Turkish Journal of Clinics and Laboratory

To cite this article: Budak AB, Gunertem OE, Tumer NB, Ozısık K, Gunaydın S. Retrograde recanalization for chronic superficial femoral artery occlusion: is it safe and effective as a primary strategy. Turk J Clin Lab 2023; 4: 782-797

Research Article

Retrograde recanalization for chronic superficial femoral artery occlusion: is it safe and effective as a primary strategy

Kronik yüzeyel femoral arter tıkanıklığında retrograd rekanalizasyon: Birincil strateji olarak güvenli ve etkili mi?

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Abstract

Aim: Peripheral arterial disease (PAD) is one the most common cause of mortality and morbidity after coronary artery disease and serebrovascular event worldwide. Endovascular treatment (EVT) of chronic occluded superficial femoral artery SFA is generally managed by antegrade approach. Retrograde popliteal access (RPA) is a valuable option when antegrad attempt fails or has also been preferred as a primary choice. We aim to compare patients in whom RPA in prone position was chosen as a first-line strategy and percutaneous intentional extraluminal angioplasty (PIER) technique was used for recanalization, with patients in whom antegrade attempt had failed and RPA in supine position with either endoluminal or bidirectional "randevous" technique was used for recanalization with 15-month follow-up.

Material and Methods: We retrospectively studied consecutive EVTs between February 2017 and April 2019, and selected all EVTs in which RPA was used for the recanalization of CTO of SFA lesions were included. The study divided patients into two groups as Group 1 (n=24): patients in whom RPA in the prone position was chosen as a first-line strategy and PIER technique was used for recanalization (with 6F Sheat) and Group 2 (n=22): patients in whom antegrade attempt had failed and RPA in the supine position with endoluminal recanalization or if the wire failed while crossing the lesion, a bidirectional "double-balloon (rendezvous)" technique was used for recanalization (Sheatless).

Results: Technical success rate was %100. RCC and ABI were improved post procedurally in both groups significantly. Primary stenting was required in more patients in group 1(70.8% vs. 45.4%; p<0.05). In group 2, randevous technique was used in 9 patients (40.9%). There was not any significant difference between the groups in terms of 30-day, and 12-month MACE. There were no major amputations, stent fracture, and death. In the 12th month, no significant differences was found between the groups for amputation-free survival (95.8% vs. 95.4%; p>0.05) .1-year limb-salvage rate was 100 ± 0 for both groups. Primary patency rates of group 2 were higher than group 1, but this difference became significant only at 6th month (95,8%, 87.5%, 79.1% for group 1vs. 100%, 95.4%, 81.8% for group 2, respectively; p<0.05 only for 6th month). The 1-year CD-TLR rate was 17,25% for whole study group, group 1 seems to have more CD-revascularization procedures but it did not reach to a significant difference (95% Cl 20.8% to 13.7%).

Conclusion: The RPA techniques has their own advantage and disadvantages. Considering safety and effectiveness, either planned as a primary strategy or needed as a back-up plan, it should be in the portfolio of vascular surgeons.

Keywords: peripheral arterial disease; chronic total occlusion; retrograde popliteal access.

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Recevied: 08.12.2023 accepted: 20.12.2023

Öz

Amaç: Periferik arter hastalığı (PAH), dünya çapında koroner arter hastalığı ve serebrovasküler olaylardan sonra en sık görülen mortalite ve morbidite nedenlerinden biridir. Kronik tıkalı yüzeyel femoral arter (SFA)'in endovasküler tedavisi (EVT) genellikle antegrad yaklaşımla yönetilir. Retrograd popliteal erişim (RPA), antegrad girişimin başarısız olduğu veya birincil seçenek olarak tercih edildiği durumlarda değerli bir seçenektir. Birinci basamak strateji olarak yüzüstü pozisyonda RPA'nın seçildiği ve rekanalizasyon için perkütanöz kasıtlı ekstralüminal anjiyoplasti (PIER) tekniğinin kullanıldığı hastaları, ileriye doğru girişimin başarısız olduğu ve sırtüstü pozisyonda RPA'nın kullanıldığı hastaları karşılaştırmayı amaçlıyoruz. 15 aylık takip ile rekanalizasyon için çift yönlü "randevous" tekniği kullanıldı.

Gereç ve yöntemler: Şubat 2017 ile Nisan 2019 arasında ardışık EVT'leri retrospektif olarak inceledik ve SFA lezyonlarının CTO'sunun rekanalizasyonu için RPA'nın kullanıldığı tüm EVT'leri seçtik. Çalışma, hastaları Grup 1 (n=24) olarak iki gruba ayırdı: Birinci basamak strateji olarak yüzüstü pozisyonda RPA'nın seçildiği ve rekanalizasyon için PIER tekniğinin kullanıldığı hastalar (6F Sheat ile) ve Grup 2 (n= 22): Antegrad girişimin başarısız olduğu ve endolüminal rekanalizasyon ile sırtüstü pozisyonda RPA'nın olduğu veya lezyonu geçerken telin başarısız olduğu hastalar, rekanalizasyon için çift yönlü "çift balon (randevu)" tekniği kullanıldı (Kılıfsız).

Bulgular: Teknik başarı oranı %100 oldu. RCC ve ABI her iki grupta da işlem sonrası anlamlı düzeyde iyileşti. Grup 1'de daha fazla hastaya primer stent gerekti (%70,8 vs. %45,4; p<0,05). Grup 2'deki hastaların 9'unda (%40,9) randevöz teknik kullanıldı. Gruplar arasında 30 günlük ve 12 aylık MACE açısından anlamlı fark yoktu. Büyük bir amputasyon, stent kırılması ve ölüm yaşanmadı. 12. ayda amputasyonsuz sağkalım açısından gruplar arasında anlamlı fark bulunmadı (%95,8 vs. %95,4; p>0,05). 1 yıllık uzuv kurtarma oranı her iki grup için de 100 ± 0 idi. Grup 2'de primer açıklık oranları grup 1'e göre daha yüksekti ancak bu fark ancak 6. ayda anlamlı hale geldi (grup 1'de sırasıyla %95,8, %87,5, %79,1'e karşı grup 2'de sırasıyla %100, %95,4, %81,8); p<0,05 yalnızca 6. ay için). Tüm çalışma grubu için 1 yıllık CD-TLR oranı %17,25 idi, grup 1'de daha fazla CD revaskülarizasyon işlemi yapılmış gibi görünüyor ancak anlamlı bir farka ulaşılamadı (%95 CI %20,8 ila %13,7).

Sonuç: RPA tekniğinin kendi avantaj ve dezavantajları vardır. Güvenlik ve etkinlik göz önüne alındığında, ister birincil strateji olarak planlanmış, ister yedek plan olarak ihtiyaç duyulmuş olsun, damar cerrahlarının portföyünde yer almalıdır.

Anahtar kelimeler: periferik arter hastalığı; kronik total tıkanıklık; retrograd popliteal erişim.

Introduction

Third leading cause of mortality and morbidity after coronary artery disease and serebrovascular events is peripheral arterial disease (PAD) (1). Symptomatic PAD refractory to medical and exercise therapy needs further planning for treatment. Chronic total occlusion (CTO) of the Superficial femoral artery (SFA) can be defined as a femoropopliteal (FP) disease can be explained as long, diffuse and complex occlusions that include high calcium rates within the plaque and the vascular wall (2). Among patients who were non-revascularized, major amputation rates can be high as 50% in one-year after critical limb threatening ischemia (CLTI) onset (3). Furthermore, the longest artery in the lower extremity was SFA and prone to flexion, compression, and torsion (4). As a result, treatment modalities usually require careful planning and back-up strategies. Although surgical bypass is recommended in the guidelines for long and complicated lesions, bypass surgery is associated with substantial morbidity; instead, endovascular treatment of chronic totally occluded SFA, including the proximal popliteal artery (PA), is successful in >90% of patients (5).

EVTs for CTO of SFA are generally performed via antegrade approach, in which either a contralateral retrograde intervention or ipsilateral antegrade access of the CFA is used (6). If the antegrade attempt with a guidewire fails, reentry catheters are sometimes useful, and Kitrou et and colleagues(7) reported a 93% success rate in usage of Outback catheter, costs and reimbursement criteria of the countries must be taken into consideration. As retrograde popliteal access (RPA) is considered to be a valuable option when the antegrade attempt fails- especially in long TASC D lesions with a reported rate of 2% (8)-, the RPA technique has also been preferred as a primary choice in procedures with CFA stenosis or occlusion, proximal lesions of SFA without a stump, presence of comorbidities such as severe obesity, concurrent iliac lesions and strong collaterals distal to the CTO.

First time in history, Tonnesen and colleagues described the retrograde popliteal approach(9), but the technique lost its popularity because of severe complications such as rupture, dissections, arteriovenous fistula, hematoma or pseudoaneurysms of the vessel which develop at the puncture site (10). Using ultrasound (US) guidance routinely while puncturing and evaluating PA is curcial to avoid complications, the recent developments in imaging technologies such as digital subtraction angiography which helps to create a roadmap and can be guide for physician while adnvancing the needle and availability of thinner sheats notably decreased the complication rate (12-14).

Since the description of the safest technique to puncture PA by Trigaux et al. (11), several methods for retrograde popliteal access have been reported (15-18), which can basically be classified into two groups according to the patient's position as prone and supine. One should plan the treatment strategy well because the need for the patient to change position during the procedure results in discomfort, anxiety, prolonged procedure duration, and compromising sterility.

Recanalization of long SFA CTOs can be accomplished by a bidirectional femoral-popliteal approach – named as "rendezvous technique (18)" or by percutaneous intentional extraluminal (subintimal) angioplasty (PIER). PIER technique was proven as a successful method in the treatment of long diameter femoropopliteal occlusions (17,19,20).

This study investigates the safety and effectiveness of the RPA in which the technique was successfully used in the revascularization of the patients with SFA CTO. We compared patients in whom RPA in the prone position was chosen as a first-line strategy, and PIER technique was used for recanalization with patients in whom antegrade attempt had failed, and RPA in the supine position with bidirectional "rendezvous" technique was used for recanalization. Besides procedural outcomes, another purpose of this study was to evaluate the 15-month follow-up results. In the current literature, there are very few studies that the same interventionalist performs both techniques, which eliminates the possible technical differences between operators, as well as comparing both techniques in terms of follow-up results.

Material and Methods

Study design

We retrospectively studied consecutive EVTs in Numune Research and Teaching Hospital, Ankara, Turkey between February 2017 and April 2019, and selected all EVTs in which RPA was used for the recanalization of SFA CTO lesions were included. The authors received no financial support from the medical industry for the research and/or authorship of this article. Inclusion and exclusion criterias of the patients are listed in table 1.

Table 1. Inclusion and exclısion criteria of the patients

Inclusion Criteria	Exclusion Criteria
• RCC 3-5 • Persistent symtoms despite medical and physical therapy >2 month • SFA occlusion not including PA regardless of the vessel diameter	• Urgent requirements for revascularization (acute ischemia • Distal lesions inaccessible via a popliteal approach • Pedal access • Patients with concomitant or staged infrapopliteal and iliac interventions.

The study population was divided into two groups as:

Group 1 (n=24): patients in whom RPA in the prone position was chosen as a first-line strategy and PIER technique was used for recanalization-with sheat

Group 2 (n=22): patients in whom antegrade attempt had failed and RPA in the supine position with endoluminal recanalization or if the wire failed to cross the lesion, a bidirectional "double-balloon (rendezvous)" technique (21-23)" technique was used for recanalization - sheatless

We compared both groups in terms of patient demographics and risk factors, procedural findings and outcomes, safety, complication rates, postprocedural outcomes, and follow-up results.

The study protocol was approved by local ethical committee. Consent form was not obtained due to retrospective nature of the study. Procedures were carried out in accordance with the 2013 Helsinki Declaration.

Patient Population and Methodology

We retrospectively studied 451 consecutive EVTs. Of these, EVT of SFA occlusion was performed in 188 patients in which a total of 46 patients who had undergone EVT via RPA were included. The study population was divided into two groups as group 1(n=24) and group 2 (n=22). All patients suffered from stable PAD (Rutherford category 3 to 5) with CTOs of the SFA.

Each patient underwent physical examination, categorized according to the RCC, had an measurement of the ankle-brachial index (ABI) and clinical risks. Demographics, symptoms, comorbidities, and risk factors for atherosclerotic vascular disease were identified for all patients. Duplex ultrasound examination or by computed tomographic angiography was used to obtain complete anatomical overview for each patient. Thus, a lower extremity digital substraction angipgraphy was always available for preprocedural planning.

Procedure Description

Prone Technique

This technique was preferred as an initial strategy for recanalization of SFA CTO in:

• Long-standing occlusions have become hard with time where the intraluminal approach would fail. Subintimal dissection plane is relatively easily created in these situations

• Long occlusions where it is difficult to maintain an intraluminal approach.

• Diffusely diseased vessels, which often have occlusions that are difficult to negotiate intraluminally.

• Flush SFA occlusions where there may be a tiny stump or no stump at all. The intraluminal approach in these situations is difficult, if not impossible.

• Heavily calcified vessels, which are often difficult to treat by conventional angioplasty but are relatively easily managed using Subintimal Angioplasty, as the wire follows the path of least resistance along the subintimal plane.

• Long stenoses which usually provide poor outcome with conventional angioplasty

• The presence of large collateral vessel proximal to the occlusion, which often lacks a stump necessary to engage the guidewire for transluminal angioplasty.

Ultrasound-guided ipsilateral retrograde PA puncture was performed in all patients. With the help of previous tomographic and/or diagnostic angiographic studies and body landmarks, an ideal diameter puncture point without a calcification was chosen after the careful examination of the PA and the surrounding muscles of popliteal fossa with B-mode ultrasound using 3.5 to 5-Mhz transducers. According to the distance from the distal tip of the occlusion, the popliteal access was maintained from popliteal fossa. Popliteal artery and vein were differentiated using a simple compression maneuver. Then the ultrasound probe was placed in a transverse fashion and to avoid the superimposition of the vein probe was tilted approximately 30° cranially. Anesthesic agent was injected locally around the popliteal artery under ultrasound. Successfully puncturing the vessel with an 18-G needle using the single-wall technique, a 6 F sheath was advanced from the PA. An angiogram showing the distal tip of the occlusion, the position of the sheat, the PA, and crural arteries was obtained before starting the procedure. After completing the preprocedural angiogram, unfractionated heparin (100mg/kg) was injected from the sheath. The PIER technique was described previously (6,19,20,24), but our technique includes some differences. The tip of the support catheter (Seeker, BD, Tempe, AZ, USA) with a guidewire inside (Supracore35, Abbott, Cal-USA / Nitrex35, Medtronic, MN-USA / Amplatzer, Boston-Scientific, MA-USA / Roadrunner. CookMedical, IN-USA / V18, Boston-Scientific, MA-USA) was brought up to the distal tip of the occlusion. Then, the subintimal slayer was entered at the distal tip of the occluded segment easily because the wire and support catheter advances into the path of least resistance, which is within a dissection plane, and entry into the subintimal plane was confirmed by injection of a small amount of diluted contrast. After five or six cases, we did not have a necessity to confirm visually, because once the guidewire enters into the subintimal layer, the guidewire advances freely with little resistance. The tip of the guidewire was then flipped to form a large loop with an approximate length of 3 to 5 cm and the loop that was supported by a catheter advanced along the length of the occlusion. Around 1 cm below the proximal tip of the occlusion or after reaching the end, we perform a few different techniques to re-enter the lumen:

· Shorten the length of the loop, make a slight twisting or screwing move

· Pull the wire back and try to find a new dissection plane.

· Change the support catheter with an angled one (Vertebral catheter, MeritMedical, UT-USA) and the screwing maneuver again

• Retract and straighten the guidewire, rotate and reposition the catheter slightly and push the guidewire towards the native vessel

• Change the wire and increase the strength and/or pushability of the wire (did only in one case-care must be taken to prevent perforation – requires experience)

Using either one of them or combination of these maneuvers, re-entry into the true lumen was successful in all cases, which was felt by the free movement of the floppy tip of the wire or confirmed by injection of the contrast medium. The crossing of CTO via a retrograde approach in a prone position is shown in figure 1.

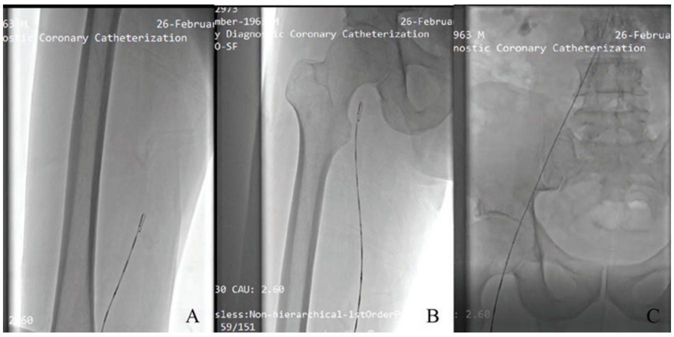

Figure 1: crossing of CTO via retrograde approach in prone position

Figure 1. (A) "loop" wire and supporting catheter. **(B)** Retrograde crossing through the lesion. (C) Guiding wire has passed through the lesion and positioned in the abdominal aorta.

Once the lesion had been crossed, the whole length of the subintimal channel was predilated with a 5F balloon catheter (Bantham, BD, Tempe, AZ, USA) using approximately 10-12 atmospheres of pressure and short segment inflations starting from the distal end of the occluded segment to the proximal segment . Any residual stenosis of more than 30% is repeatedly balloon dilated, possibly with high pressure, until a satisfactory result is achieved. After the vessel preparation was maintained successfully, drug-coated balloon angioplasty with a 6x120-mm balloon catheter (LutonixTM, BD, Tempe, AZ, USA) was performed. Stents (LifeStentTM, BD, Tempe, AZ, USA) were only deployed in the event of a suboptimal angioplasty, acute recoil, or dissection. The patient can feel some pain, especially in local calcified areas during balloon dilatation. The procedure was finished with a control angiogram confirming the technical success.

Supine Technique

All procedures were performed in the angiography laboratory. In supine position, after sterile conditions were achieved, local anesthesia was administered. As we mentioned before, group 2 patients were the patients whose procedures had first started with an antegrade approach for target lesion, which had been either (1) ipsilateral via the CFA with the insertion of a 6F sheat (2) contralateral using a 6F, 45-cm long dedicated crossover sheath (DestinationTM, Terumo, USA), and antegrade recanalization was failed because of morphological characteristics of the lesions

For the retrograde approach, either a 18-G (Terumo) or a 21-G needle cannula (Cook Inc.) was introduced distal to the occluded segment. Contralateral oblique (30°–45°) position for the C-arm was preffered to facilitate fluoroscopically-guided puncture. During the cannulation process, if you want to see the assessment of the angle of the needle as it approached the artery (should be < 70°), 90° ipsilateral position can be used to figüre out the distance of the needle tip from vessel. (Figure 2).

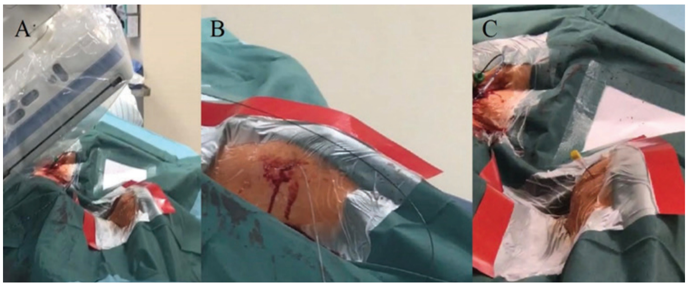

Figure 2: Positioning of C-Arm and retrograde approach via the distal SFA

(A) Position of "C" arm. **(B)** Distal SFA entrance point. **(C)** femoral and popliteal entrance points.

Furthermore, by injecting contrast via the antegrade sheath, we took a roadmap to ease our puncture and visualize the distal SFA target. After successful puncture was confirmed, a 300-cm guidewire advanced into the target vessel, the puncture needle was pulled out, and a support catheter (SeekerTM, BD, Tempe, AZ, USA) was directly introduced through the skin over the wire. The first choices guidewire to initiate the retrograde recanalization were either V-18 Control (Boston) or a 0.035-inch hydrophilic wire (Roadrunner, Cook, or Radifocus, Terumo) supported by SeekerTM. If passage failed, 0.014-inch WINN (WINN 40-80-200, Abbott), V-14 (Boston), Command (Abbott), Astato XS 40 (Asahi Intecc Co Ltd.) wires were used to penetrate the distal cap. After the first crossing goal was achieved and angiograpy confirmed the re-entry into the proximal artery, the wire was used as a guidance into the proximal sheath. Antegrade introduction of a multipurpose assisted this maneuver, Judkins right (JR4, Terumo) or vertebral catheter opposite to the catheter tip to the artery wall, aiding wire engagement into the catheter tip. After this maneuver, the wire was pushed from the distal puncture site further into the antegrade guiding catheter (externalized through the external port of the sheath) (Figure 3).

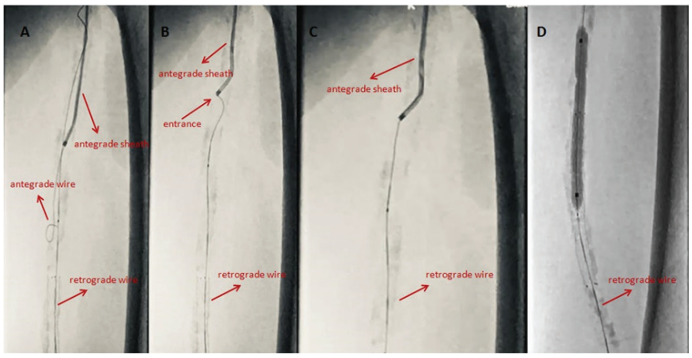

Figure 3: Wire engagement into the catheter tip and balloon angioplasty

(A) Both ante and retrograde wires are in same lumen. **(B)** Retrograde wire is being advanced into the antegrade sheath -touching the JR4 cath. **(C)** Retrograde wire is in the antegrade sheath. **(D)** Balloon angioplasty was performed

In order to re-establish the system as a standard antegrade fashion, a support catheter was withdrawn, and a 5F balloon catheter (Bantham, Bard) was inserted over the antegrade introducer distal to the target lesion. The wire was retrieved out of the balloon; after contrast injection into the balloon to be sure about proper position on the angiogram, the support catheter serving as an introducer sheath was pulled out. Hemostasis at the distal SFA puncture site was immediately achieved by local compression. At the same time, after an angiographic verification, the guiding wire was inserted again from above through the balloon and steered distal to the lesion. A blood pressure cuff was used at the puncture site for hemostasis. Inflation for % minutes of 10 mm Hg more than the systolic blood pressure can be enough. Prolonged low-pressure balloon inflation (5 minutes at 10 ± 4 atmospheres) was administered for persisten bleeding. After the vessel preparation was maintained successfully, drug-coated balloon angioplasty with a 6x120-mm balloon catheter (Lutonix, Bard) was performed. Stents were only deployed in the event of a suboptimal angioplasty, acute recoil, or dissection. The procedure was finished with a control angiogram confirming the technical success without any complication.

If the guidewire would not be able to pass through lesion retrogradely, a "double-balloon" technique was used to create 2 subintimal channels. Two 5- or 6-mm balloons were inserted at the same time antegradely and retrogradely into the occlusion. After these two balloons were positioned, caution was taken for potential ovelapping. Distance between tips of balloons should be less than 5mm. After positioning wires inside the balloons were pulled back, and they were inflated simultaneously. Once the dissection membrane separating the balloons from each other was disrupted, which facilitate the guidewire rendezvous, wire passage was attempted from either antegrade or retrograde direction. Taking all the procedures into consideration, no dedicated device (Snare, GooseNeck, etc…) was used to externalize the wire from the antegrade sheath.

Medical Therapy

The antithrombotic medication was administered as periprocedural anticoagulation with weight-based heparin (100mg/kg) to maintain activated clotting time >250 seconds. If necessary, an additional 2000 units were given every hour. All patients were on chronic single antiplatelet therapy (acetylsalicylic acid 100 mg/d) with cilostazol (200 mg/d), and they were given a single loading dose of clopidogrel 300 mg the day before the intervention.

All patients received 10.000 U Bemiparin (Hibor, Dem İlaç, Istanbul-Turkey) for two days in association with dual antiplatelet therapy as clopidogrel (75 mg/d) for four weeks followed by aspirin (100 mg/d) indefinitely.

Defınitions, Follow-Up And Outcome Measures

Critical limb ischemia (CLI) is defined in the presence of rest pain, ulcer, or gangrene due to arterial occlusive disease (25,26). Severity of PAD is determined according to the Rutherford-Becker classification (RCC) (27).

Anatomic characteristics of the SFA lesion was classified based on the TASC II classification (26). Calcium in the SFA and the popliteal artery was assessed using multiplanar DSA imaging of the vessel segment to accurately determine the extent of calcification. The calcification degree of the stenotic lesion was categorized according to the Proposed Peripheral Arterial Calcium Scoring System (PACSS): if there is no visible calcium at the target lesion site, it is categorized as grade 0 ; Unilateral calcification <5 or ≥5 cm, respectively is defined as grade 1 and 2; In grades 3 and 4 were there are bilateral calcification <5 or ≥5 cm , respectively (18).

The technical success was defined as leaving residual stenosis lower than %30 in the SFA. At least 0.10 increase in the ABI can be used as an objective evidence of increased arterial perfusion distal to the treated site (27). Technical Success of puncture was defined as retrograde placement of a sheath (group1) or support catheter (group2) into the PA without traversing the adjacent anatomical structures and without dissection or rupture. For providing objective evidence of increased arterial perfusion (hemodynamic success), an increase in the ABI of at least 0.10 is an objective parameter.(28)

Patency that is achieved without the need for additional or secondaryy surgical or endovascular procedures is defined as primary patency (28). Primary conversion refers conversion which is needed within 30 days after initial procedure(28).

Complications

A complication was defined as access-site related when its occurrence and clinical consequences were directly attributable to the puncture (hematoma, pseudoaneurysm, arteriovenous fistula, thrombosis, dissection, neuropathy, and infection) or as intervention-specific when it was directly referable to the EVT procedure (pseudoaneurysm, thrombosis, macroembolization, microembolization, arteriovenous fistula, rupture), or systemic.

Objective performans goals (OPG)

Major adverse limb events (MALE), were defined as above-ankle amputation of the index limb or major reintervention. Major adverse cardiac events (MACE) include myocardial infarction, stroke, or death. Other OPGs were freedom from MALE or postoperative death, limb salvage, survival, amputation-free survival (AFS), clinically-driven target lesion revascularization (CD-TLR), amputation, or stenosis or amputation. These goals were evaluated at 30 days and 12 months after the procedure. The secondary endpoints also included changes in clinical status according to the Rutherford-Becker classification, ABI measurements (28).

DUS imaging was the standard tool for surveillance. DUS was performed, postprocedural 1st day, 3rd month, and every 6 months (29). During follow-up if DUS suggested restenosis and/or occlusion according to the ABI or the patient suffered from recurrent symptoms, an angiograpy can be performed. Median follow- up was 15.8 ± 2.6 months.

Statistical Analysis

Data obtained in the study were analyzed statistically using IBM SPSS statistics software version 23 (IBM Corp, USA). Descriptive statistics were used to present the mean ± standard deviation (SD) or median (range) for continuous variables and the counts (percentages) for categorical variables. Cumulative patency rates with their standard errors, including determination of limb salvage rate, amputation-free survival rate, and primary and secondary patency rates were estimated using Kaplan-Meier analysis. The Wilcoxon Signed-Rank test was applied in the comparison of two dependent groups, not conforming to normal distribution. Comparisons of mean ABI and RCC at various time points were made using the Student t-test for dependent samples. A two-sided value of $p < 0.05$ was accepted as statistically significant.

Results

From February 2017 to April 2019, 46 patients with SFA CTO underwent recanalization via a retrograde approach. They were divided into two groups according to the technique of recanalization. Demographic data, risk factors, comorbidities, and procedural details are summarized in table 2. Patients in group1 were older (68.6 ± 8.3 vs. 61.8 ± 7.6 years, respectively<0.05). Mean BMI of the patients in group 2 was significantly higher than group 1 (22.4 ± 3.7 vs. 27.8 ± 4.1 kg/m2, respectively; p<0.05). Taking risk factors into evaluation, DM was more frequent in group 1 (75.0% vs 54.5%; p<0.05), but COPD was more frequent in group 2 (4.1% vs 31.8%; p<0.05). the other risk factors did not show any intergroup difference between the groups. Most of the occlusions in both groups were TransAtlantic Inter-Society Consensus (TASC) II D lesions. RCC and ABI were improved post procedurally in both groups significantly. The length of CTO was longer (26.9 ± 4.1vs. 20.6± 6.5 cm. respectively; p<0.05), and the number of lesions with severe grade 4 calcification were higher (70.8% vs. 54.5%, respectively; p<0.05) in group 1. In two patients from group 2, in-stent occlusion was diagnosed (0.0% vs 9.09%, respectively<0.05). The duration of the procedure and fluoroscopy were longer, and the amount of contrast volume administered in the index procedure was higher in group 2, respectively. Perioperative mortality and mortality occurred in neither of the groups. Primary stenting was required in more patients in group 1(70.8% vs. 45.4%; p<0.05). Mean hemostasis time was longer in group 1, respectively (39.7 ± 14.1vs 7.6 ± 7.3 min; p<0.05).

In group 2, double-balloon technique was used in 9 patients (40.9%). Access site, intervention-specific complications and time of occurrence are listed in table 3.

In 2 cases (8.3%) in group 1, a small residual bleeding were detected from the popliteal access site at postop period, one of them turned into a popliteal hematoma which was managed conservatively. In one patient (4.5%) in group 2, a groin-hematoma was detected around the antegrade CFA sheath and persisted at postop period. A pseudoaneurysm was diagnosed at postop 1st day in the hematoma and treated with DUS-guided compression. A low-flow A-V fistula was detected at the site of the distal puncture between PA and PV in one patient in group 1 (4.1%), and treated successfully with a low-pressure inflation of a plain balloon at the site of the puncture for additional 3 minutes.

Taking account into secondary endpoints, ABI and RCC were remained improved in both groups at 30-days and12th month. 30-day and 1-year MALE and mortality were 0. No significant difference found between the groups in terms of 30-day (0.0% vs 0.0%, p>0.05) and 12-month MACE (8.33% vs 9.09%, p>0.05) (Table 4). There were no major amputations, stent fracture, and death. In the 12th month, there were no differences between the groups for amputation-free survival (95.8% vs. 95.4%; p>0.05) .1-year limb-salvage rate was 100 ± 0 for both groups.

Table 2.			
Variable	Group 1 (n=24)	Group 2 (n=22)	p
Age (years)	68.6 ±8.3		<0.05
Men	21 (87.5%)	19 (86.3%)	NS
Body mass index (kg/m2)	22.4 ±3.7	27.8 ±4.1	<0.05
Risk Factors			
•Hypertension	21(87.5%)	19 (86.3%)	NS
•Diabetes	18 (75.0%)	12 (54.5%)	<0.05
•Active smoking	14 (58.3%)	13 (59.1%)	NS
•Coronary artery disease	10 (41.6%)	10 (45.4%)	NS
•Hemodialysis	4 (16.6%)	3 (13.6%)	NS
•Cerebrovascular disease	4 (16.6%)	4 (18.1%)	NS
•Dyslipidemia	11(45.8%)	10 (45.4%)	NS
•COPD	1 (4.1%)	7 (31.8%)	<0.05
Prior EVT to ipsilateral SFA	3 (12.5%)	4 (18.1%)	NS
•Balloon angioplasty	3 (12.5%)	2 (9.05%)	NS
•Stent	0 (0.0%)	2 (9.05%)	<0.05
Rutherford Class preprocedural / before discharge	3.24 ±0.7 / 2.01± 0.5 (p'<0.05)	3.41 ± 0.4 / 2.14 ±0.4(p'<0.05)	NS
TASC II class D	19 (79.1%)	17 (77.2%)	NS
Lesion			
•CTO length (cm)	26.9 ± 4.1	20.6± 6.5	<0.05
•De novo	21 (87.5%)	18 (81.8%)	NS
•In-stent occlusion	0 (0.0%)	2 (9.09%)	<0.05
ABI preprocedural / before discharge	0.51 ± 0.16 / 0.89 ± 0.12 (p'<0.05)	0.48 ± 0.17 / 0.86 ± 0.17 (p'<0.05)	NS
Technical success	100%	100%	NS
Procedure time (min)	45.6 ± 21.4	91.7 ± 18.6	<0.05
Fluoroscopy time (min)	24.4 ± 15.6	63.5 ± 17.7	<0.05
Mean contrast volume (ml)	41 ± 17.4	69.2 ± 22.9	<0.05
Primary stenting	17 (70.8 %)	10 (45.4%)	<0.05
Perioperative mortality	0 (%0.0)	0 (%0.0)	NS
Perioperative morbidity	0 (%0.0)	0 (%0.0)	NS
Mean hemostasis time (retrograde puncture site) (min)	39.7 ± 14.1 (sheath)	7.6 ± 7.3 (support cath)	<0.05

Abbreviations: COPD: Chronic obstructive pulmonary disease; EVT: Endovascular treatment; SFA: superficial femoral artery; TASC: Trans Atlantic Inter-Society Consensus; CTO: Chronic total occlusion; ABI: Ankle-Brachial Index; PACSS: Proposed Peripheral Arterial Calcium Scoring System; NS: not significant.

Table 3. Complications

Complication	Group 1(n=24)			Group 2 (n=22)		
Access-site	Intraop.	Postop.	30-days	Intraop.	Postop.	30-days
•Bleeding	0 (0.0%)	2 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Hematoma	0 (0.0%)	1 (4.1%)	0 (0.0%)	1 (4.5%)	1 (4.5%)	0 (0.0%)
•Pseudoaneurysm	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)	0 (0.0%)
•A-V fistula	1 (4.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Thrombosis	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Dissection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Infection	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Intervention-specific						
•Pseudoaneurysm	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Thrombosis	0 (0.0%)	0 (0.0%)	1 (4.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Macroembolisation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•A-V fistula	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
•Rupture	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 4. Improvements in ABI and RCC						
Variable	GROUP 1			GROUP 2		
ABI	Baseline 0.51 ± 0.16	30-days 0.87 ± 0.13[a]	12-month 0.83 ± 0.18[a]	Baseline 0.48 ± 0.17[a]	30-days 0.85 ± 0.19[a]	12-month 0.82 ± 0.16[a]
RCC	3.24 ± 0.7	1.81 ± 0.6[a]	1.51 ± 0.2[a]	3.41 ± 0.4	1.84 ± 0.7[a]	1.53 ± 0.6[a]
ap<0.05 versus baseline.						

No statistically significant difference was found in terms of restenosis/reocclusion rates as restenosis occurred in three patients (all of them were ISR) in group 1 at 5th, 7th and 11th months- they were successfully treated with DCB angioplasty, an acute stent thrombus occurred in one patient 18 days after the initial procedure which was treated successfully with catheter-directed thrombolysis and one patient underwent surgical embolectomy at postprocedural 4th month due to cessation of the antiaggregant medication.

Whereas three patients underwent catheter-based for restenosis at postprocedural 5ht, 8ht, and 10th month, and one patient underwent fem-pop bypass because of reocclusion and CLTI at postprocedural 12th month (12.5% vs. 13.6%, p>0.05).

The primary patency rates at 1, 6 and 12 months after interventions was 97,9%, 91.45% and 80.4% for whole study group. As taken intergroup differences into consideration, primary patency rates of group 2 were higher than group 1, but this difference became significant only at 6th month (95,8%, 87.5%, 79.1% for group 1vs. 100%, 95.4%, 81.8% for group 2, respectively; p<0.05 only for 6th month) (figure 4).

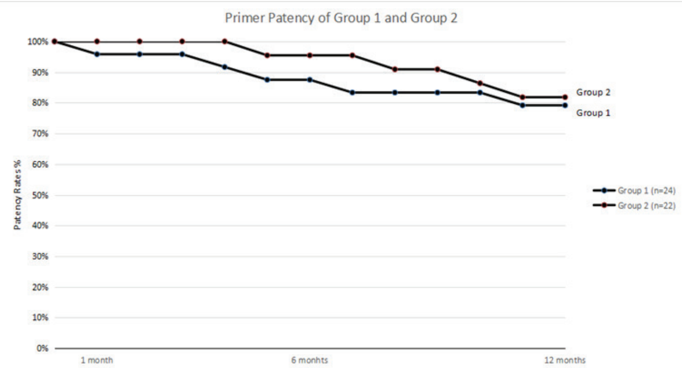

Figure 4: Kaplan-Meier analysis probability estimates of primary patency

Primary surgical conversion rate was 0% for both groups. The difference between secondary conversion rates at 12 months were (4.34 ± 0.2 vs 4.51± 0.18; p>0.05) not statistically significant. The 1-year CD-TLR rate was 17,25% for whole study group, group 1 seems to have more CD-revascularization procedures but it did not reach to a significant difference (95% CI 20.8% to 13.7%).

Discussion

PAD is a serious disease that affects an almost 10–12 million people in the United States (30). EVT is routinely prefered as a primary approach with lower procedural risks for the treatment of PAD. CTO of the SFA is a commonly encountered target lesion in patients with symptomatic lower extremity arterial disease (31), but EVT of SFA CTO is often challenging because of the lesion length and high probability of the presence of severe calcification.

EVT of SFA can be performed either the contralateral retrograde or ipsilateral antegrade CFA access (32-34). The contralateral approach can be tough in the presence of narrow aortic bifurcation. Furthermore, long introducers and devices are required, which impoverishes the pushability like transaxillary or transradial approaches. The antegrade CFA approach offers more productive usage of short instruments. Unfortunately, all these approaches are inappropriate when the SFA occlusion is either flush, or in the presence of lesions involving CFA or proximal stump of SFA. Furthermore, if the antegrade attempt fails, you need a back-up plan. An unsuccessful EVT is most often not the inability to cross the occlusion with the guidewire, but an unsuccessful re-entry of the guidewire into the true lumen distal to the occlusion (15). Devices for re-entry were produced to salvage situations in which a guidewires cross the occluded segment but fails to re-enter the true distal lumen (35,36). But high costs of these devices precludes the usage. Some situations such as wire perforation within an occluded segment or occluded stents make it impossible to pass from the antegrade direction. Furthermore, the re-entry device itself can also fail. Shin et al. (37) recently reported a 35% failure rate. In our study, we did not use any of the re-entry devices.

To summarize and focus on our study, the main indications for retrograde distal SFA or popliteal approach were a short SFA stump, flush occlusion of SFA (like in group 1), and failure of the antegrade approach (like in group 2) (12,14,16, 38).

The reason why retrograde revascularization was more effective than an antegrade approach is not apparent. However, before interpreting the results with two different techniques, we must admit that an essential limitation of RPA. Atherosclerotic lesions or occlusion extends to the distal popliteal artery is major obstacle. Percutaneous approach from in below-the-knee arteries requires a patent target vessel and has a high risk of iatrogenic injury. Consequent damage to crucial collateral arteries is an another concern(15).

Subintimal Angioplasty (SA) technique that we preferred to use in group 1as a treatment of choice can also be named as "percutaneous intentional extraluminal recanalization (PIER)." It shows a great similarity to surgical endarterectomy by which recanalizes an occluded arterial segment through an extraluminal channel between the intima and media yielding a 'bare' neo-lumen (39).

The development of the technique of PIER has largely been dominated by the extensive work of Bolia and Reekers (19,20). PIER technique aims to obtain a smooth neolumen free from atheromatic area between the tunica intima and media, which produce a possible better patency rate (19,40). But our technique is slightly different because Bolia technique requires an antegrade ipsilateral CFA puncture and the presence of at least a 5-mm stump at the origin of the SFA (19,20,40,41) and they did not use the procedure if the patient has no SFA stump (41). An alternative was brought by Heenan et al. (42). They have reported successful results in three SFA occlusions through ipsilateral RPA like our technique.

In PIER through the retrograde popliteal approach, re-entry is achieved around the deep femoral artery (DFA). Thus, inadvertent occlusion of the ipsilateral DFA while trying to re-enter the true lumen may be dangerous. This can best be avoided by entering the true lumen below or at the level of the origin of the DFA since, in the case of a high re-entry site, PTA of the subintimal space may cause occlusion of the DFA at its origin. This was the reason we preferred to try to re-enter the true lumen by a controlled catheter– guidewire manipulations instead of simple forward pushing of the catheter–guidewire combination toward the patent part of the artery. In 1994 London et al. (41) provided the first significant report of the technique for SA on 200 consecutive femoropopliteal artery occlusions with a median length of 11 cm (range 2-37). The technical success rate was 80% and was not significantly different for occlusions of more than 20 cm. They reported the factors influencing long term patency were smoking, the number of calves runoff vessels, and occlusion length. Laxdal et al. (43) reported the experience with 124 SA accumulated over a 5- year period and reported a technical success rate of 90% with a 42% primary patency at 12 months. Taking the impact of the number of distal runoff vessels on patency and to correctly evaluate both techniques' results, we excluded patients with lesions affecting the distal runoff in our study. Soga et al., (44) employed a bidirectional approach in 37% of the SA group and achieved a technical success rate of 90% (mean occlusion length= 23.5 cm).

This approach is not feasible in patients who are obese, have impaired respiratory function, or have conditions that may interfere with positioning them prone or in lateral decubitus. This factor may explain why BMI and COPD were high in group 2 because they are not suitable candidates for pron technique, and the supine technique is preferred. But before interpreting this result, we should accept that obesity can also be a situation where a CFA puncture will be very difficult or contraindicated.

Since most of the patients in group 1 had TASC D lesions and all of them had a SFA stump of <5 mm, we have chosen RPA as a first choice instead of contralateral or ipsilateral CFA access. Evaluating our results, another advantage of the pron technique has come forward as the lower duration of procedure and fluoroscopy times as well as the amount of contrast medium. This difference can partly be explained by the time passed and the contrast used during the failed antegrade attempt. But also a part of it can be attributed to the use of DUS for cannulation of PA in every case. DUS has the advantage of visualizing the vein to avoid accidental puncture and reduce the risk of arteriovenous fistulas. Performing the puncture with ultrasound guidance reduced the contrast volume used as well as the duration of fluoroscopy.

Yilmaz et al. successfully treated 32 of 39 SFA occlusions (82%) with PIER technique via RPA and reported a cumulative patency rate of 66% at 6 months (17). Noory et al. reported 56 procedures, in which after re-entry to the true lumen failed in the antegrade approach, all patients were turned to a prone position, and a 5-F or 6-F sheath was placed into the mid-segment of the PA and crossed the lesion either subintimal or endoluminal. They reported the reperfusion success as 98%, 12-month primary patency rate as 45.1%, 1- year TLR rate as 45.1% (46). Mert Dumantepe (46) published the results of the endoluminal recanalization of 28 patients with CTO of SFA via RPA with the patient in the prone position using a Rotarex device and reported a significant increase in ABI and a 1-year primary patency rate of 85.7%. Housam et al. reported 16 patients using transpopliteal artery retrograde access with the patient placed in the prone position, reported a 30-day MACE of 6% without perioperative morbidity, 30-day mortality, and 30-day MALE. The primary patency was 66 ± 9%; limb salvage was 100%, AFS was 92% at 2 years (48). Sangiorgi et al. (8) reported the treatment results of 23 patients requiring RPA for occlusive lesions with an average length of 20.6 ± 8.8 cm. This group demonstrated procedural success in 22 of 23 patients compared with group 1 as we treated longer lesions with 100% success.

Taking supine group in which a retrograde approach was achieved after the failed antegrade attempt, we adopted the sheathless approach, passing the guidewire directly through the puncture needle into the occluded artery followed by the support catheter different from the WBO technique described by Baker et al. (15) (in WBO technique, a balloon used as support catheter gives the opportunity to stepwise dilate the artery in case the wire and/or balloon encounters friction within the occlusion). We prefer to use a support catheter rather than a ballon, because a balloon after inflation has a larger diameter than an unused balloon, potentially increasing the trauma during retrieval. We used fluoroscopic guidance as well as DUS. The vicinity of the radiation source to the hands of the operator during puncturing might be of concern. However, if we decided to use fluoroscopy, we found it feasible after local anesthesia to first just pierce the skin using a roadmap or an angiogram via the proximal sheath, leaving the needle in place as a guide while performing a second angiogram to determine the distance of the needle to SFA or PA. The needle was then guided into the artery without fluoroscopy until back- bleeding was noticed.

The technique for extraction of the retrograde guidewire from the antegrade sheath maneuvered the guidewire into the tip of the catheter inserted antegrade until the guidewire tip appeared outside of the proximal sheath. This technique was successful whenever used. We think that not using the dedicated devices for this issue, potentially help to decrease the costs.

Fanelli et al. (16) published the results of 26 patients who, after the failure of an antegrade attempt, an RPA in the supine position for recanalization of SFA was preferred and reported primary patency of 80.7% at 6 months and 76.9% at 1 year. Shi et al. (48), published the results of 21 patients underwent dual femoral-popliteal recanalization in the supine position for CTO of the SFA, with much shorter mean lesion length as 87.4 mm± 5.8 compared to our study, and reported a 100% technical success, a significant increment in ABI and a primary patency rate of 80% at 6 months. But in their study, further stent stenosis had occurred in 57.1% of the patients after 6 months and decreasing the primary patency to 42% at 12 months. In their study, ABI changed from 0.48 ± 0.17 pre-interventionally to 0.89 ± 0.10 at 1 day, to 0.87 ± 0.10 at 1 month, 0.85±0.11 at 6-months and 0.84 ± 0.11 at 1 year post-interventionally. These results are in line with our study. Schmidt et al. (22), published the results of 50 patients who received retrograde recanalization via distal SFA after failed antegrade recanalization of SFA CTO with a mean lesion length of 205 ±75 mm. They utilized the rendezvous technique in 24% of the patients with a success rate of 96%. Ye M et al. (49), published an approach with infracondylar-plane access to the popliteal artery in the supine position, in which the postinterventional ABI was 0.74 ± 0.23, and the primary patency rate was 84.2% after a 6-month follow-up. In our study, we achieved an increment in ABI and an improvement in RCC post procedurally, and this improvement continued for at least 12-months. Tan et al. (18) reported 20 patients underwent EVT via retrograde access using the anterolateral popliteal puncture technique with the patient in the supine position. Their technique was different from ours' in terms of the cannulation site (P3 segment) and similar in terms of cannulation without a sheat like our group 2, and preferred usage of the rendezvous technique as we did in 9 patients in group 2. In their study, the mean hemostasis time for balloon inflation was 7.73±4.03 min. Similar to our group 2. The low profile of the support catheter made it easier to obtain hemostasis, and the supine technique allows utilization of various techniques in combination including compression, controlled inflation of a blood pressure cuff at the puncture site and a controlled prolonged intraluminal balloon inflation if necessary to provide tamponade after removal of the catheter.

Komshian et al. (50) retrospectively reviewed 148 patients with isolated SFA and PA disease treated with RPA access, compared with antegrade CFA access, and published their results in 2018. They did not give any information about the procedural techniques. They reported technical success as 80.4%, MALE-free survival as 74.5%, and patency as 70.3%, which was significantly lower than the CFA access group and lower than our study. The enormous difference in sizes of the analyzed groups presented a methodologic challenge for statistical analysis of the data (29.926 vs. 148), preventing the correct statistical comparison. Moreover, they did not standardized the groups in terms of lesion severity as the proportion of TASC II D lesions was more frequent in the RPA group (49.6% vs. 18%), leading the misinterpretation of the results.

Young-Guk Ko (51) published a review comparing SA and endoluminal angioplasty by evaluating several registry studies and concluded that SA appears to achieve a higher technical success rate than EA, whereas mid-term primary patency rates are comparable for both endovascular wiring strategies for SFA CTO. They also reviewed published studies on the primary patency of SA for femoropopliteal artery occlusions from 1994 to 2017. From their review, we can easily show the improvement of patency rates after using stents. But in most cases needs the support of stents for preventing recoil. But also we know that limited efficacy of stents in long lesions. Long stenting may have also contributed to the lower patency rates. Hong et al. (52) showed that primary patency was significantly lower with long stenting than with spot stenting following SA of long femoropopliteal occlusions. Thus, stenting strategies may play a more critical role than the wire passage method in maintaining the patency of recanalized long arterial lesions. Considering the SA technique, during the dissection maneuver, it is conceivable that damage to collateral vessels occurs. In other words, the flow in the artery beyond the occluded segment becomes static. The majority of these situations have been retrieved with the use of self-expanding stents in the site of the occlusion, where the re-coil is supposed to have been maximal. Besides, in our study, we faced more flow-limiting dissection flaps in group 1 than group 2, which mainly can be attributed to the more severe calcific nature of the CTO, which probably increased the frequency of stent deployment. On the other hand, questioning the primary stent difference between the groups, w the two patients in group 2 were treated because of in-stent occlusion, and we did not use a stent in their treatment. Since the number of patients is relatively low, this may have contributed to the intergroup statistical difference. But we always choose spot stenting in both groups for the indications we mentioned before. Since a deployed stent in SFA must deal with strong bending, compression, and torsion forces, dynamic vessel conformability is very important. We preferred The LifeStent™, which is the only FDA-approved stent for the SFA. Palena et al., published their results in PRESTO trial that they used Supera stent (Abbott, CA, USA) which was navigated in a retrograde fashion to position the first crown to be released just at the SFA ostium in 21 patients and concluded that The PRESTO technique (is a feasible and potentially useful strategy to safely and accurately deploy this type of metallic endoprostheses at the SFA ostium (53).

In 2019, Igus and Firat (54) described an alternative treatment of SFA stump occlusion by a direct puncture of occluded SFA and followed by antegrade recanalization when conventional antegrade or retrograde access was not achievable. They achieved technical success in 80% of the patients, and a significant difference between mean Rutherford pre- and post-procedural scores (4,2 ± 0,4 vs. 1,3 ± 0,5). They reported an AFS of 60%, a primary patency rate of 62.5% at 24 months.

The primary patency rates of the patients at 1, 6, and 12 months were 97,9%, 91.45%, and 80.4%. There were no intergroup differences except 6th month, which group2 has better patency. With the number of patients and the reasons for secondary interventions (one of them was a macroemboli requiring surgical intervention because of the patients' cessation of the anticoagulant management), it is difficult and will definitely be wrong to interpret this discrepancy. The 1-year CD-TLR rate was 17,25% for the whole study group without an intergroup difference.

The reason that popliteal access has not become more popular is the risk of access-site complications. However, several case series report low rates of major complications (33,55,56) with prone technique. Several authors have reported complication rates between 2.5% and 5.2% after manual compression of the popliteal artery access (42, 55,56). Possible complications in pron technique are occlusion of PA at the puncture site, distal embolization, and arteriovenous fistula due to unintentional puncture of the popliteal vein. Since the popliteal vein is located posterior to the artery, there is always a high risk of traversing both vessels with the needle when operating the RPA. By using DUS guidance, we significantly prevented these complications as DUS allows the operator a visual control of the needle, the PA, and the vein, lowering the risk of perforation of the vein and consequently, the risk of fistula formation. In our series, we had only 4 complications in group 1, which is a small hematoma in 1 patient and arteriovenous fistula in 1 patient and minor bleeding in 2 patients. But the potential problem with this technique is the usage of a 6F sheat resulting in a long hemostasis time like approximately 40 minutes. Arterial rupture is the most concerning complication associated with SA, but the incidence is relatively low, ranging from 0% to 6% (51). The risk of perforation is increased in older patients, those with diabetes, and smokers. We did not face this complication in our study. Although distal embolization was thought to occur less frequently in SA than IA due to the absence of atherosclerotic plaques and thrombus in the subintimal channel, the incidence is similar to that of IA and varies from 0% to 7.3% (51).

If we consider our supine technique, we believe that the sheathless technique avoids complications in the retrograde access site related to a large sheat. As Yilmaz and colleagues noted (57), only 3 to 10 minutes of manual compression seems to be enough to obtain complete hemostasis of the popliteal puncture site without any complication, like in our group the duration of complete hemostasis in group 2 patients was approximately 7.5 minutes. Tokuda et al. (58), reported 68 patients whom RPA in the supine position was used and divided the cohort into two groups performed with a 4-F or 6-F sheath and those with a 2.1-F microcatheter and compared the groups in terms of complications, the success of popliteal artery puncture, lesion crossing, and reperfusion. They found a significant difference in terms of mean time to hemostasis as 8.9±8.8 minutes in the microcatheter group vs. 47.7±13 minutes in the sheath group ($p<0.0001$), and the complication rate (22.2% in the sheath group vs. 2.0% in the microcatheter group) advocating the sheathless technique.

As for the shortcomings of this study, we can put forward its retrospective nature and the small number of patients. Also, adding a comparative group of patients with SFA obstructions who underwent recanalization through antegrade approach might have increased the precision. But, most of the published works in the current literature only focused on one technique, its safety and technical success without follow-up results. Comparing the safety and success of two techniques applied by the same operator, having no lost patient in follow-up, standardization of the definitions and reporting them in the same standards, investigating the prior techniques in the literature and discuss our own techniques created by removing the proven problematic parts of prior techniques and try to create an algorithm can be counted our studies' superiorities.

Conclusion

Undoubtedly, endovascular procedures becomes more invasive via bidirectional approach (femoral and popliteal) and prolongs the duration of procedure and fluoroscopy. There are options to provide re-entry into the true lumen in case of subintimal recanalization like our double-balloon maneuver when used as an adjunct to the bi-directional approach, it has been extremely useful in facilitating wire cross in casee of an inability to pass the occlusion from either direction. This is not possible with the patient lying prone for the transpopliteal approach. When the diameters of the balloons are preferred to match the artery and are not smaller, the "double-balloon" technique maneuver brings success mostly. We do not believe that a 5- or 6-mm balloon carries a significant risk of perforation. Moreover, fewer complications in distal puncture site because of not using a large introducer sheath. As we did not find a significant difference in the success rate, the sheathless method resulted in a shorter time to maintain hemostasis and a tendency of lower complication rate as the hematoma and pseudoaneurysm in group 2 occurred in the same patient and in the femoral area. There was no complication in group 2, regarding the retrograde access. On the other hand, by creating a new lumen without atheroma, the pron technique makes the length of the lesion trivial. It offers a proper, clean, uninterrupted, antegrade flow without any atheromatous plaque, shortening the duration of procedure, fluoroscopy, decreasing the amount of radiation exposure, and amount of contrast medium. Nonetheless, either planned as a primary strategy or needed as a back-up plan, it should be in the vascular surgeon's portfolio.

Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Funding

The authors report no involvement in the research by the sponsor that could have influenced the outcome of this work.

Authors Contribution

AB, OEG, NBT, KO and SG contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

*All authors read and approved the final version of the manuscript.

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