One-stage hybrid management of patients with critical limb ischemia due to complex multilevel arterial occlusions

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Aim
To evaluate the safety and efficacy of one-stage hybrid revascularization modality in patients with complex multifocal arterial occlusive lesions.
Patients and methods
A prospective study design was established. Included patients were those admitted to the Vascular and Endovascular Surgery Department between November 2015 and November 2016 and presenting with Rutherford stages 5 and 6 critical limb ischemia due to multilevel arterial occlusion involving common femoral artery and one or both of inflow (iliac) and outflow arteries (superficial femoral and leg arteries) with nonsignificant aortic lesions and underwent a one-stage hybrid revascularization procedure aiming limb salvage. Common femoral artery endarterectomy was a fixed step in all cases. For inflow lesions; plain balloon angioplasty with bare metal stenting was first attempted then a femoro-femoral bypass if failed the endovascular approach. For outflow lesions, plain balloon angioplasty with selective stenting was tried in all cases and to stop if failed provided the presence of sufficient profunda flow. The study end points were 1-year primary patency, secondary patency, limb salvage, and complication rates.
Results
This study included 30 patients (30 limbs), with a mean age of 65±10.28 years. Technical success was achieved in 46 (95.8%) of 48 performed procedures and hemodynamic or clinical success in all patients (100%). Twelve-month primary and secondary patency rates were 67 and 80%, respectively. One-year limb salvage rate was 93.3%. Postoperative complications were reported in four (13.3%) cases.
Conclusion
One-stage hybrid procedures may be considered a safe and effective modality in the treatment of patients with critical limb ischemia due to multilevel complex arterial occlusions.

Keywords:
critical limb ischemia, hybrid, multilevel arterial occlusions

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Introduction

Successful treatment of patients with critical limb ischemia (CLI) has always been a challenge for the vascular surgeon, as atherosclerotic lesions usually involve multiple vascular beds, requiring extensive, multilevel revascularization, besides the frequently associated multiple medical comorbidities, making these patients high risk for extensive open surgical procedures [1,2].

With the widespread adoption of fixed imaging systems within the vascular operating room and the developing endovascular skills of the vascular surgeon, patients now benefit from all-in-one procedures that are part open vascular surgery and part catheter-based intervention, so-called hybrid surgery. These procedures are often performed by a single vascular specialist under a single anesthetic in a single location, with clear patient benefits and cost savings of almost 50% compared with staged procedures in different locations [3].

The alternative of hybrid revascularization surgery carries the advantages of less-invasive endovascular interventions and may provide a durable and safe solution [4]. The aim of this study was to evaluate the safety and efficacy of one-stage hybrid surgical and endovascular therapy in patients with complex multifocal arterial occlusive lesions.

Patients and methods

A prospective study was conducted on patients enrolled between November 2015 and November, with 1-year follow up that ended in November 2017. The study was approved by the ethical committee, and all patients

provided written consent for study participation and before revascularization.

Potential candidates were all consecutive patients admitted to the Vascular and Endovascular Surgery Department of a tertiary referral hospital during the study period and presenting with Rutherford stages 5 and 6 CLI (ischemic ulcer or gangrene, either dry or wet) due to multilevel peripheral arterial disease involving common femoral artery (CFA) and one or both of inflow (iliac) and outflow arteries (superficial femoral and leg arteries) with nonsignificant aortic lesions. Included patients were those who underwent a one-stage hybrid revascularization procedure aiming limb salvage. Patients were excluded when found a contraindication for contrast use or nonsalvageable foot (extensive necrosis or infective gangrene requiring major amputation).

All patients underwent detailed history taking, and data were collected on age, sex, cardiovascular risk factors such as smoking, diabetes mellitus, and hypertension. Preoperative pulse examination and ankle brachial index measurement were performed for all cases. Best medical treatment was initiated from the time of admission. The Rutherford classification for limb ischemia was used to determine the clinical severity at the time of presentation as specified by the Society for Vascular Surgery reporting standards [5].

Duplex ultrasound was routinely used to evaluate all cases, initially localize the arterial lesion, and assess its severity through velocity criteria and waveform changes. Multidetector computed tomography angiography was performed to assess lesion extension, categorize patients according to their (inflow/ outflow) affection, either separately or combined, and then plan the intervention. Figure 1 demonstrates a multidetector computed tomography angiography showing complex inflow (iliac) and outflow (femoropopliteal) artery occlusion and typical collateral pathways through internal iliac and profundal artery branches.

Figure 1

MDCT angiography showing complex inflow (iliac) and outflow (femoropopliteal) artery occlusion. MDCT, multidetector computed tomography.

Hybrid procedure

CFA endarterectomy was a fixed step in all cases. For inflow lesions, plain balloon angioplasty with bare metal stenting was first attempted, then a femoro-femoral bypass, and if failed, the endovascular approach. For outflow lesions, plain balloon angioplasty with selective stenting was tried in all cases and patent well-collaterized profundafemoris artery may be sufficient for revascularization of patients suffering critical limb ischemia. No outflow bypasses were performed in the current cohort.

The initial step was a classic common femoral endarterectomy and saphenous patch angioplasty. Targeting iliac lesions, a retrograde 6-Fr sheath was inserted. Alternatively, an antegrade approach via the left brachial artery was adopted, only if failed, the retrograde access. Upon completion of inflow revascularization, the sheath was then placed in an antegrade fashion to treat femoropopliteal occlusion. Technical success was defined as restoration of antegrade in-line flow with residual stenosis less than 30% on final angiography. Types of interventions according to occlusion patterns in the current series were reported.

Follow-up visits were scheduled at 3, 6, and 12 months following the intervention. Reintervention was indicated on reappearance of symptoms or signs combined with more than 50% recurrent stenosis or occlusion. Study end points were 1-year primary patency, secondary patency, limb salvage, and complication rates.

The study end points were measured during the 1-year follow-up period. Primary patency rate was defined as the time from the revascularization procedure to either revision or the first occurrence of thrombosis of the

treated segment. Secondary patency is defined as the time from the procedure to the permanent loss of flow in the treated segment, irrespective of any interval therapies. Limbs that required minor amputation (toe, ray, or transmetatarsal amputation) but ultimately healed were considered successful limb salvage. Limbs that required major amputation (proximal to the ankle level) were considered as failed salvage.

Statistical analysis

Statistical analysis was performed using SPSS 24.0 (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were used, with continuous variables expressed as mean±SD, and categorical variables as frequencies and percentages. Univariate analysis was performed with the χ^2 for categorical variables. Survival data, including primary patency and secondary patency, were determined using Kaplan–Meier life-table analysis. A value of P value less than 0.05 was considered significant for all analyses.

Results

This study included 30 patients (30 limbs), with a mean age of 65±10.28 years. The most frequent risk factor in the current study group was smoking in 18 (60%) cases followed by diabetes in 16 (53.3%) and hypertension in 14 (46.7%). Patient characteristics are demonstrated in Table 1.

The CFA was involved with atherosclerosis in all cases. It was associated with inflow disease involving the ipsilateral iliac artery in nine (30%) cases, or with outflow disease (femoropopliteal and leg vessels) in seven (23.3%) cases, and with both inflow and outflow disease in 14 (46.7%) cases. Types of intervention performed in the current study are demonstrated in Table 2.

Technical success was achieved in 46 (95.8%) of 48 performed procedures. In two patients, there was a failure to cross the superficial femoral artery (SFA) owing to the presence of a chronic long-segment occlusion. Surgeons stopped at their preference as both patients were treated for rest pain that improved after inflow and CFA recanalization. Hemodynamic and clinical success was achieved in all patients (100%) included in the study. The mean resting ABPI improved significantly, rising from 0.34 ±0.053 preoperatively to 0.79±0.121 after the intervention ($P<0.05$).

Twelve-month primary and secondary patency rates were 67 and 80%, respectively (Figs 2–8).

Table 1 Patient characteristics

Variables	*n* (%)
Sex	
Male	25 (83.3)
Risk factors	
Smoking	18 (60)
Diabetes mellitus	16 (53.3)
Hypertension	14 (46.7)
Dyslipidemia	12 (40)
Coronary artery disease	9 (30)
History of stroke	3 (10)
Affected side	
Right lower limb	12 (40)
Left lower limb	18 (60)
Staging	
Rutherford 4	5 (16.7)
Rutherford 5	10 (33.3)
Rutherford 6	15 (50)

Table 2 Types of intervention performed in the current study

Intervention	*n* (%)
Femoral endarterectomy	
+ proximal and distal PTA	12 (40)
+femoro-femoral bypass and distal PTA	2 (6.7)
+proximal PTA	9 (30)
+distal PTA	7 (23.3)

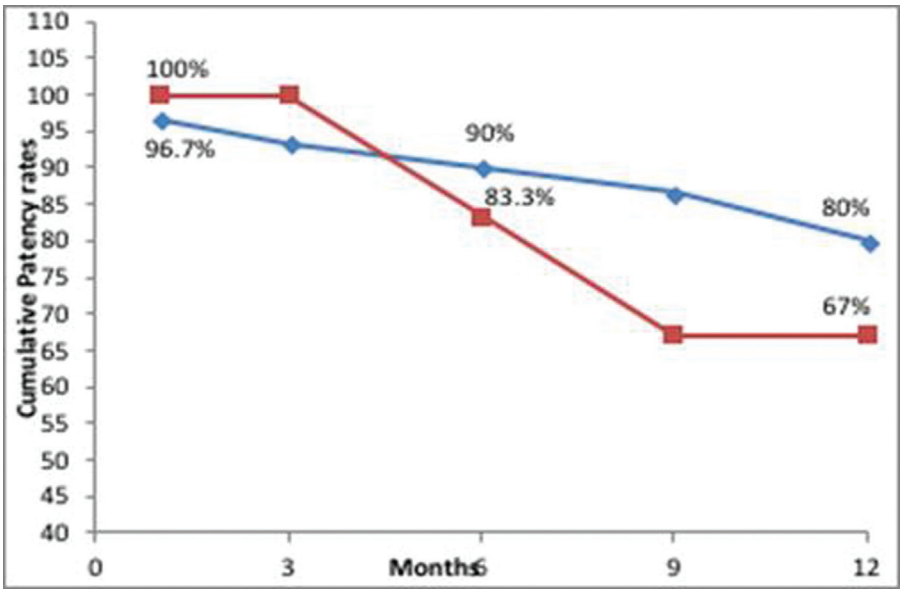
PTA, percutaneous transluminal angioplastya.

One-year limb salvage rate was 93.3%. Further subgroup analyses showed that 1-year primary patency rate was significantly lower in diabetic than nondiabetic patients (P=0.03) and lower in patients presented with combined outflow and inflow disease than those with separate inflow or outflow affection (P=0.01). Postoperative complications were reported in four (13.3%) cases: arterial thrombosis in a single case treated with fluoroscopic-guided thrombectomy, persistent groin lymphorrhea in two patients and acute myocardial infarction in a single case who were managed conservatively. There was no 30-day mortality in the current series.

Discussion

Multilevel atherosclerotic arterial disease affecting the lower extremities requires complex treatment strategies, which involve inflow and outflow arterial reconstructions, to provide patients with adequate clinical improvement. Conventional open surgical management of such lesions consists of extensive revascularization procedures in high-risk patients owing to frequently associated significant medical comorbidities. This has prompted the adoption of less-invasive interventions [6].

Figure 2



Cumulative primary and secondary patency rates in limbs treated with hybrid procedures for critical limb ischemia.

Figure 3

Preoperative MDCTA demonstrated calcific occlusion of external iliac artery, common femoral artery, SFA, and proximal popliteal artery. MDCTA, Multidetector computed tomography angiography.

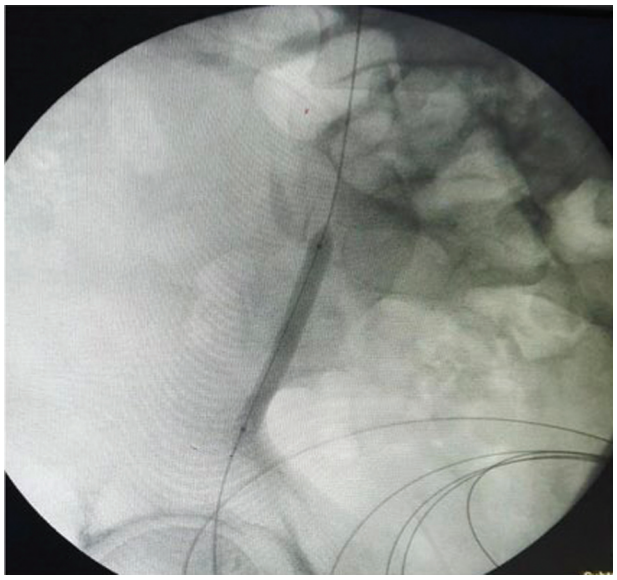
Figure 4

Diagnostic angiography showing stenosis of the right external iliac artery.

According to 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery, hybrid procedures (e.g. aortoiliac stenting and distal bypass) should be encouraged in a one-step modality when necessary [7]. Ebaugh *et al.* [3] have reported significantly longer hospital stay and almost double the cost when comparing the staged with one-stage hybrid procedures.

CFA endarterectomy remains the gold standard for management of such specific anatomical lesions as several studies reported better patency rates in favor of surgical modality compared with endovascular treatment [8–10].

Figure 5



Balloon dilatation of the right external iliac artery.

Figure 6

Postdilatation angiography demonstrating patency of the right external iliac artery.

Femoral endarterectomy was performed in all cases in the current cohort with combined inflow and outflow revascularization in 46.7% of patients and with separate inflow in 30% and outflow in 23.3% of cases. Matsagkas *et al.* [11] reported that CFA endarterectomy was combined with distal endoluminal procedures in 52.2% of limbs, with proximal endoluminal procedures in 29.5% and with both proximal and distal endoluminal procedures in only 18%.

We reported a 95.8% technical success and 100% hemodynamic and clinical success in the current series. These results were in agreement with those reported by Matsagkas *et al.* [11], in a series of 37

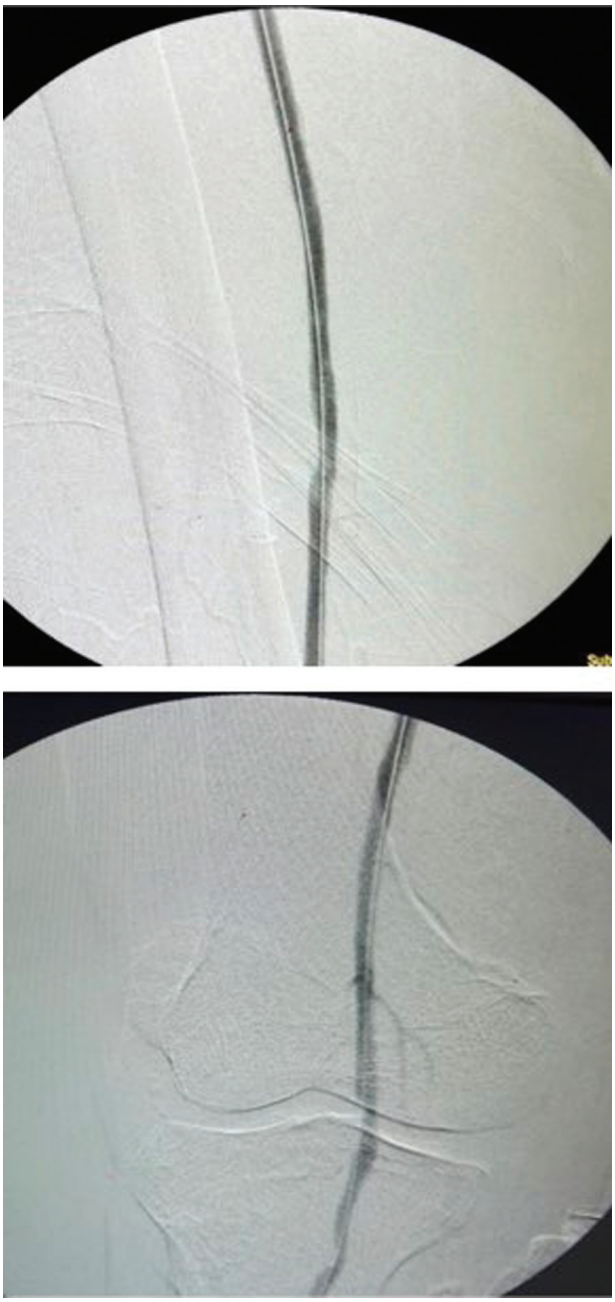
Figure 7

Balloon waist during dilatation of the occluded right SFA.

patients (44 limbs) using one-stage hybrid technique with technical and hemodynamic success rates of 96.6 and 100%, respectively. Antoniou *et al.* [6] reported technical and hemodynamic success rates of 100 and 95%, respectively, from 60 patients who underwent 61 single-step hybrid procedures. Additionally, Zou *et al.* [12] and Jung *et al.* [13] reported technical success rates of 98 and 100%, respectively, following the same management protocol.

Reported 12-month primary and secondary patency rates were 67 and 80%, respectively. One-year limb salvage rate was 93.3%. Jung *et al.* [13] studied 38 consecutive patients with CLI (43 limbs) with multilevel peripheral arterial disease who were treated by one-stage hybrid technique which combined CFA endarterectomy and additive interventional procedure. The primary and secondary patency rates at 24 months were 67.3 and 72.1%, respectively. The limb salvage rate was 95.3%.On the contrary, Matsagkas *et al.* [11] reported higher 2-year primary and secondary patency rates of 93.2 and 95.5%, respectively. This higher patency rate could be attributed to the different patient characteristics as most of their patients (52.2%) presented with rest

Figure 8



Completion angiography showing successful recanalization of right SFA and popliteal artery.

pain; furthermore, 18% of their cohort had both proximal and distal arterial lesions compared with 46.7% of our patients, which reflect more extensive and severe atherosclerotic disease.

In the current study, the primary patency rate was lower in diabetic than nondiabetic patients ($P<0.05$). This is in accordance with Spanos *et al.*, [14] who in a retrospective analysis from a single center of 132 patients who underwent hybrid procedures for the management of multisegmental chronic peripheral arterial disease reported that the hazard ratio for primary patency failure was 1.94 times higher in diabetic patients ($P=0.029$).

Limitations of our study include the small sample size, lack of control group treated with conventional bypass surgery, and the short follow-up period.

Following our data analysis and observations, we conclude that one-stage hybrid procedures may be considered safe and effective modality in the treatment of patients with CLI due to multilevel arterial occlusive disease in a subgroup of high-risk vascular patients with multiple medical comorbidities.

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Conflicts of interest
There are no conflicts of interest.

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