

Evaluation of Hybrid Intervention for Treatment of Multi Segmental Lower Limb Arterial Occlusive Lesions: Feasibility and Outcomes

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Abstract

Background: Open surgery alone for multi segmental lower limb arterial occlusion has high morbidity. Hybrid intervention can provide shorter hospital stay and less invasive procedures especially for high risk cases.

Aim of Study: To evaluate hybrid intervention for treatment of symptomatic common femoral artery (CFA) occlusive lesions combined with proximal or distal arterial lesion.

Patients and Methods: This prospective study included 53 patients with symptomatic common femoral artery occlusion combined with proximal and/or distal arterial lesions. Hybrid approach was performed for all patients; open surgery for common femoral artery lesions and endovascular interventions for other lesions. Follow up was one year.

Results: No mortality was reported but there was technical failure in two cases; Primary patency was reported in 50 patients (96.2%), 48 patients (92.3%) and 36 patients (69.3%) After one month, 6 months and 12 months respectively. Limb salvage rate was observed in 50 patients (96.2%), 44 patients (84.6%) and 40 patients (76.9%) After the first month, 6 months and 12 months respectively. Secondary patency was restored in 12 patients (23.1%) after one year.

Conclusions: Hybrid approach; play very important role in the treatment of symptomatic common femoral artery occlusion combined with iliac and/or infrainguinal arterial lesions with acceptable patency and limb salvage rates and allow satisfactory, minimal morbidity and durable intervention options especially in high risk patients to a great extent.

Key Words: Hybrid intervention – Common femoral artery occlusion – Outcomes.

Introduction

A **HYBRID** approach utilizing both endovascular and surgical repair has currently gained wide acceptance and includes bypass or endarterectomy with stent placement [1].

In the periphery, an iliac lesion with a CFA occlusion is often best treated with an iliac stent and CFA endarterectomy. The long term patency of the hybrid repair has been demonstrated to be comparable to open surgical repair [2,3].

Patient undergoing hybrid therapy for TASC C/D lesions experienced a shorter intensive care unit (ICU) stay and hospital stay than open surgery. The hybrid therapy is recommended for a high surgical risk patient regardless of TASC classification. Although stenting may be acceptable treatment for complex iliac lesions, it remains controversial whether TASC C/D infrainguinal lesions should be treated by endovascular therapy [1,4].

Endovascular intervention is better for short lesions in lower limb arterial occlusive disease whereas open surgery is better for long complex lesions. Hybrid intervention first reported in the early 1990s for Multilevel lesions [4,5].

Hybrid method is tailored for multi segmental arterial disease, for example common femoral endarterectomy combined with proximal iliac artery transluminal stenting or distal infrainguinal bypass or superficial femoral artery (SFA) angioplasty and stent. Every patient anatomy plays a role in the decision of single or multiple stages for intervention [5-8].

The best method of revascularization for treatment of symptomatic peripheral arterial disease (PAD) can be determined by the balance between the risk of intervention and durability [9,10].

Hybrid intervention can play an important role in the management of complicated common femoral artery aneurysm; open surgery to manage the aneurysm by interposition graft then endovascular management of the combined proximal and distal occlusive lesions [11,12].

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The aim of this study to evaluate the efficacy hybrid intervention for treatment of symptomatic common femoral artery (CFA) occlusive lesions combined with proximal or distal arterial lesion.

Patients and Methods

The current study was conducted after approval from local ethical committee of Benha University and National Institute of Diabetes and Endocrinology and obtaining written fully informed patients consent. Patients undergoing treatment by hybrid intervention for symptomatic common femoral artery occlusion combined with proximal or distal arterial lesion, at the vascular surgery department, Benha University and Diabetic Cairo Insurance Hospitals, were included in this study from August 2019 till August 2021; the enrollment period was one year and the patient follow-up period was one year.

This prospective study was conducted on 53 patients with symptomatic lower limb ischemic due to common femoral artery occlusion combined with proximal or distal arterial lesions. All patients were subjected to clinical and laboratory examination, Arterial Duplex, CT Angiography and Echo Doppler. Hybrid intervention was performed for all patients; open endarterectomy for common femoral artery occlusion and endovascular repair for proximal or distal lesions.

Inclusion criteria: Patients suffering from common femoral artery occlusion combined with proximal or distal arterial lesion \geq 60% diameter stenosis or Chronic Total Occlusion (CTO), Rutherford class (4 to 6) and fit for regional anesthesia.

Exclusion criteria: with Failed lesion crossing, Arteritic lesions, Thrombophilia, Life expectancy $<$ 1 year, presence of contraindication to contrast, contraindication to aspirin or clopidogrel (patient must be able to receive dual antiplatelet treatment for 2 months after the procedure), Cerebral Vascular Disease (CVD); who require interventional management first, Inability to comply with the follow-up schedule (as mental disability) also Patient who had prior bypass surgery, endarterectomy or other vascular surgery on any vessel of the ipsilateral limb.

Procedure:

All interventions were done in angio suite (Philips; Allura X per FD 20/722028164), C-arm image intensifier with road mapping was used. Patients were placed in supine position. Both groins were prepared using antiseptic solution povidone iodine (10%). Hybrid approach was performed

under Spinal anesthesia for open surgery of common femoral artery lesions and local anesthesia for endovascular interventions for other lesions.

The femoral vessels were exposed first through longitudinal or oblique incisions. The proximal extent of dissection was circumferential control of distal external iliac artery and distal extent of the dissection included circumferential control of proximal SFA and profound femoris arteries.

Then the endarterectomy began in CFA, after division and ligation of veins crossing anterior surface of profound femoris artery, femoral arteriotomy was performed beyond the posterior atheroma tongue extending a variable distance into the first or second part of profunda femoris artery. Tacking sutures may be carried out at the distal endpoint and the arteriotomy was closed with a vein or synthetic patch using 5-0 polypropylene (Ethicon). This patch was used to serve as access for further endovascular intervention of other lesions.

Access to the target iliac lesion was done by transbrachial puncture with using long sheath (better) or contralateral femoral puncture and performing a crossover technique or retrograde ipsilateral common femoral artery puncture through the patch. But Access to the target distal lesion was done by antegrade ipsilateral common femoral artery puncture through the patch.

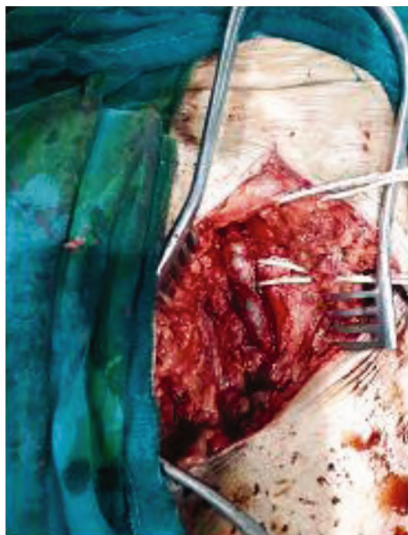
Angiography was done to confirm data obtained preoperatively. Iliac and distal lesions were identified. A guidewire was positioned through the lesion; a 0.035 hydrophilic guide wire (standard type; (Terumo, Tokyo, Japan) for stenosis and stiff type; (Terumo, Tokyo, Japan) for CTO supported by an angled-tip angiographic catheter (Bernstein 4F or 5F) (Merit Medical, South Jordan, Utah, U.S.A.).

Then a balloon catheter (Admiral extreme, Invatec S.p.A. Roncadelle (BS), Italy) of suitable diameter (3mm for tibial, 4 or 5mm for popliteal, 5 or 6mm for SFA, 7mm for EIA or 8 or 9mm for CIA) and length, was introduced over the wire to the distal extent of the lesion. The balloon was inflated till any waist has been abolished then deflated and should be re-inflated with overlaps until the whole lesion had been dilated. The inflation time was standardized; 3 minutes with heparinized saline injection after deflation. The balloon was withdrawn completely. Angiography was done to assess the result.

Then in patients of associated iliac lesions, routine stenting was done using (Visi-Pro, balloon-expandable peripheral stent system 7-9mm according to target lesion diameter) (ev3, Plymouth, MN, U.S.A.) stents in 40 patients. But in patients of SFA stenotic lesions, Indications for stenting were Elastic recoil (If the balloon was inflated fully, but the stenosis persists), A flow-limiting dissection (If prolonged balloon inflation was performed but the dissection persists). So stent (Protégé Ever flex self-expanding stent 5 or 6mm) (ev3, Plymouth, MN, U.S.A.) insertion was done selectively as a bailout in 44 patients.

The stent diameter and length were selected according to baseline CT scan estimate. The stent should cover the lesion and 2 to 5mm of the normal artery proximal and distal to the lesion. Stents were deployed at least 1 cm below origin of profunda femoral artery and 3cm above proximal margin of the intercondylar fossa of femur. Maximum of 1cm overlap was allowed in cases of 2 stents.

Associated popliteal and tibial lesions were treated only by routine angioplasty. The technical result was assessed by digital subtraction angiography. Manual compression was applied with time of compression was calculated according to sheaths size.



(A): Endarterectomy & patch repair.

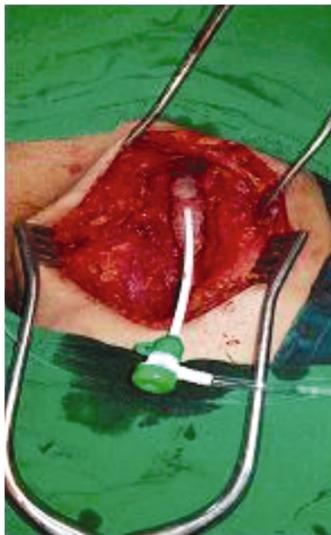


(B): Antegrade transpatch sheath.



(C): SFA total occlusion and angioplasty.

Fig. (1): Combined CFA endarterectomy and SFA angioplasty.



(A): Retrograde transpatch sheath.



(B): CIA balloon dilatation.



(C): CIA balloon stenting.



(D): Big toe distal phalanx amputation.

Fig. (2): Combined CFA endarterectomy and CIA stenting.

Post-operative follow-up:

I- Medications: All patients were maintained on dual anti-platelet agents for at least 6 months. If patients were in need for oral anti-coagulant, aspirin only was added. Patients received foot care consisting of wound dressing, minor debridement, limited amputations (up to transmetatarsal amputation (TMA)) and appropriate footwear.

II- Schedule: Clinical follow-up consisted of pulse examination and evaluation of ulcer or amputation site healing or resolution of infection. Clinical outcomes, patency rates and complications following the procedure were reported. All patients were re-examined after one week to check for access site and operative bed complications and to confirm patency. All patients were followed for one year with regular visits at 1,6 and 12 months. Follow up was in the form of clinical examination

and duplex US \pm CT angiography if needed in cases of absent or diminished pulse or recurrence of symptoms.

Statistical analysis: Collected data were tabulated and analyzed using SPSS version 16 software (SpssInc, Chicago, ILL Company) and Microstate W software (India, CNET Download.com). The means of all continuous variables were compared by appropriate parametric or non parametric tests. Categorical variables and proportions were compared the Chi Squared test or the Fischer exact test. Results are expressed as medians, percentages and as means \pm SD.

Results

This study included 53 patients with symptomatic common femoral artery occlusion combined with proximal and/or distal lesions. One patient

did not complete his follow-up so the available data was for 52 patients. The mean age was 57.6 ± 1.2 (46-73) years old; 24 patients (46.2%) were between 56-60 years old and 36 patients (69.3%) were males. Table (1).

Table (1): Patients' Pre-intervention data.

Data	Findings	
	Number (%)	Mean \pm SD (range)
Age (years):		
<i>Strate:</i>		
46-55	12 (23.1%)	49.2 \pm 3.2
56-60	24 (46.2%)	57.6 \pm 1.2
>60	16 (30.7%)	66.3 \pm 3.9
Total	52 (100%)	
Gender:		
Females ♀	16 (30.7%)	
Males ♂	36 (69.3%)	

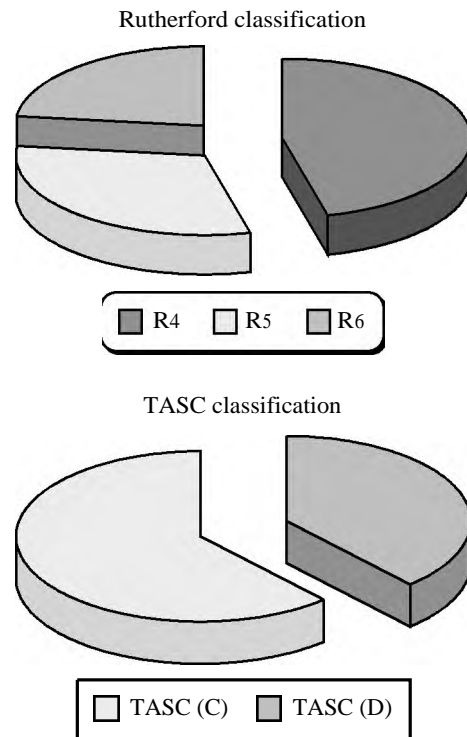
Data are presented as numbers.
Percentages & ranges are in parenthesis.

By giving concern to risk factors; smoking was observed in 40 patients (76.9%) and near half the patients clinically presented by ischemic rest pain (R5) in 24 patients (46.2%) depending on Rutherford classification. Duration of symptoms (weeks) was 6.73 ± 2.32 (5-9); Most patients 28 (53.8%) were ASA II and 32 patients (61.6%) were TASC (C). Table (2), Graph (1).

Table (2): Clinical presentation.

Data	Findings
	Number (%)
Risk factors & co-morbidities:	
Diabetics	32 (61.6%)
Hypertensive	20 (38.4%)
Smokers	40 (76.9%)
Hyperlipidemia	36 (69.3%)
Rutherford presentation:	
R4: Ischemic rest pain	24 (46.2%)
R5: Minor tissue loss, ulceration	16 (30.7%)
R6: Major tissue loss; gangrene	12 (23.1%)
American society of anesthesiologists grade (ASA):	
ASA I	16 (30.7%)
ASA II	28 (53.8%)
ASA III	8 (15.4%)
TASC classification:	
TASC (C)	32 (61.6%)
TASC (D)	20 (38.4%)
Symptoms duration (weeks)	6.73 \pm 2.32 (5-9)

More than one risk factor & co-morbidity was observed in one patient.
Data are presented as numbers; percentages & ranges are in parenthesis



Graph (1): Rutherford and TASC classification.

As regard to lesion characteristic; in addition to common femoral artery occlusion in all patients; with proximal or distal lesions as shown in Table (3).

Table (3): Lesions distribution.

Data	Findings
	Number (%)
Lesions distribution:	
Iliac artery:	
Occlusion	12
Stenosis	28
Total	40 (76.9%)
SFA:	
Occlusion	16
Stenosis	32
Total	48 (92.3%)
Popliteal artery:	
Occlusion	4
Stenosis	8
Total	12 (23.1%)
Tibial arteries:	
Single vessel	4 (7.7%)
Two vessels	32 (61.6%)
Three vessels	16 (30.7%)

More than one associated lesion was observed in one patient.
Data are presented as numbers; percentages & ranges are in parenthesis

All patients passed uneventful intra-operative course without technical failure; Common femoral artery lesions were treated mainly by endarterectomy and patch closure in addition to iliac artery stenting through ante grade (cross over in 5 patients, trans brachial in 3 patients, or retrograde access in 32 patients. Superficial femoral artery (SFA) lesions were treated either by Stenting in 44 patients (84.6%) or Femoropopliteal bypass in four patient (7.8%) but all Popliteal and infrapopliteal lesions were treated by Angioplasty. Table (4).

Table (4): Intervention data.

Data	Findings
	Number (%)
<i>Associated lesions:</i>	
Iliac angioplasty and stenting	40 (76.9%)
<i>SFA:</i>	
Angioplasty ± stenting	44 (84.6%)
Femoropopliteal bypass	4 (7.8%)

More than one procedure was observed in one patient. Data are presented as numbers. Percentages & ranges are in parenthesis.

There was no mortality during the procedure. After the first month, primary patency was reported in 50 patients (96.2%) and limb salvage was achieved in 50 patients (96.2%) because two patients had above knee amputation due to failed revascularization even after femoropopliteal bypass and spreading gangrene thus decreasing overall success rate. Debridement procedures and foot sparing amputations (Toe and Ray amputation) were done for 12 patients (23.1%).

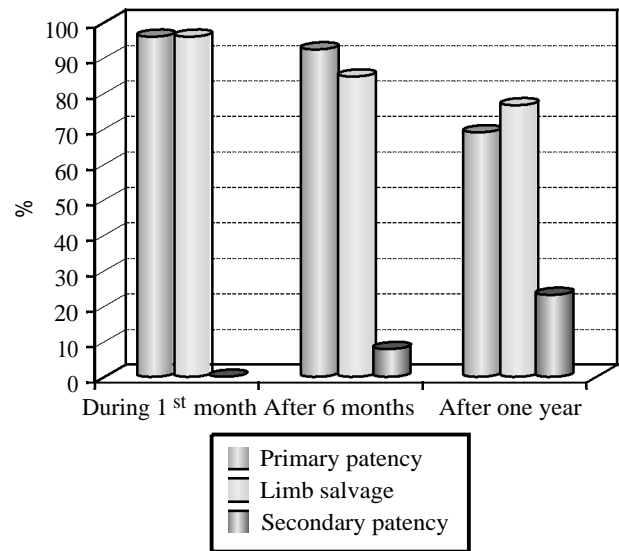
After 6 months; primary patency was observed in 48 patients (92.3%) and limb salvage in 44 patients (84.6%); this was due to acute thrombosis of popliteal and infrapopliteal arteries; a trial of thrombolytic therapy was applied to restore patency but it was unsuccessful and below knee amputation was done.

After 12 months; primary patency was noticed in 36 patients (69.3%) and limb salvage in 40 patients (76.9%). Secondary patency was restored in 12 patients (23.1%) by SFA stenting in eight patients and femoropopliteal bypass in four patients. During SFA stenting; thrombosis with trash was observed in four patients and above knee amputation was done. Table (5), Graph (2).

Table (5): Outcomes of the interentions.

Outcomes	Primary patency N (%)	Limb salvage N (%)	Secondary patency N (%)
During 1 st month	50 (96.2%)	50 (96.2%)	0 (0%)
After 6 months	48 (92.3%)	44 (84.6%)	4 (7.8%)
After one year	36 (69.3%)	40 (76.9%)	12 (23.1%)

Data are presented as numbers; percentages & ranges are in parenthesis.



Graph (2): Outcomes of the interventions of the patients.

Discussion

Open repair of multi segmental arterial lesions of the lower limb have more morbidity. For treatment of such combined lesions; Hybrid technique provides more durable and less invasive intervention especially for high risk patients [8].

This study included 52 patients with symptomatic common femoral artery occlusions combined with proximal and/or distal lesions. The mean age was 57.6±1.2 (46-73) years old; 24 patients (46.2%) were between 56-60 years old; these data were comparable to Zou et al., [13]; who reported. The average age of their patients was 69.2 years (range, 49-88 years). Aging is very strong risk factor for PAD [14-16].

In the current study; 36 patients (69.3%) were males; as reported by Zou et al., [13]; who examined gender in 40 patients having multilevel lower limb ischemia including femoral bifurcation and found similar result 27 patients (67.5%) were men. But less than that observed by Joh et al., [8]; male-to-female ratio in 76 patients was 67:9 (88.2%); this is due to the fact that men are heavy smokers [15].

By reviewing the risk factors; smoking was observed in 40 patients (76.9%); Smoking is the most dangerous risk factor for progression of PAD and more likely to require amputation or vascular intervention Joh et al., [8]. This was comparable to a study done by Zou et al., [13] and Chen et al., [17]; (67%) and (78.9%) respectively. But more than mentioned by Joh et al., [8]; (33.3%).

The indications of intervention; more than half of the patients of this study clinically presented by lesions TASC (C); 32 (61.6%) with ischemic rest pain (R4) in 24 patients (46.2%); it was found that they were near similar to study done by Joh et al., [8]; 10/21 patients (47.6%) of his hybrid group complained rest pain. But they were more than a study on 40 patients done by Zou et al., [13] who reported in his study; rest pain in (28%) and tissue loss in (36%).

Common femoral artery lesions were treated by endarterectomy and vein patch closure in addition to iliac artery stenting in 40 patients and/or Superficial femoral artery (SFA) lesions were treated either by Stenting in 44 patients (84.6%) or Femoropopliteal bypass in four patients (7.8%) but all Popliteal and infrapopliteal lesions were treated by Angioplasty. This type of repair was similar to Dosluoglu et al., [18] who reported double PAGA (prearteriotomy guidewire access) intervention in which both inflow and outflow lesions are crossed with wire before femoral endarterectomy. Also such repair was evaluated by Cotroneo et al., [19]; they carried out femoral endarterectomy and/or bypass repair concomitant with endovascular repair of associated proximal and distal lesions [20].

Femoral artery open endarterectomy is simple, has low morbidity and high patency rate and can be combined with any other endovascular technique. Many reports were proving this fact; it is an efficient with a durable outcome [13,21].

During femoral endarterectomy; profunda femoris artery eversion endarterectomy is clinically important; because adequate profunda perfusion acts as the backdoor for limb perfusion so recurrent limb ischemia is delayed [22].

By giving concern to outcomes; No mortality was reported. Primary patency was reported in 50 patients (96.2%), 48 patients (92.3%) and 36 patients (69.3%) After the first month, 6 months and 12 months respectively. This outcome was near similar to that reported by Zou et al., [13]; The primary patency rate at 12 months was (64%) and Matsagkas et al., [23]; The primary patency rate

After the first month in 37 patients was (97.3%). Limb salvage rate was mentioned in the current study in 50 patients (96.2%), 44 patients (84.6%) and 40 patients (76.9%) After the first month, 6 months and 12 months respectively. This result was less than that mentioned in the study 60 patients done by Antoniou et al., [24] who observed limb salvage was (90%) at 6 months and Matsagkas et al., [23]; who reported limb salvage was (94.6%) at one year. Secondary patency in our study was restored in 12 patients (23.1 %) at one year which was near similar to Zou et al., [13]; who mentioned secondary patency rate at one year was (78%).

The hybrid procedure has several benefits; complete vascular repair of affected limb without delay, short ICU stay and minimal access-site complications because target artery is repaired through the intervention field [1,24,25].

Conclusions: Hybrid approach; play very important role in the treatment of symptomatic common femoral artery occlusion combined with iliac and/or infrainguinal arterial lesions with adequate patency rates and limb salvage and allow satisfactory, minimal morbidity and durable intervention options especially in high risk patients to a great extent.

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تقييم التقنية الهجينة (جراحي وتداخلي ، بالقسطرة الطرفية العلاجية) في علاج انسداد لشرايين متعدد المستويات : فوائدها ونتائجها

يعد انسداد الشرايين وقصور الدورة الدموية في الساقين من الأمراض المعقدة التي تمثل تحدياً صعباً في تخصص جراحة الأوعية الدموية.

يضم علاج قصور الدورة الدموية في الساقين ثلاثة أنماط من التدخلات:
١- جراحياً.

٢- بالقسطرة التداخلية التوسيع بالبالون واستخدام الدعائم.

٣- التقنية الهجينة والتي تشمل استخدام القسطرة مع الجراحة في آن واحد.

ومن ثم، فإن الجراحة المفتوحة وحدها لعلاج انسداد الشرايين متعدد المستويات، تمثل عبئاً كبيراً على المريض، كما تزيد من مدة الإقامة في المستشفى، وحدوث المضاعفات.

ومن خلال هذا البحث، تناولنا استخدام التقنية الهجينة في علاج انسداد الشرايين متعدد المستويات، عن طريق فتح شريان الفخذ الرئيسي جراحياً، ثم علاج المستوى الأعلى منه (عكس اتجاه سريان الدم)، أو الأدنى منه بالقسطرة التداخلية (مع اتجاه سريان الدم). ودراسة ما إذا كانت هذه التقنية الهجينة فعالة وذات كفاءة عالية في علاج انسداد الشرايين متعدد المستويات لإنقاذ الأطراف من البتر.