



The use of crossing catheters in the recanalization of below-the-knee chronic total occlusions in patients with critical limb ischemia

Kritik uzuv iskemisi olan hastalarda dizaltı kronik total tıkanıklıklarının rekanalizasyonunda geçiş kateterlerinin kullanımı

Burak Teymen¹, Mehmet Özkan²

¹Department of Cardiology, Emsey Hospital, İstanbul, Turkey

²Department of Cardiovascular Surgery, Emsey Hospital, İstanbul, Turkey

ABSTRACT

Background: This study investigates the procedural success of the use of a hydrophilic crossing catheter in the recanalization of below-the-knee artery chronic total occlusions in patients with critical limb ischemia.

Methods: We retrospectively identified below-the knee chronic total occlusion interventions in 30 patients performed between March 2013 and July 2017 in our institute. The inclusion criteria were critical limb ischemia (Rutherford Class 4 or greater) and occlusion of at least one tibial vessel with revascularization performed with the use of a crossing catheter. Primary technical success was defined as placement of a guide wire in the true lumen, past the distal chronic total occlusions cap.

Results: Thirty patients underwent 34 procedures, in which 41 lesions were treated with the use of crossing catheters. Nineteen anterior tibial arteries, 18 posterior tibial arteries, and four peroneal arteries were treated. Mean length was 110.2±36 mm and 20 lesions (48.8%) were severely calcified. The primary technical success rate was 80.5%. Recanalization was achieved with a guide wire and crossing catheter in 25 lesions (76%) and with the crossing catheter alone in eight cases (24%).

Conclusion: The use of a crossing catheter showed a high rate of technical and procedural success in infrapopliteal chronic total occlusions without significant complications.

Keywords: Balloon angioplasty; below-the-knee artery; chronic total occlusion; crossing catheter.

ÖZ

Amaç: Bu çalışmada kritik uzuv iskemisi olan hastaların diz altı arterlerin kronik total tıkanıklıklarının açılmasında hidrofilik geçiş kateterinin akut işlem başarısındaki yeri araştırıldı.

Çalışma planı: Mart 2013 - Temmuz 2017 tarihleri arasında, merkezimizde diz altı arterlerde kronik total tıkanıklığı olan ve girişimsel tedavide geçiş kateteri kullanılmış 30 hasta retrospektif olarak tanımlandı. Kabul edilme kriterleri, kritik uzuv iskemisi (Rutherford Sınıf 4 veya üstü semptom) ile birlikte hastalarda en az bir dizaltı arterde tıkanıklık olması ve revaskülarizasyonunda geçiş kateterinin kullanılması idi. Primer teknik başarı, klavuz telin tıkanıklık sonrası gerçek lümene yerleştirilmesi olarak tanımlandı.

Bulgular: Otuz hastada 34 işlem uygulandı, bunlardan 41 lezyon geçiş kateteri kullanılarak tedavi edildi. On dokuz anterior tibial arter, 18 posterior tibial arter ve dört peroneal artere girişimde bulunuldu. Ortalama lezyon uzunluğu 110.2±36.0 mm ve 20 lezyon (%48.8) ciddi kalsifik idi. Primer teknik başarı oranı %80.5 idi. Lezyonların açılması 25 olguda (%76) klavuz tel ve geçiş kateteri ile sağlanırken sekiz olguda (%24) yalnız geçiş kateteri ile sağlandı.

Sonuç: Geçiş kateterinin kullanılması, infrapopliteal arter kronik total tıkanıklıklarının açılmasında önemli bir komplikasyona neden olmadan yüksek işlem başarı oranı göstermiştir.

Anahtar sözcükler: Balon anjiyoplasti; dizaltı arter; kronik total tıkanıklık; geçiş kateteri.

Received: February 26, 2018 Accepted: May 10, 2018

Correspondence: Burak Teymen, MD, Emsey Hastanesi Kardiyoloji Kliniği, 34912 Pendik, İstanbul, Turkey.

Tel: +90 216 - 585 37 00 e-mail: burakteymen@yahoo.com

Cite this article as:

Teymen B, Özkan M. The use of crossing catheters in the recanalization of below-the-knee chronic total occlusions in patients with critical limb ischemia. Turk Gogus Kalp Dama 2018;26(3):402-406.

Peripheral arterial disease is the third leading cause of cardiovascular morbidity and still leads to a large number of amputations.^[1] Patients with chronic total occlusions (CTO) are usually elderly and are affected by multiple cardiovascular risk factors, such as diabetes, coronary artery disease, and chronic renal failure; therefore bypass surgery is challenging or not possible. Endovascular therapy is an accepted “first-line” therapy in infrapopliteal occlusions with satisfying procedural success and relatively minimal risk, but recanalization of CTOs in infrapopliteal arteries is technically challenging and time-consuming. Success rates of the procedure have dramatically increased with the development of technology, devices, and techniques for crossing these CTOs.^[2-6] The main purpose of this study is to assess the acute procedural success of using a crossing catheter in the recanalization of infrapopliteal CTOs.

The study included 30 patients (41 lesions) with critical limb ischemia undergoing angioplasty of below-the-knee (BTK) vessel occlusion by using a crossing catheter, at our center. We conducted a retrospective, non-randomized study. Cardiovascular risk factors were highly prevalent with 20 diabetic patients (66.7%) and 12 hypertensive patients (83.3%). Baseline characteristics are summarized in Table 1.

PATIENTS AND METHODS

The study was approved by Emsey Hospital Ethics Committee. Consent was obtained from all patients participating in the study and our study complied with the principles outlined in the Declaration of Helsinki. Below-the-knee artery calcifications were evaluated and quantified with Doppler ultrasonography (USG) and afterwards with digital subtraction angiography. Ankle brachial index (ABI) was measured before and after the intervention.

After the femoral artery was punctured, the 5F introducer sheath was inserted, and diagnostic angiography was performed (Figure 1a, 2a) following administration of intravenous heparin (100 IU/kg). Navicross[®] support catheter (Terumo Europe) over 0.014 hydrophilic guide wire was used to cross the chronic total occlusions. The Navicross[®] support catheter is a 4Fr support catheter with a double-braided stainless steel structure and a hydrophilic coating. The catheter has a 12 mm tapered tip that is either straight or with a 30° angle and permits minimal manipulation and re-entry from the subintimal space. It is available in four shaft lengths: 65, 90, 135, and 150 cm. In the ipsilateral antegrade femoral approach, an angled 65 cm catheter was used rather than the 150 cm angled catheter used in the contralateral approach. The design of the catheter permits true 1:1 torque with complete

Table 1. Baseline characteristics (n=30)

Variable	n	%	Mean±SD
Age (year)			58.4±6.2
Gender			
Male	17	54.5	
Female	13	45.5	
Diabetes mellitus	20	66.7	
Hypertension	25	83.3	
Hypercholesterolemia	16	53.3	
Active smoker	16	53.3	
Former smoker	9	30.0	
Coronary artery disease	20	66.7	
Chronic kidney disease	3	10.0	
Baseline ankle-brachial index			0.45±0.03
Ankle-brachial index after intervention			0.87±0.07
Cerebrovascular disease	2	6.7	
Congestive heart failure	5	16.7	
Baseline wound	10	33.3	

SD: Standard deviation.

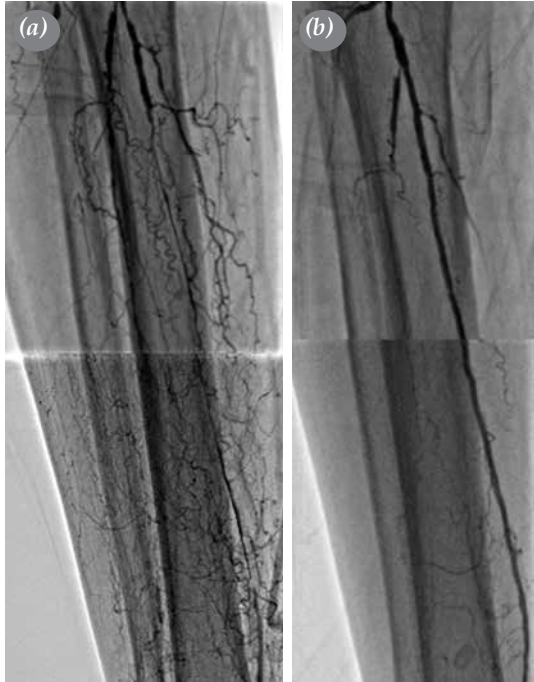


Figure 1. (a) Occlusion of all infrapopliteal arteries. (b) Final angiogram showing peripheral arterial disease fully opened after drug-eluting balloon angioplasty to peripheral arterial disease using crossing catheter.

force transmission from hand to the tip of the catheter without lag time or delay. In the distal end, three radiopaque markers are embedded allowing accurate intraluminal measurement for stent and balloon length selection (tip marker signs 1 mm, the second 40 mm, and the third 60 mm from the tip). The crossing

catheter was advanced over a standard guide wire to the proximal end of the lesion. A hydrophilic guide wire was then placed within the catheter as support. We advanced through the support catheter with the guide wire to cross the occlusion. When the guide wire failed to cross the occlusion, the catheter was retracted back and the classic loop technique was used. Recanalization was achieved with the crossing catheter alone in eight cases. Further intervention with angioplasty was continued after angiographic confirmation that we were in true lumen (Figure 2b). Primary technical success was defined as placement of the guide wire in the true lumen, past the distal CTO cap. We used Kitewire deep® (Terumo Europe) and v 14® (Boston Scientific USA) guide wire to cross the lesions and used coronary balloons over PT2 Guide wire® (Boston Scientific USA) in distal and heavily calcified lesions when we were unable to cross with standard peripheral balloons.

We preferred drug-eluting balloon (DEB) angioplasty in BTK lesions, therefore all lesions were predilated before treatment with DEB. Standard balloons that were available during the study period had a diameter of 2.0 to 4.0 mm and a length of 40 to 200 mm. Minimum DEB inflation time was two minutes, but the operators generally preferred longer inflation times up to three minutes. In case of flow-limiting dissection or residual stenosis of >50%, another prolonged dilation of up to three minutes was performed. Drug-eluting coronary stents used as bailout was needed in one lesion. A completion angiogram concluded the procedure (Figure 1b, 2c). Procedural details are summarized in Table 2. All patients were



Figure 2. (a) Distal posterior tibial artery chronic total occlusions. (b) Crossing catheter before crossing an occlusion in posterior tibial artery. (c) Final angiogram showing posterior tibial artery fully opened.

Table 2. Procedural characteristics (n=41)

Variable	n	%	Mean±SD
Mean length (mm)			110.2±36.3
Total occlusion	41	100.0	
Primary technical success	33	80.5	
Bailout stenting	1	3.3	
Anterior tibial artery	19	46.3	
Recanalization of anterior tibial artery**	15	78.9	
Posterior tibial artery	18	43.9	
Recanalization of posterior tibial artery**	15	83.3	
Peroneal artery	4	9.8	
Recanalization of peroneal artery**	3	75	
Severe calcification	20	48.8	
Baseline wounds*	9	30.0	
Posterior tibial artery above the knee*	8	26.7	

SD: Standard deviation; * Patient number (n=30); ** Target vessel number

discharged with three months dual antiplatelet therapy consisting of aspirin (100 mg per day) and clopidogrel (75 mg per day) and continued with aspirin alone after three months. Proper medication for risk factors such as coronary artery disease, hypertension, and hyperlipidemia was administered after intervention.

Statistical analysis

Data was reported as mean, standard deviation, median, frequency, and ratio. Wilcoxon signed ranks test was used to test the difference between preoperative and postoperative values. The results were evaluated in a 95% confidence interval and a significance level of $p < 0.05$.

RESULTS

Thirty patients with BTK vessel occlusions underwent angioplasty with the use of a hydrophilic crossing catheter in our institute between March 2013 and July 2017 (34 procedures, 41 lesions). Primary technical success was achieved in 33 lesions (80.5%). The CTO was unable to be crossed in eight lesions (19.5%). This failure resulted in two minor (6.7%) and one major amputation (3.3%) in three patients. In two of these eight patients, minor extravasation was managed with balloon inflation before the extravasation site followed without any clinical significance. Stent implantation was necessary in one patient because of dissection affecting flow after balloon angioplasty. Revascularization was successful in 33 occlusions and was achieved with the guide wire in 25 lesions (76%)

and with the catheter alone in eight cases (24%). Two cases of access-related hematoma occurred (6.7%) which resolved on digital pressure. All of the patients were discharged the day after intervention without any major cardiovascular events.

DISCUSSION

Crossing the total occlusion is one of the most difficult and important phases of endovascular therapy in revascularization of BTK lesions. The subsequent use of crossing catheters and devices, as well as advances in guide wires, has improved technical success rates. Our study is one of the few trials to our knowledge that assesses the acute procedural success of using a crossing catheter in the recanalization of infrapopliteal CTOs.

Failure of endovascular therapy in infrapopliteal CTOs is most often due to the inability to cross through the calcified true lumen or reentering the true lumen after subintimal approach to the occluded segment. The success rate is moderate when crossing the CTOs with the conventional technique using the standard guide wires and catheters.^[7] The advantage of using devices and catheters over conventional methods is the reduction of procedural and radiation exposure times, since these support catheters facilitate true lumen crossing. The subintimal angioplasty of CTOs has relatively higher success rates.^[8,9] We also preferred the subintimal approach when using a hydrophilic guide wire and support catheter which achieved a high

success rate of 80.5% in BTK CTOs. Significant increase in postoperative ABI demonstrated a notable hemodynamic success in our study (0.42, $p=0.001$, Table 1).

Several devices are available for crossing peripheral arterial CTOs. These devices had success rates of over 80%, but mostly in series with above-the-knee lesions.^[10-14] We also had similar success rates compared to these devices although the patients in our study had BTK CTOs in which procedural outcomes tend to be poorer than those for femoropopliteal CTOs. Another advantage of the use of crossing catheters instead of using other complex devices led to significant cost savings. A recent study showed that the use of dedicated CTO crossing devices provided significantly higher technical success and lower reintervention and amputation rates, at a net cost of \$423.80 per procedure at 12 months.^[15]

Atherectomy devices were not used in patients in this study because of our past experiences with these devices. Even with the use of thrombectomy devices we experienced perforations in BTK arteries; therefore it was not preferred in our patient cohort. We used coronary balloon over hydrophilic guide wire in distal and severely calcified lesions when we were unable to cross with standard peripheral balloons.

The main limitations of our study were the small cohort sample and our study being a retrospective study. Another limitation was that no intravascular imaging modality was used to confirm true luminal crossing of the entire CTO, and only angiographic contrast injection into the distal vessel was used as confirmation for analysis.

In conclusion, the use of the crossing catheter showed a high rate of technical and procedural success, even in infrapopliteal chronic total occlusions, without significant complications.

Research materials can be accessed by hospital archives and pax center.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Funding

The authors received no financial support for the research and/or authorship of this article.

REFERENCES

1. Fowkes FG, Rudan D, Rudan I, Aboyans V, Denenberg JO, McDermott MM, et al. Comparison of global estimates of

prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet* 2013;382:1329-40.

2. Sethi S, Mohammad A, Ahmed SH, Germanwala S, Sarode K, Ortiz-Lopez C, et al. Recanalization of popliteal and infrapopliteal chronic total occlusions using Viance and CrossBoss crossing catheters: a multicenter experience from the XLPAD Registry. *J Invasive Cardiol* 2015;27:2-7.
3. Sewall LE. Treatment of Chronic Total Occlusions Using the Avinger Ocelot Crossing Catheter. *Semin Intervent Radiol* 2015;32:370-3.
4. Liang GZ, Zhang FX. Novel devices and specialized techniques in recanalization of peripheral artery chronic total occlusions (CTOs)--a literature review. *Int J Cardiol* 2013;165:423-9.
5. Cannavale A, Ali T, Shen CY, Kassimis G, Krokidis M. Recanalization of peripheral chronic total occlusions: 'no fancy devices, just a crossing catheter'. *Expert Rev Cardiovasc Ther* 2017;15:221-5.
6. Banerjee S, Sarode K, Patel A, Mohammad A, Parikh R, Armstrong EJ, et al. Comparative Assessment of Guidewire and Microcatheter vs a Crossing Device-Based Strategy to Traverse Infrapopliteal Peripheral Artery Chronic Total Occlusions. *J Endovasc Ther* 2015;22:525-34.
7. van der Heijden FH, Eikelboom BC, Banga JD, Mali WP. Management of superficial femoral artery occlusive disease. *Br J Surg* 1993;80:959-63.
8. Lazaris AM, Tsiamis AC, Fishwick G, Bolia A, Bell PR. Clinical outcome of primary infrapopliteal subintimal angioplasty in diabetic patients with critical lower limb ischemia. *J Endovasc Ther* 2004;11:447-53.
9. Met R, Van Lienden KP, Koelemay MJ, Bipat S, Legemate DA, Reekers JA. Subintimal angioplasty for peripheral arterial occlusive disease: a systematic review. *Cardiovasc Intervent Radiol* 2008;31:687-97.
10. Shetty R, Vivek G, Thakkar A, Prasad R, Pai U, Nayak K. Safety and efficacy of the frontrunner XP catheter for recanalization of chronic total occlusion of the femoropopliteal arteries. *Invasive Cardiol* 2013;25:344-7.
11. Pigott JP, Raja ML, Davis T. A multicenter experience evaluating chronic total occlusion crossing with the Wildcat catheter (the CONNECT study). *J Vasc Surg* 2012;56:1615-21.
12. Selmon M. CONNECT II study. Presented at the Vascular Interventional Advances (VIVA) Conference. Las Vegas, Nevada: 2012.
13. Cawich I, Marmagkiolis K, Cilingiroglu M. Ocelot catheter for the treatment of long SFA occlusion. *Catheter Cardiovasc Interv* 2014;83:144-7.
14. TruePath CTO Device ReOpen study data. Boston Scientific, 2013. Available from: <http://www.bostonscientific.com/truepath/clinical-data.html>.
15. Banerjee S, Jeon-Slaughter H, Tsai S, Mohammad A, Foteh M, Abu-Fadel M, et al. Comparative Assessment of Procedure Cost and Outcomes Between Guidewire and Crossing Device Strategies to Cross Peripheral Artery Chronic Total Occlusions. *JACC Cardiovasc Interv* 2016;9:2243-52.