the common and external iliac arteries. However, treatment was successful in only three of eight patients in their study. In another study conducted in Germany, Hausegger et al.[10] reported 42 patients treated percutaneously for chronic total iliac occlusions. The overall technical success rate was found to be 83%. Blum et al.[11] also reported similar outcomes in patients with either acute or chronic occlusions, but they had a higher (98%) technical success rate. In our study including 45 patients, we achieved a technical success rate of 95.5%, similar to Blum et al.[11]

Although endovascular treatment is minimally invasive, there are still certain complications, such as contrast nephropathy, puncture site bleeding, hematoma, pseudoaneurysm, arteriovenous fistula, infection, and other complications.[12] In their study, Ichihashi et al.[3] found a complication rate of iliac stenting to be 4 to 6%. In addition, Kavaliauskienė et al.[13] reported a complication rate ranging between 3 and 7.9% in their iliac PTA series. In our study, one patient developed seroma, two developed infections, and one developed a pseudoaneurysm of the femoral artery. To reduce the complication rates and increase the success of these procedures, clinicians must conduct a detailed examination and evaluate the patient concerning the indication, and decide whether the patient is eligible for an endovascular intervention in an experienced center. All patients included in this study were either not eligible for surgery due to comorbidities or refused open surgery.

In a study, Ozkan et al.[14] reported an early mortality rate after iliac stent implantation of 0.7 to 3.6% and a periprocedural mortality rate of 0%. Similarly, the periprocedural mortality rate was 0% in our study and there were no deaths or amputations during follow-up. This may be explained by relatively small sample size and short follow-up period, compared to the study of Ozkan et al.[14]

Furthermore, many studies have shown higher patency rates with TASC II C/D lesions. Araki et al.[15] reported a primary patency rate of 96.5% at two years with a self-expandable stent for chronic total occlusions of the iliac artery. Another study by Ichihashi et al.[3] reported a primary patency rate of 90% at one year. Kashyap et al.[16] reported endovascular interventions for aortoiliac occlusive disease with a primary patency rate of 74% at three years. Our results for complex lesions appear to be compatible with previous studies with a patency rate of 83.3%. On the contrary, these results may seem satisfactory due to small sample size and short follow-up period. However, as cardiovascular surgeons, we routinely use PTA with bail-out stenting for the last five years in our institute.

The primary objective of our study was not to compare the outcomes of open surgery and endovascular procedures. The results of open surgery seem superior compared to endovascular procedures for patients with chronic occlusion. The study of Sachwani et al.[17] showed a primary patency rate of 69 to 95% for endovascular procedures and 91 to 97% for open procedures up to six years. Similarly, a large meta-analysis reported the primary patency rates at one, three, and five years which were higher in the open surgery group (94.8% vs. 86%, 86% vs. 80%, and 82.7% vs.71.4%, respectively).[12] The initial success rate of endovascular treatment for chronic total occlusion of the superficial femoral artery was reported as 81 to 94%.[18] One-year and five-year primary patency rates were found to be 82.1% and 69.4% in the bypass surgery and 67.8% and 45.2% in the endovascular procedures in TASC C and D patients with claudication, respectively.[18] Nevertheless, Mayor et al.[19] revealed higher complication rates in the open surgery group (43.3% vs. 17.8%), as the meta-analysis also showed an increased complication rate (18% vs. 13.4%) in the open surgery group.[12] As a result, open procedures have better patency and worse complication rates. However, endovascular procedures may be the appropriate choice for patients who are ineligible for surgery and for patients who refuse open surgery.

In conclusion, the endovascular treatment strategy of iliac and femoral artery occlusions is acceptable with less morbidity and good patency rates. We can perform endovascular procedures for patients with aortoiliac and femoral occlusive lesions with existing comorbidities, and not eligible for surgery and for those who refuse open surgery. Cardiovascular surgeons should be encouraged in the field of endovascular treatment of PAD including chronic total occlusion.

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REFERENCES

1. Marrocco-Trischitta MM, Bertoglio L, Tshomba Y, Kahlberg A, Marone EM, Chiesa R. The best treatment of juxtarenal aortic occlusion is and will be open surgery. J Cardiovasc Surg (Torino) 2012;53:307-12.
2. Galaria II, Davies MG. Percutaneous transluminal revascularization for iliac occlusive disease: long-term outcomes in TransAtlantic Inter-Society Consensus A and B lesions. Ann Vasc Surg 2005;19:352-60.
3. Ichihashi S, Higashiura W, Itoh H, Sakaguchi S, Nishimine K, Kichikawa K. Long-term outcomes for systematic primary stent placement in complex iliac artery occlusive disease classified according to Trans-Atlantic Inter-Society Consensus (TASC)-II. J Vasc Surg 2011;53:992-9.
4. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG; TASC II Working Group. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). J Vasc Surg 2007;45:S5-67.
5. Gerhard-Herman MD, Gornik HL, Barrett C, Barshes NR, Corriere MA, Drachman DE, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation 2017;135:e686-e725.
6. Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. J Vasc Surg 1997;26:517-38.
7. Timaran CH, Prault TL, Stevens SL, Freeman MB, Goldman MH. Iliac artery stenting versus surgical reconstruction for TASC (TransAtlantic Inter-Society Consensus) type B and type C iliac lesions. J Vasc Surg 2003;38:272-8.
8. Bisdas T, Borowski M, Torsello G; First-Line Treatments in Patients With Critical Limb Ischemia (CRITISCH) Collaborators. Current practice of first-line treatment

strategies in patients with critical limb ischemia. J Vasc Surg 2015;62:965-73.
9. Colapinto RF, Stronell RD, Johnston WK. Transluminal angioplasty of complete iliac obstructions. AJR Am J Roentgenol. 1986;146:859-62.
10. Hausegger KA, Lammer J, Klein GE, Flückiger F, Lafer M, Pilger E, et al. Percutaneous recanalization of pelvic artery occlusions--fibrinolysis, PTA, stents. Rofo 1991;155:550-5.
11. Blum U, Gabelmann A, Redecker M, Nöldge G, Dornberg W, Grosser G, et al. Percutaneous recanalization of iliac artery occlusions: results of a prospective study. Radiology 1993;189:536-40.
12. Indes JE, Pfaff MJ, Farrokhyar F, Brown H, Hashim P, Cheung K, et al. Clinical outcomes of 5358 patients undergoing direct open bypass or endovascular treatment for aortoiliac occlusive disease: a systematic review and meta-analysis. J Endovasc Ther 2013;20:443-55.
13. Kavaliauskienė Z, Antuševas A, Kaupas RS, Aleksynas N. Recent advances in endovascular treatment of aortoiliac occlusive disease. Medicina (Kaunas) 2012;48:653-9.
14. Ozkan U, Oguzkurt L, Tercan F. Technique, complication, and long-term outcome for endovascular treatment of iliac artery occlusion. Cardiovasc Intervent Radiol 2010;33:18-24.
15. Araki M, Hirano K, Nakano M, Ito Y, Ishimori H, Yamawaki M, et al. Two-year outcome of the self-expandable stent for chronic total occlusion of the iliac artery. Cardiovasc Interv Ther 2014;29:40-6.
16. Kashyap VS, Pavkov ML, Bena JF, Sarac TP, O'Hara PJ, Lyden SP, et al. The management of severe aortoiliac occlusive disease: endovascular therapy rivals open reconstruction. J Vasc Surg 2008;48:1451-7, 1457.e1-3.
17. Sachwani GR, Hans SS, Khoury MD, King TF, Mitsuya M, Rizk YS, et al. Results of iliac stenting and aortofemoral grafting for iliac artery occlusions. J Vasc Surg 2013;57:1030-7.
18. Aihara H, Soga Y, Mii S, Okazaki J, Yamaoka T, Kamoi D, et al. Comparison of long-term outcome after endovascular therapy versus bypass surgery in claudication patients with Trans-Atlantic Inter-Society Consensus-II C and D femoropopliteal disease. Circ J 2014;78:457-64.
19. Mayor J, Branco B, Chung J, Baker F, Kougias P, Mills Sr J, et al. Outcome Comparison between Open and Endovascular Management of TASC II D Aortoiliac Occlusive Disease. Presented at the Annual Meeting of the Society for Vascular Surgery (SVS), 2017, San Diego, USA.