Management of Critical Lower Limb Ischemia in Endovascular Era: Experience from 511 Patients

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Abstract

This study aims at the assessment of the achievability of the endovascular treatment of patients with critical limb ischemia (CLI) and the role of bypass in such patient. This is a prospective study conducted on patients with chronic atherosclerotic critical lower limb ischemia presenting to us over a period of 3 years. Patients presenting with nonsalvageable limbs requiring primary major amputation and nonatherosclerotic causes of CLI were excluded. Endovascular treatment was the first choice modality of treatment in revascularization of all patients. Open surgery was offered selectively for patient whom endovascular failed or complicated and for long TransAtlantic Inter-Society Consensus (TASC) II lesions in fit patients. This study included 511 cases of CLI, and the mean age was 64.5 years. Patients with Rutherford IV, V, and VI were 19.25, 60.5, and 19.25%, respectively. The TASC II aortoiliac lesions were as follows: A, B, C, and D in 33.7, 12, 15.7, and 38.6%, respectively, and infrainguinal lesions were A, B, C, and D in 3.7, 19, 35.4, and 68.3%, respectively. A total of 78.3% of patients were treated by endovascular totally, while 16% were treated by surgery from the start, 3.7% of endovascular cases were converted to open surgery after failure of endovascular treatment, and 2% was offered hybrid treatment. Crossing of lesions by subintimal and intraluminal was 12.5 and 87.5%, respectively. Technical success in endovascular was 94%; however, we could successfully revascularize 96.8% of all CLI presented in this study by either surgery or endovascular. On 24 months follow-up, primary patency, secondary patency, and limb salvage by percutaneous transluminal angioplasty are 77.8, 84.7, and 90.7%, respectively. Revascularization by endovascular achieves high technical success and limb salvage in CLI, hence should be considered as preferred choice of treatment. However, both endovascular and surgery should not be counteracting each other and using both can revascularize 96.6% of CLI.

Keywords

- critical limb ischemia
- peripheral occlusive disease
- peripheral angioplasty
- limb salvage
- survival

Critical limb ischemia (CLI) is characterized by multilevel disease, high burden of comorbidity, and limited life span. The care of patients with CLI is not straightforward because many of them have significant comorbidities including renal disease and advanced age.¹

Successful revascularization decreases the major amputation rate in patients with CLI. The efficacy of peripheral bypass grafts and percutaneous transluminal angioplasty in accomplishing limb salvage has been recognized.²

On the contrary, in recent publications, hesitation is still expressed regarding the feasibility, effectiveness, and long-term results of PTA, mainly in the treatment of infrapopliteal disease and CLI.

In our protocol for the treatment of all patients with TransAtlantic Inter-Society Consensus (TASC) criteria of CLI, PTA is the first choice revascularization procedure. This study aims at the assessment of the achievability of the endovascular treatment of patients with CLI and the role of bypass in

such patient and determines the percentage of open versus endovascular treatment in management of these patients. Finally, we assess the technique used, the technical success rate and the short-term follow-up (patency rate and limb salvage rate), and complications (with review of its management) of the endovascular option for the treatment of critical lower limb ischemia.

Patients and Methods

Patient Selection

This is a prospective study that has been conducted on patients presenting to our department of vascular and endovascular surgery, Cairo University hospitals in a period of 3 years. All patients presenting with chronic atherosclerotic critical lower limb ischemia were included in this study.

We defined chronic critical lower limb ischemia following the TASC II guidelines as lower limb with more than 2 weeks of rest pain, ulcers, or tissue loss attributed to arterial occlusive disease.³

Patients presenting with nonsalvageable limbs requiring primary major amputation and nonatherosclerotic causes of CLI were excluded from this study. The decision of amputation was taken on the basis of severe tissue loss (when whole foot lost) and nonreconstructable arterial occlusion after adequate study either by angiography or computed tomography angiography.

Endovascular treatment was the first choice modality of treatment in revascularization of all patients. Open surgery was offered selectively for patient whom endovascular failed or complicated and for long TASC II D lesions in fit patients according to the American Society of Anesthesia score. In case of aortoiliac disease, surgery was preferred for extensive disease (occlusion of whole length of the common iliac and external iliac arteries). While in femoropopliteal disease, surgery was preferred in extensive disease (occlusions of whole length of the superficial femoral artery [SFA] and also upper popliteal occlusion and runoff on lower popliteal in fit patient and available vein).

Preprocedure Assessment

All patients were subjected to history, taking careful physical examination, and radiological imaging.

Consent

Detailed explanation of the procedure, its indications, methods, risks, and outcome were done. After which an informed consent was signed by all the included patients. Patients were assessed and decision was taken to either operate via endovascular technique or open surgery. Approval from ethical committee in our department was taken before the beginning of the study.

Technique

All endovascular procedures were done in our angi suite under local anesthesia and all open surgeries were done in the operating room under epidural or general anesthesia.

The Procedure Outcome

The outcome was evaluated for every case immediately postprocedure, and 3, 6, 12, 18, and 24 months later. Immediate evaluation was based on clinical assessment (pulse, capillary refill, and warmth) and angiography. Follow-up was according to clinical reassessment and duplex. The success of the procedure was determined by the following:

- Angiographic success defined as good flow with less than 30% residual stenosis at the narrowest point of the arterial lumen.
- Technical success was diagnosed by patent completion angiography and clinical retrieval of distal pulse.
- Clinical success which may be:

Definitive success in the form of regain of pulse.

Clinical improvement (good capillary circulation, warmth, relief of symptoms, and good healing of ulcer or minor amputation).

Primary end point: technical success, primary patency, secondary patency.

Secondary end point: limb salvage and wound healing.

Follow-Up

On follow-up, clinical success was diagnosed by clinically presence of distal pulse, improved patient symptomatology, and healing of tissues imaging; duplex was done routinely for all patients on their follow-up.

Statistical Methods

Data were collected using Excel software, with anonymous coding. The comparisons between patients each risk factor and the outcome were performed using a chi-square test and the important relations were expressed in the form of *p* value.

Results

This study included 511 cases of CLI, and the mean age was 64.5 years. Patients with Rutherford IV, V, and VI were 19.25, 60.5, and 19.25%, respectively. Level of occlusions included iliac, SFA, and crural in 15.9, 58.5, and 25.6%, respectively. Multilevel diseases were encountered in 92% patients. Aortoiliac disease constitutes approximately 16% of total patients, while infrainguinal was 84%. The TASC II aortoiliac lesions were as follows: A, B, C, and D in 33.7, 12.15.7, and 38.6%, respectively, and infrainguinal lesions were A, B, C, and D in 3.7, 19, 35.4, and 68.3%, respectively. A total of 78.3% of patients were treated by endovascular totally, while 16% were treated by surgery from the start, 3.7% was shifted from endovascular to open after failed endovascular, and 2% was offered hybrid treatment. Crossing of lesions by subintimal and intraluminal was 12.5 and 87.5%, respectively. Technical success in endovascular and open was 93 and 85%, respectively. On 24 months follow-up, primary patency, secondary patency, and limb salvage were 77.8, 84.7, and 90.7%, respectively. The overall mortality was 5.3%. SFA stenting was done in 97 cases (48%), while iliac artery stenting was used in 36 cases (90%). No stents were used in crural vessels. In angioplasty group, morbidity was 23%. Flow limiting dissection was

the main complaint in about 20% of endovascular cases (all were treated by stents except one requiring surgery). Other complications were 4%, which included extravasation, embolization, retroperitoneal hematoma, acute pulmonary edema, and failed endovascular revascularization. In surgery group, severe infection and acutely thrombosed graft occurred in 2.4% of cases. In angioplasty group, mortality was 4.4%, in surgery group 7.2%, and overall mortality rate over 24 months was 5.3%. Thirty days mortality was 2.4%, 1 year was 2.2%, and 2 years mortality was 1%. The number of patients lost from follow-up at 1 year was 10.8% of total patients, while total number of patients who lost follow-up at 2 years was 19.4%.

Revascularization was attempted in 511 patients. Revascularization by endovascular techniques were attempted in 84.1%. Technical success rate was achieved (evident by good refilling in completion angiography and/or return of distal pulses) in 93%. Revascularization by open surgery was attempted in 15.9%. Technical success rate was achieved (evident by postoperative duplex and/or return of distal pulses) in 85.6%. The total technical success rate of revascularization (by endovascular therapy [EVT] or bypass) was 96.8% (495 patients of 511). It has to be noted that 3.7% was crossed from endovascular to open after failed endovascular and 2% was offered hybrid treatment. Total number of surgery from the start (due to anatomical not feasible for EVT and fit patient) was 15.9% (► **Tables 1** and **2**).

Important Relations

1. Diabetes did not prove to significantly affect the revascularization outcome (technical success, patency, and limb salvage; $p = 0.142, 0.153, \text{ and } 0.128$, respectively).
2. Patients with cardiac and/or renal disease showed lower rates of patency and limb salvage ($p = 0.02$ and 0.04 , respectively).
3. The presence of major tissue loss showed a significantly worse limb salvage rate ($p = 0.001$).
4. Multilevel affection of the arterial system had lower patency and limb salvage rates ($p = 0.002$ and 0.04 , respectively).
5. Infrainguinal TASC classification showed significant relation to the technical success, patency, and limb salvage being worse in TASC D ($p = 0.05, 0.001, \text{ and } 0.001$, respectively).
6. Intraluminal crossing of lesions has a better outcome than the subintimal approach ($p = 0.002$ and 0.001 , respectively).

Table 1 Follow-up and outcome after 12 and 24 months

	No. of patients after exclusion of lost follow-up	Primary patency	Secondary patency	Limb salvage
12 mo	456	396 (88%)	400 (89%)	413 (91.8%)
24 mo	412	336 (77.8%)	366 (84.7%)	392 (90.7%)

Table 2 Outcome in surgery and endovascular in different level

	Technical success surgery (%)	Technical success endovascular (%)	Primary patency surgery (%)	Primary patency endovascular (%)	Secondary patency surgery (%)	Secondary patency endovascular (%)	Limb salvage in surgery (%)	Limb salvage in endovascular (%)
Iliac	100	92	64	61	92	79	97.50	85
Femoropopliteal	94	90	61	70	73	73.50	81	83
Crural	93	93	46	84	53	86	66	93.50

7. The length of lesion was important in technical success being worse if the lesion was longer than 10 cm ($p = 0.016$).

Discussion

Specific considerations apply to CLI patients. CLI is characterized by multilevel disease, high burden of comorbidity, and limited life span. Thus, decision making in revascularization strategies in CLI differs substantially from that in patients with claudication. In CLI, different treatment aims are wound healing, limb salvage, and maintaining ambulation, where area is in claudication, treatment aims at improved walking ability. Long-term patency as such is probably of less importance. The choice of endovascular treatment may be supported by the presence of major comorbidities and hence high risk for open interventions.¹

The prognosis is poor and patients have a high risk of major amputation and death, the 1-year amputation rate being more than 20%, and the 1- and 5-year mortality around 20 and 40 to 70%, respectively.⁴

This study aims at the assessment of the achievability of the endovascular treatment of patients with CLI and the role of bypass in such patient and determines the percentage of open versus endovascular treatment in management of these patients. Finally, we assess the technique used, the technical success rate and the short-term follow-up (patency rate and limb salvage rate), and complications (with review of its management) of the endovascular option for the treatment of critical lower limb ischemia.

The current study included 511 cases presented with critical lower limb ischemia along with the period of 3 years. All patients were offered a trial of revascularization whether endovascular or open surgery. The age and sex did not show significant differences than most of the published literature.⁵⁻⁹

In the current study, the main associated comorbidity was 87.9% diabetic, 61.3% smokers, and 67.3% hypertensive. Other associated diseases included 39.1% of cardiac patients. As shown in ►Table 3, the current study results were coinciding

with recent literature (in the incidence of diabetes and smoker). This may be attributed to increased incidence of atherosclerosis with these risk factors. Although there was a slight difference in hypertension and cardiac compromise (being less than was mentioned by the literature), these differences in prevalence of comorbidities may reflect the different geographical effect and consequently the different exposure to life stress effects. Increased life stress and obesity predispose to our high incidence of diabetes in Egypt. However, there was a great difference in the incidence of renal failure patients being less than was mentioned in other studies, yet it has the same bad effect on the outcome. Also cardiac patients showed worse limb salvage and primary patency.

The presence of diabetes has not been found to be statistically significant in relation to technical success, patency, and limb salvage. This may be attributed that more than 87% of our patients were diabetic and this may render statistical analysis invaluable. However, there is much debate concerning the effect of diabetes on the presentation and outcome, yet no one can deny the major effects of diabetes on vascular patients in term of morbidity and mortality.

The role of diabetes mellitus (DM) as a risk factor for vascular surgery is important because a large proportion of vascular surgical patients have DM. In the future, their number will increase due to the aging of population. This is particularly true in patients with critical lower limb ischemia. Cardiovascular events are the main reason for perioperative mortality and morbidity after vascular surgery, and it has been suggested that DM further increases the risk.¹⁰ Hynes et al found that the incidence of diabetes, especially type 2, in population is increasing as population ages. Diabetes is known to be associated with increased calcification, multi-level disease, and infrapopliteal lesions, as well as a mortality rate up to 10 times higher than in nondiabetics.¹¹ It was mentioned by Akbari and LoGerfo, and Bakken et al that in their study comparing the CLI in DM and non-DM among those with CLI, particularly those with tissue loss, limb salvage rates are lowered for the diabetic groups (insuline dependent diabetes mellitus [IDDM] and non insuline dependent diabetes mellitus [NIDDM]) despite equivalent patency

Table 3 Comparison of our study and different literature in comorbidities

	Diabetic patients	Hypertensive	Smoker	Cardiac	COPD and asthmatic	Renal insufficiency	Stroke
Current study in %	87.9	67.3	61.3	39.1	2.3	1.6	4.9
Chisci et al, 2012	52.5	83.7	60.2	58.5	48	28	15.2
Faglia et al, 2005	64.4	72	53.5	62.5	NA	4.8	1
Cull et al, 2010	53	NA	NA	29	20	2	1
Chung et al, 2006	66	72	51	51	17	13	16
Kudo et al, 2005	58	57	40	58	5	20	13
Rueda et al, 2008	61	76	NA	64	NA	30	NA
Iida et al, 2012	69	77	30	52	3	60	29
Engelhardt et al, 2012	54.8	83.7	43	69	15.4	8.7	18.5

and restenosis rates and the prevalence of these patients is increasing. Among patients with a more advanced limb ischemia grade, the prevalence of DM is often higher. Patients with DM tended to have a greater systemic vascular disease burden based on their comorbidities and also had increased rates of restenosis and decreased assisted primary patency significantly lower limb salvage rates than the nondiabetic patients despite having less complex lesions according to the TASC system of categorization.^{12,13}

However, in a study done by Awad et al, they concluded that diabetes seems to have no significant impact on the current revascularization practice in patients with CLI, as it influences neither the type of treatment being offered nor the clinical outcome of these patients. Given a similar limb salvage rate in those undergoing revascularization procedures, diabetics should not be prejudiced against and the decision to amputate or treat conservatively rather than revascularize should be based on suitability for revascularizations, appropriate anatomy, and the presence of medical conditions other than diabetes.⁴ Also Fernandez et al found that diabetes was not a negative predictor of wound healing or limb salvage.¹⁴ Hynes et al found that in those patients deemed suitable for revascularization, there was no statistical significant difference in the limb salvage rate between diabetic and nondiabetic patients.¹¹

On the contrary, endovascular treatment in diabetic patients with end-stage renal disease ESRD remains a challenge, mainly due to the presence of heavy calcification and the involvement of more than one vascular segment. Diabetic patients with critical ischemia and ESRD should be treated at an early stage, ideally before tissue loss appears.¹⁵ Rabellino et al achieved 58.6% limb salvage in patients with CLI with ESRD during a mean follow-up period of 12.4 months. In addition, they observed that no major amputations were required on patients presenting with rest pain.¹⁵ Aulivola et al reported 52.5% limb salvage rates after infrapopliteal endovascular treatment in diabetic patients with ESRD compared with 84.4% in diabetic patients without ESRD.¹⁶

Most of the patients presented tissue loss in 413 cases (80.8%) where tissue loss in forefoot minor was 38.6%, while rest pain in 98 cases (19.2%). As seen in **Table 4**, this study

includes more patients with tissue loss 80.8% including ulcer, minor gangrene, and extensive gangrene with or without infection. As many of our patients were diabetic and diabetes is characterized by extensive and distal vessels disease that may explain the high number of tissue loss in our study. In the current study, it is found that the presence of major tissue loss showed worse limb salvage rate (p value 0.001). It is commonly documented that a more severe state of the limb, especially Rutherford 6 with ulcer or gangrene, more likely cause a higher major amputation rate. The need for major amputation is twofold higher in patients with ulcers or gangrene than in patients with only rest pain as severe tissue loss reflects the great load of the disease.⁹

In this study, 78.8% of contralateral limb was affected by ischemia and 44% of them infrapopliteal disease but they were asymptomatic. This raises the issue that was mentioned by Faglia et al that 50% of diabetic patients with unilateral CLI would develop a CLI in the contralateral limb over a 6-year period. That force us to closely follow-up and proper health education (as stop smoking and lipid lowering medication, exercise program) to prevent progression to CLI.¹⁷

In the current study, angiographic study and PTA were performed in the same session. This was mentioned by Faglia et al, and they recommend this approach as it reduces both patient stress and the amount of contrast given, which are especially significant in subjects with cardiac or renal insufficiency (taking into consideration the high number of diabetic in our study with possible diabetic nephropathy even if normal creatinine).²

In the current study, lesions more than 10 cm were 54.8% of cases and femeropopliteal segment was the highest tree affected by both long lesions and multiplicity. Infringuinal TASC D was found in 50.7%, while aortoiliac TASC D is approximately 39%. Infringuinal TASC classification showed significance in relation to technical success, patency, and limb salvage being worse in TASC D (p value < 0.05). This study includes a high percentage of TASC D (57%). This reflects that the CLI to occur needs extensive disease and long occlusion not simply short stenosis or occlusion and this was consistent with other studies and the same time reflects the difficulties in management of such difficult lesions and the technical success of PTA and could be used as the first choice.^{7,15,18,19}

Table 4 Comparison of our study and different literature in clinical presentation

Presentation	Current study (%)	Chung et al ³⁹ (2006)	Kudo et al ¹⁸ (2005)	Rueda et al ⁸ (2008)	Lida et al ⁹ (2012)	Faglia et al ⁷ (2012)	Simons et al (2010)	Chisci et al ⁵ (2012)
Total number of cases	511	334	111	450	406	344	1012	480
Rest pain	19.2	40.4	45%	28	21	3.2%	27.3%	19.3%
Ulcer	22	74.9%	NA	72	NA			
Tissue loss	80.8		55%	NA	79%		50	
1. Minor	38.6	23.6	NA	NA	58%	27.9%		43.3%
2. Major	19.2	8.7	NA	NA	21	68%		37.4%

However, it was mentioned by Lida et al and Bakken et al that TASC A and B can cause CLI as diabetic patient had in addition microvascular deficiency (microangiopathy) because the presence of DM appears to reduce blood flow to the microvascular bed via arteriovenous fistulae leading to symptomatic disease with less advanced femoropopliteal disease.^{9,13}

Leville et al criticized the usage of TASC II as they pointed out that the indications for treatment were based on technical considerations 6 years ago, since when new techniques have developed. For example, a lesion classified as type D by TASC at this time can be treated in most cases by an endovascular rather than open surgical approach.²⁰ Also, Faglia et al stated that in clinical practice, these patients with TASC C and D are first preferred for an endovascular option.^{2,21} Furthermore, Graziani et al indicate that diffuse involvement is very common in diabetic patients with ischemic foot lesions. They pointed out that a second limitation of TASC classification and TASC criteria do not cope with this common anatomic situation of multilevel disease because they consider separately each lesion individually. This means that the TASC categories fail to describe either the severity of the disease or correct treatment.²² Although TASC II was criticized by most of the authors, yet most of them still using it even for referral of disease severity by common international language.

In the current study, technical success was significantly affected by length of lesion being less in lesions more than 10 cm (p value 0.016). In a study done by Faglia et al on patients with CLI where most patients would have been in C or D according to TASC guidelines, PTA was feasible in 84% and during a median follow-up of 23 months while the cumulative 5-year primary patency was 88%.² Baril et al stated that endovascular interventions for TASC II D lesions can be safely achieved with excellent hemodynamic improvement and better limb salvage rates.²³ Vraux et al have also reported that the length of the occlusion (> 10 cm) is a predictor of subintimal angioplasty (SA) technical success and patency.²⁴ Han et al published their results of endovascular treatment stratified by TASC lesion type and showed that in 243 CLI patients, limb salvage rates 24 months after endovascular treatment were 81, 81, and 71.9% for TASC A + B, TASC C, and TASC D lesions of the SFA, respectively.²⁵ Similar limb salvage rates were obtained by Taneja et al in CLI patients with long-segment occlusions treated with bare nitinol stents; however, primary patency rates were rather low with 61.5 and 27% after 6 and 12 months, respectively.²⁶

As it was mentioned by Pentecost et al that 5-year patency is 80 to 85% for ideal short-segment lesions less than 5 cm, with patency decreasing to approximately 65 to 75% for stenoses in > 5 cm. Although longer lesions can be successfully dilated, the long-term patency is lower, and surgical treatment would be preferred in patients with low surgical risk.²⁷ In addition, Setaccia et al in 2011 recommend a system depend on the length of lesion instead of the TASC for research applications and clinical management and also urge that future research should prove the applicability and reproducibility of the classification and the additional value of a potential subdivision of stenotic versus occlusive lesions

(Level 5; Grade D). It was mentioned by Setaccia et al that short SFA lesions (< 5 cm) are preferably treated with angioplasty. Stenting of short lesions should only be performed when suboptimal results are obtained with PTA alone (Level 1a; Grade B) and the preferred treatment of intermediate SFA lesions (5–15 cm) is PTA with primary bare nitinol stenting (Level 1b; Grade B) and in long SFA lesions (> 15 cm) endovascular treatment (intraluminal or subintimal) with a stent graft seems acceptable when the patient's condition precludes an open procedure (Level 3b; Grade C).¹ However, in a study done by Antusevas et al, there was no statistical significance effect of length of lesion more than 10 cm and technical failure.²⁸

Another limitation of TASC II classification in management of infrapopliteal disease as the commonly encountered occlusions longer than 2 cm or diffuse disease in the tibial and peroneal arteries are defined as TASC D, which indicates for bypass surgery according to the TASC guideline, and few patients with CLI consequently are clinically indicated for angioplasty based on anatomical morphology. However, EVT with traditional angioplasty currently is most broadly used in the infrapopliteal region for the reason that it achieves technical and clinical success rate of up to 90 and 70%, respectively. Furthermore, patients are commonly not suitable surgical candidates secondary to comorbidities, advanced age, and presence of nearby infection. Based on the above-mentioned considerations, the TASC-based morphological classification of infrapopliteal lesions does not govern revascularization modality selection in current clinical practice.⁹

In the current study, on 24 months follow-up, the primary patency, secondary patency, and limb salvage in PTA were 77.8, 84.7, and 90.7%, respectively. It is now recognized that the patency of revascularization is not important as limb salvage and actually there is a population of asymptomatic patients with subclinical lower extremity ischemia and very low perfusion pressures and the concept of situational perfusion enhancement arise. These patients become symptomatic only when they develop incidental foot ulceration and do not have the circulatory reserve to heal. A boost in arterial perfusion, even transiently, usually allows healing of the ulcer. Once the ulcer is healed, maintenance of enhanced perfusion is not critical, and recurrent ischemia is usually well tolerated as the patient resumes the subclinical ischemic state (situational perfusion enhancement). Percutaneous intervention proponents therefore argue that inferior reconstruction patency rates after such interventions are inconsequential.²⁹ In a study done by Bakken et al, they reported 1-year limb salvage rates of 91% for EVT compared with our 1-year limb salvage rates of 90.7% for CLI patients.¹³ Although the limb salvage rate was also the same in studies done by Akbari and LoGerfo, and Wölfle et al, however, this result was for nondiabetic patients while they mentioned that in diabetic patients (whether IDDM or NIDDM) that limb salvage was lower ranged from 67 to 73%.^{12,30}

In the current study, technical success in endovascular treatment was 94%. However, we could successfully revascularize 96.8% of all CLI presented in this study by either surgery or endovascular. Faglia et al assessed the feasibility

Table 5 Comparison of our study and different literature in outcome

Study and year	Total no.	Follow-up (y)	Endovascular % of cases	Technical success	Primary patency	Secondary patency	LSR	Mortality	Complications	Note
Current study	511	1	84%	96.8%	77.8	84.7	90.7	Total 5.3 Endo 4.4 Surg 7.2	Endo 29.5 Surg 10.8	
Dosluoglu et al, 2009 ¹	344	2	NA	97%	76%	91%	93% 1 y 82% 2 y	16% in surg 3% in endo	NA	> 80 y
Brosi et al, 2007 ²	376	1	46%	NA	35%	62%	80%	33 in surg 31 in endo	NA	> 80 y
Faglia et al, 2005	933	5	83%	NA	88%	NA	NA	12%	3.4% (all major)	
Lida et al, 2012	406	5	100	94	NA	NA	80 2 y	14% 1 y	NA	TASC D 97%
Faglia et al, 2012	344	2	58	96	NA	NA	NA	19.5	NA	AMP 5.3%
Giles et al, 2008	163	1	100	93	53	NA	84	19	9	All TF in TASC D
Flu et al, 2010	106	6	37	Failed endo 5% Surg 24%	52	77	87.5	28 at 3 y	25% endo 31% open	Assess functional outcome
Cieri et al, 2011	248	2	60.5	NA	83.3	NA	90	NA	NA	Assess function
Faglia et al, 2006	564	5	74	NA	78	81	78.5	30.7	4.2 endo 10.2% surg	
Engelhardt et al, 2012	104	3	45	NA	NA	NA	81	35 at 1 y	NA	
Taylor et al, 2009	677	5	48	NA	73	NA	75	16%	NA	PT oriented outcome
Adam et al, 2005	452	5	49	NA	NA	NA	Endo 68% 1 y Open 71	41 PTA 57% surg	NA	80% SFA 62 distal DS
Chisci et al, 2012	480	2	66.5	91 PTA 95 surg	NA	NA	50 1 y	50 1 y		
Tefera et al, 2005	76	1	NA	85%	NA	NA	83.5	1.5	NA	

Abbreviations: DS, distal superficial femoral artery; Endo, endovascular; LSR, limb salvage rate; NA, not available; surg, surgery; TASC, TransAtlantic Inter-Society Consensus.

of revascularization in CLI and it was successful in 96% of cases and only 4% was not successful in revascularization. This was comparable to our study where we could revascularize 96.8% of all cases whether EVT or bypass.⁷ It was found by Dattilo and Casserly that it is apparent that EVT for CLI is associated with high rates of technical success (90%), low rates of periprocedural mortality (2%), and complication (5%) and that intermediate term (1–2 years) limb salvage rates of more than 80% are typical.³¹ A study done by Engelhardt et al demonstrated that two-thirds of all patients presenting with their first episode of CLI to a vascular surgical center can be offered some form of direct revascularization. Approximately half of these candidates for revascularization will undergo surgery and half can be treated by catheter-based interventions. Patients who are not eligible for revascularization approximately one-fifth of all patients can be offered at least some type of medical and general supportive treatment. Primary amputation is required in less than 10%³² (→ Table 5).

In the current study, although the high rate of complications encountered in endovascular group (29.5 vs. 10.8%) than in surgery group. However, 96% of the complications encountered in endovascular group were treated (most of them were by endovascular treatment). Moreover, the mortality rate was higher in surgery group than endovascular group (4.4 vs. 7.2%). This makes the endovascular treatment an attractive method of treatment of such patients with CLI who have multilevel disease, high burden of comorbidity taking into consideration that there is a bias in this study as endoluminal therapy was the first line of treatment offered. There is an explanation mentioned by Giles et al rationalize the high rate of complications observed in endovascular group that the patients who preferentially undergo a percutaneous intervention tend to be sicker than patients in whom bypasses are the first line of treatment. An attempt at percutaneous intervention may be performed as a “salvage” procedure in patients who have limited life expectancies and extensive comorbidities who would have otherwise undergone a primary amputation, which is associated with perioperative mortality rates of 5 to 17%. Although the minimally invasive nature of infrapopliteal PTA has obvious appeal, it also has potential disadvantages. These may include conversion of an elective to emergency procedure, loss of bypass targets, a less durable solution, lengthy procedures causing excessive radiation exposure, and the potential for rising costs of care if multiple interventions are necessary. The delay to surgery caused by an inadequate or failed intervention could cause increased ischemia and lead to worsening wounds, minor amputations, and even limb loss, despite the ability to construct a durable bypass graft.³³ On the contrary, in a study done by Faglia et al, the survival of amputated patients who had previously undergone revascularization was significantly better than that of nonrevascularized amputees, even when unable to avoid major amputation. In addition, they demonstrated that this revascularization reduces the rate of major amputation. Moreover, data indicated that the rate of below-the-knee amputation in

PTA patients was significantly higher than that of non-revascularized patients, as well as than that of amputated patients because of bypass closure. The outcomes of below-the-knee amputation are superior to those of the above-the-knee amputation. They further encourage performing revascularization in all diabetic patients with CLI.⁷

Although the current study has higher rate of complications in the endovascular group, this may be attributed that we included minor complications that were treated in the same procedure as dissection or deserve no treatment as groin ecchymosis and minor hematoma.

In approaching a patient with CLI, several questions should be asked that will help form the foundation for the decision regarding the appropriate primary treatment strategy.

- Is the limb salvageable?
- Is the limb worth saving?
- Is revascularization possible?
- What is the risk-benefit ratio of revascularization?

These questions are interrelated and reinforce the complexity of the decision-making process that is best performed by a multidisciplinary team of health care.³¹

Study Limitation

There are some limitations of the present study. First, this is a single-arm study without a control group. Therefore, the rates of technical success and vascular complications when routinely using the crossover approach were not assessed for comparison.

Second, the results of the present study were derived from a single-center experience with a high work volume where certain techniques have been routinely adopted for many years as a first choice. It is therefore likely that the selection of techniques with its own limitations may differ largely from centers with another experience.

Third, in most of our patients, computed tomographic angiogram or a magnetic resonance angiogram was not a baseline performed before the intervention. An extensive use of these diagnostic tools might have impact on the decision process.

Fourth, this study is also defective in assessment of functional status and effect of revascularization after the patient quality of life and ambulation. We only assess the patency and we hope that we can assess such important parameter in our future study.

Finally, we have relatively large number of patients that lost follow-up. This may be attributed to socioeconomic factors and lack of proper insurance system. So, the lower mortality rate in this study cannot be taken with certainty.

Conclusion

Although most of the results were already mentioned in the literature to be the same and most of them are repetitive, the current study has emphasized on several points regarding treatment of such frail high-risk patients and we hope that

these results can add to previous literature and formulating a more comprehensive protocol of treatment for CLI.

1. Revascularization by endovascular achieves high technical success and limb salvage in CLI, hence should be considered as preferred choice of treatment. However, both endovascular and surgery should not be counteracting each other and using both can revascularize 96.6% of CLI.
2. Diabetes did not prove to significantly affect the revascularization outcome, but this should not be taken simply as most of our patient was diabetic and further studies are needed to confirm such results.
3. Patients with cardiac and/or renal disease showed lower rates of patency and limb salvage.

Conflict of Interest

None

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