



Our experiences on endovascular and hybrid treatment of peripheral arterial diseases

Periferik arter hastalıklarında endovasküler ve hibrid tedavi deneyimlerimiz

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ABSTRACT

Background: This study aims to present our experiences on endovascular and hybrid treatment of peripheral arterial diseases.

Methods: Between March 2008 and April 2016, 86 patients who underwent endovascular treatment and 17 patients who underwent hybrid treatment for peripheral arterial disease in our clinic were retrospectively analyzed. The treatment approaches, success of treatments, complications and outcomes of these patients were studied.

Results: No mortality was seen during the procedures. Following the procedure, the patients were hospitalized in the intensive care unit under standard heparin treatment for six hours at least. Anticoagulation was maintained with low-molecular-weighted heparin for three days, followed by dual oral antiaggregant (acetylsalicylic acid 100 mg + clopidogrel 75 mg). Repeated Doppler ultrasonography revealed no in-stent thrombosis or restenosis at the site of ballooning during hospitalization. None of the patients with normal renal functions preoperatively experienced severe renal failure. Although nearly all femorodistal interventions were performed in the antegrade way, none of the patients had bleeding complications at the site of intervention. All patients were discharged within 1 to 16 days.

Conclusion: Endovascular and hybrid modalities are safe and comfortable in the treatment of peripheral arterial diseases for vascular surgeons having a hybrid room.

Keywords: Endovascular treatment; hybrid treatment; peripheral arterial disease.

ÖZ

Amaç: Bu çalışmada, periferik arter hastalıklarının endovasküler ve hibrid yaklaşım ile tedavisinde edindiğimiz deneyimler sunuldu.

Çalışma planı: Mart 2008 - Nisan 2016 tarihleri arasında periferik arter hastalığı nedeniyle kliniğimizde endovasküler tedavi yapılan 86 hasta ve hibrid tedavi yapılan 17 hasta retrospektif olarak incelendi. Tedavi yaklaşımları, tedavi başarıları, komplikasyonları ve prognozları değerlendirildi.

Bulgular: İşlemler sırasında mortalite görülmedi. İşlem sonrası hastalar standart heparin tedavisi altında en az altı saat yoğun bakım ünitesinde kaldı. Üç gün düşük molekül ağırlıklı heparin ile antikoagülasyonu takiben ikili oral antiagregan (100 mg asetilsalisilikasit + 75 mg klopidogrel) başlandı. Kontrol Doppler ultrasonografide hastanede yatış süresince stent içi tromboz veya balon uygulanan bölgede restenoza rastlanmadı. Ameliyat öncesi böbrek fonksiyonları normal olan hastaların hiçbirinde ciddi böbrek yetmezliği gelişmedi. Femorodistal girişimlerin neredeyse tamamında antegrad yol kullanılmasına rağmen, hiçbir hastanın girişim yerinde kanama komplikasyonu görülmedi. Hastaların tümü 1 ila 16 günde taburcu edildi.

Sonuç: Endovasküler ve hibrid yöntemler; periferik arter hastalıklarının tedavisinde, hibrid salonu bulunan damar cerrahları için güvenli ve konforludur.

Anahtar sözcükler: Endovasküler tedavi; hibrid tedavi; periferik arter hastalığı.

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In the treatment of peripheral arterial diseases, minimally invasive techniques are the currently considered vascular approaches instead of conventional open surgery. Endovascular methods have been shown by many studies to have lower mortality and morbidity rates compared to open surgery, and although they are primarily considered during treatment, this is not possible in all cases.^[1] At this juncture hybrid techniques offer the optimal solution for treatment in most cases; in recent years the rate of use of hybrid procedures for arterial reconstruction has increased from 5 to 20%.^[2] With the rapid advances in endovascular technology, an almost complete treatment of peripheral arterial diseases will be possible in the near future. The most important questions awaiting surgeons in the treatment of these patients include the method of endovascular treatment, and the timing of hybrid therapy if necessary.^[3] Cardiovascular surgeons have the competence to implement hybrid techniques and the ability to intervene immediately to complications; and the fact that they are able to successfully perform endovascular treatment methods which continue to evolve with every passing day, will be a great advantage to patients.

We believe that complete revascularization can be achieved using hybrid procedures, with the current increase in opportunities and experiences in endovascular interventions, even in patients with multiple peripheral artery lesions. Our aim in this study is to share our eight years' experience in endovascular and hybrid therapy, which has a high success rate in peripheral arterial disease, following the establishment of a hybrid endovascular hall in our clinic.

PATIENTS AND METHODS

This study was performed retrospectively at the Cardiovascular Surgery Unit of the GATA Haydarpaşa Training Hospital between March 2008 and April 2016, on patients who were subjected to endovascular or hybrid peripheral arterial procedures. The study protocol was approved by the former Ethics Committee of Sultan Abdülhamid Han Training and Research Hospital. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Retrospective examination of 103 peripheral artery pathologies subjected to endovascular or hybrid treatment demonstrated that only 86 cases underwent endovascular surgery, while 17 cases underwent open surgery (hybrid therapy) simultaneously or progressively with endovascular treatment. A total of 146 endovascular procedures were performed on these patients.

Ninety-one patients received stent implantation (with drug in two patients) or balloon angioplasty (with drug in one patient) for obstructive peripheral arterial disease, while seven patients underwent stent-graft (covered stent) implantation for aneurysm, pseudoaneurysm, fistula, or rupture. Stent implantation was performed in three patients after atherectomy for totally occluded arterial lesions. In addition, coil embolization was performed to stop arteriovenous (AV) malformation in one patient and pseudoaneurysm in another.

In addition to endovascular treatment, hybrid procedures performed include, femoropopliteal (fem-pop) bypass (four of which occurred during other sessions) in 12 patients, femoral profundoplasty in one patient, femoral patchplasty in one patient and embolectomy in two patients. In addition, the patient who was subjected to coiling due to AV malformation progressively completed treatment in a hybrid manner with vascular tumor excision one day later (Table 1).

Endovascular procedures and simultaneous hybrid procedures were performed in the hybrid endovascular hall of our clinic. Clopidogrel 300 mg was administered orally before the procedure. Sodium bicarbonate and fluid infusion and treatment with N-acetylcysteine were provided before and after the procedure, as nephroprotection. All endovascular procedures were performed under local anesthesia. Areas of intervention were determined preoperatively by Doppler ultrasonography found in our clinic. The site of the lesion was accessed in nearly all the operations distal to the superficial femoral artery (SFA) using antegrade intervention.

Approach to arterial lesions of the upper extremity

Complete patency was restored in six patients who underwent balloon expandable stent implantation for subclavian artery (SCA) stenosis. Traumatic axillary artery rupture and traumatic brachial artery pseudoaneurysm were repaired with a Gore-Tex stent-graft.

Approach to iliac artery lesions

Endovascular approach: attempts were made to open 24 common iliac artery (CIA) stenoses (one of which was bilateral) and 10 external iliac artery (EIA) stenoses, mostly with self-expandable stents. However, there was a need for balloon dilatation in some of the cases using self-expandable stents.

The hybrid approach (iliac stent implantation + fem-pop bypass): In the event an iliac lesion during

Table 1. Distribution of endovascular and hybrid procedures

Peripheral artery region	Pathology	Procedure performed	Number of procedures	Simultaneous hybrid procedure	Progressive hybrid procedure
Upper extremity	SCA stenosis	Stent	6		
	Traumatic axillary artery rupture	Closed stent	1		
	Traumatic brachial artery pseudoaneurysm	Closed stent	1		
Pelvic (iliac)	CIA stenosis	Stent	22	Profundoplasty, femoropopliteal x2, Embolectomy	
	B-CIA stenosis	Stent	2		B-femoropopliteal
	CIA aneurysm	Stent-graft	3		
	B-CIA aneurysm	Kissing stent-graft	1		
Infrainguinal (femoral)	EIA stenosis	Stent	9	Femoropopliteal x3	Femoropopliteal
		Balloon	1		Femoropopliteal x2
	SFA stenosis	Stent	40	CFA patchplasty	
		Balloon	17		
	Traumatic femoral arteriovenous fistula	Closed stent	2		
	Arteriovenous malformation	Coil	1		Vascular tumor excision
	SFA occlusion	Atherectomy	2		
	PopA stenosis	Balloon	3		
	Femoropopliteal graft stenosis	Balloon	1	Embolectomy	
	PopA stenosis	Stent	1		
		Balloon	6	Femoropopliteal x3	
	PopA occlusion	Atherectomy	1		
	L-tibioperoneal trunk lesion	Balloon	2		
Infragenicular	ATA stenosis	Balloon	12		
	Traumatic ATA pseudoaneurysm	Coil	1		
	PTA stenosis	Balloon	5		
		Stent	1		
	Peroneal stenosis	Balloon	5		

SCA: Subclavian artery; B-CIA: Bilateral common iliac artery; EIA: External iliac artery; CFA: Common femoral artery; SFA: Superficial femoral artery; PopA: Popliteal artery; ATA: Anterior tibial artery; PTA: Posterior tibial artery.

Important Note: Intra-stent balloon dilatation procedures performed after stent implantation with consecutive stent implants and balloon dilatations have not been included.

preoperative CT angiographic evaluations of patients who underwent femoropopliteal bypass surgery, endovascular iliac arterioplasty is primarily planned

both to ensure complete distal flow and a longer graft patency. Hybrid therapy was completed with bilateral fem-pop bypass performed five days after stent

implantation for bilateral CIA lesion. Eight patients with bilateral iliac artery lesions who underwent stent implantation/balloon angioplasty (two); five of them immediately before surgery (simultaneous) and three a few days/one week after surgery (progressive),

were subjected to ipsilateral fem-pop bypass surgery immediately after the surgery. Eventually, the arterial flow of the 10 lower extremities was provided by “iliac stent + fem-pop bypass” experience. The femoral artery bifurcation lesion of a patient who

Table 2. Variety of stents and balloon used during endovascular procedures

Region	Brand of stent (-graft)	Number of procedures	Brand of balloon	Number of procedures
Subclavian artery	Cordis® Palmaz Genesis	2	Bard® Dorado	1
	Medtronic® Assurant	2		
	Boston-Scientific® Innova	1		
	Biotronik® Dynamic	1		
	Gore® Viabahn (covered)	2		
Iliac artery	Boston-Scientific® Express	11	OptiMed® Mars	4
	Medtronic® Assurant	8	Boston-Scientific® Sterling	3
	eV3® Protege	5	Abbott® Fox Plus	2
	Abbott® Absolute	4	Polimed®	1
	OptiMed® Sinus XL	4		
	Vascutek® Anaconda	3***		
	Cordis® Palmaz Genesis	2		
	Invatec® Maris Plus	2		
	Biotronik® Astron	1		
	Gore® Viabahn (covered)	1*		
	Terumo® Misago	1		
Femoral artery	eV3® Protege	9	OptiMed® Mars	14
	Terumo® Misago	6	Abbott® Fox Plus	4
	Boston-Scientific® Innova	6	eV3® NanoCross	3
	Abbott® Absolute	5	Cordis® Powerflex	3
	OptiMed® Sinus Superflex	4	Terumo® Renma	2
	Medtronic® Assurant	4	Cook® Advance	2
	Invatec® Maris Plus	3	Medtronic®	1
	Gore® Viabahn (covered)	2*/**	Invatec® Maris plus	1
	Cordis® Palmaz Genesis	1	Bipore®	1
	Bard® E. Luminexx	1	Eurocor® Freeway	1
	Atrium® iCast (covered)	1**	(drug-eluted)	
Popliteal artery	Cook® Zilver-PTX (drug-eluted)	2	eV3® Nanocross	5
			OptiMed® Mars	4
			Boston-Scientific® Maverick	1
			ClearStream®	1
Tibioperoneal trunk	Biotronik® Tenax	1	ClearStream® Nimbus	1
			Cook® Advance	1
			OptiMed® Mars	1
Tibial arteries			eV3® Nano cross	15
Peroneal artery			ClearStream® Nimbus	5
			Terumo® Renma	2
			Stron® PYXIS-vq	1

* Used for the repair of rupture and/or dissection complications; ** Used for AV fistula/pseudoaneurysm repair; *** used on patients with iliac aneurysm.



Figure 1. Angiographic images of the superficial femoral artery lesion before (a) and after (b) stent implantation in a diabetic patient.

had stent implantation for CIA lesion was treated with simultaneous profundoplasty surgery to complete nourishment of the extremity. In addition, stent

implantation to the ulcerated plaque in the CIA, which was considered as an embolic source, was performed during angiography with simultaneous embolectomy in a patient who presented with acute thromboembolism, in the hybrid endovascular hall.

Approach to femoral artery lesions

Fifty-seven endovascular procedures (39 stent implantations, 17 balloon angioplasty and one atherectomy operations) were performed to the SFA, the most commonly encountered atherosclerotic segment. Furthermore, in some patients with self-expandable stent implants, balloon dilation was required and full lumen patency was achieved in all patients. In a patient with occlusion of the SFA, flow was generated with consecutive stent implantation after atherectomy. On the other hand, the graft lumen was opened with intra-graft balloon dilatation following embolectomy in a patient who was detected with thrombosis of an old fem-pop bypass graft. In our patient with the only congenital peripheral arterial pathology (thigh hemangioma fed by femoral artery and vein), subjected to endovascular procedure, coil embolization was



Figure 2. Treatment of a wide and infectious neuropathic ulcer (a) on the sole of the feet of a diabetic patient, through marine and subaquatic medicine (debridement, periodic dressing and hyperbaric oxygen therapy), infectious diseases (IV antibiotherapy), cardiovascular surgery and radiology [subliminal passage of the superficial femoral artery occlusion (b) with (c) stent (d) revascularization (e)] clinical management using a multidisciplinary approach [1st month (f)].

performed in order to reduce the risk of hemorrhage before excision surgery and to minimize the mass.

Approach to infragenicular artery lesions

Endovascular approach: Balloon angioplasty was preferred in 30 procedures at this level, except for a stent that was used after balloon dilatation in peroneal artery stenosis due to a drug-coated stent placed in the popliteal artery (PopA) stenosis and calcification, due to the small size of the calibrations in arterial lesions below the knee. Flow was ensured by balloon angioplasty following atherectomy in an occluded PopA.

In addition, above-the-knee and below-the-knee angioplasty procedures were performed simultaneously. Distal revascularization of the extremity was completed by opening the SFA stenosis with a stent in six different patients, after balloon dilatation in the ATA, PTA, or the peroneal artery.

Hybrid approach (Fem-pop bypass + below-the-knee balloon angioplasty): Popliteal balloon

arterioplasty was performed after fem-pop bypass with the hybrid approach to lesions both above and below the knee which we encountered in the three patients with diabetes.

The brand and numbers of use of the stent and balloon dilatation catheters used for angioplasty in all our endovascular procedures are summarized in Table 2.

RESULTS

Complications observed during endovascular procedures were treated with endovascular methods and successful results were reported in all the cases. No procedure was reverted to open surgical operation and no mortality was observed. The patients were discharged on days 1-16 (mean of 3.4 days). Patients were followed-up after the procedure for at least six hours in the intensive care unit under anticoagulation therapy (1000 U/hour heparin infusion). Subsequently, anticoagulation was achieved with low molecular

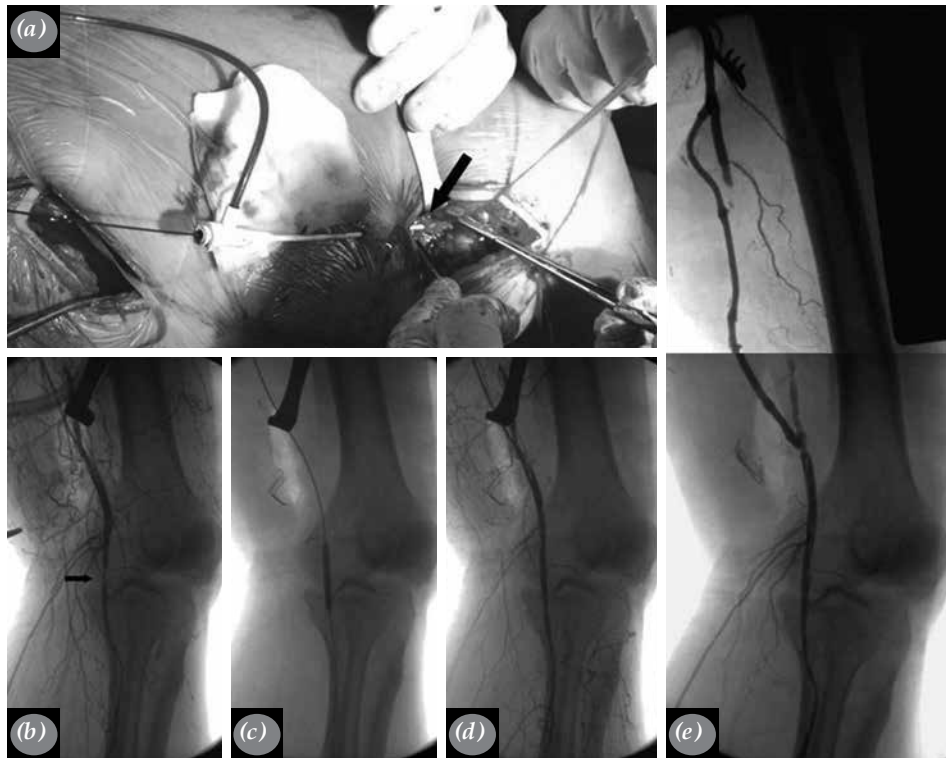


Figure 3. In a diabetic foot; surgery for lesions above the knee, and hybrid revascularization therapy with the endovascular approach for lesions below the knee: Use of proximal popliteal artery prepared for distal anastomosis of fem-pop bypass, as a conduit artery for endovascular approach under surgical visualization (black arrow) (a), Sequential angiographic images of the critical lesion (b), applied balloon angioplasty (c), followed by vessel patency (d) in the distal popliteal artery below the knee. Fem-pop bypass and distal flow imaging in the angiogram obtained following completion of the hybrid procedure (e).

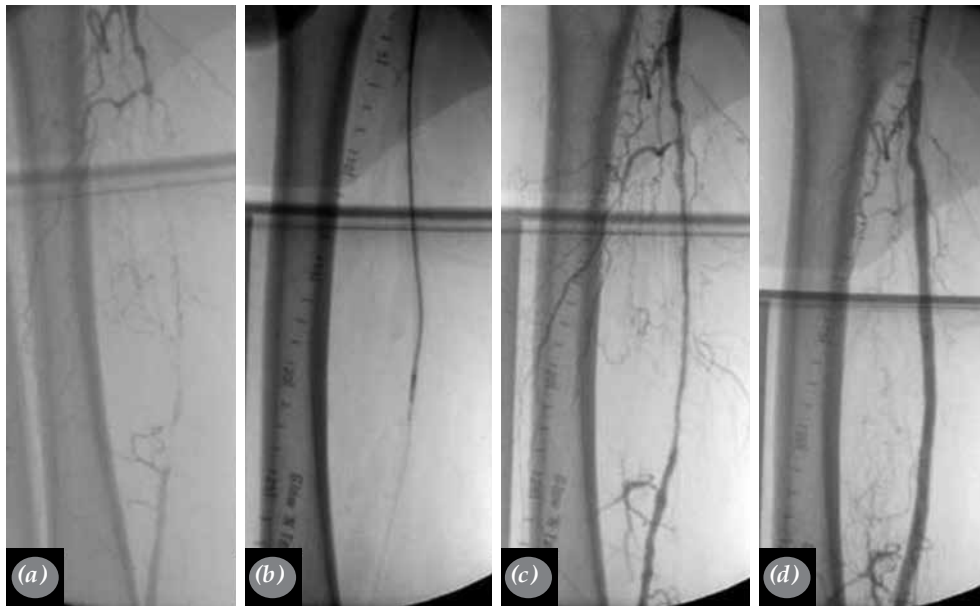


Figure 4. (a) Total occlusion of the right SFA lesion in a diabetic patient. (b) Access of the lesion with total occlusion guide wire. (c) Post excision of plaques with atherectomy blade. (d) Angiographic images obtained after stent placement in a partially opened lesion.

weight heparin for three days followed by double oral antiaggregant (100 mg acetylsalicylic acid + 75 mg clopidogrel).

Patient follow-up

Patients were closely followed-up, with regards to complication or procedural success, by manual palpation and with the auditory Doppler device to detect distal peripheral pulses of the extremity in question. On the first postoperative day, ankle brachial indexes were measured and compared with preoperative ones. Patients did not have stent restenosis or balloon-assisted restenosis during color Doppler USG follow-ups performed daily during the hospitalizations and at the first week's follow-up visits.

Complications

Encounters during the procedure: Treatment was completed by a second procedure in the two patients with covered-stent placement following the detection of rupture and/or suspicion of dissection on the follow-up angiogram, which was performed after stent implantation to superficial femoral artery stenosis.

Encounters during clinical follow-ups: The mild elevation in urea and creatinine levels observed in half of the patients was corrected by hydration and no serious kidney failure was observed in any of the

patients with normal preoperative renal function. Patients on chronic hemodialysis were directed to the dialysis unit a day before the procedure and subjected to hemodialysis. Excess hydration was prevented during the procedure and during the subsequent follow-ups. Hemodialysis was performed on the first postoperative day on patients detected with indications, by contacting the dialysis unit and nephrology clinic.

Non-diabetic atherosclerotic arterial lesions are observed at the level of the iliac and femoropopliteal bifurcation regions; arterial lesions in diabetic patients are predominantly in the region below-knee. The main causes of non-diabetic atherosclerosis are; hypertension, hyperlipidemia and cigarette smoking. Considering the fact that atherosclerosis could affect all arterial structures including the coronary and carotid systems of the body, the procedure was performed after obtaining cardiology views and recommendations particularly in high-risk patients. Patients with coronary disease who underwent endovascular treatment for peripheral arteries after performing endovascular or surgical treatment for coronary artery disease were taken in for the procedure, after detecting coronary angiographic lesions and their severity when necessity during coronary screening tests. All patients were scanned with carotid artery Doppler USG before the procedure.

DISCUSSION

Endovascular and hybrid applications remain the first choice in the treatment of peripheral arterial disease, with every day increases in success rates. We always first offer the opportunity of obtaining endovascular intervention, if possible, at every stage of the treatment for patients who visit our clinic. As cardiovascular surgeons, our primarily aim is treatment with minimal invasive approaches, thanks to the hybrid endovascular hall in our clinic. The biggest problem we face in this regard is to overcome the unfamiliarity with angiographic procedures, despite our advanced experience in vascular disease and surgical treatment. We believe that we have come a long way, with the diversity of our sample size and application techniques, and hence wish to share our experiences.

Our aim in the treatment of peripheral arterial diseases is primarily to provide endovascular treatment and, in some cases, complete recovery with the help of open surgery. Hybrid approaches are becoming more and more available due to the presence of treatment opportunities for the management of multiple-level arterial disease completely and in a single treatment session. Advantages of hybrid therapy performed during the same treatment session include; short hospital stay, no delay in complete revascularization (no progression of ischemia), and low cost.^[4] The most important reason for this choice in patients undergoing a progressive hybrid procedure is the presence of chronic renal failure or general health state impairment.

In stenotic or occlusive diseases, percutaneous transluminal balloon angioplasty and/or endovascular stent implantation applied to multiple consecutive lesions was sufficient for revascularization in most patients. Percutaneous intervention alone was used to treat 73 (83%) of 90 patients with peripheral artery disease (82 lower extremity, 8 upper extremity), whereas complete revascularization was achieved through the addition of fem-pop bypass in 11 of these patients.

Peripheral artery diseases were mainly localized in the iliofemoral region (74%; 72/97). Percutaneous transluminal angioplasty is considered a permanent and reliable method in cases isolated iliac artery stenosis. Femoropopliteal angioplasty has also been reported to be successful in patients with claudication with focal lesions; however, long-term results are currently unsatisfactory.^[5]

With the widespread use of small diameter vessel balloons and guide wires, infrapopliteal angioplasty has

become a suitable alternative in selective cases. Results of the study showed that percutaneous transluminal angioplasty can be used in the majority of diabetic patients with pedal ulcerations and it is effective in foot revascularization.^[6] However, multilevel occlusive diseases with inadequate distal run-off have been reported in most limb salvage cases. Percutaneous transluminal angioplasty may be inadequate for simultaneous intervention in all of these lesions.

Hybrid treatment strategy with intraoperative femoral balloon angioplasty combination prior to distal bypass offers many advantages such as saphenous vein preservation, maintenance of small incision wound and needless for an incision parallel to the ankle.^[7]

The success rate of endovascular treatment in 62 patients with traumatic peripheral arterial injuries involving the femoral, iliac and subclavian arteries was reported as 94%.^[8] Treatment of patients with traumatic arteriovenous fistula and arterial pseudoaneurysms (two superficial femoral arterial-venous fistulas, one brachial artery pseudoaneurysm, one axillary artery rupture); with endovascularly implanted covered stent was reported to be possible. Endovascular coiling was also performed a patients detected with traumatic anterior tibial artery pseudoaneurysm. Endovascular aortobiliac stent-graft implantation was performed in three patients with iliac artery aneurysm which included the distal aorta, another case using a covered stent-graft.

The success of endovascular applications in lesions of the artery feeding the lower extremity depends on the localization of the stenotic segment, and the degree and length of the stenosis.^[9] Although the long-term patency of the stents used for iliac artery lesions is reported to be good, the same success rate has not yet been achieved in the distal region. Similar results were obtained in our study.

Many studies have been published in the past 15 years concerning peripheral endovascular and hybrid interventions, with very high technical success and low early-to-mid-term morbidity-mortality rates.^[4] About 18% of our patients (17/103) required application of the hybrid procedure. This shows that, although endovascular interventions can be performed in the halls where only angiographic procedures are undertaken, a surgical infrastructure is necessary for complementary treatment in patients with peripheral arterial diseases.^[10] At the same time, the vascular experience of cardiovascular surgeons makes it possible to apply more radical and complementary therapies during endovascular procedures. Present day vascular

surgeons, who are in their graceful years, should continuously engage in improving their experience in both open and endovascular revascularization techniques. We believe that materials used on patients who participate in the study should not be obtained from a single company; this would help us gain more experience in terms of increasing familiarity with the various materials from different companies.

Developments such as subintimal advanceable guidewires, drug-coated and lytic stents in endovascular procedures will also provide treatment opportunities in larger patient populations. However, severe renal failure which develops due to diabetic nephropathy still remains as the most difficult comorbidity factor to be overcome for angiographic procedures in this group of patients.

Graft occlusion, which appears as a long-term complication of peripheral artery surgery, can easily be overcome with the developing endovascular opportunities and hybrid skills. In a case published in 2015 by Badak *et al.*,^[11] patency of the occluded aortobifemoral graft was provided by atherectomy, and the additional infragenicular saphenous vein bypass and hybrid approach was completed, ensuring vascularity of the ischemic extremity.

Success of the operation could not be determined in those who were scheduled for amputation since this was not a comparative study. Furthermore, the decision to lower the level of amputation was not clarified due to the operation performed.

In conclusion, we suggest that minimally invasive techniques can be used as a convenient and safe method in the majority of peripheral artery diseases. Additional surgical interventions and hybrid techniques may also be used for complete treatment, when necessary, during the same procedural session or within a short period of time. However, it is necessary to establish hybrid endovascular operations in all cardiovascular surgery departments in the near future and rapidly spread the experience for these procedures, which are of great comfort to both patients and surgeons.

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