

Original Article

Endovascular management of Critical Limb Ischaemia: Study of 100 Cases

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Abstract:

Key Words :

Critical limb ischemia,
 Endovascular therapy,
 peripheral vascular disease.

Background: Critical limb ischemia (CLI) is the most severe form of Peripheral Artery Disease (PAD) and represents approximately 1% of the total number of patients with PAD. CLI is associated with a higher risk of limb loss in the absence of revascularization. Objectives of the study are to find out the modality of treatment in CLI, different types of endovascular therapy in CLI and their outcome.

Methods: A retrospective study evaluated 100 patients with CLI reported to cardiovascular surgery department in Combined Military Hospital (CMH), Dhaka between July 2016 to June 2018. Patients with disabling claudication or rest pain and tissue loss are included in the study. All patients were evaluated by peripheral angiogram and revascularisation of limbs was done by endovascular procedure in 79 patients, by surgical intervention in 12 patients.

Results: Forty-four patients (44%) presented with rest pain and disabling claudication, 56 patients (56%) presented with tissue loss. Revascularization of limbs was done in 91 patients (93%). No intervention could be done in 9 patients (9%). Endovascular interventions were done in 79 patients (87%). Twelve patients (13%) underwent surgical bypass. All patients with rest pain remains asymptomatic in 6 months follow up; 2 patients developed reocclusion within 1 year. No major amputation in patients with only rest pain.

Conclusion: Revascularization is the main modality of treatment in CLI. Most of the patient can be treated by endovascular percutaneous procedure. Early intervention in CLI patient without tissue loss carries excellent outcome.

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Introduction:

The prevalence of peripheral arterial disease (PAD) continues to increase worldwide.¹ PAD refers to atherosclerosis involving the aorta, iliac and lower extremity arteries and is associated with significant morbidity and mortality.² Critical limb ischaemia (CLI) is the most severe form of PAD and represents approximately 1% of the total number of patients with PAD.³ CLI is associated with a higher risk of limb loss in the absence of revascularization. Primary limb amputation continues to be required in 10% to 40% of CLI patients because of overwhelming infection or unreconstructable vascular disease.⁴

Advances in endovascular therapies during the past decade have broadened the options for treating peripheral vascular disease percutaneously.

Endovascular treatment offers a lower risk alternative to open surgery in many patients with multiple comorbidities. In general, endovascular treatments have greater long-term durability for aortoiliac disease than femoral popliteal disease. But developments in endovascular therapy (EVT) have raised expectations for improvement of the traditionally poor prognosis of CLI associated with infrapopliteal lesions.^{3,4}

Primary angioplasty is now widely used for the treatment of infrapopliteal arterial lesions in CLI patients because of its favourable clinical outcome at a lower procedural cost compared with open bypass therapy.⁵ Balloon angioplasty and stenting are the mainstays of endovascular therapy. New well-tested innovations include drug-eluting stents (DES) and drug-coated balloons (DCB).

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Methods:

A retrospective study evaluated 100 patients with critical limb ischaemia reported to cardiovascular surgery department in CMH Dhaka between July 2016 to June 2018. Patients with disabling claudication or rest pain and tissue loss are included in the study. Simple claudication and patients with severe ischaemia and non salvageable limbs were not included. Non-invasive physiological tests and arterial imaging precede an endovascular intervention and help localize the disease and plan the procedure. All patients were evaluated by peripheral angiogram and revascularization of limbs was done by endovascular procedure in 79 patients, by surgical intervention in 12 patients. Nine patients were found not suitable for any intervention for revascularisation. All patients were advised to continue antiplatelets, antilipids and vasodilators drugs (aspirin + clopidogrel, statins and cilostazole) for 1 year and Aspirin / clopidogrel for life long. There were 11 female (11%) and 89 male (89%) patients. 20 Average age was 55 years (32 years – 80 years).

Results:**Table-I***Age distribution of patients (n=100).*

Age	No. of patients	Percentage
30-40	18	18
41-50	37	37
51-60	28	28
61-70	11	11
71-80	4	4
81-90	2	5

Table-I shows average age of the patients was 55 years (32 years – 87 years).

Table-II*Sex distribution of patients (n=100).*

Sex	No. of patients	Percentage
Male	89	89
Female	11	11

Table-II shows there were 11 female (11%) and 89 male (89%) patients.

Table-III*Clinical presentation of patients (n=100).*

Presentation	No. of patients	Percentage
Rest pain/severe claudication	44	44
Tissue loss (Ulcer/Gangrene)	56	56

TABLE-III shows 44 patients (44%) presented with rest pain and disabling claudication, 56 patients (56%) presented with tissue loss (ulcer/ gangrene of toes and foot).

Table-IV*Revascularization procedure (n=91).*

Procedure	No. of patients	Percentage
Endovascular	79	87
Surgery	12	13

Table-IV shows revascularization of limbs was done in 91 patients (93%). No intervention could be done in 9 patients (9%) due to infrapopliteal chronic total occlusions of artery and poor distal run off. Endovascular interventions were done in 79 patients (87%). Twelve patients (13%) underwent surgical bypass.

Table-V*Endovascular procedure for revascularization (n=79).*

Procedure	No. of patients	Percentage
Angioplasty only	14	18
Angioplasty with stenting	51	65
*DCB	9	11
**DES	5	6

* DCB = Drug coated balloon

** DES = Drug eluting stent

Table-V shows in endovascular procedure – angioplasty with stenting was done in 51 patients (65%), 14 patients were treated by angioplasty (18%) only, 1 patient (11%) was treated by drug coated balloon and 5 patients (6%) angioplastied by drug eluting stent.

Table-VI*Surgical procedure for revascularization (n=12).*

Procedure	No. of patients	Percentage
*Fem-Pop bypass	7	58
**Fem-Fem cross over bypass	2	17
***Fem-PT bypass	1	8
Femoral endarterectomy	2	17

*Fem-Pop bypass = Femoral artery-Popliteal artery bypass

**Fem-Fem cross over bypass = Femoral artery-opposite femoral artery bypass

***Fem-PT bypass = Femoral artery-posterior tibial artery bypass

Table-VI shows in surgical procedure 7 patients (58%) were treated by Fem-Pop bypass, 2 patients (17%) by Fem-Fem cross over bypass, 1 patient by Fem PT bypass and 2 patients by Fem oral endarterectomy.

Table-VII

Limb salvage surgery after revascularization (n=47).

Procedure	No. of patients	Percentage
Wound debridement	14	30
Wound debridement with Skin graft	10	21
Minor amputation (Ray / TMA amputation)	9	19
Minor amputation with NPWT	7	15
Major amputation	6	13
New bypass graft construction	1	2

TABLE-VII shows 7 patients with tissue loss required minor amputations of gangrenous part. 6 patients need major amputations after revascularization.

Table-VIII

Limb loss after revascularization (n=91).

Time	No. of patients	Percentage
6 months	6	7
1 year	8	9

TABLE-VIII shows 6 patients needs major amputation within 6 months and 8 patients needs major amputation within 1 year of revascularization.

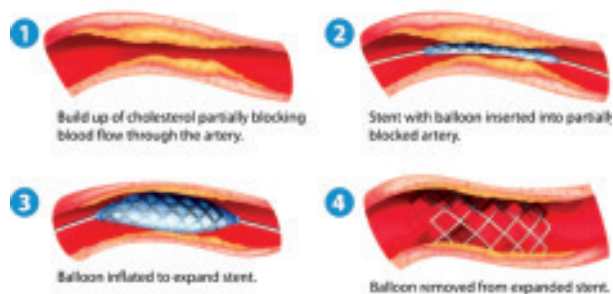


Fig-1: Balloon angioplasty and Stent deployment (DCB)18 (copyright@azuravascularcare.com).



Fig-2: Drug coated balloon19 (copyright@ Medtronic USA).



Fig-3: Critical stenosis of abdominal aorta.



Fig-4: After angioplasty and stent deployment.

Discussion:

PAD is one of the most prevalent cardiovascular diseases, affecting up to 5% of individuals over 55 years of age.6 CLI is considered the “end stage” of PAD.7

According to the Inter-Society Consensus for the Management of PAD (TASC II), CLI is defined by the presence of chronic ischemic rest pain, ulceration or gangrene attributable to arterial occlusive disease.⁴

The diagnosis of CLI is usually the result of clinical evaluation associated with one or more instrumental examinations. Among the first-level examinations, we find ankle brachial index (ABI), toe systolic pressure and toe brachial index (TBI), transcutaneous oxygen pressure (TcPO₂) and ultrasound (US) colour duplex. The second-level examinations are magnetic resonance angiography (MRA) and computed tomography angiography (CTA).⁸

Revascularization is the cornerstone of therapy to prevent limb amputation and both open vascular surgery and endovascular therapy play a key role in the treatment of patients with critical limb ischemia. A simultaneous medical intervention is required for pain management, control of cardiovascular risk factors and optimization of glycaemic control.¹¹

There is an open debate whether open surgery is preferable or not to angioplasty. The decision is related to many factors: anatomical lesions, distribution of arterial disease, patient's health status, co-morbidities, presence of foot ulcer / gangrene and local expertise.

In our study, we found most of the patient is male (89%) and average age is 55 years.

Most of the patient presented with tissue loss (56%).

Endovascular procedure done in 87% patients.

Advances in endovascular therapies during the past decade have broadened the options for treating peripheral vascular disease percutaneously. Endovascular treatment offers a lower risk alternative to open surgery in many patients with multiple co morbidities.

Bisdas T et al., confirmed in interim analysis of CRITISCH Registry that when physicians are free to individualize therapy to CLI patients, the endovascular-first approach achieved a no inferior AFS rate compared with bypass surgery.¹²

Abu Dabrh AM et al., suggests that bypass surgery and endovascular approaches may have similar effect on mortality and major amputations.

However, better primary and primary assisted patency can be expected with surgery.¹³

Eighteen percent patient was treated with only balloon angioplasty whereas 65% patient was revascularized by balloon angioplasty and stenting for femoral popliteal disease.

We consider length of lesion, anatomic location and nature of lesion in choice of procedure.

Krankenbergh H et al., showed -balloon angioplasty offers similar results to stenting in short lesions (<100mm) when there is good arterial expansion without flow limiting dissections. Nitinol self-expanding stents offer better long-term patency in longer lesions.¹⁴

Drug coated balloon angioplasty performed in 11% patients. We use DCB in reocclusion cases and infrapopliteal disease.

Introduction of drug coated balloon offers percutaneous transluminal angioplasty (PTA) as a useful option to treat infrapopliteal disease in CLI.^{9, 10}

Cassese S et al. (2012) Rosenfield K et al., (2015) Tepe G et al., (2015) showed- Drug-coated balloons offer lower rates of restenosis than balloon angioplasty alone in patients with infrapopliteal and SFA disease and claudication.¹⁵⁻¹⁷

Limitations of the study: Data for long term outcome is not yet studied.

Conclusion:

CLI is a severe form of PAD which is associated with a higher risk of limb loss in the absence of revascularization. Patients receiving endovascular procedures need a structured surveillance plan for follow-up care. This includes intensive treatment of cardiovascular risk factors to prevent myocardial infarction and stroke, which are the main causes of death. Limb surveillance aims to identify restenosis and new disease beyond the intervened segments, both of which may jeopardize patency and lead to recurrent symptoms, functional impairment, or a threatened limb.

Conflict of Interest - None.

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