

*Research Article***Hybrid technique with endovascular privilege in management of critical lower limb ischemia****Mostafa N. El-Sanadeky, Othman A. Othman, Wael M. Kamel and Mostafa H. Abdelsalam**

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Abstract**Introduction:** Peripheral arterial disease (PAD) represents a local manifestation of a lethal systemic disease atherosclerosis and portends a 2-6fold increase in both cardiovascular and cerebrovascular events. The diagnosis is also associated with an annual mortality rate of 4%-6%. (Malyar et al., 2016).**Aim of the work:** 1- Evaluation of the feasibility and efficacy of the hybrid surgical and endovascular therapy in patients with complex multifocal steno-occlusive vascular disease. 2- Report short and midterm outcomes through assessment of patency and salvage rate. 3- Evaluate safety of hybrid procedure, and report complications and re-intervention if needed.**Patients and Methods:** A prospective study was carried out on twenty patients (20 limbs) presented with critical lower limb ischemia due to multi-level peripheral arterial disease involving CFA presented to the vascular and endovascular surgery unite, General surgery department, Minia university hospital. **Results:** The study included twenty patients (20 limbs) who were suffering from multilevel peripheral arterial disease with critical lower limb ischemia, who underwent hybrid procedures at vascular and endovascular surgery unit Minia University Hospital, Egypt. **Summary:** Our results show that CFA endarterectomy or bypass surgery in compination with inflow or outflow endovascular procedures can simplify the management of multilevel PAD in this group of high risk patients, as each lesion in different patho-anatomical configuration can be treated with an approach that will best optimize outcomes and ensure safety for the patients as a whole.**Keywords:** Peripheral arterial disease, endovascular, cardiovascular and cerebrovascular**Introduction**Peripheral arterial disease (PAD) represents a local manifestation of a lethal systemic disease atherosclerosis and portends a 2-6fold increase in both cardiovascular and cerebrovascular events. The diagnosis is also associated with an annual mortality rate of 4%-6%.⁽¹⁾Critical limb ischemia (CLI) deteriorates patients' quality of life because it leads to severe pain, non-healing wounds, uncontrollable infection, and higher mortality rates. Notably, 40% of patients with CLI lose their limbs within 6 months if prompt revascularization treatment is not performed.⁽²⁾

Advanced peripheral arterial disease (PAD) due to atherosclerosis is the leading cause of CLI, and recent improvements in endovascular techniques and treatment device development have enabled more patients with PAD to be treated in a minimally invasive manner.

Endovascular treatment (EVT) has already had a major role in treating lower extremity arterial lesions, particularly lesions in the iliac artery and superficial femoral artery (SFA). However, EVT has inferior results in common femoral artery (CFA) lesions; thus, surgical endarterectomy of atherosclerotic plaques remains the standard treatment.⁽³⁾With the widespread adoption of fixed imaging systems within the vascular operating room and the developing endovascular skills of the vascular surgeons, patients now benefit from all-in-one procedure that are part open vascular surgery and part catheter-based intervention, so called hybrid surgery.⁽⁴⁾Patients with CLI typically present with multiple complex lesions in their lower extremities. When these lesions involve the CFA, a hybrid procedure, combining femoral endarterectomy and EVT, is a good treatment option.⁽⁵⁾

The hybrid approach offers adequate access for the treatment of both inflow and outflow lesions while dealing with the CFA lesion in the most appropriate way. The main advantage of hybrid procedures is the ability to treat more complex anatomy by less invasive procedures in patients considered high medical risk.⁽⁶⁾

The alternative of hybrid revascularization surgery carries the advantages of less-invasive endovascular interventions and may provide a durable and safe solution of surgical management⁽⁷⁾

Aim of the work

1. Evaluation of the feasibility and efficacy of the hybrid surgical and endovascular therapy in patients with complex multifocal stenotic occlusive vascular disease.
2. Report short and midterm outcomes through assessment of patency and salvage rate .
3. Evaluate safety of hybrid procedure , and report complications and re-intervention if needed .

Patients and Methods

A prospective study was carried out on twenty patients (20 limbs) presented with critical lower limb ischemia due to multi level peripheral arterial disease involving CFA presented to the vascular and endovascular surgery unite, General surgery departement , Minia university hospital .

Subjects

Pre procedural evaluation

a) Inclusion critiria:

- 1) Patients with critical lower limb ischemia presented with rest pain and / or tissue loss (Rutherford categories 4,5 and 6).
- 2) Obstructive arterial disease in the Femoral artery bifurcaion segment (including the common femoral artery, the origin of the superficial femoral artery and the prfounda femoris artery) and at least one level among the iliac or femoropopliteal or infragenicular arteries .

B) Exclusion critiria :

- 1) Patients presented with extensive necrosis or infective gangrene requiring primary major amputaion .

- 2) Patients with significant contraindications to the angiography including patients with borderline kidney diseases who are susiptable for contrast induced nephro-pathy and perminant renal impairment , and those with marked hypersensitivty to contrast.

All patients underwnet :

• Full history taking :

Detailed medical history is necessary to diagnose CLI. Clinical picture including ischemic rest pain , ischemic ulcers or gangrene

Risk factors including diabetes mellitus, smoking, hypertension, coronary artery disease, renal insufficiency, history of cerebrovascular strokes and history of major amputaion was documented for each patient.

Medications in use as anticoagulants, anti-platelets, statins, beta blockers, insulin and oral hypoglysemic drugs)

History of previous vascular interventions should be reported in the history .

• Clinical examination:

The extremities should be carefully examined for signs of chronic vascular diseases such as ulcers, hair loss, and skin changes.

Pulse examination of the lower extremity is diagnostic of PAD and the level of pulse deficit predicts the site of arterial occlusion. The pulse examination should be supplemented with measurement of the Ankle brachial index using Doppler ultrasonography, thus objectively quantify the severity and extent of the ischemia and provide a baseline for the post interventional follow up.

Results

The study included twenty patients (20 limbs) who were suffering from multilevel peripheral arterial disease with critical lower limb ischemia, who underwent hybrid procedures at vascular and endovascular surgery unit Minia University Hospital, Egypt.

Age and Sex

The current study included 20 patients 17(85%) of them were males and 3(15%) were females. Mean age of the studied patients was 67.35 years with range between 56 and 80 years.

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In our study 11(55%) patients were suffering from CLI in the right lower limb and 9(45%)

patients were suffering from CLI in the left lower limb.

Table (1): Mean age of the studied patients

Age	Total (n=20)
Mean ± SD	67.35±7.97
(Range)	(56-80)

Table (2): Sex distribution of studied patients

Sex	Number of patients (n=20)	Percentage
Male	17	85%
Female	3	15%

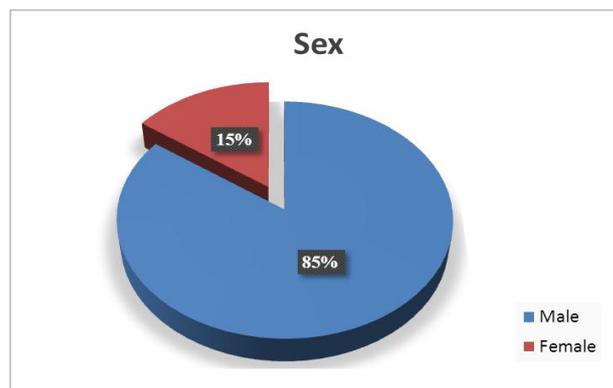


Figure: sex distribution in the current study .

Discussion

Critical limb ischemia (CLI) is the most severe form of peripheral arterial disease which is linked with a high risk of loss of affected limb, results in the greatest morbidity and risk of mortality to patients and health care system.⁽⁸⁾

However, the ideal treatment for CLI is revascularization. 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 and multilevel revascularization procedures.⁽⁹⁾

The current study aims at evaluating the safety and efficacy of hybrid procedures as a treatment of chronic critical limb ischemia in prospective trials through assessing the primary technical success, the possible complications and limb salvage.

Our study include 20 cases who were suffering from multilevel peripheral arterial disease with critical limb ischemia along a period of one

year who were managed by hybrid procedures. the mean age of the studied patients was 67.35 years with range between 56 and 80 years . with male a predominance (17 males, 85%).

Berchiolli et al., (2019) reported 43 cases (34 men and 9 women) in their study with mean age 74.4 years⁽¹⁰⁾ . in accordance, Zou et al., (2012) reported mean age 69.2 years with a male predominance 67.5%.⁽¹¹⁾

In current study, diabetes mellitus was the commonst risk factor in (75%) of studied patients followed by hypertension (65%), smoking (65%), coronary artery disease (45%) and history of cerebrovascular strokes in (15%).

Taurino et al., (2014) reported hypertension as the main risk factor (91.7%) followed by smoking (83.3%) the incidence of diabtes as a risk factor was (33.3%).⁽¹²⁾

Jung et al., (2018) also reported hypertension as the main associating risk factor (81.7%) followed by diabetes (73.7%).⁽¹³⁾

According to Rutherford classification, the majority of patients (55%) were treated for digital gangrene (Rutherford category 5), (25%) were treated for major tissue loss (Rutherford category 6) and (20%) were treated for rest pain only without any tissue loss (Rutherford category 4).

Jung et al., (2018) reported that (62.8%) were treated for tissue loss and (37.2%) were treated for rest pain.⁽¹⁴⁾ Berchiolli et al., (2019) reported that (37.2%) were treated for minor tissue loss (Rutherford category 5), (34.8%) were treated for major tissue loss (Rutherford category 6) and (27.9%) were treated for rest pain (Rutherford category 4).⁽¹⁵⁾

In our study, femoral endarterectomy with patch angioplasty was done in 14(70%) cases combined with infra popliteal angioplasty in all cases, femoro-popliteal angioplasty in 12 (85.7%) cases and 4(28.6%) cases under-went iliac stenting. While femoropopliteal bypass compined with infrapopliteal angioplasty was done in 4(20%) cases and femoro-femoral

crossover bypass compined with femoro-popliteal and infrapopliteal angioplasty was done in 2(10%) of cases⁽¹⁶⁾.

Conclusion and Recommendations

The results of this study vaha led to the following notes:

- We concluded that hybrid revascularization procedures are considered to be safe and effective in treatment of critical limb ischemia due to multilevel arterail occlusive disease.
- Hybrid procedures combine the well established patency benefits of open surgical revascularization procedures with the advantages of less invasive endovascular revascularization procedures to provide a durable and safe solution.
- Marked atheroscleris involvement of infrapopliteal vessels with poor distal run off was associated of poor outcome and decrease in limb salvage rate.
- We recommend hybrid intervention as a first strategy for treatment of critical limb ischemia with multilevel vascular diseases in patients who cannot tolerate open surgical revascularization related morbidity and mortality and endovascular management is not sufficient alone to treat their conditions.

References

1. Aboyans, V., Criqui, M. H., Abraham, P., Allison, M. A., Creager, M. A., Diehm, C., . . . Lacroix, P. (2012). Measurement and interpretation of the ankle-brachial index: a scientific statement from the American Heart Association. *Circulation*, 126(24), 289-290.
2. Anderson, J. L., Halperin, J. L., Albert, N., Bozkurt, B., Brindis, R. G., Curtis, L. H., . . . Kovacs, R. J. (2013). Management of patients with peripheral artery disease (compilation of 2005 and 2011 ACCF/AHA guideline recommendations): a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Journal of the American college of cardiology*, 61(14), 1555-1570 .
3. Armstrong, P. A., & Bandyk, D. F. (2010). Duplex scanning for lower extremity

- arterial disease Noninvasive Peripheral Arterial Diagnosis (pp. 47-55): Springer.
4. Asbeutah, A. M., Riha, A. Z., Cameron, J. D., & McGrath, B. P. (2005). Reproducibility of duplex ultrasonography and air plethysmography used for the evaluation of chronic venous insufficiency. *Journal of ultrasound in medicine*, 24(4), 475-482.
 5. Balaz, P., Rokosny, S., Bafnec, J., & Björck, M. (2012). The role of hybrid procedures in the management of peripheral vascular disease. *Scandinavian Journal of Surgery*, 101(4), 232-237.
 6. Haring, R., Trivison, T. G., Bhasin, S., Vasani, R. S., Wallaschofski, H., Davda, M. N., . . . Murabito, J. M. (2011). Relation between sex hormone concentrations, peripheral arterial disease, and change in ankle-brachial index: findings from the Framingham Heart Study. *The Journal of Clinical Endocrinology & Metabolism*, 96(12), 3724-3732.
 7. Kawasaki, D., Tsujino, T., Fujii, K., Masutani, M., Ohyanagi, M., & Masuyama, T. (2008). Novel use of ultrasound guidance for recanalization of iliac, femoral, and popliteal arteries. *Catheterization and Cardiovascular Interventions*, 71(6), 727-733 .
 8. Kuma, S., Tanaka, K., Ohmine, T., Morisaki, K., Kodama, A., Guntani, A., . . . Mii, S. (2016). Clinical outcome of surgical endarterectomy for common femoral artery occlusive disease. *Circulation Journal*, CJ-1177-15 .
 9. McClary, K. N., & Massey, P. (2019). Ankle, Brachial Index (ABI) (StatPearls [Internet]): StatPearls Publishing.
 10. Mozaffarian, D., Benjamin, E. J., Go, A. S., Arnett, D. K., Blaha, M. J., Cushman, M., . . . Howard, V. J. (2015). American heart association statistics committee and stroke statistics subcommittee. Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*, 131(4), e29-e322 .
 11. Peng, J., Luo, F., Ruan, G., Peng, R., & Li, X. (2017). Hypertriglyceridemia and atherosclerosis. *Lipids in health and disease*, 16(1), 233.