

Hybrid Management of Critical Limb Ischemia in Assiut University Hospital

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Abstract

Background: The alternative of hybrid revascularization surgery combines the well-established patency benefits of open vascular surgery with the advantages of less-invasive endovascular interventions to provide a durable and safe solution for critical limb ischemia.

Aim of Study: The aim of this study was to evaluate the feasibility and efficacy of hybrid therapy in patients with complex multifocal steno-obstructive vascular disease and report short and midterm outcomes through assessment of patency and salvage rates.

Patients and Methods: This study was conducted prospectively on thirty patients who presented to the Department of Vascular Surgery of Assiut University Hospital with critical limb ischemia due to multilevel peripheral arterial disease involving CFA from November 2015 to November 2016. All patients underwent detailed history taking, and data were collected on age, sex and risk factors. Patients were further evaluated using clinical examination, measurement of the Ankle Brachial Index (ABI), duplex ultrasound, and computed tomography angiography if needed.

Results: Our study had male predominance (83.3%) with a mean age of 65 years. The most frequent risk factor was smoking in 18/30 (60%). According to Rutherford classification, the majority of patients (50%) were treated for digital gangrene, followed by minor tissue loss (33.3%) and rest pain (16.7%). Femoral endarterectomy was done in all cases, combined with both proximal and distal endoluminal procedures in 40% of patients, with proximal endoluminal procedures only in 26.7% and with distal endoluminal procedures in 26.7%. Technical success was achieved in 95.8% of procedures. The primary patency rate at 1st, 6th and 12th months were 96.7%, 90% and 80% respectively. Secondary patency rates at 1st, 6th and 12th months were 100%, 83.3% and 67% respectively while limb-salvage rate at 1st, 6th and 12th months were 100%, 100%, and 93.3% respectively. Diabetes has been found to reduce 1-year patency rate with statistically significant difference.

Conclusion: Hybrid lower extremity revascularization procedures can be used to treat CLI with low perioperative

morbidity and mortality and good immediate and midterm patency and limb salvage.

Key Words: Hybrid – Revascularization – Critical limb ischemia – Peripheral arterial disease.

Introduction

CRITICAL Limb ischemia (CLI) is a condition in which patient presents a clinical status of pain at rest or at night and presence of tissue loss (ulceration, gangrene), and it is linked with a high risk of loss of the affected limb. CLI is therefore clearly responsible for increasing morbidity and mortality and consumes considerable social and healthcare resources [1].

Successful treatment of patients with CLI has always been a challenge for the vascular surgeon, as atherosclerotic lesions usually involve multiple vascular beds, requiring extensive, multilevel revascularization procedure [2].

Moreover, CLI is frequently associated with multiple medical comorbidities, making these patients high risk for extensive open surgical procedures [3].

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 to staged procedures in different locations [4].

The alternative of hybrid revascularization surgery combines the well-established patency

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benefits of open vascular surgery with the advantages of less-invasive endovascular interventions to provide a durable and safe solution [5].

Patients and Methods

This study was conducted prospectively on thirty patients (30 limbs) who presented to the Department of Vascular Surgery of Assiut University Hospital with critical limb ischemia due to multilevel peripheral arterial disease involving CFA from November 2015 to November 2016. The study was approved by the Ethical Committee of our institution. Patients or relatives of patients provided written consent for study participation.

Inclusion criteria:

- Patient with Critical Limb Ischemia presented with rest pain or tissue loss (Fontaine III-IV, Rutherford 4-6).
- Obstructive arterial disease in the femoral bifurcation segment (including the common femoral artery, femoris profunda, or the origin of the superficial femoral artery), and at least one level among the iliac, femoropopliteal and infragenicular arteries.

Exclusion criteria:

- Patient with a significant contraindication to angiography:
 - i- Patient with renal impairment.
 - ii- Patient with hypersensitivity to the dye.
- Patients presented with extensive necrosis or infective gangrene requiring primary major amputation.

All patients underwent detailed history taking, and data were collected on age, gender, cardiovascular risk factors such as smoking, Diabetes Mellitus (DM) and hypertension.

Patients were further evaluated using clinical examination, measurement of the Ankle Brachial Index (ABI) using Doppler, duplex ultrasound, and multi-detector Computed Tomography Angiography if needed.

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 (SVS) reporting standards [6].

All patients underwent CFA endarterectomy in combination with endovascular repair of inflow and/or outflow lesions in the same surgical setting. CFA endarterectomy was performed using the

standard technique under an ipsilateral common femoral bifurcation exposure through a longitudinal groin incision. During endarterectomy, adequate Profunda Femoral Artery (PFA) outflow was always preserved or restored.

Reconstruction of the common femoral artery and bifurcation was typically completed using a patch (autogenous saphenous vein or synthetic material).

We then proceed to the endovascular part of the procedure; a standard 6 French sheath was inserted by puncture to distal part of the patch. The sheath was introduced only a short distance inside the artery to avoid subintimal placement.

A guide wire and a catheter were directed to the intraluminal space of external iliac artery and the iliac artery is treated endovascularly.

In the case of an iliac occlusion, the retrograde approach is the first choice, and the antegrade approach via the left brachial artery was adopted only if retrograde approach failed.

For patients with critical ischemia and infrainguinal multilevel arterial disease, open femoral endarterectomy and distal intervention can be done simultaneously. The sheath is then placed in an antegrade fashion to treat femoropopliteal or tibial lesions.

Hemostasis was established by placing a Prolene suture at the puncture site. Final angiography was done to verify patency of the runoff arteries.

All patients were followed by clinical evaluation, ABI and colour duplex at 1, 6 and 12 months.

Technical success was defined as residual stenosis <30% on completion intraoperative arteriography.

Statistical analysis:

Statistical analysis was performed using Windows Version 20.0 (SPSS; SPSS Inc., Chicago, Illinois, USA). Categorical variables were reported as numbers with percentages. Continuous variables were reported as means with standard deviation. Chi-square test was used to compare qualitative data between different groups.

All *p*-values <0.05 were considered significant. The primary patency rate on an intention-to-treat basis of angioplastied vessels was calculated by the survival analysis techniques (Kaplan-Meier curve).

Results

The study included 25 (83.3%) males and 5 (16.67%) females with a mean age of 65 ± 10.28 years (range: 50-85 years) (Table 1).

In our study 12 (40%) patients were suffering from CLI in right lower limb and 18 (60) patients were suffering from CLI in left lower limb.

The most frequent risk factor in the current study group was smoking where 18 (60%) patients were smokers followed by Diabetes in 16 (53.3%), hypertension in 14 (46.7%) and dyslipidemia in 12 (40%) of patients. Other risk factors in the current study were history of coronary artery diseases and stroke in 9 (30%) and 3 (10%) patients respectively (Table 2).

Clinical presentation of the study group is shown at (Table 3). Digital gangrene (Rutherford category 6) was the most frequent presentation where it presented in 15 patients (50%) followed by lower limb ulcer (Rutherford category 5) in 10 patients (33.3%) and rest pain (Rutherford category 4) in 5 patients (16.7%).

The CFA was involved with atherosclerosis in all cases (100%). It was associated with inflow disease involving the ipsilateral iliac artery in 8 cases (26.7%), with outflow disease (Femoropopliteal and leg vessels) in 8 cases (26.7%), and associated with both inflow and outflow disease in 14 cases (46.6%).

Femoral endarterectomy was combined with both proximal and distal endovascular angioplasty interventions in 12 cases. In two cases femoral endarterectomy was combined with surgical bypass and distal endovascular intervention.

Femoral endarterectomy was combined with proximal endovascular angioplasty in eight cases, and with distal endovascular angioplasty in another eight cases (Table 4).

Technical success was achieved in 46 out of 48 (95.8%) of procedures. In two patients, there was a failure to cross the SFA owing to the presence of a chronic long-segment occlusion. In these two cases, no intervention in addition to the CFA endarterectomy and iliac angioplasty was attempted, because both patients were treated for rest pain and the decision made was to assess the effect on each patient's symptoms.

Hemodynamic and clinical success was achieved in all patients (100%) patients included in the study. The mean resting ABPI improved signifi-

cantly, rising from 0.34 ± 0.053 preoperatively to 0.79 ± 0.121 after the intervention (*p* < 0.05).

Only 4 cases had post-operative complications that were managed successfully. These complications represent 13.3% of the whole study group, their frequency of occurrence and their management is shown in (Table 5). There was no post-operative 30 day mortality.

The primary patency rate at 1st, 6th and 12th months were 96.7%, 90% and 80% respectively. Secondary patency rates at 1st, 6th and 12th months were 100%, 83.3% and 67% respectively as shown in Fig. (1).

In our study limb-salvage rate at 1st, 6th and 12th months were 100%, 100%, and 93.3% respectively as shown in Fig. (2).

The 1-year patency rate was significantly lower in diabetic patients than among non-diabetic (*p*-value=0.03).

The 1-year patency rate was significantly lower in patients presented with combined outflow & inflow disease than among patients with inflow or outflow disease only (*p*-value=0.01).

The 1-year patency rate was significantly higher when vascular stents were placed than among non-stented arteries (*p*-value 0.03).

Table (1): Sex distribution in the study group.

Sex	Frequency (n (%))
Male	25 (83.3%)
Female	5 (16.67%)
Total	30 (100%)

Table (2): Risk factors.

Risk factors	Frequency (n (%))
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%)

Table (3): Clinical presentations in the current study group.

Rutherford category	Clinical description	Frequency (n (%))
4	Ischemic rest pain	5 (16.7%)
5	Minor tissue loss (ulcer)	10 (33.3%)
6	Major tissue loss (gangrene)	15 (50%)

Table (4): Types of intervention in the current study group.

Intervention	Frequency (n (%))
<i>Femoral endarterectomy:</i>	
Proximal and distal PTA	12 (40%)
Surgical bypass and distal PTA	2 (6.6%)
Proximal PTA	8 (26.7%)
Distal PTA	8 (26.7%)

Table (5): Complications of interventions of the current study group.

Complication	Frequency (n (%))	Management
• Arterial thrombosis	1 (3.3%)	• Thrombectomy • Remained in the coronary ICU for 3 days, and was discharged on the 15 th day in good general condition
• Acute myocardial infarction on the 2nd post-operative day	1 (3.3%)	

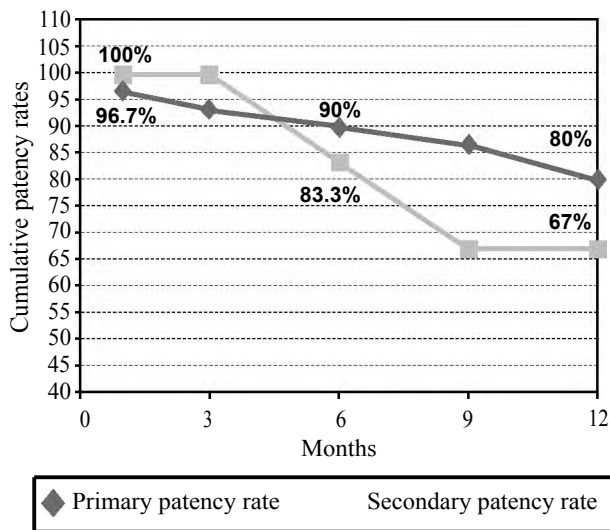


Fig. (1): Kaplan-Meier curve shows cumulative primary and secondary patency rates in limbs treated with hybrid procedures for critical limb ischemia.

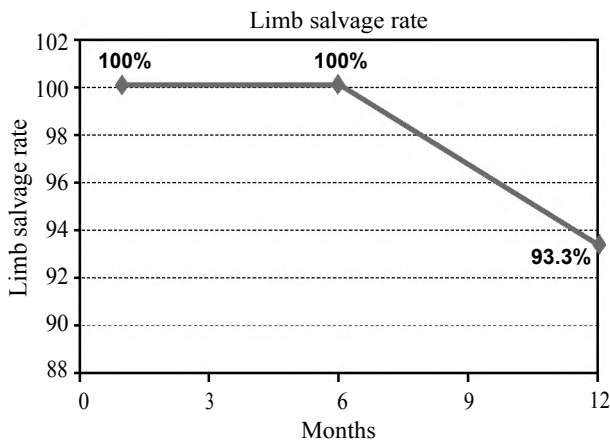


Fig. (2): Kaplan-Meier curve shows limb salvage rate in limbs treated with hybrid procedures for critical limb ischemia.

Discussion

Multilevel atherosclerotic arterial disease affecting the lower extremities requires complex treatment strategies, which involve inflow and outflow arterial reconstructions, in order to provide patients with adequate clinical improvement. Conventional open surgical management of such lesions consists of extensive re-vascularization procedures. However, multisegmental arterial disease is frequently associated with significant co-morbidities and critical lower extremity ischemia, categorizing these patients as high risk for major operative procedures. This has prompted the adoption of less-invasive interventions [7].

The alternative of hybrid revascularization surgery combines the well-established patency benefits of open vascular surgery with the advantages of less-invasive endovascular interventions to provide a durable and safe solution for critical limb ischemia [3].

According to 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS), Hybrid procedures (e.g. aortoiliac stenting and distal bypass) should be encouraged in a one-step modality when necessary [8].

Our study group had male predominance (83.3%), with a mean age of 65±10.28 years (range: 50-85 years). In accordance, Zou et al., (2012), reported mean age 69.2 years with 67.5% males [9].

In the current study, smoking was reported in (60%) of patients, followed by diabetes mellitus (53.3%), hypertension (46.7%), coronary artery disease (30%) and dyslipidemia (40%). Contrary, Taurino et al., (2014), and Jung et al., (2016), reported hypertension as the main associated risk factor (91.7%) and (81.6%) respectively [10,11].

According to rutherford classification, the majority of patients (50%) were treated for digital gangrene, followed by minor tissue loss (33.3%) and rest pain (16.7%). In accordance Jung et al., [11], reported tissue loss as the main clinical presentation of the study group (62.8%) [11]. On the other hand, Matsagkas et al., [12], reported (52.3%) of the patients were treated for rest pain.

In our study, femoral endarterectomy was done in all cases combined with both proximal and distal PTA in 40% of patients, with proximal PTA only in 26.7% and with distal PTA in 26.7%. One fem-

orofemoral bypass and one iliofemoral bypass were combined.

Contrary, Matsagkas et al., [12], 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%.

In our study, stenting was used selectively for flow-limiting arterial dissections or when angioplasty alone did not produce a satisfactory result (residual stenosis of $\geq 30\%$) [13].

Stenting was deemed necessary in 56.7% of cases because of residual stenoses in 70% of stented cases, and arterial dissection in the remaining 30%. No stenting was used in the infra-popliteal arteries because of lack of evidence that primary stenting improves patency or limb salvage compared with angioplasty alone [14].

Similarly, Jung et al., (2016), reported stenting in 48.6% of angioplastied lesions with no stenting in angioplastied infrapopliteal vessels [11]. However, Matsagkas et al., [12] and Zou et al., [9], recorded stenting in 77% and 70% of procedures respectively.

In our study, we achieved technical success in 95.8% (46 out of 48) of procedures. In two patients, there was a failure to cross the SFA owing to the presence of a chronic long-segment occlusion.

Hemodynamic and clinical success was achieved in all patients (100%) of patients included in the study. The mean resting ABI improved significantly, rising from 0.34 ± 0.053 preoperatively to 0.79 ± 0.121 after the intervention ($p < 0.05$).

The results we observed are in agreement with those reported by Matsagkas et al., [12], in a series of thirty-seven patients (44 limbs) using hybrid techniques during a single procedure. Technical and hemodynamic success rates were 96.6% and 100%, respectively.

In our series only 4 cases had post-operative complications that represent 13.3% of the whole study group. One case had arterial thrombosis that was managed successfully by thrombectomy; another case suffered an acute myocardial infarction on the 2nd post-operative day, remained in the coronary ICU for 3 days, and was discharged on the 15th day in good general condition. The remaining two perioperative complications were lymphorrhea and were managed conservatively without need for any intervention.

Our results are in line with those of Jung et al., [11], they reported a complication rate of 11.6%. Contrary Antoniou et al., (2009) reported a higher complication rate of 36% varying between infective complications, either local or systemic (10%), cardiac complications (myocardial infarction, cardiac failure) in (8%) and acute renal failure in (3%) because of higher incidence of associated cardiovascular risk factors in relation to our study group, as hypertension (75%), coronary artery disease (43%) and dyslipidemia (50%) [7].

Hybrid therapy allowed us to obtain a 12-month follow-up, the primary patency rate at 1st, 6th and 12th months were 96.7%, 90% and 80% respectively. Secondary patency rates at 1st, 6th and 12th months were 100%, 83.3% and 67% respectively while limb-salvage rate at 1st, 6th and 12th months were 100%, 100%, and 93.3%.

Our results are in agreement with Jung et al., (2016) followed 38 consecutive patients (43 limbs) with multilevel peripheral arterial disease in critical limb ischemia who were treated by simultaneous hybrid operation which combined common femoral artery endarterectomy and additive interventional procedure by single surgeon. The primary and secondary patency rates at 24 months were 67.3 and 72.1%, respectively. The limb salvage rate was 95.3% [11].

On the other hand, Matsagkas et al., [12], in a series of thirty-seven patients (44 limbs) using hybrid techniques during a single procedure, 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 fact that most of their patients (52.2%) were presented with rest pain, unlike our study where 50% of patients presented with digital gangrene and 33.3% presented with minor tissue loss (ulcer) which would be associated with worse outcome. Furthermore, in their study only 18% of patients had both proximal and distal arterial lesions compared to 40% of our patients which reflect more extensive and severe atherosclerotic disease.

The 1-year patency rate was higher when vascular stents were placed than among non-stented arteries with statistically significant difference (p -value=0.03), but it was lower in combined inflow and outflow lesions than among inflow only or outflow only with statistically significant difference (p -value=0.01).

In the current study, the primary patency rate was lower in diabetic than non-diabetic patients with statistically significant difference (p -value

<0.05). In accordance with Spanos et al., [15], in retrospective analysis from a single center of 132 patients who underwent hybrid procedures for the management of multisegmental chronic peripheral arterial disease the Hazard Ratio for primary patency failure was 1.94 times higher in diabetic patients (p -value=0.029).

Limitations to our study include the small number of patients involved, the short period of follow-up and the absence of control group(s) for comparison. CLI patients are frequently elderly and frail, with short life expectancy and mortality approaching 70% at 5 years and 95% at 10 years [16].

Conclusion:

Hybrid interventions are considered to be safe and effective modality in the treatment of critical limb ischemia due to multilevel arterial occlusive disease in the fragile vascular patient population.

There is a substantial need for endovascular training during vascular surgical education programs, as modern vascular surgeons need to master both open and endovascular techniques, and combine them in a creative fashion, to the benefit of our patients.

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Nil.

Conflicts of interest:

There are no conflicts of interest.

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العلاج الهجين للقصور الدموي الحرج بالأوعية الدموية للطرف السفلى داخل مستشفى جامعة أسيوط

إن حالات القصور الدموي الحرج لشرابيين الطرفين السفليين فى تزايد مستمر نتيجة زيادة الإصابة بتصلب الشرايين الطرفية للجسم نتيجة الإفراط فى التدخين وإرتفاع نسبة الإصابة بأمراض إرتفاع ضغط الدم والسكري وأمراض السمنة.

ظهر دور العلاج الهجين بإستخدام التدخل الجراحى مع توسع الشرايين بإستخدام البالون فى نفس الجلسة نتيجة تعدد مستويات الضيق والإنسداد بالشرابيين فى حالات القصور الحرج للشرابيين وذلك داخل غرف عمليات مجهزة بالأنوات الجراحية والقساطر والبالونات تحت جهاز الأشعة التداخلية.

تهدف هذه الداسة إلى تقييم سلامة وفعالية تقنية العلاج الهجين للقصور الدموي الحرج بالأوعية الدموية للطرف السفلى من خلال تقييم النجاح التقنى الأولى، فترة هذا النجاح بدون تدخلات أخرى، المضاعفات المحتملة (مع مراجعة لكيفية التعامل مع هذه المضاعفات)، وقياس معدل إنقاذ الأطراف.

قد أجرينا دراسة على ٣٠ مريض يعانون من نقص حرج فى الدورة الدموية لأطرافهم، خضعوا للعلاج الهجين بإستخدام التدخل الجراحى مع توسيع الشرايين بالبالون فى نفس الجلسة داخل غرفة عمليات مجهزة.

إحتوت الدراسة على (٨٣.٣٪) من الذكور و (١٦.٧٪) من الإناث ويبلغ متوسط أعمارهم ٦٥ عاما، وكان عامل الخطر الأكثر شيوعا هو التدخين فى (٦٠٪) من المرضى، يليه مرض السكرى فى (٥٣.٣٪) من المرضى، ثم مرض إرتفاع ضغط الدم فى (٤٦.٧٪) من المرضى، وعسر شحميات الدم فى (٤٠٪) من المرضى، وأخيرا أمراض الشرايين التاجية فى (٣٠٪) من المرضى.

كان معدل المرضى الذين يعانون من آلام أثناء الراحة هو (١٦.٧٪) و (٣٣.٣٪) يعانون من قرح بالأطراف، و (٥٠٪) من غرغرينا بالأطراف.

كان النجاح الفنى الأولى (٩٥.٨٪)، مع معدل النجاح الإبتدائى (٩٦.٧٪) خلال أول ٣٠ يوم و (٨٠٪) خلال ١٢ شهر على التوالى مع معدلات أعلى لإنقاذ الأطراف وصلت إلى (٩٣.٣٪) خلال ١٢ شهر.

فيما يخص مضاعفات ما بعد الجراحة، فقد حدثت فى (١٣٪) من المرضى، وقد تمكنا من التعامل معها جميعا بنجاح.

قد خلصنا من نتائج هذه الدراسة أن العلاج الهجين بإستخدام كلا من الجراحة وتوسيع الشرايين بالبالون فى نفس الجلسة هو تقنية آمنة وفعالة فى علاج القصور الحرج فى الدورة الدموية للأطراف.