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Midterm Outcomes of Common Femoral Endarterectomy Combined with Inflow and Outflow Endovascular Treatment for Chronic Limb Threatening Ischaemia

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WHAT THIS PAPER ADDS

This prospective study investigated a group of patients with chronic limb threatening ischaemia due to complex multilevel arterial disease treated homogenously using common femoral endarterectomy combined with inflow and outflow endovascular treatment. This option should provide a great benefit for a subset of high risk patients with an extensive disease pattern as it is considered safe with accepted patency rates despite the need for secondary interventions. Predictors of primary patency loss and degree of limb threat should guide the decision of whether to stage the procedure or perform a simultaneous inflow and outflow complete recanalisation.

Objective: To assess mid term outcomes of common femoral endarterectomy combined with an inflow and outflow endovascular revascularisation procedure in patients with chronic limb threatening ischaemia (CLTI).

Methods: This was a prospective study. All patients who, for the first time, underwent planned one stage hybrid common femoral artery (CFA) endarterectomy combined with an inflow and/or outflow endovascular revascularisation procedure to achieve limb salvage in patients with CLTI due to multilevel disease were included between January 2015 and May 2017. Demographics, and clinical and lesion characteristics for each patient were reported. The primary outcome was primary patency. Secondary outcomes were technical success, peri-operative morbidity and mortality, assisted primary patency, secondary patency, clinically driven target lesion revascularisation and amputation free survival.

Results: Three groups were created according to the endovascular treatment zone: group 1 (inflow, $n = 60$); group 2 (outflow, $n = 46$); and group 3 (combined inflow and outflow, $n = 53$). CFA endarterectomy was a fixed step in all cases. The overall technical success was 98%. The peri-operative complication rate was 14% and the mortality rate was 2%. Patients in group 3 demonstrated a significantly lower primary patency rate (53.9% $\pm$ 7.1%; $p < .001$) at 24 months but improved secondary patency rate of (94.0% $\pm$ 3.4%). Based on the outcomes of the Cox regression multivariable analysis, lesion length (hazard ratio [HR] 1.10, 95% confidence interval [CI] 1.06—1.14; $p < .001$), chronic total occlusion (CTO) (HR 0.50, 95% CI 0.25—0.98; $p = .046$), peripheral artery calcium scoring system (PACSS) grade 4 (HR 2.44, 95% CI 1.27—4.68; $p = .008$), incomplete revascularisation (HR 3.32, 95% CI 1.64—6.73; $p = .001$), and dyslipidaemia (HR 0.50, 95% CI 0.27—0.93; $p = .031$) were the only significant independent predictors of loss of primary patency.

Conclusion: Common femoral endarterectomy combined with an inflow and outflow endovascular revascularisation procedure in patients with CLTI is safe, with acceptable patency rates, despite the need for secondary interventions. Dyslipidaemia, lesion length, CTO, PACSS grade 4, and incomplete revascularisation are independent predictors of primary patency loss. The current study analysis supports the recommendation to stage the procedure based on patient risk and degree of limb threat.

Keywords: Chronic limb threatening ischaemia (CLTI), Hybrid surgery, Multilevel revascularisation
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INTRODUCTION

Multilevel arterial disease in patients with chronic limb threatening ischaemia (CLTI) presents a major revascularisation challenge to vascular surgeons. The goal of treatment is a single procedure that results in an excellent technical result without associated complications or the need for further interventions.[1]

CLTI is almost never related to isolated aorto-iliac or superficial femoral artery (SFA) disease; tandem lesions involving the femoropopliteal combined with aorto-iliac or infrapopliteal segments are mostly encountered. Recent guidelines on the management of peripheral vascular arterial disease recommend an endovascular first strategy in treating short arterial occlusions, and accept that indication in extensive lesions in high risk patients, or when conventional surgical options are not possible. However, common femoral artery (CFA) disease remains an area of surgical priority.[2] A less invasive one stage hybrid procedure combining both endovascular and surgical modalities avoids the need for extensive surgery or staged interventions in such patients.[3]

Current data clearly show a wide regional variation in the use of open or endovascular interventions.[4] The effectiveness of the various first line treatment strategies that are applied among centres remains unclear.[5] What is lacking is a uniform definition of the clinical stages of disease and key patient focused outcomes, limiting the evidence base available to guide daily practice.[6]

The aim of the current study was to assess mid term outcomes of common femoral endarterectomy combined with the inflow and outflow endovascular revascularisation procedure in patients with CLTI. Comparisons with CFA endarterectomy combined with either inflow or outflow endovascular therapy, and further multivariable analysis were made to determine possible predictors of loss of primary patency (PP).

METHODS

Study design

A non-randomised prospective study with patient enrolment ran from January 2015 to May 2017 and a two year follow up period ended in May 2019. The Institutional Review Board approved the study protocol, which was developed in accordance with the Declaration of Helsinki. All patients gave written informed consent for the revascularisation procedure and inclusion in the study. Retrospective re-evaluation of patient and lesion characteristics was performed to conform with the most recently published global vascular guidelines on management of CLTI.[6]

Inclusion/exclusion criteria

Inclusion targeted all consecutive patients admitted to the vascular and endovascular surgery department of a tertiary referral hospital during the study period, presenting with intermediate and advanced limb threatening conditions (wound, ischaemia, and foot infection [WIfI] stages 2—4) associated with significant perfusion deficits (WIfI ischaemia grades 2—3)[7] due to Global Anatomic Staging System (GLASS) stage IB—IIB aorto-iliac (inflow) disease and/or GLASS grade 2—4 femoropopliteal/0—4 infrapopliteal (outflow) disease.[6] Included patients underwent a planned one stage hybrid CFA endarterectomy combined with an inflow and/or outflow endovascular revascularisation procedure for the first time. Exclusion criteria were (i) lesions involving the distal abdominal aorta as considered for aorto-bifemoral bypass surgery ($n = 27$); (ii) isolated iliac or femoropopliteal arterial occlusion not involving the CFA ($n = 697$), endovascular therapy of either inflow or outflow arteries ($n = 638$), open bypass surgery for either inflow ($n = 20$) or outflow ($n = 39$); (iii) acute limb ischaemia ($n = 396$); and (iv) ischaemia associated with vascular trauma ($n = 284$), hypercoagulability ($n = 12$) or non-atherosclerotic vascular disorders ($n = 23$).

Patient evaluation

Patient baseline characteristics and risk factors were reported. Pre-operative pulse examination and ankle brachial index (ABI)/toe brachial index (TBI) measurements were performed in all cases. Best medical treatment, including statins, was initiated from the time of admission. All patients underwent pre-operative high quality multidetector computed tomography (MDCT) angiography to define the anatomical pattern of the arterial disease and select the preferred target artery path (TAP) in each patient. Calcification of target lesions was quantified according to the peripheral artery calcium scoring system (PACSS),[8] which stratifies calcification into five grades: grade 0 (no visible calcium at the target lesion site); grade 1 (unilateral calcification $<$ 5 cm long); grade 2 (unilateral calcification $\geq$ 5 cm); grade 3 (bilateral wall calcification $<$ 5 cm); and grade 4 (bilateral calcification $\geq$ 5 cm).

Procedure description

All procedures were performed under local or regional (spinal and epidural) anaesthesia in a hybrid operating room equipped with a mobile digital angiographic system (C-arm, Philips BV Pulsera; Philips Medical Systems, Eindhoven, the Netherlands). The hybrid procedure under study was a planned one stage intervention including CFA endarterectomy as a fixed step in all cases and an inflow and/or outflow endovascular revascularisation step.

Included patients were subsequently divided into three groups according to the endovascular treatment zone as follows: group 1 (inflow: common and external iliac endovascular procedure); group 2 (outflow: femoropopliteal and/or infrapopliteal recanalisation); and group 3 (combined inflow and outflow treatment).

The initial step was a classic CFA exposure extended to the first 3 cm of the SFA and/or profunda. Femoral endarterectomy with or without profundaplasty and patch angioplasty were performed. For subsequent endovascular procedures, the patch was punctured and the endoluminal step performed under continuous blood flow. A 6 F sheath was inserted over the wire; retrograde for inflow lesions and antegrade to complete the outflow recanalisation. In cases where inflow and outflow were both diseased, the proximal lesions were treated first.

An antegrade approach via the left brachial artery was adopted if retrograde access for inflow lesions failed. Retrograde (crural) access ($n = 23$) using a fluoroscopically guided 21 G needle was a backup step for failed anterograde outflow recanalisations. After successful puncture, a 0.018 inch guidewire was inserted. No sheath was used through leg arteries.

Crossing the lesion was achieved using a combination of guidewires (0.035 Radifocus, standard/stiff type [Terumo Medical, Somerset, NJ, USA]; V-18 [Boston Scientific, Marlborough, MA, USA]; 0.018 Glidewire Advantage [Terumo]; and 4—5 F support catheters [TrailBlazer; Medtronic, Santa Rosa, CA, USA]; and CXI [Cook Medical, Bloomington, IN, USA]). Intraluminal and subintimal techniques were attempted; if they failed, the "double balloon" technique was used.[9]

Inflow lesions were managed by plain balloon angioplasty (PBA) with selective bare metal stenting for chronic total occlusion (CTO). Outflow lesions were treated by PBA, regardless of lesion severity, and stenting was reserved for flow limiting dissections or residual stenosis >30%. Balloon and stent diameters ranged from 7 to 9 mm for inflow arteries and from 5 to 6 mm for the femoropopliteal segment, and lengths ranged from 40 to 80 mm in iliac vessels and from 80 to 200 mm in the outflow arteries. The balloons used were Admiral Xtreme (Medtronic) and the stents were either balloon expandable (Visi-Pro; Medtronic) or self expandable (EverFlex [Medtronic]; E-Luminexx [Bard Peripheral Vascular, Tempe, AZ, USA]).

When all three leg vessels were diseased (group 2, $n = 33$; group 3, $n = 45$), every attempt was made to achieve at least one inline flow to the foot. The infrapopliteal artery within the TAP was selected for treatment on the basis of angiosomal preference. The source artery directly supplying the target lesion was attempted first; if this failed, the least diseased indirect vessel was treated (group 2, $n = 12$; group 3, $n = 20$). Attempts to recanalise more than one leg vessel including the source artery were made whenever feasible in certain cases to achieve the best chances for wound healing, as indicated by the treating surgeon (group 2, $n = 7$; group 3, $n = 8$). Incomplete revascularisation described all cases with failed leg vessel recanalisation in groups 2 and 3, or unattempted therapy in group 1 patients. Unfractionated heparin (100 U/kg) was administered before clamping. All patients were kept on lifelong daily aspirin 100 mg plus 75 mg clopidogrel for a minimum of 30 days after the procedure.

Follow up

ABI/TBI measurements, and duplex scanning were performed for all patients at follow up visits scheduled at three month intervals. Patients with worsening clinical symptoms and physical examination were further investigated, and re-intervention was indicated for >50% recurrent stenosis or occlusion, as documented by duplex ultrasound or MDCT angiography. Repeat procedures were PBA with selective bare metal stenting to achieve inline flow with <30% residual stenosis.

Study outcomes

The primary outcome measure was PP, defined as freedom from clinically driven target lesion revascularisation (CD-TLR) and freedom from restenosis (duplex ultrasonography peak systolic velocity ratio $\leq$ 2.4). Secondary outcome measures were (i) technical success, defined as residual stenosis of <30% in treated lesions, as demonstrated on completion angiography; (ii) peri-operative morbidity and mortality, defined as complications and death occurring within 30 days of the procedure; (iii) assisted PP, defined as patency maintained by the use of an additional surgical or endovascular procedures as long as occlusion of the primary treatment site had not occurred; (iv) secondary patency (SP), defined as patency obtained by the use of an additional procedures after occlusion had occurred; (v) CD-TLR, defined as any re-intervention at the target lesion(s) due to symptoms or a drop of ABI/TBI of $\geq$20% or > 0.15 *vs.* the post-procedure baseline ABI/TBI; and (vi) amputation free survival (AFS), defined as the time to a major (above ankle) amputation of the index limb, or death from any cause.

Statistical analysis

Statistical analysis was performed using SPSS 25.0 (IBM, Armonk, NY, USA), MedCalc 16.8 (MedCalc Software, Ostend, Belgium), and G*power 3.0.10 (G*power Software, Düsseldorf, Germany). Post hoc power analysis of the sample size yielded a statistical power of 0.8. Continuous variables were expressed as mean $\pm$ standard deviation and/or median, and categorical variables as frequency and percentage. Comparisons of continuous variables were computed via *t* test (for pre- and post-ABI/TBI), and analysis of variance (for three groups), while categorical variables were computed using the chi square test. Patency rates were analysed on an "intention to treat" basis using Kaplan—Meier survival curves, reported as proportion $\pm$ standard error, and intergroup differences were compared using the log rank test. Multivariable analysis using the Cox proportional hazards regression model with backward elimination was generated by including variables with a p value $<$ .20 in univariable analysis to assess the influence of various demographic and lesion characteristics on PP, with results presented as hazard ratio (HR) and 95% confidence interval (CI). A p value $<$ .05 was considered to be statistically significant.

RESULTS

Between January 2015 and May 2017, 159 patients (159 limbs) were included for further analysis. Three groups were created: group 1 (inflow, $n = 60$); group 2 (outflow, $n = 46$); and group 3 (combined inflow and outflow, $n = 53$). There were no significant differences in the distribution of baseline demographics, clinical presentation, and lesion

Table 1. Demographics and clinical characteristics of 159 patients with chronic limb threatening ischemia (CLTI) due to multilevel disease studied for mid-term outcomes of common femoral endarterectomy combined with inflow (Group 1), outflow (Group 2) or inflow and outflow (Group 3) endovascular revascularisation procedure between January 2015 to May 2017

Characteristic	Group 1 (n = 60)	Group 2 (n = 46)	Group 3 (n = 53)	p
Age – years	65.5 ± 9.3	67.3 ± 7.6	69.3 ± 8.3	.065
Male sex	46 (77)	37 (80)	42 (79)	.89
Diabetes	49 (82)	35 (76)	40 (75)	.68
Hypertension	19 (32)	17 (37)	15 (28)	.65
Coronary artery disease	13 (22)	13 (28)	18 (34)	.34
Previous coronary artery bypass graft	8 (13)	4 (9)	3 (6)	.37
Previous stroke/transient ischaemic attack	4 (7)	2 (4)	6 (11)	.40
Chronic kidney disease (60 > eGFR > 15)	11 (18)	15 (33)	13 (25)	.24
Chronic obstructive pulmonary disease	9 (15)	8 (17)	11 (21)	.72
Obesity (BMI > 30 kg/m^2)	6 (10)	6 (13)	9 (17)	.55
Current smoking	26 (43)	22 (48)	32 (60)	.18
Dyslipidaemia	28 (47)	29 (63)	30 (57)	.23
American Society of Anesthesiologists score	2.5 ± 0.8	2.6 ± 0.9	2.8 ± 0.9	.091
WIfI stage				.093
II	21 (35)	15 (33)	18 (34)	
III	34 (57)	22 (48)	23 (43)	
IV	5 (8)	9 (19)	12 (23)	

Continuous data are presented as mean ± standard deviation; categorical data are presented as n (%). BMI = body mass index; eGFR = estimated glomerular filtration rate (mL/min/1.73 m^2); WIfI = wound, ischaemia, and foot infection.

Table 2. Characteristics of lesions treated with common femoral endarterectomy combined with inflow (Group 1), outflow (Group 2) or inflow and outflow (Group 3) endovascular revascularisation procedure of 159 patients with chronic limb threatening ischemia (CLTI) due to multilevel disease

Lesion characteristics	Group 1 (n = 60)	Group 2 (n = 46)	Group 3 (n = 53)	p
GLASS aorto-iliac stage				–
IB	23 (38)	NA	24 (45)	
IIB	37 (62)	NA	29 (55)	
GLASS femoropopliteal grade				–
0	NA	0 (0)	0 (0)	
I	NA	0 (0)	0 (0)	
II	NA	16 (35)	9 (17)	
III	NA	19 (41)	31 (58)	
IV	NA	11 (24)	13 (25)	
GLASS infrapopliteal grade				–
0	NA	13 (28)	8 (15)	
I	NA	2 (4)	6 (11)	
II	NA	5 (11)	2 (4)	
III	NA	11 (24)	17 (32)	
IV	NA	15 (33)	20 (38)	
Lesion length – cm	9.2 ± 2.5	21.1 ± 3.4	28.5 ± 5.2	<.001
Chronic total occlusion	31 (52)	28 (61)	29 (55)	.64
PACSS grade 4	10 (17)	7 (15)	11 (21)	.75
Incomplete revascularisation	13 (22)	9 (20)	8 (15)	.66

Continuous data are presented as mean ± standard deviation; categorical data are presented as n (%). NA = not available; GLASS = Global Anatomic Staging System; PACSS = peripheral artery calcium scoring system.

characteristics among the study groups except for lesion length (p = .001) (Tables 1 and 2).

Early outcomes

The overall technical success rate was 98% (n = 156/159), with a non-statistically significant difference among study groups (Table 3). Failure was reported in three cases (group 1, n = 2; group 3, n = 1) and attributed to failed wire passage in severely calcified iliac vessels. A femorofemoral bypass was performed to treat the inflow lesions in these patients. Profundaplasty was performed in 29 of 34 cases with occluded profunda (group 1, n = 13; group 2, n = 5; group 3, n = 11). Post-operatively, the mean ABI/TBI increased significantly from 0.45 ± 0.12 to 0.82 ± 0.06 in group 1, from 0.42 ± 0.13 to 0.80 ± 0.07 in group 2, and from 0.39 ± 0.13 to 0.79 ± 0.07 in group 3 patients (p < .001 for all groups).

The overall peri-operative complication rate was 14% (22 patients). Medically related complications included non-

Table 3. Perioperative and late procedural outcome of 159 patients with chronic limb threatening ischemia (CLTI) due to multilevel disease studied for mid-term outcomes of common femoral endarterectomy combined with inflow (Group 1), outflow (Group 2) or inflow and outflow (Group 3) endovascular revascularisation procedure between January 2015 to May 2017

Study outcomes	Group 1 (n = 60)	Group 2 (n = 46)	Group 3 (n = 53)	p
Ankle brachial index/toe brachial index				
Pre	0.45 ± 0.12	0.42 ± 0.13	0.39 ± 0.13	.074
Post	0.82 ± 0.06	0.80 ± 0.07	0.79 ± 0.07	.15
Peri-operative outcomes				
Technical success	58 (97)	46 (100)	52 (98)	.46
Peri-operative mortality	0 (0)	1 (2)	2 (4)	.33
Non-fatal myocardial infarction	1 (2)	2 (4)	0 (0)	.28
Stroke	0 (0)	1 (2)	2 (4)	.33
Pneumonia	0 (0)	0 (0)	1 (2)	.37
Haematoma	3 (5)	0 (0)	1 (2)	.25
Pseudoaneurysm	0 (0)	1 (2)	0 (0)	.29
Seroma	1 (2)	0 (0)	2 (4)	.38
Superficial wound infection	1 (2)	2 (4)	1 (2)	.64
Deep wound infection	0 (0)	0 (0)	0 (0)	NA
Late outcomes				
Clinically driven target lesion revascularisation	4 (7)	15 (33)	21 (40)	<.001
Major amputation	0 (0)	2 (4)	3 (6)	.19
Late mortality	1 (2)	0 (0)	3 (6)	.17
Amputation free survival	59 (98)	43 (93)	45 (85)	.025

Continuous data are presented as mean ± standard deviation; categorical data are presented as n (%).

fatal myocardial infarction, stroke, and pneumonia. No significant renal complications were reported. Temporary changes were detected in three patients due to contrast induced nephropathy, and serum creatinine returned to baseline within two weeks of the procedure. These complications were managed successfully with the appropriate medical treatment. There were three 30 day deaths due to myocardial infarction (group 2, n = 1; group 3, n = 2; overall mortality rate 2%). Wound complications included superficial infection (n = 4; 8%), seroma (n = 3; 6%), and haematoma (n = 4; 7%). Surgical wound drainage, debridement, or control of lymph leak were required in three patients. Standard wound care, with suitable dressings and antibiotics, were provided for these cases. Operative re-intervention was required in one patient to repair a pseudoaneurysm successfully. There was no statistically significant difference between the groups regarding peri-operative morbidity or mortality (Table 3).

Late outcomes

The mean follow up was 31.9 ± 6.2 months (range 24—50 months; median 31 months). Kaplan—Meier analysis yielded overall primary, assisted primary, and secondary

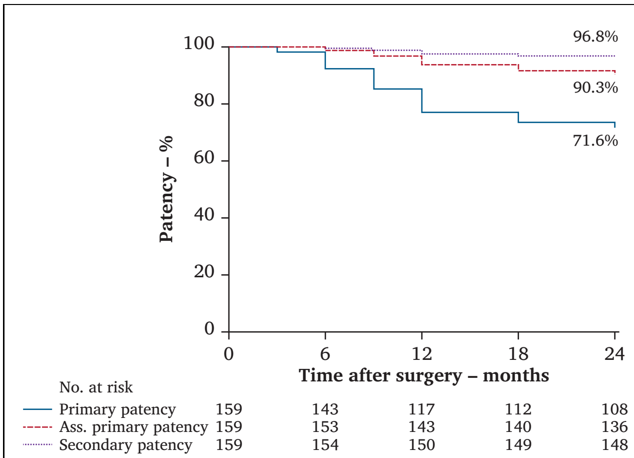

Figure 1. Cumulative Kaplan—Meier estimate of overall primary, assisted primary, and secondary patency in patients treated by hybrid multilevel revascularisation, including common femoral endarterectomy for chronic limb threatening ischaemia due to multilevel disease.

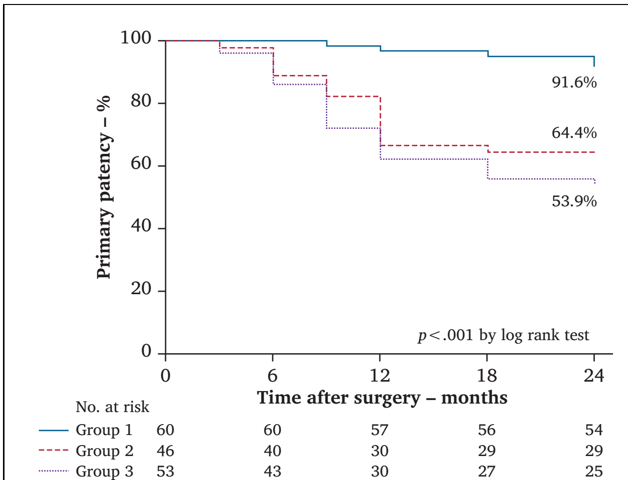

Figure 2. Cumulative Kaplan—Meier estimate of primary patency in patients for whom common femoral endarterectomy was combined with inflow (group 1), outflow (group 2), or inflow and outflow (group 3) endovascular revascularisation.

Table 4. Univariable and multivariable analysis of predictors of primary patency loss of lesions treated with common femoral endarterectomy combined with inflow (Group 1), outflow (Group 2) or inflow and outflow (Group 3) endovascular revascularisation procedure in patients with chronic limb threatening ischemia (CLTI) due to multilevel disease

Variables	Univariable analysis		Multivariable analysis	
	HR (95% CI)	*p*	HR (95% CI)	*p*
Patients demographics				
Age	1.02 (0.99–1.06)	.22		
Male sex	1.20 (0.61–2.37)	.60		
Diabetes	1.29 (0.66–2.49)	.46		
Hypertension	1.52 (0.83–2.78)	.18		
Coronary artery disease	1.14 (0.60–2.18)	.69		
Previous coronary artery bypass graft	0.47 (0.11–1.92)	.29		
Previous stroke/transient ischaemic attacks	1.56 (0.62–3.94)	.35		
Chronic kidney disease	1.09 (0.57–2.12)	.79		
Chronic obstructive pulmonary disease	1.24 (0.59–2.56)	.57		
Obesity	1.19 (0.53–2.67)	.66		
Current smoking	0.91 (0.50–1.63)	.74		
Dyslipidaemia	0.64 (0.35–1.18)	.15	0.50 (0.27–0.93)	.031
Lesion characteristics				
Lesion length	1.08 (1.04–1.11)	<.001	1.10 (1.06–1.14)	<.001
Chronic total occlusion	0.49 (0.26–0.93)	.030	0.50 (0.25–0.98)	.046
PACSS grade 4	2.29 (1.20–4.37)	.012	2.44 (1.27–4.68)	.008
Incomplete revascularisation	2.25 (1.18–4.29)	.014	3.32 (1.64–6.73)	.001

HR = hazard ratio; CI = confidence interval; PACSS = peripheral artery calcium scoring system.

patency rates of 71.6% ± 3.6%, 90.3% ± 2.4%, and 96.8% ± 1.4%, respectively, at 24 months (Fig. 1). Patients in group 3 had significantly lower PP rates at 24 months (91.6% ± 3.6% for group 1, 64.4% ± 7.1% for group 2, and 53.9% ± 7.1% for group 3; $p < .001$) (Fig. 2).

During the follow up period, loss of PP occurred in 44 patients. CD-TLR was deemed necessary in symptomatic cases ($n = 40/44$): PBA/stenting ($n = 29$), thrombolysis ($n = 8$), and thrombectomy ($n = 3$) followed by PBA/stenting of the target lesions to restore patency.

Re-interventions increased assisted PP to 96.7% ± 2.3% in group 1, 91.1% ± 4.2% in group 2, and 81.9% ± 5.5% in group 3, and SP to 100% in group 1, 95.6% ± 3.1% in group 2, and 94.0% ± 3.4% in group 3 at 24 months.

CD-TLR rates were statistically significantly higher in group 3 compared with the other two groups (40% for group III *vs.* 7% and 33% for group 1 and 2, respectively; $p < .001$). Group 3 patients also demonstrated lower AFS at 24 months ($p = .025$) (Table 3).

Univariable analysis for predictors of loss of PP is reported in Table 4. Based on the outcomes of the Cox regression multivariable analysis, lesion length (HR 1.10, 95% CI 1.06–1.14; $p < .001$), CTO (HR 0.50, 95% CI 0.25–0.98; $p = .046$), PACSS grade 4 (HR 2.44, 95% CI 1.27–4.68; $p = .008$), incomplete revascularisation (HR 3.32, 95% CI 1.64–6.73; $p = .001$), and dyslipidaemia (HR 0.50, 95% CI 0.27–0.93, $p = .031$) were the only significant independent predictors of loss of PP (Table 4).

DISCUSSION

Continuous advances in endovascular techniques and materials have made complex lesions treatable and have led surgeons to attempt an endovascular first strategy in both the inflow and outflow lower extremity arteries.[10,11] However, open CFA endarterectomy remains the gold standard for several reasons, including nature of the plaque, an unfavourable stenting zone being located in a highly flexible area, simultaneous profundaplasty to optimise the runoff, and to provide an access point for inflow and/or outflow endovascular treatment.[12]

Initial reports of hybrid procedures date from the 1970s.[13] Since then, most studies have investigated CFA endarterectomy or femorofemoral bypass combined with inflow endovascular therapy. They have reported comparable long term results to open surgical procedures, with lower or equal morbidity and mortality rates.[14]

The current prospective study aimed to assess the mid term outcomes of common femoral endarterectomy combined with an inflow and outflow endovascular revascularisation procedure as an alternative for high risk patients with CLTI. Included cases were treated rather homogenously under local or regional anaesthesia. Possible limitations in similar studies, making comparisons difficult and less meaningful, were lack of uniform reporting; involvement of both simple and complex arterial lesions; and inclusion of multiple surgical interventions. Table 5 demonstrates summary data retrieved from other relevant studies.[3,14–17]

Hybrid procedures in the current series constituted 18% of all reconstructions performed to achieve limb salvage, which is similar to other reports of 5%–21%, with a 7% increase in lower extremity hybrid interventions.[11,18,19] The overall peri-operative mortality rate in the current study was 2%, with no significant difference between the groups. All three deaths occurred in patients with poor cardiac

Table 5. Summary table of relevant studies reporting on hybrid multilevel revascularisation procedures

Relevant studies	Wieker *et al.*[16]	Takayama *et al.*[15]	Antoniou *et al.*[3]	Dosluoglu *et al.*[17]	Aho *et al.*[14]
Number of procedures	255	95	61	108	213
Lesion description	NS	TASC (A/B/C/D)	TASC (A/B/C/D)	Simple hybrid (TASC A/B)	NS
	Inflow lesions (71.2%)			Complex hybrid (TASC C/D)	Included IC (28.8%), CLI (70.2%), others (1.9%)
	Included IC and CLI				
Procedure	CFA endarterectomy (isolated [$n = 458$] or hybrid [$n = 255$])	CFA endarterectomy + inflow and/or outflow endovascular therapy	Endovascular treatment either proximal or distal to surgery site	CFA endarterectomy (75% in complex hybrid *vs.* 23% in simple hybrid)	Inflow endovascular procedure (60.5%) + CFA endarterectomy (38.6%), bypass (61.4%)
	CFA endarterectomy + inflow and/or outflow endovascular therapy	Femoropopliteal bypass ($n = 8/24$, TASC D lesions)	CFA endarterectomy (86.8%), others: femorofemoral, femoropopliteal, femorodistal bypass and graft/SFA thrombectomy	Others: infra-inguinal bypass, femorofemoral bypasses	Outflow endovascular procedure (34.8%) + CFA endarterectomy (78.1%), bypass (21.9%)
				Inflow endovascular procedures: 91% in simple hybrid *vs.* 88% in complex hybrid procedures	
Measured outcomes	7 year PP 78.6%*	3 year PP 64% (CR), 76% (IR)	12 month PP 71%	36 month PP (aorto-iliac) 81% ± 9%	Technical success rate 98.6%
	All groups limb salvage rate 92.6%	AFS 97% (CR), 81% (IR)	Overall limb salvage rate 95%	36 month PP (infra-inguinal) 84% ± 8%	PP/AFS (not mentioned)
Morbidity/ mortality	7 year complication rate 11.5%	Wound infection (8.1% CR, 4.2% IR)	Complication rate 6%	Post-operative mortality rate 6.4%	30 day mortality rate 1.4%
	Survival rate 60.1%	Mortality 5 (14%) CR, 4 (17%) IR	Peri-operative mortality 3%	Complication rate <16%	30 day amputation rate 0.4%

NS = not specified; TASC = Transatlantic Intersociety Consensus; IC = intermittent claudication; CLI = critical limb ischaemia; CFA = common femoral artery; SFA = superficial femoral artery; PP = primary patency; CR = complete revascularisation; IR = incomplete revascularisation; AFS = amputation free survival.

* PP evaluated the CFA segment.

function who were not in turn, candidates for extensive open surgery.

The current study included all consecutive patients who presented with CLTI due to multilevel arterial disease involving the CFA. Conventional bypass surgery was performed during the study period in isolated inflow ($n = 47$, 24 month PP 89%/SP 95%) or outflow ($n = 39$, 24 month PP 69%/SP 89%) occlusions, not involving the CFA. Combined inflow and outflow arterial disease requires special attention from treating physicians trying to overcome this challenging situation involving high risk patients with multiple comorbidities, and extensive occlusions that make a bypass option impossible in most cases.

In the current series, patients in group 3 had a significantly lower PP rate (53.9% ± 7.1%). However, re-interventions (CD-TLR 40%) successfully increased the assisted primary and SP rates to 81.9% ± 5.5% and 94.0% ± 3.4%, respectively. Lower patency rates in this group could be attributed to the more extensive and advanced atherosclerotic disease, in accordance with those reported in other studies in which multilevel disease was an independent risk factor for outcomes after angioplasty.[20,21]

Better results in group 1 and multivariable analysis that demonstrates lesion length as a significant predictor of PP loss (HR 1.10, 95% CI 1.06—1.14; $p < .001$) support the recommendation to stage the procedure whenever possible based on patient risk and degree of limb threat.[6]

Cox regression multivariable analysis in the current series yielded other significant predictors such as dyslipidaemia, lesion severity, extensive vessel calcification in the treatment zone, and incomplete revascularisation ending the procedure with poor runoff. Several studies reported better revascularisation results with improving the runoff, through SFA and profunda for inflow lesions,[22—24] and leg and pedal arteries for outflow lesions.[25,26] The association between dyslipidaemia and the development or progression of atherosclerosis has been studied extensively. Also, statins are strongly recommended as part of the best medical treatment for peripheral arterial disease.[6]

The CRITISCH registry group examined the outcomes of all first line strategies for the treatment of critical limb ischaemia.[27] AFS was the primary end point, and Cox regression analysis identified chronic kidney disease (CKD) and Rutherford 6 as factors compromising the endovascular procedure. These data could support the results, as CKD is linked to accelerated vessel calcification, altered remodelling, and Rutherford 6, which is major tissue loss beyond metatarsal level, indicating an underlying multilevel or complex arterial occlusion.[28]

Study limitations are the absence of a control group treated by conventional open surgery, and referral or selection bias pattern that could exist in studies conducted by individual centres. The new GLASS was not incorporated into multivariable analysis among other possible predictors of PP loss; however it should be mentioned that continuous validation of new grading systems or classifications is highly recommended to help uniform reporting and better research methods.

Future studies should focus on the impact of vessel preparation techniques or complementary endovascular materials such as drug eluting balloons or stents, lithotripsy, atherectomy devices, and stent grafts, on patency rates in high risk patients with complex long lesions involving both inflow and outflow vessels.

Conclusion

Common femoral endarterectomy combined with inflow and outflow endovascular revascularisation procedure in patients with CLTI is safe with accepted patency and limb salvage rates, despite the need for secondary interventions. Dyslipidaemia, lesion length, CTO, PACSS grade 4, and incomplete revascularisation are independent predictors of PP loss. The analysis of the current study supports the recommendation to stage the procedure based on patient risk and degree of limb threat.

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COUP D'OEIL

Iliac Artery Stripping as a TAVI Access Related Complication

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A 78 year old man with severe aortic stenosis was treated by transcatheter aortic valve implantation (TAVI). Owing to severe vessel tortuosity and calcification the delivery system was damaged, and the stent of the valve was trapped at external iliac artery level without being able to advance or withdraw it. An infrainguinal approach with deep undermining of the inguinal ligament allowed proximal control without retroperitoneal exposure, before pulling the system that resulted in complete stripping of external iliac and femoral arteries. An external iliac to superficial femoral artery bypass with re-implantation of the profunda femoris artery was performed successfully.

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