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Original Research

One-Year Outcomes of Femoropopliteal Chronic Total Occlusions Treated With Percutaneous Provisional Approach: A Single Center Experience (Percutaneous Treatment of Femoropopliteal CTO)

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ABSTRACT
Objective: The aim of the present study was to evaluate the results of percutaneous treated femoropopliteal chronic total occlusions (CTOs).
Methods: A total of 204 limbs (167 patients) that were treated with drug-coated balloon angioplasty and/or self-expandable stent implantation between January 2015 and December 2017 were assessed. Immediate and follow-up features were expressed with frequency tables, and Kaplan–Meier analysis was calculated for primary, primary-assisted, and secondary patency rates.
Results: In 202 (99%) cases, optimal targeted success was achieved. Death, arterial rupture requiring surgery, and myocardial infarction were not observed in the hospital period. In only 6 (3%) cases, an entry site hematoma developed but recovered without any intervention. Restenosis in 22 patients (5 in the first 6 months and 17 in the second 6 months) and reocclusion in 8 patients (2 in the first 6 months and 6 in the second 6 months) were observed in a 1-year follow-up. Primary, primary-assisted, and secondary patency rates were found to be 85.1%, 96%, and 98%, respectively, at the end of the first year.
Conclusion: Percutaneous revascularization of femoropopliteal CTOs appears to be safe and effective.
Keywords: Chronic total occlusion, drug coated balloon, peripheral artery disease

INTRODUCTION

Peripheral arterial disease (PAD), which is quite common worldwide, constitutes most of the circulatory problems in addition to coronary and cerebral arteries. Patients with PAD are presented with a wide range of clinical manifestation, such as claudication, rest pain, ischemic ulcer, and tissue loss. Owing to these clinical problems, a decrease in the quality of life, depression, and loss of functionality can be observed. To treat this disease, management of risk factors, exercise programs, antithrombotic therapy, and surgical or percutaneous intervention are applied in case of inevitable situations, such as critical limb ischemia (1-3). In developing world, percutaneous interventions with low complication rates and short hospitalization time are becoming increasingly more attractive than surgical treatment options for PAD. In cases of high risk of surgery or when femoropopliteal lesions are ≤25 cm or when there is no appropriate vein graft, percutaneous interventions are recommended as the first choice for all of Trans-Atlantic Inter-Society Consensus Document II (TASC II) lesions (4). Moreover, due to the developments in techniques and materials which are being used, long segment and calcified lesions can be revascularized percutaneously with high success rates. Some recently published series show that long superficial femoral artery (SFA) lesions have been treated percutaneously with high success and low periprocedural complication rates (5-7).

The aim of the present study was to determine the success of percutaneous femoropopliteal chronic total occlusion (CTO) treatment and to present the 1-year follow-up results in our center.

METHODS

Patient Selection

A total of 204 limbs (167 patients; 142 patients with claudication Rutherford category 2-3, 17 patients with Rutherford cate-

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gory 4, and 8 patients with Rutherford category 5-6) with femoropopliteal CTO which were treated percutaneously between January 2015 and December 2017 were prospectively included in the study. Patients who had previously undergone surgery and/or percutaneous intervention in the iliac and more distal arterial segments were excluded from the study. In addition, patients with glomerular filtration rate <90 mL/min (calculated by Cockcroft & Gault formula) and women with suspected pregnancy were also excluded. All procedures performed in the study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consent was obtained from all of the patients. Ethics committee approval was received for this study from the ethics committee University of Health Sciences Elazığ Training and Research Hospital, on 12.11.2014 and number 8419.

Procedure

Six hundred mg clopidogrel and 100 mg acetylsalicylic acid (ASA) were administered orally to all patients prior to the procedure. In the first month, dual antiplatelet (ASA+clopidogrel) and, after that, single antiplatelet (ASA) were given to all patients. Moreover, for patients who needed oral anticoagulant (OAC) therapy, in the first month, dual therapy (OAC+ASA) and, after that, only OAC were administered. Percutaneous interventions were performed by an interventional cardiologist under local anesthesia. To reach the responsible lesion, a crossover long arterial 6-French (F) sheath was used from the contralateral extremity common femoral artery to the related limb artery (45 cm) (Destination, Terumo, Japan). To pass the lesions, antegrade intimal wiring, subintimal tracking and reentry (STAR), or subintimal arterial flossing with antegrade and retrograde intervention (SAFARI) techniques were applied. In some cases, to do distal access, distal SFA, popliteal artery, and below the knee (BTK) arteries were punctured with a 21-gauge needle and were placed in a 4F radial sheath (7 cm) (Radifocus Introducer II transradial kit; Terumo, Japan). In general, the majority of cases, 0.035" hydrophilic wire (Radifocus; Terumo, Japan) and 4F 100 cm support catheter (Tempo Acqua Berenstain II; Cordis, USA) were used to pass the lesions. Astato 30 g (Asahi Intecc., Japan) extrastiff wire was used in cases where the hydrophilic wire could not pass the true lumen. No reentry device was used, and all of the lesions were passed through the wire, support catheter, and balloon. After the wire passage was achieved, all lesions were dilated for 5 min with a paclitaxel-coated balloon (Inpact Pacific; Medtronic, USA), which is appropriate to the distal and proximal reference vessel diameter measured by quantitative angiography. In case of flow limiting dissection, a bare self-expandable metal stent (Supera Stent; Abbott Vasc., USA) that has the same diameter with the vessel was implanted at dissected segments (provisional stenting). In the event that residual stenosis remained >30% on the treated lesion, post-dilation was performed with the same balloon catheter.

Technical success for all cases was defined as residual stenosis <50% after the procedure. Primary patency rate was defined as the percentage of patients without any restenosis or occlusion in the arterial segment undergoing intervention during the follow-up period. Primary-assisted patency rate was defined as the percentage of patients without restenosis or occlusion and patients who achieved patency via additional endovascular interventions in the arterial segments suffering restenosis. Secondary patency rate was defined as the percentage of patients without restenosis or occlusion and patients who achieved patency utilizing additional endovascular interventions in the occluded arterial segments. Restenosis was defined as >50% luminal diameter loss which is seen on angiography or duplex scanning (8).

Follow-Up

Before discharge, on months 1, 6, 9, and 12, all patients were called for control and evaluated clinically and ultrasonographically.

Statistical Analysis

All data were analyzed using the Statistical Package for Social Sciences (SPSS) program (SPSS Inc.; Chicago, IL, USA). Continuous variables were expressed as mean±standard deviation, and categorical variables were expressed as number and percentage (%). The demographic and comorbidity data were calculated for each patient, and patency data were calculated for each limb. Primary, primary-assisted, and secondary patency rates were calculated by Kaplan-Meier analysis using Log-rank test. A p value <0.05 was considered statistically significant.

RESULTS

Patients and Lesions Characteristics

A total of 204 femoropopliteal occlusions (167 patients) underwent percutaneous intervention. The mean age of the patients was 62.9±9.4 years, and most of the patients were male (82%). Of the 167 patients, 67 (40.1%) had diabetes mellitus, and 116 (69.4%) had hypertension. All demographic characteristics and baseline clinical and angiographic features are given in Table 1. The mean lesion length was 124±51.4 (19-279) mm, and all lesions were totally occluded before the procedure. Of the 202 lesions, 187 (92.1%) were in only SFA, 14 (7.3%) were in only popliteal artery, and 1 (0.5%) was in both arteries. According to the TASC II classification lesions, 7 (3.4%) of them were classified in class A, 112 (55%) in class B, 64 (31.4%) in class C, and 21 (10.3%) in class D. Moreover, there were 10 (4.9%) extremities with distal run-off one-vessel occlusion, 7 (3.4%) extremities with two-vessel occlusion, and 3 (1.5%) extremities with three-vessel occlusion.

Immediate Results after the Procedure

The lesions were passed via intimal wiring in 68 (33.7%) cases, STAR technique in 124 (61.4%) cases, and SAFARI technique in 10 (5%) cases. While in 28 (13.7%) cases, bail-out stenting was performed due to flow limiting dissection or recoil of the lesion following balloon angioplasty, in 176 (86.3%) cases, optimal results were achieved only for balloon dilatation (Figure 1). Post-dilation was performed in 6 (2.9%) cases. In 2 (1%) cases, distal BTK embolization was observed, but both did not lead to clinical signs. Optimal targeted interventional success was achieved in 202 (99%) cases (1 case had no distal flow and 1 case had >50% residual stenosis). Death, major arterial rupture requiring surgery, and myocardial infarction were not observed in any cases. In only 6

Table 1. Demographic features and baseline characteristics

No. of patients (extremity)	167 (204)
Age (mean±SD)	62.9±9.4
Male (%)	137 (82)
Diabetes (%)	67 (40.1)
Hypertension (%)	116 (69.4)
CAD (%)	95 (56.9)
Hyperlipidemia (%)	88 (52.7)
Carotid artery disease (%)	5 (3)
Statin use (%)	31 (18.5)
CVA (%)	5 (3)
MI (%)	9 (5.4)
CHF (%)	4 (2.4)
COPD (%)	24 (14.4)
Smoking (%)	129 (77.2)
Rutherford claudication class (%)	
2	11 (6.6)
3	131 (78.4)
4	17 (10.2)
5	5 (3)
6	3 (1.8)
Bilateral disease (%)	131 (78.4)
Severe calcification (%)	12 (5.9)
Target BTK disease (%)	39 (19.1)
Run-off vessel occlusion (%)	
1 vessel	10 (4.9)
2 vessel	7 (3.4)
3 vessel	3 (1.5)
Lesion length (mm)	124.5±51.4
Artery	
SFA (%)	188 (92.1)
Popliteal (%)	15 (7.3)
SFA+popliteal (%)	1 (0.5)
TASC II classification	
A (%)	7 (3.4)
B (%)	112 (55)
C (%)	64 (31.4)
D (%)	21 (10.3)

SD: standard deviation; CAD: coronary artery disease; CVA: cerebrovascular accident; MI: myocardial infarction; CHF: congestive heart failure; COPD: chronic obstructive pulmonary disease; BTK: below the knee; SFA: superficial femoral artery; TASC: trans-atlantic inter-society consensus

(3%) cases, entry site hematoma developed but spontaneously recovered without any intervention. In 2 (1%) cases, contrast nephropathy was observed without requiring dialysis. Basal renal functions were obtained with only fluid replacement. Life-restraining claudication and rest pain disappeared or receded to a mild level in all patients who underwent revascularization before discharge. One patient who had no reflow after balloon angioplasty had knee amputation on day 14, and one patient who had distal run-off three-vessel occlusion had knee amputation on day 23. The list of details of the interventions and follow-up are given in Table 2.

Table 2. Immediate results after the procedure and 1-year follow-up parameters

Time of procedure (min, IQR)	36 (31–42)
Type of recanalization	
Antegrade intimal	68 (33.7)
Antegrade STAR	124 (61.4)
SAFARI	10 (5)
Bail-out stenting (%)	28 (13.7)
Post-dilation (%)	6 (2.9)
Fluoroscopy time (min, IQR)	28 (23–34)
Opaque amount (mL, IQR)	179 (159–204)
Balloon diameter (mm, IQR)	6 (5–6)
Flow limited dissection (%)	22 (10.8)
Residual stenosis >50% (%)	2 (1)
Distal embolization (%)	2 (1)
Intervention success (%)	202 (99)
Target limb amputation at follow-up (%)	2 (1)
Primary patency, 12 months (%)	172 (85.1)
Primary-assisted patency, 12 months (%)	194 (96)
Secondary patency, 12 months (%)	198 (98)
CV death, 12 months (%)	1 (0.5)
All cause death, 12 months (%)	2 (1)
Major adverse event, 12 months (%)	11 (5.4)
Thrombosis, 12 months (%)	1 (0.5)
Contrast-induced nephropathy	2 (1)
Hematoma	6 (3)

IQR: interquartile range; CV: cardiovascular

Follow-Up Results

All patients were called for control on months 1, 6, 9, and 12, except for one patient who died because of anterior myocardial infarction on month 5 and one patient who died because of pancreatic cancer on month 9. Clinical and ultrasonographic examinations were performed for all patients. The restenotic and reoccluded lesions were revascularized, and those cases' follow-up program was continued until on month 12.

Acute thrombosis developed in one patient on month 2, and that problem was solved with manual thrombectomy through 6F multipurpose catheter (Boston Scientific, USA) in 7F long

Figure 1. a-f. Example from the study, 34th case. (a, b) Basal angiograms; (c, d) angioplasty with DCB; (e, f) final angiograms

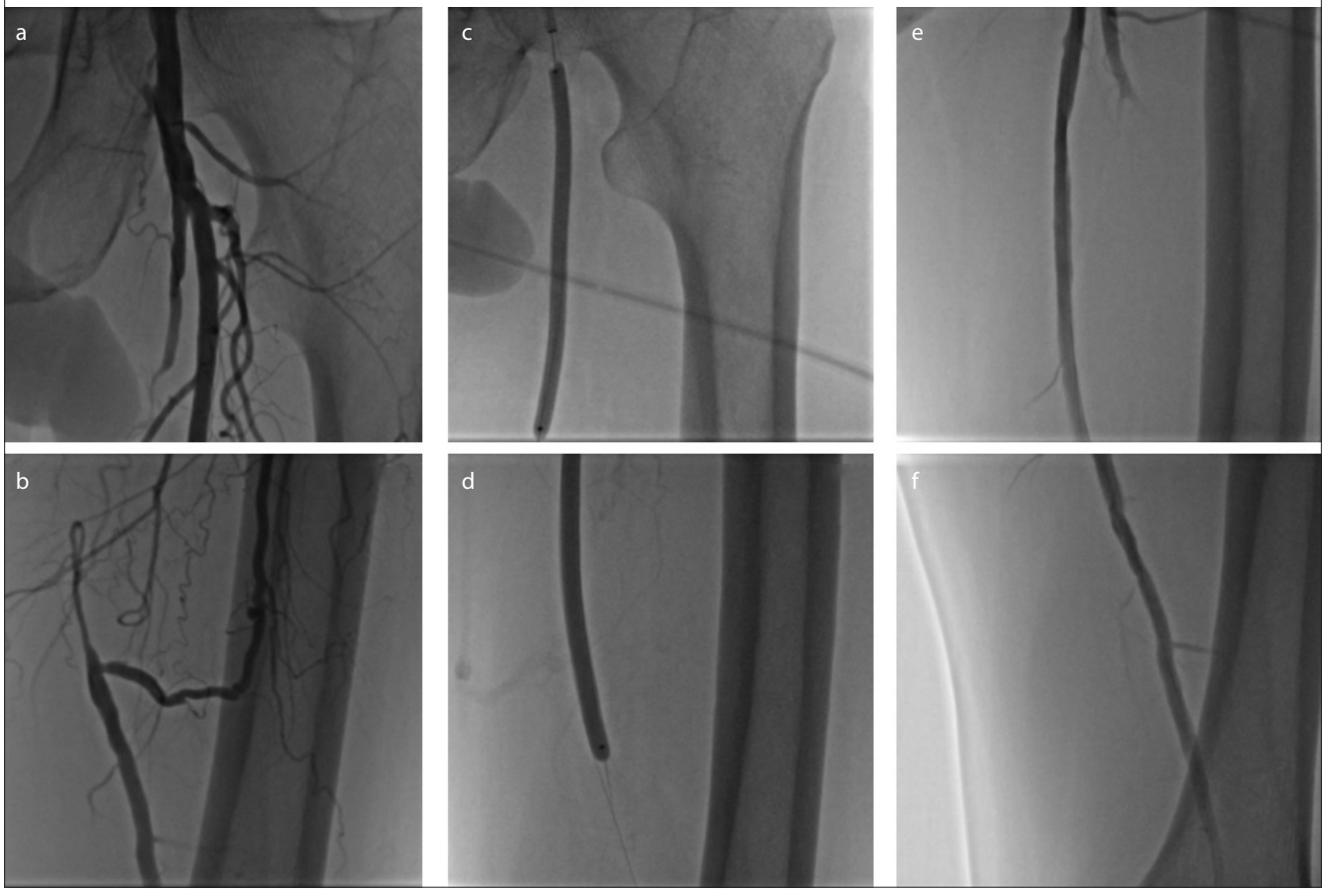
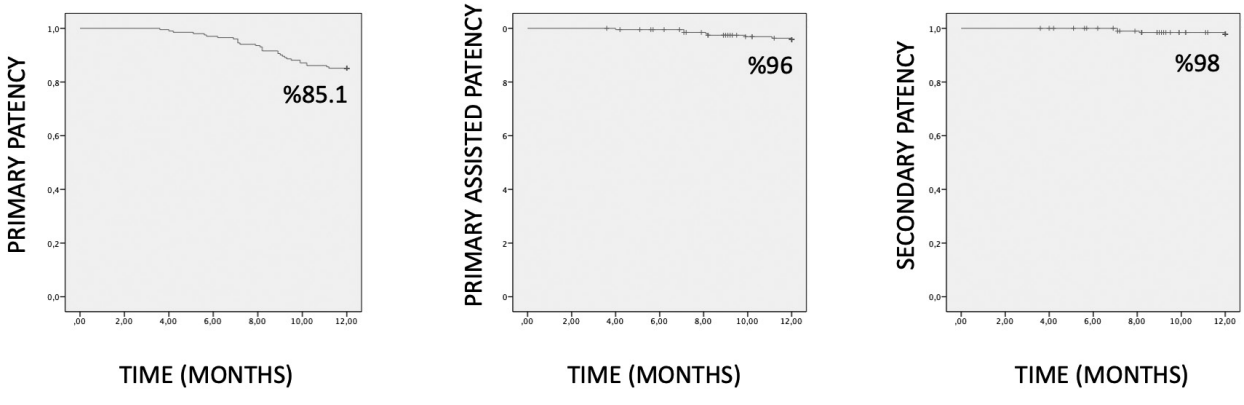


Figure 2. For the first year after intervention, primary, primary-assisted, and secondary patency rates



sheath (Destination, Terumo, Japan) and self-expandable stent implantation (Supera; Abbott, USA).

In a 1-year follow-up, 22 restenoses (5 in the first 6 months after the procedure and 17 in the second 6 months after the procedure) and 8 reocclusions were observed. On month 12, primary patency rate was 85.1%, primary-assisted patency rate was 96%, and secondary patency rate was 98% (Figure 2).

In addition, three patients underwent percutaneous angioplasty and stent implantation more than once during follow-up for optimal revascularization of the target extremity.

DISCUSSION

In this prospective observational study, 98% of the cases were successfully revascularized, and nearly all patients were followed up for 1 year. Since the primary aim of our study was to determine the patency and durability of the successful revascularization in the femoropopliteal CTO, the primary, primary-assisted, and secondary patency rates were calculated by using only the data of successfully revascularized patients although all patients were followed up for 12 months.

In recent years, the treatment approach in peripheral CTOs has changed due to advances in endovascular techniques, materials, and experiences (9-11). The endovascular approach has begun to surpass surgery worldwide, and the results are satisfactory, especially in femoropopliteal lesions (12-15). Xu et al. (16) explained primary patency rate as 84.1% for 12 months in femoropopliteal lesions in which drug-coated balloon (DCB) angioplasty was performed in their study. Moreover, Schienert et al. found that primary patency rate is 91.1% for 12 months in long lesions (>15 cm) treated with DCB and provisional (bail-out) stenting similar to our study (17). The primary patency rate of our study was 85.1% for 12 months, which is relatively lower than that study. However, the fact that all lesions in our study were CTO may be the main reason of this difference. In addition, primary-assisted patency and secondary patency rates in our study were as satisfactory at 96% and 98%, respectively. We think that patients were followed up closely and repeat revascularized if necessary is the main reason for these results. Therefore, in our point of view, percutaneous revascularization will be more useful and effective in daily practice without exposing to the morbidity and long hospitalization period of surgery in femoropopliteal CTOs.

Another issue which we want to focus is that provisional or primary stenting in femoropopliteal CTOs is still controversial. While some authors claim that routine stenting is not useful, many studies advice primary stenting, especially in long lesions. Surowiec et al. (18) showed that both approaches are not different with respect to patency and extremity revascularization. However, a previously published meta-analysis recommends primary stenting, especially in long lesions (19). Nevertheless, it is clear that there is a need for large-scale randomized studies to make a clear judgment on this issue.

Another remarkable issue which came up with the meta-analysis published in 2018 by Katsanos et al. (20), the risk of death following the application of paclitaxel-coated balloons and stents in the femoropopliteal artery has increased. According to this research, in which 28 randomized clinical trials were assessed, there is an increased risk of death with performed DCBs and stents. However, Schneider et al. (21) showed that there is no correlation between any level of paclitaxel exposure and mortality in their published meta-analysis.

When it comes to the restrictions of this real-life recording study, first, since the follow-up period was shorter than the international recording studies, it was not possible to have an idea about the durability of the femoropopliteal CTO interventions after 12 months. Second, because there were no patients with primary stenting as a control, a comparison could not be made between the two approaches. Third, this study has a limited number of diseased limbs because of being a low volume single center.

CONCLUSION

Percutaneous revascularization of femoropopliteal CTOs appears to be safe and effective. Provisional stenting is of acceptable results in these areas. Although restenosis is a common clinical entity, these problems can be easily solved thanks to close follow-up and re-intervention possibilities.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee University of Health Sciences Elazığ Training and Research Hospital (date: 12.11.2014; number: 8419).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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Conflict of Interest: The authors have no conflicts of interest to declare.

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