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■ Original Article

Hybrid strategy in iliac artery disease and infrainguinal arterial occlusive disease

İliyak arter ve infrainguinal arter tıkkayıcı hastalığında hybrid strateji

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ABSTRACT

Aim: The treatment of peripheral arterial disease has encompassed different therapy options. Hybrid therapy method (endovascular treatment plus surgery) has recently been used in lower extremity arterial disease. This study has examined hybrid therapy practice in iliac and infrainguinal arterial disease.

Materials and Methods: This study included 76 patients with occlusive iliac artery disease and performed iliac artery endovascular treatment from January 2010 to August 2015. While 56 patients underwent only iliac artery stenting, 20 of 76 patients underwent additionally infrainguinal vascular surgery (hybrid therapy).

Results: In 20 hybrid patients group, iliac artery lesion length was 31.0 ± 7.6 mm. Seven patients had TASC-II A iliac artery class, while 13 patients had TASC-II B class. According to femoropopliteal lesions, eight patients had TASC-II C, while 12 patients had TASC-II D. One patient died in postoperative period. Graft stenosis developed in one patient, which was resolved through catheter therapy. In the one-year follow-up, in one patient, iliac stent restenosis developed, ABI was 0.91 ± 0.20 .

Conclusion: Hybrid therapy is a feasible option for multilevel lower extremity artery disease, including iliac artery disease and TASC-II C or D femoropopliteal disease. This technique has favorable patency with lower complication rates.

Keywords: Iliac arterial disease, infrainguinal arterial disease, hybrid therapy

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ÖZ

Amaç: Periferik arter hastalığının tedavisi farklı tedavi seçeneklerine sahiptir. Son zamanlarda hibrid tedavi yöntemi (endovasküler tedavi artı cerrahi) alt ekstremitte arter hastalığı tedavisinde kullanılmaktadır. Bu çalışmada iliyak arter ve infrainguinal periferik arter hastalığında hibrid tedavi incelenmiştir.

Gereç ve Yöntemler: Bu çalışma Ocak 2010 ile Ağustos 2015 yılları arasında tıkalı iliyak arter hastalığı olan ve endovasküler tedavi yapılan 76 hastayı içermektedir. 56 hastaya sadece iliyak arter endovasküler tedavi uygulanırken, 20 hastaya iliyak arter endovasküler tedaviye ilave infrainguinal vasküler cerrahi uygulanmıştır.

Bulgular: Yirmi hibrid tedavi kolunda, iliyak arter lezyon uzunluğu $31,0 \pm 7,6$ mm idi. Yedi hasta TASC-II A iliyak arter sınıfında iken, 13 hasta TASC-II B iliyak sınıfında idi. Femoropopliteal lezyonlara göre 8 hasta TASC-II C, 12 hasta TASC-II D. Bir hasta postoperatif dönem öldü, bir hastada greft tıkanıklığı gelişti ve kateter yöntemi ile tedavi edildi. Takipte bir hastada iliyak arter stent tıkanıklığı gelişti. Bir yıllık takipte ayak bileği/ kol sistolik basınç oranı $0,91 \pm 0,20$ idi.

Sonuçlar: Hibrid tedavi iliyak arter ve infrainguinal arter hastalığını içeren çoklu alt ekstremitte arter hastalığında uygun bir tekniktir. Bu teknik daha az komplikasyon oranlı açıklık oranına sahiptir.

Anahtar Kelimeler: İliyak arter hastalığı, infrainguinal arter hastalığı, hibrid tedavi

Introduction

The treatment of peripheral arterial disease has encompassed different therapy options. One of these options, hybrid therapy (endovascular treatment plus surgery) has recently been used in lower extremity arterial disease. The outcomes of the patients with the hybrid therapy in terms of complication rates has improved [1]. The treatment procedure for iliac artery disease used to be surgical repair, however, today endovascular management therapy has been a priority because of its procedural success and long-term efficacy [2-5]. On the other hand, surgical revascularization is superior to endovascular therapy in patients according to TransAtlantic Inter-Society Consensus (TASC II) C and D femoropopliteal disease [3]. In the practice of the interventional cardiology and vascular surgery team, true hybrid therapy choice can be made. This study has examined hybrid therapy practice in iliac and infrainguinal arterial disease.

Materials and Methods

This retrospective study was performed of all consecutive patients underwent endovascular therapy or hybrid treatment between January 2010 and August 2015. We declare that the study was performed in accordance with the ethical standards laid down in the Helsinki Declaration of 1975, as revised in 1983. There were 76 patients with occlusive iliac artery disease and they were performed iliac artery endovascular treatment. While 56 patients were performed only iliac artery stenting, 20 of 76 patients underwent additionally infrainguinal surgery (hybrid therapy group).

The primary criterion used for the inclusion of the patients in the study was TransAtlantic Inter-Society Consensus (TASC II) A and B iliac occlusive disease. 20 patients underwent by-pass surgery according to Trans-Atlantic Inter-Society Consensus (TASC)-II C and D femoropopliteal lesions [3]. Hybrid therapy group (20 patients) underwent both iliac endovascular therapy and lower extremity surgical treatment.

The patients exhibited clinical signs and symptoms of peripheral arterial disease (PAD) such as pain localized in the buttock or thigh, diminished pulsation of the femoral artery and/or popliteal artery and reduced ankle brachial index (ABI). The symptoms were recorded according to the Fontaine classification. The patients had a baseline percentage diameter stenosis of at least 80% in iliac arteries at the target lesion in angiography and 100% stenosis in superficial or popliteal artery.

All of the patients' demographics, and baseline characteristics were shown in Table 1. On the other hand, stenting in the hybrid therapy group (Table 2) was selectively performed in the left common iliac artery in (35%), right common iliac artery (35%), left external iliac artery (15%), right external iliac artery (5%), and combined common and external iliac artery (10%).

The study excluded patients with aortic thrombosis, concomitant abdominal aortic or iliac aneurysms, concomitant visceral artery revascularization, and acute limb ischemia, traumatic etiology.

Table 1. Baseline clinical characteristics of Iliac artery endovascular treatment patients

Age (years)	63.6 ± 7.6	
Ankle brachial index	0.72 ± 0.08	
BMI (kg/m ²)	26.0 ± 4.7	
	n (%)	
Female	19 (25)	
Current smoker	59 (76.6)	
Quitting smoking after procedure	32 (41.5)	
Hypertension	49 (63.6)	
Diabetes Mellitus	38 (49.3)	
Hyperlipidemia	22 (28.5)	
Known CAD	24 (31.1)	
Previous CVA	14 (18.1)	
Atrial Fibrillation	16 (20.7)	
Fontaine Classification	Stage IV	45 (58.4)
	Stage III	32 (41.5)
Chronic renal failure (serum creatinine >2 mg/dl)	11 (14.2)	
ACE/ARB	40 (51.9)	
Beta-blockers	22 (28.5)	
CaCB	35 (45.4)	
Diuretics	18 (23.3)	
Statin	58 (58.4)	
Aspirin	68 (88.3)	
Cilostazol	38 (49.3)	
Pentoxifylline	24 (31.1)	
Clopidogrel	37 (48)	
Warfarin	15 (19.4)	

BMI: body mass index, CAD: coronary artery disease, CVA: cerebrovascular accident, ACE/ARB: angiotensin converting enzyme inhibitor/angiotensin receptor blocker, CaCB: calcium canal blocker

Table 2. Hybrid therapy interventions (n=20)

Iliac lesion length (mm)	31.0 ± 7.6
	n (%)
Location of iliac lesion	
Left common iliac	7 (35%)
Right common iliac	7 (35%)
Left external iliac	3 (15%)
Right external iliac	1 (5%)
Common and external iliac	2 (10%)
Surgery	
Femoropopliteal bypass above knee	8 (40%)
Femoropopliteal bypass infragenual	8 (40%)
Femoropopliteal bypass tibial	2 (10%)
Femoropopliteal bypass below knee - composite	2 (10%)
TASC-II iliac artery disease	IIA 7 (35%) IIB 13 (65%)
TASC-II femoropopliteal disease	C 8 (40%) D 12 (60%)

Endovascular Treatment

Balloon-expandable stents (either Abbott Vascular, which is L-605 Cobalt alloy stents or Cordis-Palmaz Genesis, which is 316L stainless steel stents) or self-expandable nitinol stent were used for all of the iliac artery disease. They were given clopidogrel (600 mg) and aspirin (300mg) 6 hours before the procedure. On the following day, the patients continued to take aspirin 100 mg and clopidogrel 75 mg once day.

Iliac stent intervention was performed with contra-lateral crossover approach (32 patients in 76 the patients) or with retrograde approach (44 patients in 76 the patients) through femoral arterial access. During the procedure, an eight French (8 Fr) sheath was placed in the common femoral artery using by Seldinger technique. Then, a catheter (right Judkins, Boston Scientific) was advanced around the aorto-iliac bifurcation and advanced in an antegrade fashion through the contra-lateral iliac system and positioned with its tip proximal to the target lesion. Alternatively, direct retrograde approach was used as a way through femoral artery. The stent-balloon assembly was positioned at the site of the intended intervention and the stent was deployed by means of inflating the balloon. The stent diameter was determined according to the width of the disease-free portion of the vessel. Balloon-expandable stent through 0.035 extra-stiff guide-wire (Terumo) was implanted in the target lesion nominal average 8 atm.

The procedural success was 100%. Pre-stent and post-stent region gradient was found to be less than 5 mmHg after the procedure. That is, none of the patients was identified with hemodynamically significant gradient.

Hemodynamic success was defined as an increase of the ABI of 0.10 or more during the whole follow-up period compared with the value at the pre-treatment assessment. Patency of the iliac artery segment treated in the study was defined as a peak systolic velocity ratio of less than 2.5 at duplex ultrasound [6].

Surgical Therapy

Surgical repair was added to endovascular procedures on 20 of the patients. Femoropopliteal bypass were performed on each patient. Eight of the patients were TASC -II C and 12 were TASC II D. Severe intermittent claudication in active patients were the indications of concomitant surgical treatment. Eight of these patients with TASC II -C group were treated by above knee femoropopliteal bypasses with prosthetic grafts (PTFE grafts). Eight patients on TASC II -D group were classified as critical limb ischemia. These patients were treated by infragenual femoropopliteal bypasses with reversed autogenous saphenous veins.

Two patients with severe foot ulcers on group TASC -D had sequential grafting on femoropopliteal to posterior tibial artery. Two patients on the same group had composite grafts, because of lack of adequate length of autologous vein. Composite grafts consist of combined proximal prosthetic (PTFE) graft with a saphenous vein graft.



Follow-up Protocol

Follow-up visits were conducted within one-month, 3 months, 6 months and one-year periods. During the visits, symptoms interrogation (according to Fontaine classification), vascular examination (ankle brachial index), and Doppler ultrasound were performed. If need, angiography were performed.

Statistical Analysis

Patient characteristics and outcomes of the patients were investigated. The categorical data percentages and continuous variables were presented as mean ± standard deviation (SD). All data were analyzed using SPSS 13.0 software for Windows (SPSS, Chicago, IL, USA). A P < 0.05 was considered statistically significant.

Results

In hybrid group, heart failure developed in two patients with CABG, but this improved by medical therapy. Postoperative myocardial infarction was not observed. Acute graft failure developed in one patient, which died in postoperative period due to metabolic problems. Wound infection occurred in one patient, which got better by medical therapy.

In iliac artery stent patients, iliac artery lesion length was 31.0 ± 7.6 mm. Seven patients had TASC-II A iliac artery class, while 13 patients had TASC-II B class. In infrainguinal surgery patients, eight patients had TASC-II C, while 12 patients had TASC-II D. In the one-year follow-up, ABI was 0.91 ± 0.20 .

The most frequently applied hybrid procedure was a combination of femoropopliteal bypass and iliac stenting. The procedural success was 100% in iliac stenting.

The complications included myocardial infarction, stent restenosis, acute graft failure, subacute graft stenosis, heart failure, and wound infection (Table 3).

	n
Myocardial infarction	1
Stent restenosis	1
Acute graft failure	1
Subacute graft stenosis	1
Heart failure	2
Wound infection	1

In the follow-up, in the first month after the intervention, ABI was found to be 0.91 ± 0.20 . In symptom assessment, one patient had leg pain complaint. Graft stenosis developed in one patient. We found femoropopliteal bypass graft subacute occlusion and thus thrombus aspiration via Fogarty catheter was performed. Iliac artery stent restenosis developed in one patient. In the second visit, (11 ± 2 months) Doppler ultrasound was performed. One patient died of congestive heart failure. This study showed that primary patency rate at 12 months was 90% (Table 4).

Revascularization	1
Restenosis	1 (graft), 1 (stent)
Ankle brachial index	0.91 ± 0.20
Artery patency	90%
Death	1

Discussion

With the advent of endovascular techniques, the majority of the patients with iliac artery occlusive disease are being treated with minimally invasive techniques with excellent outcomes [7]. The Dutch Iliac Stenting Trial (DIST) is the only prospective randomized trial compared to primary stenting versus primary PTA. The DIST researchers showed that stent placement following PTA leads to better symptomatic success in the short run than in the cases with PTA only. Thus, in the long run, primary stent placement results in less re-intervention and fewer complication rates. Balloon-expandable stents (Palmaz; Johnson and Johnson Interventional Systems, which is stainless steel stent) were used in DIST. One-year patency rate of iliac stenting was roughly 90% [8]. A prospective, multicenter study stated that the balloon-expandable Assurant cobalt chromium iliac stent demonstrated sustained patency with obvious improvements. This study showed that primary patency rate during a 9-month period was 99.2% [9]. The outcomes of two different self-expanding stents for the treatment of iliac artery lesions were compared in a multicenter prospective randomized trial. The one-year primary patencies were 94.7% and 91.1%, respectively [10].

Studies have shown that long-term patency rates following endovascular intervention is the highest in common iliac artery lesions, and the lower the diseased region is, the more progressively the long-term patency rates decrease at the lower extremity arterial vasculature [11].

Some studies stated that the primary patency rate of bypass surgery was considerably higher than endovascular treatment in femoropopliteal arterial diseases [12,13]. The endovascular treatment can be the first choice in the case of poor condition [14]. The endovascular treatment achieved an immediate improvement in the quality of life, but this effect was not maintained in the long term [15]. With TASC II-C and D lesions, bypass surgery with a vein graft remains the best treatment for infrainguinal PAD [3]. Long-term graft patency depends on the quality of the inflow and outflow vessels and the conduit available [19]. Continuous, high quality, autogenous greater saphenous vein signifies the optimum conduit [20].

Recently, hybrid therapy (endovascular treatment plus surgery) has been used in lower extremity arterial disease. The hybrid therapy has several advantages including complete revascularization, reduced hospitalization, and reduced

complication rates. Ideally, the vein bypass is performed distally, and the proximal lesions are treated endovascularly [19]. At present, different hybrid therapy techniques have been used. Dosluoglu et al. noticed using at least 10 different types of hybrid procedures in completing 108 hybrid interventions [16]. In another study, 171 patients underwent common femoral artery endarterectomy and iliac stenting [17]. In that study, technical success rate was 98%. Thirty-day mortality was 2.3%. Aho and Venermo have indicated that the annual number of hybrid therapy has been growing [18]. The significant heterogeneity of interventions do not allow for comparing their outcomes with results of open or endovascular treatment [19]. However, hybrid therapy seems to be developing, and cardiology and vascular surgery together will play a notable role in the management of lower extremity artery disease. In the current study, eight of the patients were treated by infragenual femoropopliteal bypasses with reversed autogenous saphenous veins. Two patients had sequential grafting on femoropopliteal to posterior tibial artery. Two patients had composite grafts. Technical success was 100%. In the one-year follow-up, primary patency was 90%. Complication rate was seen significantly lower.

Our study has some limitations. This study is a retrospective, nonrandomized study, thus, regular follow-up is extremely difficult.

In conclusion hybrid therapy is a feasible option for multilevel lower extremity artery disease, including iliac artery disease and TASC-II C or D femoropopliteal disease. This technique has favorable patency with lower complication rates.

Declaration of conflicting interests

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References

1. Dosluoglu HH, O'Brien-Irr MS, Lukan J, Harris LM, Dryjski ML, Cherr GS. Does preferential use of endovascular interventions by vascular surgeons improve limb salvage, control of symptoms, and survival of patients with critical limb ischemia? *Am J Surg* 2006; 192: 572-6.
2. Lam C, Gandhi RT, Vatakencherry G, Katzen BT. Iliac artery revascularization: overview of current interventional therapies. *Interv Cardiol* 2010; 2: 851-9.
3. Norgren L, Hiatt WR, Dormandy JA, et al. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg* 2007; 45(Suppl.S): S5
4. Faries P, Morrissey NJ, Teodorescu V, et al. Recent advances in peripheral angioplasty and stenting. *Angiology* 2002; 59: 617-26.
5. Rosanio S, Tocchi M, Uretsky BF, Stouffer GA. Use of intraluminal stents in the treatment of carotid, renal and peripheral arterial disease. *Am J Med Sci* 2000; 319: 575-96.
6. Spijkerboer AM, Nass PC, de Valois JC, et al. Iliac artery stenoses after percutaneous transluminal angioplasty: follow-up with duplex ultrasonography *J Vasc Surg* 1996; 23: 691-7
7. Selvin E, Erlinger TR. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000. *Circulation* 2004; 110: 738-43.
8. Klein WM, Graaf YVD, Seegers J, et al. Dutch Iliac stent trial: Long-term results in patients randomized for primary or selective stent placement *Radiology* 2006; 238: 734-44.
9. Molnar RG, Gray WA; ACTIVE Trial Investigators. Sustained patency and clinical improvement following treatment of atherosclerotic iliac artery disease using the Assurant cobalt iliac balloon-expandable stent system. *J Endovasc Ther* 2013; 20: 94-103.
10. Ponc D, Jaff MR, Swischuk J, Feiring A, Laird J, Mehra M. The Nitinol SMART stent vs Wallstent for suboptimal iliac artery angioplasty: CRISP-US Trial results. *J Vasc Interv Radiol* 2004; 15: 911-8.
11. Dieter RS, Laird JR. Overview of restenosis in peripheral arterial interventions. *Endovascular Today* 2004; 10: 36-8.
12. Siracuse JJ, Giles KA, Pomposelli FB, et al. Results for primary bypass versus primary angioplasty/stent for intermittent claudication due to superficial femoral artery occlusive disease. *J Vasc Surg* 2012; 55: 1001-7.
13. Twine CP, McLain AD. Graft type for femoro-popliteal bypass surgery. *Cochrane Database Syst Rev* 2010; 12: CD001487. doi: 10.1002/14651858.CD001487.pub2.
14. Miura T, Soga Y, Aihara H, Yokoi H, Iwabuchi M. Prevalence and clinical outcome of polyvascular atherosclerotic disease in patients undergoing coronary intervention. *Circ J* 2013; 77: 89-95.
15. Aihara H, Soga Y, Mii S, et al. RECANALISE Registry Investigators. Comparison of long-term outcome after endovascular therapy versus bypass surgery in claudication patients with Trans-Atlantic Inter-Society Consensus-II C and D femoropopliteal disease. *Circ J* 2014; 78: 457-64.
16. Dosluoglu HH, Lall P, Cherr GS, Harris LM, Dryjski ML. Role of simple and complex hybrid revascularization procedures for symptomatic lower extremity occlusive disease. *J Vasc Surg* 2010; 51: 1425-1435.e1.
17. Chang RW1, Goodney PP, Baek JH, Nolan BW, Rzucidlo EM, Powell RJ. Long-term results of combined common femoral endarterectomy and iliac stenting/stent grafting for occlusive disease. *J Vasc Surg* 2008; 48: 362-7.
18. Aho PS1, Venermo M. Hybrid procedures as a novel technique in the treatment of critical limb ischemia. *Scand J Surg* 2012; 101: 107-13.
19. Slovut DP1, Lipsitz EC. Surgical technique and peripheral artery disease. *Circulation* 2012; 126: 1127-38.
20. Pereira CE, Albers M, Romiti M, Brochado-Neto FC, Pereira CA. Meta-analysis of femoropopliteal bypass grafts for lower extremity arterial insufficiency. *J Vasc Surg* 2006; 44: 510-7.