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Risk Factor Analysis for Crossing Failure in Primary Antegrade Wire-Catheter Approach for Femoropopliteal Chronic Total Occlusions

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Abstract

Introduction: Antegrade wire-catheter crossing remains the primary approach for femoropopliteal interventions. Nonetheless, data reporting on crossing failure are limited. Aim of this study is to identify risk factors for antegrade crossing failure in patients with femoropopliteal chronic total occlusions (CTOs).
Methods: This is a single-center, retrospective analysis. Patients with femoropopliteal CTOs treated between May 2018 and February 2020 were included into this study. Primary endpoint of this analysis was primary crossing success defined as successful antegrade crossing without the use of retrograde access, crossing or re-entry devices. The assisted crossing success was additionally analyzed. A logistic regression analysis identified risk factors for failed primary antegrade crossing.
Results: Data from 300 patients were analyzed. The majority (n=183, 61%) presented with lifestyle limiting claudication. The mean lesion length was 180 mm [interquartile range (IQR) 100–260 mm], whereas the median CTO length was 100 mm (IQR=50–210 mm). A chronic total occlusion crossing approach based on plaque morphology (CTOP) type I configuration was observed in 9% (n=26) of the lesions, type II in 61% (n=183), type III in 8% (n=25), and type IV in 66 CTOs (n= 66, 22%). Severe calcification based on the Peripheral Arterial Calcium Scoring Scale (PACSS), Peripheral Academic Research Consortium (PARC), and 360° grading systems was identified in 17%, 24%, and 28% of the lesions, respectively. A contralateral femoral access was used in 278 cases (93%). The primary crossing success amounted to 70% (n=210). The use of a re-entry device in 28 patients (9%) or of a combined antegrade–retrograde approach in 11% (n=34) of the cases increased the assisted crossing success to 89% (n=267). The presence of calcification (odds ratio [OR]=4.2, 95% CI=1.7–10.2) or of circumferential calcium (OR=2.5, 95% CI=1.3–4.9), a CTOP class III or IV (OR=1.9, 95% CI=1.4–2.6), a proximal superficial femoral artery (SFA) occlusion (OR=3.5, 95% CI=1.7–7.4) and a CTO at P3 (OR=4.1, 95% CI=1.5–10.8) were associated with an increased risk for antegrade crossing failure.
Conclusions: In this study, chronic total occlusions (CTO) morphology, calcification burden, and lesion's location were identified as independent risk factors for failed antegrade crossing. Nonetheless, the use of alternative crossing strategies significantly increased the overall crossing success.

Keywords

peripheral artery disease, crossing techniques, chronic total occlusion, femoropopliteal segment, occlusive disease

Introduction

Minimally invasive techniques have continued to improve in recent years and endovascular therapy (ET) is considered nowadays the primary treatment strategy for patients with peripheral arterial disease (PAD).[1,2] Nonetheless, specific lesion characteristics might influence the procedural success and the durability of endovascular reconstructions. The presence of severe calcification, chronic total occlusions (CTO), and long lesions has been associated with inferior acute and long-term outcomes.[3,4]

Femoropopliteal CTOs are present in up to 50% of patients with symptomatic PAD and represent a challenging subset of lesions.[5,6] The crossing of a CTO can be technically demanding, while the inability to cross a lesion is the main reason for endovascular treatment failure.[7] An antegrade wire-catheter approach is usually preferred as the initial crossing strategy, while retrograde recanalization techniques, crossing device, or re-entry devices can be alternatively or additionally used.[7,8]

However, and despite the increased prevalence of femoropopliteal occlusive disease, data reporting on parameters associated with crossing failure in femoropopliteal CTOs is missing. Previously published studies included mixed patient populations (aortoiliac, above-the-knee, and below-the-knee disease), excluded heavily calcified lesions or enrolled a limited number of patients leading to a relevant gap of evidence.[5,7–12] Aim of this study is to identify risk factors for primary antegrade wire-catheter crossing failure in patients with femoropopliteal CTOs.

Methods

Study Design

This is a single-center, retrospective analysis of prospectively collected data, performed in line with the requirements of the local ethics committee and adhering to the declaration of Helsinki.

Patients presenting with symptomatic PAD (Rutherford class 3–6) between May 2018 and February 2020 with CTOs of the superficial femoral artery (SFA) and/or popliteal artery and endovascular intention to treat were included into this study.

Patients with stenotic femoropopliteal lesions, acute limb ischemia, femoropopliteal aneurysm disease, non-femoropopliteal CTOs, vascular trauma, and bypass graft occlusion were excluded. Patients presenting with CTOs of permanent scaffolds were included only if the occlusion extended beyond the edges of the scaffold. All patients underwent a thorough clinical examination at baseline. Patient demographics and comorbidities as well as imaging and clinical data were prospectively collected and retrospectively analyzed. A Duplex Ultrasound Scanning was performed prior to every intervention. A computed tomography angiography (CTA) or magnetic resonance angiography (MRA) was additionally performed for the procedural planning. Lesion morphological assessment was using the pre-interventional imaging (CTA/MRA) and the intraoperative digital subtraction angiography (DSA).

A primary antegrade wire-catheter crossing was the preferred initial approach. A variety of straight and angulated support catheters (Trailblazer Medtronic, Mansfield, MA, USA), QuickCross (Phillips, Colorado Springs, CO, USA), NaviCross (Terumo, Somerset, NJ, USA), Bernstein II (Cordis, Cordis, Hialeah, FL, USA), and guidewires were used. In case of failed antegrade crossing, a retrograde tibial or popliteal access or a re-entry device (OUTBACK Elite Cordis, Hialeah, FL, USA) were used as alternative crossing strategies. The device selection and the bailout crossing strategy was at the discretion of the treating physician. Nonetheless, depending on the morphology of the lesion, certain combinations of support catheters and wires were used. In long non-calcified SFA CTOs, we preferably used the combination of a straight Quick-Cross catheter and a V18 (Boston Scientific, Marlborough, MA, USA) guidewire. A Bernstein II catheter was used to penetrate a resistant proximal CTO cap or in case of subintimal recanalization to enter the true lumen from the subintimal space. A NaviCross catheter in combination with an Advantage Glidewire (0.018 or 0.014) (Terumo, Somerset, NJ, USA) was used for the crossing of mixed morphology (stenotic and CTO) as to have better navigation through the stenotic vessel. In heavily calcified lesions, a variety of guidewires and support catheters were selected. 0.035 guidewires were rarely used and primary for subintimal crossing. CTO guidewires (Asahi Intecc, Tustin, CA, USA) were used after failed attempts with "softer" guidewires in heavily calcified lesions. The sheath selection was based on the treatment strategy applied. A 6F Destination sheath (Terumo, Somerset, NJ, USA) was used for the crossing. When a "vessel prep" strategy was indicated, this was exchanged to a larger sheath (7F or 8F). All retrograde crossing attempts were performed sheathless. The V18 guidewire was primary used for retrograde access. Every effort was made not to risk the target vessel for a bypass graft.

Endpoints and Definitions

Primary endpoint of this study was the primary crossing success defined as successful antegrade crossing without the use of retrograde access or re-entry devices. Secondary endpoint was the assisted crossing success defined as successful lesion crossing with or without the use of adjunctive

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crossing strategies. Crossing success was defined as guidewire placement in the distal true lumen after the distal CTO cap. CTO was defined as completely occluded arterial segment for more than 3 months. The chronic total occlusion crossing approach based on plaque cap morphology (CTOP) classification was used in order to describe the proximal and distal cap morphology. The lesions were accordingly classified into 4 types (I, II, III, or IV). Type I has concave proximal and distal caps, type II has a concave proximal and a convex distal CTO cap, type III has convex proximal and concave distal CTO caps, and type IV has convex proximal and distal caps.[8]

Given the lack of a commonly accepted definition of calcium burden, 3 different grading systems were used to quantify the vessel wall calcification, the Peripheral Arterial Calcium Scoring Scale (PACSS), the Peripheral Academic Research Consortium (PARC), and the circumferential characterization classification proposed from Fanelli et al.[13–15] In the PACSS scale, grade 0 represents the lack of visible calcium at the target lesion, grade 1 refers to unilateral calcification <5 cm, grade 2 to unilateral wall calcification >5 cm, grade 3 is the presence of bilateral wall calcification <5 cm, and finally, grade 4 is defined as bilateral wall calcification with calcium extension >5 cm. For the PARC classification, the calcium extension is defined as grade 0 in the absence of visible calcification, grade 1 when only one side of the vessel wall and <50% of the total lesion length is affected, grade 2 when one side of the vessel wall and >50% of the total lesion length is calcified, grade 3 when both vessel wall sides and <50% of the total lesion length is interested, and grade 4 when both vessel wall sides and >50% of the total lesion length are calcified. Finally, Fanelli et al used a modified version of the PACSS grading system assessing the presence of calcium in 1 or more of four 90° sectors: grade 0 (no detectable calcification), grade 1 (0°–90°), grade 2 (0°–180°), grade 3 (0°–270°), and grade 4 (0°–360°). CTO length was defined as angiographic distance between the proximal and distal CTO cap, whereas lesion length was defined as the angiographic distance between 2 healthy vessel segments.

Statistical Analysis

For the statistical analysis and graphics, the MedCalc Statistical Software (version 12.4.0.0; MedCalc Software, Ostend, Belgium) was used. Continuous variables have been presented as mean values ± standard deviation or median (interquartile range), while categorical data have been given as the counts. Logistic regression analysis was performed in order to detect independent factors of antegrade crossing failure. An additional logistic regression was also conducted to evaluate the relationship of baseline characteristics for every CTOP Type against the summation of the remaining: CTOP type I vs II, III, IV; CTOP type II vs I, III, IV; CTOP type III vs I, II, IV; and CTOP type IV vs I, II, III. Outcomes of the logistic regressions were reported as the odds ratio (OR) with 95% confidence interval (CI). Statistical significance was defined with the threshold of $p<0.01$. Technical failure among CTOP classification was calculated using chi-square analysis for trend.

Results

Baseline characteristics

Data from 300 patients were analyzed. Median age was 72 years (range 64–80) and 175 patients (n=175, 58%) were male. One hundred eighty-three patients (n=183, 61%) presented with lifestyle limiting claudication, 34 patients (n= 34, 11%) with ischemic rest pain, 77 patients (26%) had minor tissue loss, and 6 subjects (2%) with foot gangrene. Table 1 summarizes the baseline characteristics of this cohort.

A CTO of the proximal SFA was found in 114 patients (n=114, 38%) and a flush SFA occlusion in 68 patients (n=68, 23%). A CTO of the distal SFA was observed in 184 patients (n=184, 61%), while a middle SFA CTO in 180 patients (n=180, 60%). The baseline angiogram revealed a proximal popliteal CTOs (PI segment) in 109 patients (36%), whereas CTOs of the middle (PII) and distal popliteal (PIII) segments were found in 58 patients (19%) and 30 patients (10%), respectively. The mean lesion length was 180 mm [interquartile range (IQR) 100–260 mm] and the median CTO length was 100 mm (IQR 50–210 mm). In 122 patients (40%), the lesion length was > 150 mm and 60 patients presented with lesions longer than 250 mm (20%). A CTOP type II configuration was observed in 183 patients (n=183, 61%), a CTOP type IV in 66 (22%), a CTOP type I in 26 (9%) and CTOP type III in 25 (8%). An in-stent-occlusion was found in 39 patients (n=39, 13%). Regarding the calcification burden, in 85 patients (n=85, 28%), there was no visible calcium in the target lesion. Based on the PACSS scale, the severity of calcification was classified as grade 1 in 80 lesions (n=80, 27%), grade 2 in 25 (n=25, 8%), grade 3 in 59 (n=59, 20%), and grade 4 in 51 (N=51, 17%). Seventy-six (n=76) patients presented with PARC class 1 (n=76, 25%), 30 with PARC class 2 (n=30, 10%), 37 with PARC class 3 (n=37, 12%), and 72 patients with PARC class 4 (n=72, 24%). Finally, a circumferential calcium grade I was observed 42 patients (n=42, 14%), grade II in 63 (n=63, 21%), grade III in 27 (n=27, 9%), and grade IV in 83 patients (n=83, 28%).

A contralateral common femoral artery access was used in 93% (n=278) of the procedures, whereas an antegrade ipsilateral access was chosen in the remaining 20 patients (n=20, 7%). A primary brachial artery access was indicated in 2 patients (0.7%). A retrograde access was additionally used in 37 patients (13%), namely, a transpopliteal access in 29 patients (10%) and a tibial access in 8 patients (3%).

Table 1. Demographics.

Parameters	Results
Total number	300
Males	175 (58%)
Median age (IQR), in years	72 (64–80)
Arterial hypertension	259 (86%)
Diabetes mellitus	102 (34%)
Chronic kidney disease	54 (18%)
End-stage renal disease	16 (5%)
Dyslipidemia	173 (58%)
Coronary artery disease	48 (16%)
Rutherford class	
Class 3	183 (61%)
Class 4	34 (11%)
Class 5	77 (26%)
Class 6	6 (2%)

Abbreviation: IQR, interquartile range.

A primary antegrade crossing was feasible in 210 patients leading to a primary crossing success of 70%. The use of a re-entry device in 28 patients (9%) and of a combined antegrade–retrograde approach in 34 patients (11%) led to an assisted crossing success of 89% (n=267).

Regarding the crossing success in the different CTOP classes, a primary antegrade crossing was feasible in 162 patients (n=162, 88.5%) with CTOP type II lesions and in 22 patients (n=22, 84.6%) with CTOP type I lesions. On the contrary, CTOs were crossed in an antegrade fashion in 35 patients (n=35, 53.1%) presenting with CTOP type IV lesions and in 11 patients (n=11, 44%) with CTOP III lesions (Figure 1). Accordingly, a higher risk for technical failure was observed in patients with CTOP morphology III and IV ($p<0.0001$, Chi-square for trend). Figure 2 shows the utilization of alternative crossing strategies in the different CTOP classes.

Femoral access complications requiring surgery occurred in 2 patients (n=2, 0.7%). In a single patient (n=1, 0.3%), a pseudoaneurysm formation was observed following a retrograde access. A flow limiting dissection occurred in 38 patients (n=38, 13%) and the final angiogram did not reveal any persisting perforation or distal embolization. Four (n=4, 1%) in-hospital occlusions were observed and 13 (n=13, 4%) in-hospital reinterventions were performed. Table 2 provides an overview of the applied treatment strategies.

The logistic regression analysis revealed a higher risk for primary crossing failure in the presence of calcified disease (OR=4.20, 95% CI=1.71–10.30, p=0.0017) and circumferential calcification (>180°) (OR=2.53, 95% CI=1.32–4.86, p=0.0053). Furthermore, proximal SFA CTO (OR=3.52, 95% CI=1.68–7.39, p=0.0009), occlusion of the distal popliteal artery (OR=4.06, 95% CI=1.52–10.84, p=0.0051), and the cap morphology based on the CTOP type III or IV (OR=1.90, 95% CI=1.40–2.60, $p<0.0001$) increased the risk of antegrade crossing failure. Table 3 provides an overview of the univariate analysis and Table 4 shows the logistic regression analysis for risk factors for technical failure of antegrade crossing.

Discussion

Despite the current advances in endovascular treatment, crossing of femoropopliteal CTOs can be technically demanding. Additionally, specific lesions characteristics can further increase the complexity of a procedure. In this cohort, the presence of calcified disease, of CTOP classes III and IV, of proximal SFA or distal popliteal occlusions increased the risk for antegrade recanalization failure. However, the adjunctive use of retrograde access and re-entry devices enabled the crossing of the vast majority of femoropopliteal CTOs.

Vascular wall calcification impedes the endovascular treatment of peripheral atherosclerosis as it increases the risk for periprocedural complications and loss of patency on the long run.[3,4,14,16] In the current analysis, calcified disease and circumferential calcification were associated with higher rates of crossing failure when a primary antegrade wire-catheter approach was selected. Previous observational studies showed that severe calcification is an independent risk factor for unsuccessful crossing of femoral and tibial CTOs despite the utilization of retrograde/antegrade recanalization strategies.[8] Moreover, an increased risk for recanalization failure in calcified vessels has been reported with the use of both crossing and re-entry devices.[12,17] In this context, severe calcification increases the likelihood of unsuccessful crossing regardless the primary recanalization strategy. Thus, a combination of different techniques might be needed in heavily calcified disease. However, the lack of a vessel lumen in cases of calcified obstructions makes an intraluminal crossing attempt unfeasible. A subintimal approach might also be particularly challenging given the difficulty to advance the support catheters or re-entry devices in the subintimal space and guide the wire in the vessel lumen.

The CTOP study assessed the likelihood of successful recanalization using different crossing strategies (antegrade vs retrograde vs combined antegrade–retrograde) based on the proximal and distal cap morphology of tibial and femoropopliteal CTOs. The authors found that CTOP type I lesions were the easiest to cross in antegrade fashion, while in types II, III, and IV, the use of retrograde access might be beneficial.[8] In our analysis, classes III and IV significantly increased the risk for antegrade recanalization failure. The concave proximal morphology of types I and II enables the positioning of the guidewire in the vessel lumen, whereas the convex proximal shape of type III and IV reflects the

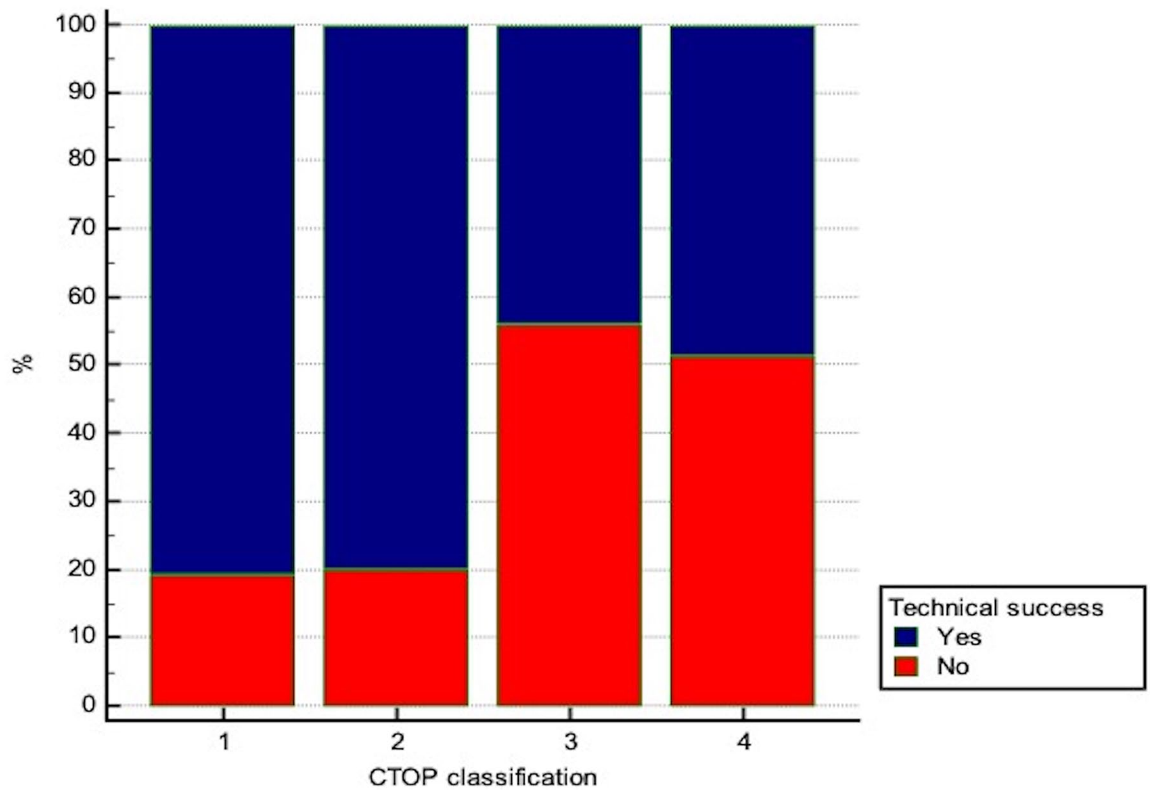

Figure 1. Technical success of solely antegrade crossing classified by chronic total occlusion crossing approach based on plaque cap morphology (CTOP) classification.

guidewire in the subintimal space. Therefore, the use of retrograde access and re-entry devices was higher in CTOP classes III and IV. Thus, determining the morphology of the CTOs caps might be particularly helpful and could guide the peri-interventional decision-making. Even if a primary antegrade crossing is attempted, the interventionist should be aware that a change of strategy to retrograde access or re-entry devices might be required in CTOP classes III/IV and flush occlusions.

Furthermore, lesion's location might be an important parameter, given that proximal SFA occlusions and distal popliteal CTOs led more frequently to unsuccessful antegrade recanalization. CTOs involving the distal popliteal artery represent a challenge given the difficulty to guide the wire in the target vessel without risking the patency of the other tibial vessels. In these cases, securing the tibial run off through a retrograde tibioperoneal access might be crucial.

Finally, lesions length was not identified as an independent risk factor for crossing failure. Of note, for the purposes of this article, we included only lesions with endovascular intention to treat. Thus, very long lesions that should be treated by primary bypass grafting were excluded from this analysis. This represents a selection bias of centers offering primary both treatment options. In an endovascular first approach, regardless the lesions characteristics, the length of the lesion would probably affect the crossing success.

In cases of failed crossing an individualized approach was offered. In young/low comorbidity claudicants with SFA CTOs, the option of a bypass grafting above the knee was discussed with the patient. If an above-the-knee surgery was not feasible, a below-the-knee surgery was rarely performed. In older/higher risk claudicants, a conservative treatment was preferred. In patients with chronic limb-threatening ischemia (CLTI), a bypass grafting was most of the times indicated, while in very high-risk patients with acceptable WIfI score, a conservative treatment was suggested. In this context, the CTOP class did not influence our treatment algorithm, and our decision was mainly based on the clinical status of the patient.

Limitations

Although, to our knowledge, this analysis represents the largest real-world data evaluation regarding femoropopliteal CTO crossing, this study carries the well-known limitations of retrospective registries and represents a single-center data assessment. CTO analysis was based on CTA and angiographic imaging and not on extravascular or intravascular imaging,

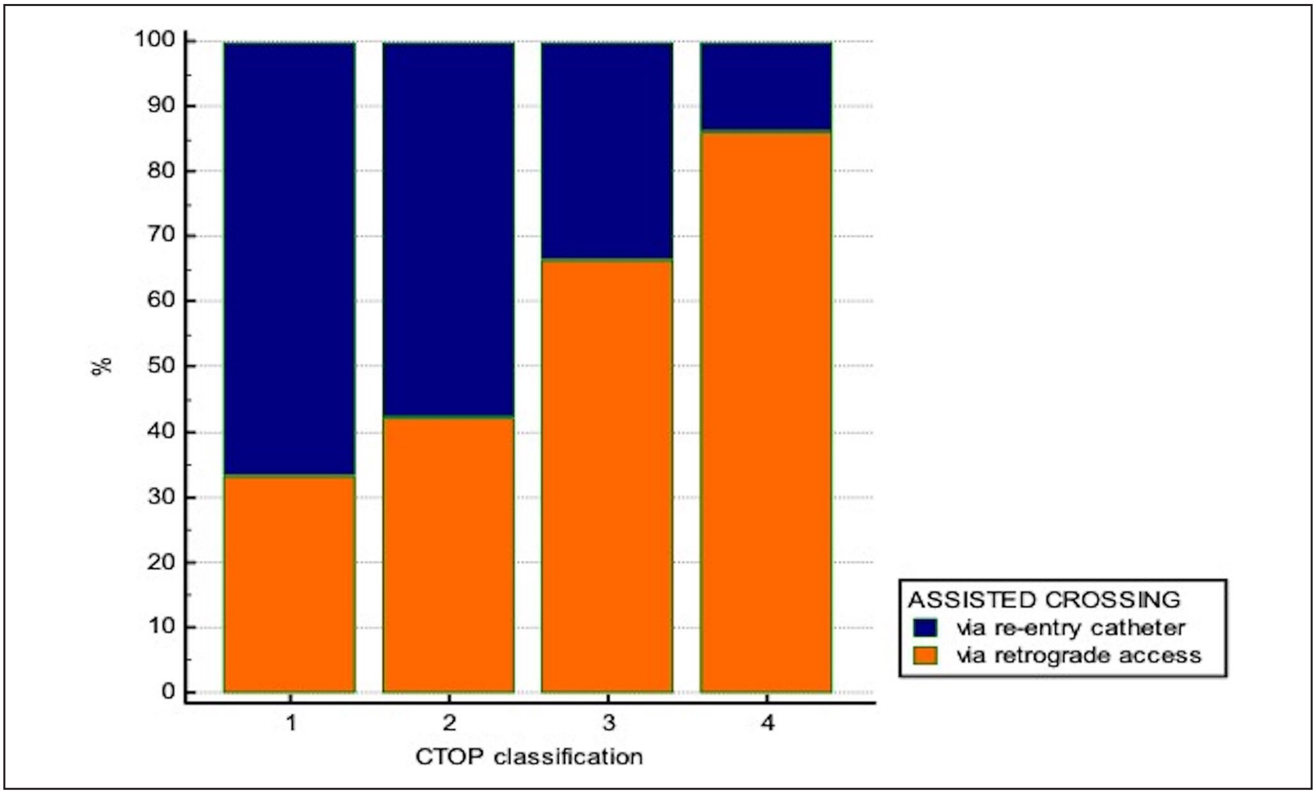

Figure 2. Utilization of retrograde access and re-entry catheter for successful crossing according to the chronic total occlusion crossing approach based on plaque cap morphology (CTOP) classification.

Table 2. Applied Treatment.

Parameters	Results
Plain angioplasty	236 (79%)
Scoring balloon	9 (3%)
Chocolate angioplasty	11 (4%)
Directional atherectomy (fluoroscopic)	17 (6%)
Directional atherectomy (OCT)	20 (7%)
Intravascular lithotripsy	13 (4%)
Rotational thrombectomy	46 (15%)
Orbital atherectomy	4 (1%)
Drug-coated balloon	170 (57%)
Bare metal stents	117 (39%)
Drug-eluting stents	48 (16%)
Interwoven stents	29 (10%)
Other	17 (6%)

Abbreviation: OCT, optical coherence tomography.

which was reported in the CTOP classification.[8] There is no angiographic core lab adjudication. Neither crossing devices nor retrograde access were primary used in this cohort, and our findings apply only to an initial antegrade wire-catheter approach. Finally, an antegrade femoral access was used in only 7% of the patients. A Flush SFA occlusion was observed in 23% of the patients. However, other important parameters might contraindicate an antegrade transfemoral approach. In this cohort, 38% of the patients presented with a proximal SFA CTO and in 14% of the patients a concomitant iliac lesion had to be treated. Moreover, the median lesion length was 180 mm and many patients presented with stenotic proximal SFA disease extending beyond the CTO. Although proximal SFA stenotic disease can be treated by antegrade access, this might be associated with technical limitations, especially in obese patients. Additionally, in 32% of the cases, a vessel prep device was used requiring a larger sheath up to 8F. Again, although an antegrade access can be performed, this might increase the risk for local complications. The contralateral retrograde femoral approach is currently the preferred vessel access for peripheral interventions. Siracuse et al recently reported on the vascular access used for infrainguinal occlusive disease within the Vascular Quality Initiative database. Of the 45 816 cases identified, the majority (39 216; 85.6%) were performed using a contralateral femoral access.[18] However, antegrade access might reduce the risk for crossing failure in distal CTOs/disease and is particularly helpful for concomitant tibial disease requiring treatment.

Conclusion

In conclusion, in our study, CTO morphology, calcification burden, and lesions localization have been identified as independent risk factors for unsuccessful antegrade

Table 3. Univariate Analysis for Crossing Failure.

Parameter	Group of technical success	Group of technical failure	p-value
Total	*210 (70%)*	*90 (30%)*	
CTOP class 1	21 (10%)	5 (6%)	p<0.0001*
CTOP class 2	146 (70%)	37 (41%)	
CTOP class 3	11 (5%)	14 (17%)	
CTOP class 4	32 (15%)	34 (38%)	p<0.0001
Lesion length > 15 cm	67 (32%)	55 (61%)	p<0.0001
Lesion length > 25 cm	25 (12%)	35 (39%)	p<0.0001
Calcification	134 (64%)	81 (90%)	p<0.0001
Flush SFA occlusion	36 (17%)	32 (36%)	p=0.0005
Proximal SFA CTO	61 (29%)	53 (59%)	p<0.0001
Mid SFA CTO	115 (55%)	65 (72%)	p=0.0047
Distal SFA CTO	125 (60%)	59 (66%)	p=0.3264
P1 CTO	72 (34%)	37 (41%)	p=0.2608
P2 CTO	35 (17%)	23 (26%)	p=0.0745
P3 CTO	16 (8%)	14 (16%)	p=0.0361
ISR CTO	28 (13%)	11 (12%)	p=0.7935
Circumferential calcium	19 (9%)	32 (36%)	p<0.0001

Abbreviations: CTOP, chronic total occlusion crossing approach based on plaque cap morphology; CTO, chronic total occlusions; SFA, superficial femoral; ISR, in-stent restenosis.
*p < 0.05 statistically different.

Table 4. Logistic Regression Analysis Identifying Risk Factors for Antegrade Crossing Failure.[a]

Variable	Odds ratio	95% confidence interval	p-value
Calcification	4.20	1.71–10.29	0.002
Circumferential calcium	2.53	1.32–4.86	0.005
CTO of the proximal SFA	3.52	1.68–7.39	0.0009
CTO of the P3 segment	4.06	1.52–10.84	0.005
CTOP type III or IV	1.91	1.39–2.60	<0.0001

Abbreviations: CTO, chronic total occlusions; SFA, superficial femoral; CTOP, chronic total occlusion crossing approach based on plaque cap morphology.
[a]Variables analyzed in the model not reaching statistical significance: Flush SFA occlusion, lesion length > 25 cm, lesion length > 15 cm, Mid SFA CTO, Distal SFA CTO, P1 CTO, and P2 CTO.

transfemoral crossing. In the presence of these parameters, an adjunctive crossing strategy either with re-entry devices or retrograde approach can improve the success rate of the procedure and enables the recanalization of the majority of CTOs. Thus, interventionists should be familiar with these alternative crossing approaches.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: K.S. declared consulting for Phillips, Shockwave, and Terumo and received Honoraria from Medtronic, Boston Scientific, and Biotronik. T.B. declared consulting for Boston Scientific, Biotronik, Medtronic, BARD, and COOK Medical.

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