Hybrid revascularization techniques in the management of multiple level peripheral vascular disease

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Objective
Extensive multilevel atherosclerotic disease is common in patients with ischemia of the lower extremities. It is frequently associated with multiple medical comorbidities, resulting from disease in distant vascular territories and making these patients the high-risk group for extensive open surgical procedures. The purpose of this study is to evaluate the feasibility and efficacy of simultaneous, combined endovascular, and open lower extremity arterial reconstruction.

Patients and methods
A case series study with retrospective analysis of prospectively collected nonrandomized data.

Results
Thirty-five patients with multilevel ischemic peripheral vascular disease underwent hybrid procedures during the period from September 2014 to September 2016 with 100% technical success rate. Inflow endovascular procedure was performed in 48.57% and outflow in 37.14% of the cases. For five (14.28%) patients, both inflow and outflow percutaneous transluminal angioplasty were performed together with an open surgical revascularization. The open surgical procedures were a femoral procedure in the groin (34.3%) or with a bypass (65.7%). Patients are maintained on clopidogrel 75 mg daily for at least 6 weeks after hybrid interventions. Thereafter, lifelong aspirin therapy can be substituted for clopidogrel. The mean duration of the operation for all hybrid procedures was 290±110 min (range: 60–580 min). It was longest in procedures where an inflow percutaneous transluminal angioplasty (±stenting) and distal bypass were combined (279 min).

Conclusion
Hybrid revascularization procedures for the treatment of multilevel vascular disease in the fragile vascular patient population seem to be as good as with open revascularization, but with less morbidity and shorter intensive care and hospital stay.

Keywords:
hybrid, peripheral, revascularization

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Introduction

Extensive multilevel atherosclerotic disease is common in patients with ischemia of the lower extremities. It is frequently associated with multiple medical comorbidities, resulting from disease in distant vascular territories and making these patients high risk for extensive open surgical procedures. The mainstay of treatment for peripheral arterial disease has been arterial bypass surgery, but recent advanced endovascular interventions have challenged surgery as the first-line treatment [1].

The Trans-Atlantic Inter-Society Consensus (TASC) classification suggests the choices for first-line therapy and predicts successful intervention after endovascular or open surgical therapy mainly according to the site of the lesion and its length [2].

However, peripheral arterial disease usually affects multiple levels of the iliac femoral, popliteal, tibial, and peroneal arteries, especially in patients with critical limb ischemia. The anatomic variables, combined with patient-specific comorbidities, make the therapeutic decisions more complex. This difficulty in making the therapeutic decisions is made easier by using hybrid reconstruction techniques [3].

This study was performed to assess the efficacy of hybrid techniques for lower limb arterial revascularization in patients with critical lower limb ischemia.

Aim

The aim of this study was to evaluate the feasibility and efficacy of hybrid revascularization techniques in the management of multilevel peripheral vascular diseases.

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Patients and methods

This is a case series study with retrospective analysis of prospectively collected nonrandomized data. The study was conducted on patients from the Vascular Surgery Department of Menoufia University Hospital. It was done retrospectively on a 24-month period (September 2014–September 2016).

The patients who had been selected for this study had their hybrid revascularization techniques according to the localization and morphology of the arterial lesions, disease stage, comorbidities, and risk factors.

All patients had preoperative, clinical, and paraclinical evaluation, including their risk factors and medical comorbidities, followed by an imagistic diagnostic procedure: Doppler ultrasound and contrast-enhanced computed tomography angiography.

The Rutherford classification was used to determine the clinical category of the patients [4].

These procedures were performed in the hybrid operating room, equipped with a Ziehm Vision® FD Imaging Co. (Nuremberg, Germany) Hybrid Edition and a moveable radiolucent surgical table.

The procedures were performed under local or regional (i.e. spinal and epidural) anesthesia. All patients were administered preoperative prophylactic cefepime intravenously. Typically, we begin the hybrid procedure with surgical exposure of the vessels. Unfractionated heparin is given intravenously (1 mg/kg) before vessel clamping. An additional dose of heparin is administered (usually half of the first dose) at 90 min after the first dose if the revascularization takes longer. The ipsilateral femoral bifurcation was exposed through a longitudinal inguinal incision. The open arterial reconstruction was followed by upward or downward endovascular revascularization in all patients; the latter was performed under continuous blood flow. The sheath was placed through a direct puncture of the prosthetic material (patch or graft).

The following three techniques were applied in this study.

Common femoral artery (CFA) endarterectomy/patch angioplasty with proximal ipsilateral iliac artery angioplasty and stenting or distal endovascular intervention.

Femoropopliteal bypass with proximal ipsilateral iliac artery stenting or infrapopliteal (distal) endovascular intervention.

Femoropopliteal bypass with proximal ipsilateral iliac artery stenting and infrapopliteal (distal) endovascular intervention.

Reconstruction of the CFA and bifurcation is typically completed using a patch (synthetic) or an interposition synthetic graft, depending on the length of the treated segment.

The mean follow-up was 15±8.3 months (median: 15 months; range: 0–24 months) and had the following endpoints: primary and secondary patency, initial technical success, complication rate, morbidity and mortality associated to each technical procedure, symptomatology improvement, and limb-salvage rate.

Patients are maintained on clopidogrel 75 mg daily for at least 6 weeks after hybrid interventions. Thereafter, lifelong aspirin therapy can be substituted for clopidogrel.

Analysis of the operative indications as well as the risk factors with influence on the post-therapeutic outcome was also done. All patients in the study gave written consent for their respective procedures. The study had full approval from the respective Hospital Ethics Committee. Technical success was defined as residual stenosis of less than 30% as demonstrated on intraoperative arteriography. Hemodynamic success was defined as an increase in the ankle-brachial pressure index by more than 0.1.

Clinical improvement was defined as an upward shift by at least one clinical Rutherford category, except when actual tissue loss existed, in which case there should be moving up of at least two categories. Perioperative morbidity and mortality included complications and death occurring within 30 days from surgical intervention. In this study, patency refers to the status of the reconstructed arterial segments. Patients with rest pain or tissue loss (Rutherford category 4 or 5) were used to determine the limb-salvage rates.

Statistical analysis

The data were evaluated via descriptive statistics (mean, median, and SD) and compared with the χ^2 or Fisher's test for the categorical data and the Student's t test for the continuous variables. Lesion severity and clinical results were evaluated in relationship to the clinical and preprocedural and postprocedural angiographic variables. The statistical

analysis was performed with the SAS software (SAS Institute, Cary, North Carolina, USA). A *P*-value of less than 0.05 was considered statistically significant.

Results

This study included a total of 35 patients with multilevel peripheral vascular disease. The median age was 65±13.2 years (range: 49–78 years). Of the patients, 25 (71.4%) were men and 10 (28.6%) were women, and their underlying risk factors were hypertension in 27 (77.1%) patients, diabetes mellitus in 30 (85.7%) patients, dyslipidemia in 14 (40%) patients, coronary artery disease in 14 (40%) patients, a history of cerebrovascular disease in eight (22.8%) patients, with 100% technical success rate in 35 procedures done. Inflow endovascular procedure was performed in 17 (48.57%) and outflow in 13 (37.14%) of the cases. For five (14.28%) patients, both inflow and outflow percutaneous transluminal angioplasty (PTA) were performed together with an open surgical revascularization. The open surgical procedures were a CFA endarterectomy/patch angioplasty in 12 (34.3%) or with a femoropopliteal bypass in 23 (65.7%). The mean duration of the operation for all hybrid procedures was 290±110 min (range: 60–580 min). It was longest in procedures where an inflow PTA (±stenting) and distal bypass were combined (279 min) (Tables 1–5).

Table 1 Patients' demographic and clinical data

Variables	*N* [*n* (%)]
Age [mean±SD (range)] (years)	65±13.2 (49–78)
Sex (male/female)	25/10
Comorbidity	
Hypertension	27 (77.1)
Diabetes	30 (85.7)
Dyslipidemia	14 (40)
Coronary artery disease	14 (40)
Cerebrovascular disease	8 (22.8)

Table 2 Anatomical characteristics of the lesions and the type of procedure done

Lesions	*N*	Procedure
Iliac artery stenosis/ obstruction with localized CFA lersion	4	Iliac angioplasty and senting with CFA endartectomy and Patch graft
Iliac artery stenosis/ obstruction with SFA occlusion	9	Iliac angioplasty and senting with femoropopliteal bypass graft
Localized CFA lesion with infragenicular lesions	7	CFA endartectomy and patch graft with infragenicular angioplasty
SFA occlusion with infragenicular lesions	10	Femoropopliteal bypass with infragenicular angioplasty
Localized CFA lesion with inflow and outflow lesions	1	Iliac angioplasty and senting with CFA endartectomy and patch graft with infragenicular angioplasty
SFA occlusion with inflow and outflow lesions	4	Iliac angioplasty and senting with femoropopliteal bypass graft with infragenicular angioplasty

CFA, common femoral artery.; SFA, superficial femoral artery.

Overall technical success was achieved in 35 (100%) of 35 cases. Before discharge, the ABI increased significantly from 0.42±0.19 to 0.80±0.24 (*P*=0.007). Out of the 30 diabetic patients, three had incompressible arteries, which excluded them from mean ankle-brachial pressure index calculations.

The clinical status improved greatly (+3 Rutherford categories) in 24 (68.5%) patients; there was a moderate improvement (+2 Rutherford categories) in seven (20%) patients, and two (5.7%) patients had no clinical improvement. No mortality occurred in our study. Minor infections occurred in four patients in our study. All of them are managed early by proper antibiotics and wound care. The length of hospital stay in our study was (4.8±7.0 days) (Table 6).

The mean follow-up was 15±8.3 months (median: 15 months; range: 0–24 months). Loss of primary patency occurred in seven patients between 0 and 24 months, three of which were related to abnormalities detected in the endovascular-treated segments (42.85%) and three related to the bypass, one was related to the endarterectomized segment. In the seven patients who needed interventions for maintaining patency, one had PTA of infrapopliteal restenosis, and one needed angioplasty of the endarterectomized

Table 3 Technical success and mortality

	n (%)
Technical success	35 (100)
Mortality	0 (00)

Table 4 Clinical improvement according to ankle-brachial pressure index

	Preoperative (min)	Postoperative (min)	*P*-value
Ankle-brachial pressure index	0.42±0.19	0.8±0.024	0.007

Table 5 Clinical improvement according to Rutherford categories

Rutherford categories	*n* (%)
+3 Rutherford categories	24 (68.5)
+2 Rutherford categories	7 (20)
No improvement	4 (11.5)

Table 6 Primary failures and their management

Initial procedure	Failure	*N*	Reintervension
CFA endarterectomy with inflow stenting	CIA occlusion	1	PTA and restensting
Bypass with infragenicular outflow angioplasty	Infragenicular stenosis	2	PTA
Bypass with infragenicular angioplasty	Graft thrombosis	2	Bypass graft thrombectomy
CFA endarterectomy with outflow angioplasty	Endraterectomy restonosis	1	PTA of endarterectomized segment

CIA, common iliac artery; CFA, common femoral artery; PTA, percutaneous transluminal angioplasty.

Figure 1

Femoral–popliteal bypass with infragenicular angioplasty.

segment. Two had bypass graft thrombectomies and revisions, one had iliac thrombolysis and restenting and one had been treated conservatively; the secondary patency rate was 100% during the follow-up period (Figs 1–12).

Figure 2

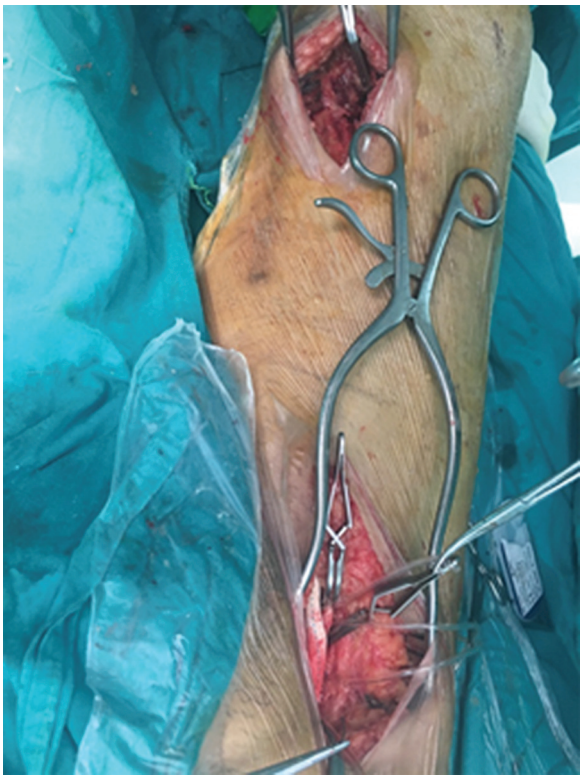
Femoral obstruction with inflow and outflow lesions.

Discussion

Treatment of multilevel ischemic peripheral vascular disease is often a difficult exercise. Conventional open surgical management of such lesions required extensive revascularization and lengthy procedure, commonly associated with significant morbidity and mortality. Endovascular interventions should be preferred for the elderly, high-risk patients, but in practice we often encountered situations in which it was difficult to proceed with angioplasty solely because of simultaneous calcifications and stenosis of the multilevel arteries [4].

This difficulty in making the therapeutic decisions are made easier by using hybrid reconstruction techniques in which endovascular treatment used for inflow and outflow lesions or both in combination with open surgery for the intermediate lesions, during a single session [5].

Figure 3

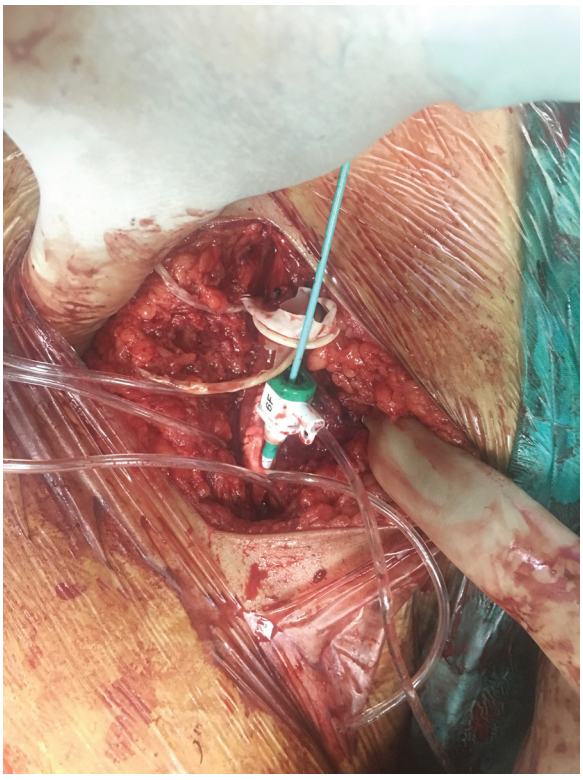


Femoral–popliteal bypass graft.

Figure 4

Infragenicular lesion after femoral endarterectomy.

Figure 5



Infragenicular angioplasty.

Figure 6

Pretransluminal angioplasty stenosis in the ostium and proximal segment of anterior tibial artery and another stenosis in the distal segment of anterior tibial artery/high-grade stenosis in the tibioperoneal trunk.

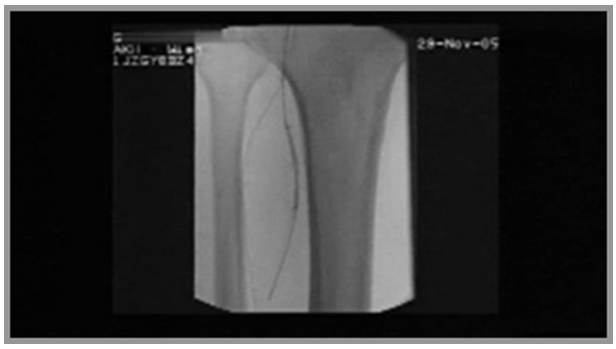
In our study, immediate technical and hemodynamic success rates were 100 and 94.4%, respectively, and those were achieved, confirming the immediate efficacy of this combined approach, matched with Dosluoglu *et al.* [6] who reported that the hybrid procedure for the infrainguinal vessel was comparable to the bypass procedure, with a technical successful rate of 92% and a limb salvage rate of 91% at 5 years. The hybrid procedures shorten the length of the operation.

The mean duration of the operation for all hybrid procedures was 290±110 min (range: 60–580 min). It was longest in procedures where an inflow PTA

Figure 7

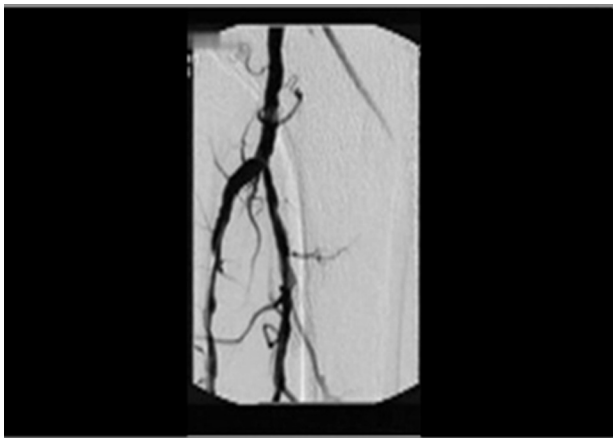
Balloon in the proximal segment of anterior tibial artery.

Figure 8



Balloon in the tibioperoneal trunk.

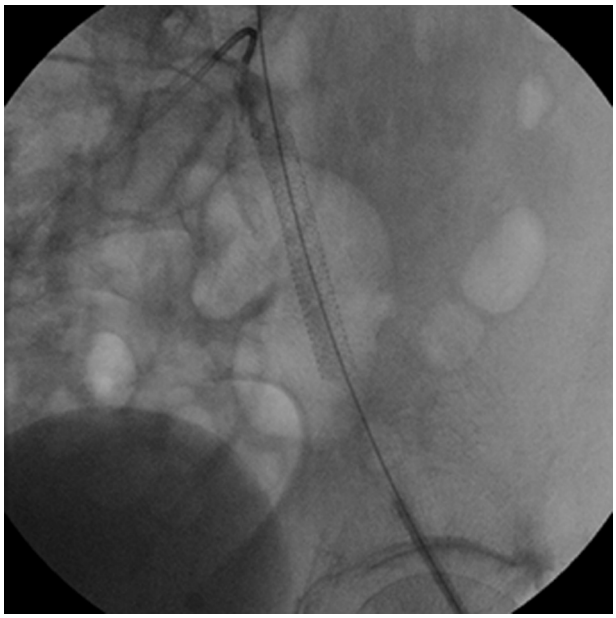
Figure 9



Post-transluminal angioplasty in the proximal segment of anterior tibial artery and tibioperoneal trunk.

(±stenting) and distal bypass were combined (279 min), reduced the hospital cost, and decreased the length of hospital stay. The length of hospital stay in our study was 4.8±7.0 days, these results were compatible with Schneider PA.

Figure 10



Iliac guidewire.

Figure 11

Iliac ballooning.

Iliac angioplasty and stenting in association with infrainguinal bypasses: timing and techniques.

When we perform an infrapopliteal bypass, it is necessary to secure a sufficient length of vein grafts. The hybrid procedure permits vascular surgeons to use shorter bypass grafts. The hybrid procedure allowed us to obtain a primary patency rate of 78.78%, a secondary patency rate of 100%, an amputation-free survival rate of 100%, and a freedom from secondary intervention rate of 78.8% during the follow-up period.

Figure 12

Iliac stent.

We obtained results were comparable to or better than those reported in several previous studies, and these results justify our hybrid treatment [7–9].Schrijver *et al.* [10] reported that the primary patency, secondary patency, limb salvage, and patient survival rates were 56.8, 62.7, 78.2, and 48.6%, respectively, at 5 years.

Cotroneo *et al.* [11] followed up 44 patients (24 with claudication and 20 with critical limb ischemia) after hybrid procedures and reported 2-year primary and secondary patency rates of 79.1 and 86.1%, respectively. Nishibe *et al.* [12] reported a 3-year experience with hybrid procedure for multifocal peripheral TASC D lesions. The primary patency rates were 94, 70, and 70% at 6, 12, and 24 months, respectively.

Our study also matched with the open surgery literature, as regards primary and secondary patency of Norgren [13], van Den Berg [14], McQuade [15], Neville [16], Reed [17]. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II).

Zero mortality in these study groups demonstrates the minimally invasive character and superiority of the hybrid techniques for the elderly patients with high operative risk.

Conclusion

Hybrid revascularization procedures for the treatment of multilevel vascular disease have the following benefits:

(1) Complete revascularization of the ischemic limb occurs in a single session.
(2) Open surgery can immediately repair inadequate endovascular results and *vice versa*.
(3) Puncture complications related to angioplasty are eliminated.
(4) Potential infectious complications of long open intervention or two separate interventions are minimized.
(5) Lower the anesthetic complication risks especially in high-risk patients.
(6) Hospital stay is shortened and possibly cheaper.
(7) Primary patency and secondary patency have the same results as in open surgery.
(8) This technique helps the vascular surgeons to have an upper hand in the treatment of their patients.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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