OPENAIMJ ORIGINAL ARTICLE

Role of Hybrid Procedures in Treatment of Critical Lower Limb Ischemia

Vascular Surgery

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ABSTRACT

Background: The lower limb peripheral arterial disease (PAD) is the third-largest atherosclerotic disease site along with heart disease and cerebrovascular disease, a condition that was often overlooked in the past, but which has been a growing cause of Cardiovascular Disability and Mortality, in recent years.
Aim of work: Assessment of the results of hybrid procedures using Endovascular and open techniques for surgery simultaneously, in patients with critical lower limb ischemia caused by arterial multi-levelocclusive disease, as regards to patency as well as the complications.
Patient and Methods: This randomized study was conducted on 40 patients attending at Al-Azhar University Hospitals with arterial multisegmental lesionsaffecting lower limbs. They all treated with hybrid techniques.
Results: Technical success in 93.22% (55 of 59) of the procedures.The pre-intervention mean ABPI for the 40 patients was 0.32 ± 0.04, which improved to 0.70 ± 0.15 immediately post-intervention (P<0.01).The primary rate of patency at 12 months was 72.5%. The cumulative limb salvage rate at 12 months was 77.5% (standard error: <10%). It was seven major and ten minor complications in the perioperative period for an overall rate of 27.5%. Mortality occurred in two patients (5%).
Conclusion: the hybrid procedures of this high-risk group of patients can simplify the management of multilevel PAD and optimize limb salvage while minimizing total patient risk.

Keywords: *Hybrid; treatment; critical lower limb ischemia; Angioplasty; open surgical repair.*

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INTRODUCTION

Critical limb ischemia (CLI) is the term used to determine which conditions have resulted in foot pain even at rest or skin breakdowns (ulcer or gangrene).[1]

Usually patients with lower extremity ischemia are split into two groups; intermittent claudication, and CLI, according to presenting symptoms, claudication and CLIs are treated differently as a result of major natural historical differences and expected clinical results following treatment.[2]

CLI is the last stage of the occlusive peripheral arterial disorders. The forecast is low with amputation rates of up to 30% and deaths of up to 25% after 1 year.[3]Consequently, CLI is responsible for increased morbidity and mortality and consumes substantial health and social resources.

Revascularization which can be performed by conventional surgical (bypass) or endovascular (angioplasty) techniques is the perfect treatment to treat CLI.[4]Combined endovascular procedure and open operations were first reported in 1970.[5]

The patients are treated in hybrid reconstruction simultaneously, usually at different levels, using both endovascular and open revascularization techniques. These multi-level reconstruction have been more frequently used in recent years, especially by vascular surgeons who master both endovascular and open surgical skills and have developed endovascular techniques.[5]

For patients with multiple co-morbidities, hybrid procedures are less invasive and have recently become preferred where possible. In these minimally invasive techniques, lower morbidity and mortality and lower hospital and intensive care are benefits.[5]

The primary objectives of CLI treatment are pain relief, neuro-ischemic ulcer healing, limb loss prevention, patient function,and quality of life improvement, and long survival. In the end, most patients need a revascularization procedure to achieve these results. Primary amputation may be the best possible treatment for some patients with severe co-morbidities or very few probabilities of successful revascularisation.[6]

PATIENTSAND METHODS

This is a prospective randomized controlled clinical.The study was done in Al-Azhar University Hospitals vascular surgery department. In the period from April 2018 to April 2020. It was conducted on forty patients complaining of critical lower limb ischemia caused by multilevel occlusive arterial disease (Iliac-Femoral and Distal arteries). Informed consent was taken.

The study excludes patients with acute or sub-acute thrombus in the target arteries,previous surgical bypass at the target lesion, asymptomatic chronic ischemia in the lower limb, occlusion or aneurysm of the Aorta of the abdomen, hypercoagulable status, non-compensated heart failure, known allergy to contrast agents with iodine, Metastatic malignancy or othersurvival limiting diseases,inability or unwillingness to complete with the follow-up schedule or severe renal impairment.

Patients have been assessed for intermittent claudicating or rest pain, ulceration, foot or toes gangrene, ankle brachial index, duplex ultrasound, and angiography by computed tomographyto ensure the presence of different levels of arterial occlusive disease.In an operating room, all procedures were carried out.

Both open and endovascular revascularization techniques were used to treat patients at the same time. Follow up was done at 1, 3, and 12 months after the procedure at the outpatient clinic.

Statistical assessment was done using SPSS v20. The study was accepted by the Al-Azhar University Ethics Board.

RESULTS

Table 1 presents the study group's demographic and clinical features. The sample was 67.5% males and the average age of 64.3 ± 5.7 (range: 50-78).

Associated comorbidities	N	%
Hypertension	31	77.50%
Diabetes mellitus	15	37.50%
Coronary artery disease	24	60.00%
Chronic renal insufficiency	2	5.00%
Dyslipidemia	18	45.00%
Smoking	25	62.50%

Table 1: Associated comorbidities

In 22 (55%) of the patients, ischemic rest pain (category 4) was found Minor loss of tissue in 11 (27.5%) was observed (Category 5 Rutherford). Major loss of tissue (Category 6 Rutherford) was found in 7 (17.50%) of the study patients.

CTA findings: Patients were presented by combined lesions proximally and distally. Iliac lesions were detected in 13 patients, femoropopliteal lesions in 28 patients,and infrapopliteal lesions in 18 patients. All are summarized in Table 2.

Lesion	TASC	N	%
Iliac lesion	A	5	21.74%
	B	2	8.70%
	C	4	17.39%
	D	2	8.70%
Femoro-popliteal lesions	A	10	34.48%
	B	7	24.14%
	C	6	20.69%
	D	5	17.24%
Infrapopliteal lesions	A	4	26.67%
	B	8	53.33%
	C	5	33.33%
	D	1	6.67%
Total Lesions		59	

Table 2: Summary of vascular lesions treated**.**

Operative details:Four patients (10%) treated under general anesthesia, 19 (47.5%) received spinal anesthesia and the remaining 7 (17.5%) were locally anesthetized.

CFA endarterectomy was combined with iliac angioplasty in 5 limbs (12.5%), with femoral angioplasty in 9 (22.50%) and with tibial angioplasty in 7 (17.50%) of the patients.

Supra-genicularfem-pop bypass was done in 19 (47.50%) of patients. It was combined with iliac angioplasty in 8 (20%) patients and with tibial angioplasty in 11 (27.50%) of the included patients. Angioplasty was done by only balloon dilatation. See Table 3.

	N	%
CFA endarterectomy		
With iliac angio	5	12.50%
With femoral angio	9	22.50%
With tibialangio	7	17.50%
Supra-genicular Fem-Pop Bypass		
With iliac angio	8	20.00%
With tibialangio	11	27.50%

Table 3: Hybrid procedures are done.Procedure time: The procedure time was estimated from the time of the start of general or spinal anesthesia to the end of the procedure. It ranged from 110 min to 165 minutes.

Post-operative data:In 93.22% (55 Out of 59) Of such procedures, technical success was achieved.One patient had proximal femoral lesions treated by only femoral endarterectomy with no additional interventions. Two patients failed to pass the iliac and tibial lesions. The last patient was not completed due to hemodynamic instability.

The hospital stay ranged from 3 to 17 days in the included patients with amedian of 6 days.

Ankle Brachial Pressure Index (ABPI) evaluation:

The pre-intervention mean ABPI was 0.32 ± 0.04, which improved to 0.70 ± 0.15 immediately post-intervention (P<0.01).

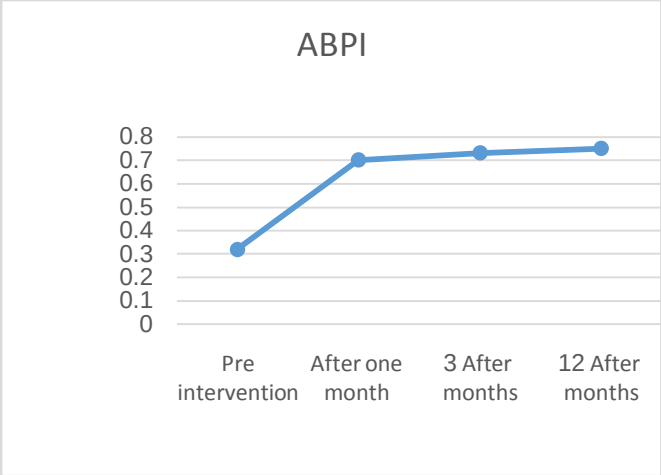

Fig 1: ABI Changes

Clinical success in all patients.In the immediate postoperative period, none of the treated limbs deteriorated.

Patency rates: At 12 months, the cumulative primary patent rate was 72.5%.

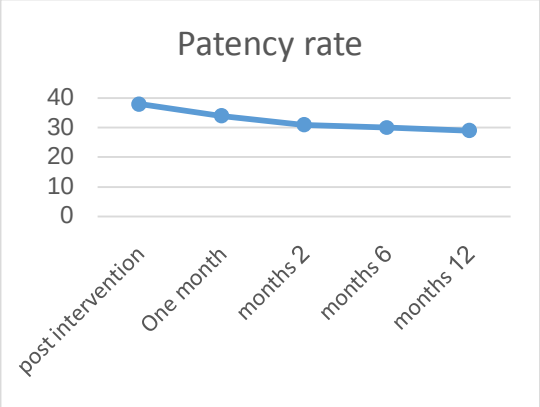

Fig 2: Cumulative Patency rate

Limb salvage: Limb salvage was defined as the absence of major amputations.Amputations of a toe, ray, or trans metatarsal were considered minor amputations.

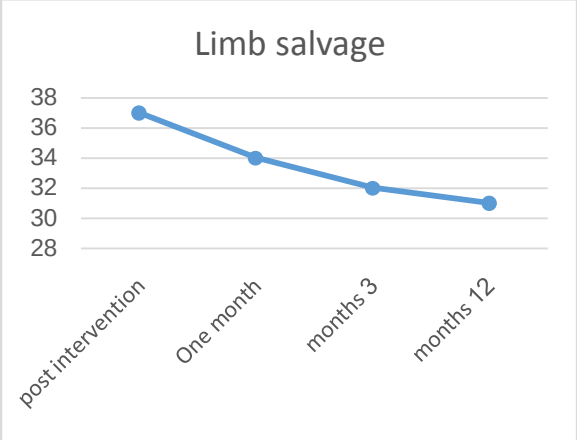

Fig 3: Limb salvage

The 12-month cumulative limb salvage was 77.5% (standard error: < 10%). No patient-related factors were predictive of reduced primary patency utilizing Cox regression analyzes.

Complications : In the perioperative period, there were seven major and ten minor complications with a total rate of 27.5%.

Complications	N	%
Minor complications:	10	25.00%
Ecchymosis	4	10.00%
Lymphorrhea	2	5.00%
Pain and parathesia	4	10.00%
Major complications:	7	17.50%
Acute thrombosis	1	2.50%
Infection	3	5%
Pseudo-aneurysm	1	2.50%
Groin hematoma	1	2.50%
Acute MI	1	2.50%
Acute renal failure	1	2.50%

Table 4: Postoperative complications 1 month postoperatively.

Amputation rate: Seven of nine patients had minor amputation from Rutherford ischemia (category 6). The other two were healed after debridement of heel gangrene.

Amputation	post intervention	One month	3 months	12 months
Minor	3	2	1	2
Toe	1	2	0	1
Metatarsal	2	0	1	1
Major	0	1	2	1
Below Knee	0	0	1	0
Above Knee	0	1	1	1

Table 5: Amputation events during follow up.

Mortality rate: Mortality occurred in two patients (5%); one of them due to myocardial infarction and the other one due to cerebral infarction. They occurred in the 5th and 8th months respectively. No other patients were lost during the period of follow-up. Mortality was not related to the procedure but was attributed to the associated co-morbidities.

DISCUSSION

CLI patients typically have a multi-level occlusive arterial disease and major comorbidities that increase their perioperative risk. Succeeded salvage of limbs traditionally required lengthy and often stages involving significant morbidity and mortality. The short survival and mortality of these patients is around 70% at five years and 95% at 10 years.[3]

Endovascular techniques in peripheral arterial disease (PAD) treatments have been used with increasing frequency, presenting an appealing alternative to open interventions particularly in high-risk patients. TASC A and B (and perhaps the TASC C) balloon angioplasty and/or stenting iliac lesions have demonstrated very strong patency rates and are becoming favorite initial treatment.[3]Nevertheless, CLI was long known as asign of bypass surgery[7]. The growing familiarity with endovascular procedures has helped to better classify patients and lesions best managed by percutaneous therapies.[8]This protocol has been identified for 12 years and has been demonstrating that balloon angioplasty treatment not only as safe and effective but may also be the preferred method for primary and secondary CLI management. However, the primary use of lower limb endovascular treatment has not been very effective. [9, 10]

The CFA is the main inflow vessel for the entire lower limb and a major arterial access site. For small studies with variable success, endovascular treatment of symptomatic CFA stenosis has been attempted and is not used regularly.

A study from Johnston et al. has shown that mid-term outcomes in CFA balloon angioplasty are suboptimal, with clinical success rates decreasing by between 78% in 1 month and 58% respectively and by 36% in 1 and 3 years .[11]

In 20 patients Silva et al. registered A 90 percent event-free survival rate,indicating 11.4 months of follow-up (43% CLI). The event-free rate of survival was described as the Liberty to death, amputation and revascularisation of the arteries. [12]

After stenting of the CFA bifurcation,Stricker and Jacomella followed 33 limbs recording 87 and 83% respectively 1-and 3-year patency. Most patients (82%) suffered from claudication and stenotic lesions were heterogeneous, including eight Cases of pathophysiologic anastomotic stenosis distinct from atherosclerotic lesions in native vessels.[13]

The athero-sclerosing lesions in this region appear to be extremely calcified and bulky, not allowing optimum dilation of the vesselAnd may have long-lasting elastic recoil. CFA balloon angioplasty often fail. Such lesions often have a major chance of dissections of deep femoral artery (PFA) osteal occlusion.

Endarterectomy continues with patch angioplasty the treatment for CFA occlusive disease, Has proven effectiveness and durability [14]. It also has the additional advantage of being able to restore or improve the PFA perfusion simultaneouslyHence, maintaining a significant collateral course.The endovascular aspect of the hybrid procedure can be safely performed Patch angioplasty before or after, and such a technique remains at the surgeon's discretion. However, in the case of lesions proximal to CFA, our approach was to conduct the endovascular procedure Following the endarterectomyand Beforehand, angioplasty patching.

In this way, artery catheterization is performed under a clear vision, reducing the chance of proximal dissection. The length of patch angioplasty was usually very short, although the patient Stayedheparinisedthroughout the whole operation. These two facts reduce the risk of stent thrombosis during patch angioplasty success and our findings support that already because we didn't have such a complication.

Successful revascularization strategies at CLI Combine open and endovascular procedures in the same setting (hybrid procedure) or as a step-by - step method. The stagedmethod raises many issues for the patient and the surgeon, including pain, timing post-intervention antiplatelet therapy,and the additive cardiac risk with multiple procedures[15].

In the study, we treated 40 patients with multisegment severe PAD with a hybrid approach involving CFA endarterectomy or femoropopliteal bypass.

Both patients had significant comorbid risk factors and different degrees of CLI. Perioperative mortality was not recorded, and there were comparable levels of clinical progress and limb recovery to other studies.

Cumulative salvage rate for the limbs in our 12-month studywas 77.5% (Standard Mistake: < 10 percent). No patient-related factors were predictive of reduced primary patency through the study.

All cases in this study were done in the same setting as the preoperative decision was taken by the hybrid technique.Regarding postoperative complications, in the perioperative period, there were seven major and ten minor complications with an overall rate of 27%. Minor complications occurred during the operation and postoperatively. None of these complications led to serious morbidity.

Staged Approaches involved more complications, including groin wound problems and problems at the

site of the puncture[16]. Such drawbacks make the hybrid solution an appealing choice for surgeons, as well as CLI patients.

The hybrid approach applies the proven durability of CFA endarterectomy, which also offers excellent access to both the inflow and outflow lesions for endovascular care. Without major hemodynamic changes, minimal blood loss, and reduced risk of perioperative complications, extensive revascularizations can be achieved. In our study, CFA endarterectomy was combined with iliac angioplasty in 5 limbs (12.5%), with femoral angioplasty in 9 (22.50%) and with tibial angioplasty in 7 (17.50%) of the patients.

Supra-genicular fem-pop bypass was done in 19 (47.50%) of patients. It was combined with iliac angioplasty in 8 (20%) patients and with tibial angioplasty in 11 (27.50%) of the included patients. Angioplasty was done by only balloon dilatation. Professional success was obtained in 93.22 percent of the procedures (55 of 59).

The effectiveness of the hybrid approach has been recorded before. After combined CFA endarterectomy and iliac stenting, Nelson et al. reported short-term results (59% of patients had CLI). The primary patency rate was 84% in 1 year and increased with secondary interventions to 97% [17].

The pre-intervention mean ABPI in our study was 0.32 ± 0.04, which improved to 0.70 ± 0.15 immediately post-intervention (P<0.01). Clinical success has been achieved in all cases. In the immediate postoperative period, neither of the treated limbs deteriorated. The 12-month primary patency rate was 72.5 percent.

Cotroneo et al. followed 44 patients (24 with claudication and 20 with CLI) after hybrid revascularization procedures, and recorded primary and secondary patenting rates of 79.1% and 86.1% for 2 years , respectively.[18].

In their study of a heterogeneous patient cohort (47% CLI) using several different forms of reconstructive procedures, Antoniou et al. reported primary and secondary patency levels of 71% and 98%, respectively, at 12 months. [19].

The long term results are also excellent. Chang et al.[20] 20 reported 60%primary, and secondary patency, 90%, and 98%, respectively, over five years. Nevertheless, none of the above studies focused on a single population, as they all included in their cohort patients suffering from irregular claudication and CLI. In the study, two patients failed to pass the lesion by the endovascular approach. One was iliac and the other was tibial lesion. Failure to complete the endovascular component is usually unpopular.Additional revascularisation procedures in such cases based on the severity of the ischemia of the limbs and the location of the lesion not treated. . Inflow to the CFA needs to be restored. Clinical presentation should be considered for the management of untreated outflow lesions.

In 25 limbs Kang et al.14 followed with documented femoropliteal lesions. The authors claimed that, without significant loss of tissue (Rutherford Class 6),the limbs with residual lesions had similar freedom from reinterventioncompared with those without Remnant lesions. Within this setting, hemodynamic improvement after CFA endarterectomy may be acceptable in this setting for patients with rest pain or slight loss of tissue .[14]

In such patients when faced with failure to complete the distal endovascular intervention, we usually avoid surgical bypass in the original surgical setting. We may allow a simultaneous bypass only when dealing with significant tissue loss or even minor tissue loss in a patient with diabetes. Since the technical failure of the hybrid technique does not negatively impact possible surgical reconstruction, a bypass may be performed whenever necessary as a staged operation, given the increased risk of redo groin dissection.

Mortality Happened in two patients (5%); one of them due to myocardial infarction and the other one due to cerebral infarction. They occurred in the 5th and 8th months respectively. No other patients were lost during the period of follow-up. Mortality was not related to the procedure but was attributed to the associated co-morbidities.Antoniou et al. registered a 3 percent perioperative mortality rate.

Our research limitations included a smallpatients' sample size, the small follow-up duration (12 months), and we have no control group for comparison.

CONCLUSION

in the present study results showed that : hybrid procedures with combination of inflow or omutflow endovascular procedures can simplify the management of multilevel PAD in this group of high-risk patients and optimize limb salvage while minimizing the overall risk for the patients.

the present study confirms the efficacy of a hybrid strategy in these high-risk surgical candidates as it relates to morbidity, mortality, and limb salvage.

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