

Original Article

Hybrid-based approach for pervasive occlusive disease of iliofemoral arteries

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Abstract

Aim: Simultaneous multilevel hybrid-based reconstructions using both endovascular and open femoral endarterectomy merit the interest with the widespread adoption of these techniques by vascular surgeons. Here we presented our experience on hybrid-based approach to treat total occlusive iliofemoral lesions and study the technical success and mid-term results of combined femoral endarterectomy and endovascular treatment of iliac occlusion.

Material and Methods: This retrospective single center study included patients with only total occlusion in the unilateral iliac artery. The patients underwent hybrid procedure—open femoral endarterectomy and endovascular revascularization of the external or common iliac artery—between 2016 and 2022. Statistical analysis was performed by using SPSS software version 25.

Results: Totally 103 patients who underwent hybrid procedures for pervasive unilateral iliac artery occlusions were included in this study. Of the study cohort, 76% were male patients with a mean age of 74 ± 8.7 years. Technical success rate was 89.3%. Acute myocardial infarction was the most common complication. The 30-day mortality was 7.8% (n=8) and all of them were in-hospital deaths. The survival rates of this cohort at 30 days, 6 months and 12 months were 92.2%, 88.1% and 83.7%, respectively. The primary patency at 30 days, 6 months, and 12 months were 98.1%, 96.6%, and 93.7%, respectively.

Conclusion: The clinical and technical outcomes in this study suggest that the hybrid approach to pervasive iliofemoral occlusions, combining femoral endarterectomy and endovascular iliac revascularization, is an effective and applicable treatment in terms of patency rates and perioperative complications.

Keywords: Hybrid procedure, open femoral endarterectomy, endovascular revascularization, iliac artery

INTRODUCTION

Peripheral arterial diseases (PAD) including extensive lesions of iliofemoral arteries due to chronic occlusive atherosclerosis can lead to reduced quality of life with symptoms such as mild claudication, and also chronic limb-threatening ischemia. Although the standard revascularization approach is open surgical bypass, currently, primary endovascular interventions are the most common modality for iliofemoral occlusive disease [1].

However, chronic total occlusive (CTO) lesions of common femoral artery are not always appropriate for only endovascular revascularization because of anatomical difficulty including high risk of in-stent restenosis and thrombosis of deep femoral artery [2]. The results of endovascular recanalization are promising, but in case of extensive femoral bifurcation lesions, open endarterectomy can be crucial [3]. Therefore, nowadays, simultaneous multilevel hybrid-based reconstructions using both endovascular and open femoral endarterectomy merit the interest with the widespread adoption of these techniques by vascular

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surgeons, in treating transatlantic inter society consensus (TASC) II classification C and D type lesions with favorable outcomes. European Guidelines on Peripheral Artery Diseases (2017) also support a hybrid approach in iliofemoral lesions [4].

These techniques allow for eliminating the patency difference between open and endovascular approaches. A report demonstrated that the short-term outcomes of treating aforementioned lesions by using hybrid intervention are acceptable with 95% primary patency at 13 months [5]. Besides these, hybrid-based approach provides benefits in terms of less complications, length of hospital stay and surgical trauma.

Here we presented our experience on hybrid-based approach to treat total occlusive iliofemoral lesions and study the technical success and mid-term results of combined femoral endarterectomy and endovascular treatment of iliac occlusion.

MATERIAL AND METHODS

Data Collection

This single center retrospective observational study included patients who underwent a hybrid procedure—open femoral endarterectomy and endovascular revascularization of the external or common iliac artery—between January 2016 and December 2022 by using local electronic medical database, retrospectively. Patients with only total occlusion in the unilateral iliac artery were selected, based on computer tomography angiography scans and digital subtraction angiography. Patients were not included if there was a history of iliac and femoral artery interventions and aortic lesion requiring intervention. Patients with an ankle-brachial index (ABI) higher than 1.0 were not included in this study. Eligible patients had been suffering from moderate intermittent claudication to diffuse pedal ischemia according to the Rutherford classification (Class 2 to 5). A written informed consent was obtained from each patient. The study protocol was approved by the local ethics committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

All clinical, perioperative, and demographical data were obtained through review of original hospital and physician records. Demographics and clinical data include age, gender, smoking status, diabetes mellitus, hypertension, hyperlipidemia, chronic renal insufficiency, hemodialysis, chronic obstructive pulmonary disease, coronary artery disease, cerebrovascular disease, chronic atrial fibrillation, antiplatelet and statin use.

The primary outcomes of this study were technical success (no more than 30% residual stenosis in the final angiogram), 30-day morbidity, mortality and patency. Our secondary outcome measures were changes in ABI and freedom from amputation.

Operative Technique

All operations were performed by a vascular surgeon in a hybrid

operating room with a C-arm (GE Medical Systems SCS, 283 Rue, De La Miniere, 78530, BUC, France). Under general anesthesia, open surgical endarterectomy was performed after endovascular surgical procedure. Femoral artery exposure was obtained via groin approach. After full heparinization, according to the surgeon's discretion, contralateral or ipsilateral common femoral artery (CFA) or superficial femoral artery (SFA) puncture was first performed with 18-gauge needle and subsequent placement of a 6F sheath to get guidewire access. In few cases, brachial artery access was used. Graft stents (GSs) or bare metal stents (BMSs) were used for treating the iliac lesions. Following the iliac artery revascularization, femoral arteriotomy, and then standard endarterectomy was performed from femoral bifurcation extending as proximally as possible up to the external iliac artery and at least 2 cm above the proximal edge of the arteriotomy, in order to make possible the iliac stent to cover the proximal end of the endarterectomy to maintain a safe zone in terms of stenosis, except for shorter lesions of iliac arteries. Great attention was paid to ensuring preservation or restoration of the origin of the deep femoral artery, also its outflow. Bovine pericardium (Edwards Lifesciences Services GmbH, Edisonstrasse 6, 85716 Unterschleissheim, Germany) or Dacron (Intervascular SAS, ZI Athelia 1, 13705, La Ciotat Cedex, France) patch was used for femoral artery patch angioplasty. Prosthetic femorofemoral or aortofemoral bypass was performed for unsuccessful revascularizations. Figure 1 and Figure 2 illustrated the representative DSA images of patients having this type of procedure.



Figure 1. Angiogram image of patient, before hybrid revascularization, common and proximal part of external iliac artery are occluded



Figure 2. Angiogram image of patient after endovascular in-flow revascularization and common femoral artery endarterectomy

Statistical Analysis

Statistical analysis was performed by using SPSS Statistics software, version 25 (IBM). Power analysis was conducted and the actual sample size needed for this study was determined. Simple random sampling was used. The results of descriptive statistics were reported as mean±standard deviation (SD) or median (min-max). Categorical data were reported as frequencies and percentages. The Shapiro-Wilk test was used to check the normal distribution of continuous variables. Pearson’s Chi-square was used to assess categorical variables. Dependent group variables were compared by Wilcoxon test. A p value of <0.05 was considered to show statistical significance.

RESULTS

During the study period, 103 consecutive patients underwent hybrid procedures for unilateral extensive iliac occlusions. Of the study cohort, 76% were male patients with a mean age of 74±8.7 years. Hypertension and hyperlipidemia are the leading comorbidities with high incidence. Demographical data and lesion characteristics of the patients are shown in Table 1. The indication for surgery was critical limb ischemia (CLI) in 60.2% with the remainder having lifestyle-limiting claudication. Median length of hospital stay was 3 days (range, 1-39 days). Median operation time was 251 minutes (range, 56-425 minutes). The procedural characteristics were detailed in Table 2.

The technical success rate was 89.3%. In 11 cases, recanalization

was not achieved successfully and converted into an open procedure including 10 femoro-femoral cross-over bypasses and 1 iliofemoral bypass due to EIA rupture. No other immediate rupture or dissection was observed.

Table 1. Patient demographics and lesion characteristics, n (%) or mean (sd)	
Age (years)	74 (8.7)
Men	69 (61.2)
Active smoking	72 (69.9)
Comorbidity	
Diabetes mellitus	42 (40.8)
Hypertension	68 (66.1)
Hyperlipidemia	79 (76.7)
Chronic renal insufficiency	10 (9.7)
Chronic obstructive pulmonary disease	31 (30.1)
Coronary artery disease	47 (45.6)
Cerebrovascular disease	12 (11.6)
Chronic atrial fibrillation	13 (12.6)
Antiplatelet therapy	41 (39.8)
Statin use	29 (28.2)
NHYA Class	
I	10 (9.7)
II	66 (64.1)
III	21 (20.4)
IV	6 (5.8)
Rutherford classification	
2	20 (19.4)
3	21 (20.4)
4	30 (29.2)
5	23 (22.3)
6	9 (8.7)
TASC II classification of iliac artery	
C	22 (21.4)
D	81 (78.6)
Length of occlusion (mm)	89 (37.6)
Involvement of occlusion	
Common iliac artery	49 (47.6)
External iliac artery	87 (84.5)
Surgery timing	
Elective	83 (80.6)
Emergency	20 (19.4)

Table 2. Procedural characteristics n (%)

Recanalization access	
Retrograde	75 (81.6)
Antegrade (contralateral cross-over)	13 (14.1)
Antegrade (brachial)	4 (4.3)
Types of stent employed	
Bare metal stent	67 (72.8)
Graft stent	16 (17.4)
Both types	9 (9.8)
Location of stent	
Common iliac artery	19 (20.6)
External iliac artery	26 (28.3)
Combined	47 (51.1)

Complications within 30 days after procedure were shown in Table 3. Acute myocardial infarction (AMI) was the most common complication (n=10, 10.9%). Acute kidney insufficiency was seen in 3 patients and one of them needed temporary hemodialysis. Revision was performed for six patients with groin seroma and hematoma. Local infection was treated with surgical debridement and remainder with antibiotherapy. Acute thrombosis occurred in 5 cases and all of them recovered by emergency thrombectomy.

Table 3. Complications, n (%)

Acute myocardial infarction	10 (10.9)
Cerebrovascular event	2 (2.2)
Postoperative ventral hernia	1 (1.1)
Wound infection	5 (5.4)
Graft infection/erosion	1 (1.1)
Groin seroma	3 (3.3)
Groin hematoma	3 (3.3)
Pneumonia	2 (2.2)
Acute kidney insufficiency	3 (3.3)
Acute thrombosis	4 (4.4)

The 30-day mortality was 7.8% (n=8) and all of them were in-hospital deaths. Five of the deaths were due to AMI, whereas two were due to acute stroke and one was due to pneumonia. Perioperative death rate was higher in patients operated urgently. However, indications for surgery, surgery timing and Rutherford categories had no statistically significant correlation with mortality.

The mean follow-up duration was 14.8±8.9 months. All of the patients who had underwent hybrid procedure, could be evaluated with ABI measurements and duplex ultrasonography

(DUS), except deaths. Survival analysis demonstrated a survival of 92.2%, 88.1% and 83.7% at 30 days, 6 months and 12 months, respectively. Three symptomatic restenosis which were diagnosed by DUS, were revascularized with endovascular procedure. Six patients had limb claudication with iliac artery occlusion on follow-up. Four of them were recanalized with endovascular approach, but the remaining occlusions underwent bypass surgery. This delivers a primary patency of 98.1%, 96.6%, and 93.7% at 30 days, 6 months, and 12 months, respectively. There was a significant difference regarding primary patency between patients with GS and BMS, in favor of GS. Patient demographics or lesion characteristics were not found to be a predictor for patency, whilst reporting the lower patency rates of patients with longer target lesion.

The ankle-brachial index (ABI) measurements of patients were improved significantly on follow-up. The mean improvement in ABI was found as 0.25 (median, 0.28) (p<.001). Eighty-one patients (88.1%) required no further intervention. Freedom from amputation was at 30 days, 6 months and 12 months of 100%, 99.1% and 98.1%. One patient with claudication had minor tissue loss.

DISCUSSION

The goal of PAD treatment is to improve the quality of life of patients by relieving symptoms and providing limb salvage. This is a challenging issue especially for extensive iliofemoral occlusive disease. While endovascular interventions have a large share among conventional open surgical methods for treating iliofemoral occlusive disease, as it became preferred by cardiovascular surgeons [6], a new paradigm shift has emerged and paved the way for hybrid-based approach as open surgical femoral endarterectomy with endovascular in-flow recanalization [7]. The aim of this study was to further explain a less invasive procedure that has been approved safe in treating severe occlusions in iliac artery [4].

Recanalization of totally occluded iliac arteries is very arduous, therefore technical success rates can vary. In a recent study which reported the mid-term results of revascularization of chronic total occlusion of iliofemoral arteries, technical success rate of 95.5% was reported [8]. A large series with 713 patients who underwent either endovascular or hybrid revascularization denoted a technical success of 99.3% [9]. In this study, we found a technical success rate of 89.3% which is consistent with the study of Santos et al. which reported a success rate of 88.3% [5].

Current studies have reported a rising tendency for hybrid approaches with comparable patency rates to conventional open surgery [10]. We reported 12-month primary patency rates to be 83.7%. Similarly, Nelson et al. found a 1-year primary patency rate of 84% [11]. Another study revealed a two-year patency as 88.5% [12] 36-month primary patency rates were found to be

91% in a study which reported long term results of hybrid repair [10]. Limited number of studies published long term results and primary patency rates of other hybrid approaches were reported as 60% and 87% [13,14]. Previous publications included a higher ratios of patients with critical limb ischemia similar to our study [14]. Although patient symptom was not found to be a statistically significant predictor for patency, it may have an impact on patency rates. Multicenter studies agreed on improved patency for complex iliac occlusions when using GS versus BMS.

Wide range of symptoms at admission probably cause complication rates varying from 2% to 22% [13,15]. The proportion of patients with CLI is remarkably high in our study, nevertheless complications are not higher than previously published studies. Prolonged operative duration is an important risk factor for death and complications [16]. Operation duration of this study is in line with literature, although distal bypass surgery prolonged the duration of the procedure [7].

We found slightly high perioperative mortality as 7.8%. Patients' baseline characteristics could probably be responsible for this. Perioperative death rate was higher in patients operated on an emergency condition, but there was no statistical significance, contrary to literature [17].

A mean ABI improvement of 0.25 was reported in this study. This improvement reflected a hemodynamic successful intervention by reporting standards which are likely to correlate with the literature [18,19]. A prospective randomised trial showed a significant ABI improvement in all patients [20].

There are several limitations to this study. This is a single-center, retrospective study with a potential selection bias. Reporting ABI and toe pressure does not allow differentiation of infrainguinal disease from stent patency, and furthermore reflects the overall hemodynamics of the extremity. This study could not assess long-term outcomes.

CONCLUSION

In conclusion, the clinical and technical outcomes of this study propose that the hybrid approach to pervasive iliofemoral occlusions, combining femoral endarterectomy and endovascular iliac revascularization, is an effective and applicable treatment in terms of perioperative complications and patency rates. This series can pave the way for trials with larger populations.

Ethics Committee Approval: The study protocol was approved by the Ankara University Faculty of Medicine's ethics committee Protocol No: 2023000487 (2023/487).

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

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REFERENCES

- Gowing JM, Heidenreich MJ, Kavanagh CM, Aziz A. Hybrid-based iliofemoral endarterectomy for severe and complete iliofemoral occlusive disease. *J Vasc Surg.* 2014;73:903-10.
- Zou J, Xia Y, Yang H, Ma H, Zhang X. Hybrid endarterectomy and endovascular therapy in multilevel lower extremity arterial disease involving the femoral artery bifurcation. *Int Surg.* 2014;97:56-64.
- Jia X, Sun ZD, Patel JV, Flood, K, Stocken DD, Scott DJA. Systematic review of endovascular intervention and surgery for common femoral artery atherosclerotic disease. *Br J Surg.* 2019;106:13-22.
- Santos JS, Laukontaus S, Laine M, Pellicer PV, Sonetto A, Venermo M, et al. Hybrid revascularization for extensive iliofemoral occlusive disease. *Ann Vasc Surg.* 2023;88:90-9.
- Kavanagh CM, Heidenreich MJ, Albright JJ, Aziz A. Hybrid external iliac selective endarterectomy surgical technique and outcomes. *J Vasc Surg.* 2016;64:1327-34.
- Timaran CH, Prault TL, Stevens SL, Freeman MB, Goldman MH. Iliac artery stenting versus surgical reconstruction for TASC (TransAtlantic Inter-Society Consensus) type B and type C iliac lesions. *J Vasc Surg.* 2003;38:272-8.
- Ray JJ, Eidelson SA, Karcutskie CA, Meizoso JP, DeAmorim H, Goldstein LJ, et al. Hybrid revascularization combining iliofemoral endarterectomy and iliac stent grafting for TransAtlantic inter-society consensus C and D aortoiliac occlusive disease. *Ann Vasc Surg.* 2018;50:73e9.
- Yiğit G, Sarıcaoğlu MC, Çetinkaya F, Özen A, İşcan HZ. Endovascular treatment of chronic total occlusion of iliac/femoral arteries: Mid-term follow-up. *Turk J Vasc Surg.* 2020;29:7-12.
- Piffaretti G, Fargion AT, Dorigo W, Pulli R, Gattuso A, Bush RL, et al.; ILIACS Registry Group. Outcomes from the multicenter Italian registry on primary endovascular treatment of aortoiliac occlusive disease. *J Endovasc Ther.* 2019;26:623e32.
- Piazza M, Ricotta JJ, Bower TC, Kalra M, Duncan AA, Cha S, et al. Iliac artery stenting combined with open femoral endarterectomy is as effective as open surgical reconstruction for severe iliac and common femoral occlusive disease. *J Vasc Surg.* 2011;54:402-11.
- Nelson PR, Powell RJ, Schermerhorn ML, Fillinger MF, Zwolak RM, Walsh DB, et al. Early results of external iliac artery stenting combined with common femoral artery endarterectomy. *J Vasc Surg.* 2002;35:1107-13.

12. Leo SG, Montbriand J, Eisenberg N, Roche-Nagle G. Outcomes of hybrid procedures for peripheral arterial disease: 5-year single center experience. *Cir Cir.* 2022;90:610-16.
13. Chang RW, 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.
14. Maitrias P, Deltombe G, Molin V, Reix T. Iliofemoral endarterectomy associated with systematic iliac stent grafting for the treatment of severe iliofemoral occlusive disease. *J Vasc Surg.* 2017;65:406-13.
15. Madenci AL, Ozaki CK, Gupta N, Raffeto JD, Belkin M, McPhee JT. Perioperative outcomes of elective inflow revascularization for lower extremity claudication in the American College of Surgeons National Surgical Quality Improvement Program database. *Am J Surg.* 2016;212:461-467.e2.
16. Cheng H, Clymer JW, Chen BPH, Sadeghirad B, Ferko NC, Cameron CG, Hinoul P. Prolonged operative duration is associated with complications: a systematic review and meta-analysis. *J Surg Res.* 2018;229:134-44.
17. Mullen MG, Michaels AD, Mehaffey JH, Guidry CA, Turrentine FE, Hedrick TL, et al. Risk associated with complications and mortality after urgent surgery vs elective and emergency surgery: implications for defining “quality” and reporting outcomes for urgent surgery. *JAMA Surg.* 2017;152:768-74.
18. Giusti JCG, Fernandes JR, Soares SP, Dos Santos KR, Rossi FH, Beraldo JPN, et al. Alternative iliofemoral revascularization in extensive aortoiliac occlusive disease. *J Vasc Bras.* 2019;18:e20180083.
19. Ahanchi SS, Panneton JM, Stout CL. A hybrid approach to recanalization of a chronic iliofemoral occlusion. *J Vasc Surg.* 2013;57:230-3.
20. Starodubtsev V, Mitrofanov V, Ignatenko P, Gostev A, Preece R, Rabtsun A, et al. Hybrid vs. open surgical reconstruction for iliofemoral occlusive disease: a prospective randomised trial. *Eur J Vasc Endovasc Surg.* 2022;63:557-65.