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Original Article

Clinical Outcomes Following Surgical Revascularization for Acute Lower Limb Ischemia

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Abstract

Objectives: To assess the clinical outcomes of surgical revascularization in patients diagnosed with acute lower limb ischemia (ALI). The primary outcome was defined as the limb salvage rate within 30 days after surgery.

Methods: This is a retrospective single-center study. The target population was recruited from the Prapokklao Hospital database between January 2019 – December 2023. Patients who were diagnosed with acute occlusion of the artery according to the International Classification of Disease 10th Revision (ICD-10) code I74.0, I74.3, and I74.5 were identified. Medical records were analyzed for demography, clinical presentation, etiology, Rutherford severity classification, revascularization procedures, major amputation, mortality within 30 days after revascularization, and data during follow-up.

Results: This study enrolled a total of 70 patients, 46 men (65.71%) and 77 affected limbs. The mean age was 65.67 years (SD 13.69 years), and the median was 65 years, ranging from 19 to 94 years. Co-morbidities: 42 (60%) hypertension, 28 (40%) peripheral arterial disease, 26 (37.14%) atrial fibrillation. Etiologies: 36 (51.43%) thrombosis (34.29% in-situ thrombosis of the native vessel) and 34 (48.57%) embolism. Rutherford classification of severity categories I, IIa, and IIb was 1 (1.42%), 21 (30.0%), and 48 (68.58%), respectively. The modalities of revascularization included 70 (100 %) thromboembolectomy with a Fogarty catheter, 30 (42.86%) intra-arterial angioplasty with balloon or stent, 8 (11.43%) bypass procedure, 6 (8.57%) endarterectomy and 8 (11.42%) fasciotomy. Technical success was 98.57 %. The mean operative time was 195.07 minutes (SD 95.51 minutes). The median hospital stay was 8 days. Post-operative complications were 8 (11.43%) bleeding, 7 (10%) compartment syndrome, 5 (7.14%) reperfusion injury, 5 (7.14%) acute kidney injury, 2 (2.86%) pneumonia and 1 (1.43%) acute myocardial infarction. The 30-day major amputation rate and mortality were 10.0% and 5.71%, respectively. At 30 days, sixty-three patients (90%) had limb salvage, and Four (5.71%) patients had died.

Conclusion: Clinical outcomes following surgical revascularization for acute lower limb ischemia in our hospital showed high technical success and limb salvage rates. The limb salvage rate was 90.0%, and the mortality rate was 5.71%.

Keywords: Acute lower limb ischemia (ALI), Embolism, Thrombosis, Revascularization, Limb salvage

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Introduction

Acute lower limb ischemia (ALI) is defined as a sudden decrease in limb perfusion, causing a potential threat to limb viability. Presentation less than 2 weeks (14 days) following the acute event.[1] Acute arterial occlusion is caused by embolism and thrombosis. Embolism results from material passing through the arterial tree and obstructing a peripheral artery. The common embolism originates from the heart (atrial fibrillation, myocardial infarction, valvular disease), and another source is arterial pathology (atherosclerosis, aneurysm). Thrombosis results from blood clotting within an artery and usually occurs at the point of atherosclerotic vessels, bypass graft, and in the stent.[2] The other cause of acute thrombosis can occur in the state of hypercoagulability (malignancy), low arterial flow (congestive heart failure, shock, arterial dissection), and hyperviscosity (polycythemia vera, dehydration).[3]

Once arterial blood flow is obstructed, it results in ischemia of the leg tissues, including nerves, skeletal muscles, and skin. The classic clinical symptoms of ischemic limbs are characterized by abrupt onset of progressive pain in the affected limb, pulselessness, poikilothermia, pallor, paresthesia, and paralysis. The Rutherford classification defines the extent of ischemia based on clinical findings (sensory loss and muscle weakness) and Doppler measurements (arterial and venous signal) divided into three classes: class I-viable, class IIa-marginally threatened, class IIb-immediate threatened, and class III-irreversible.[4] In class III, there is no indication to improve the blood supply; major amputation and conservative care are appropriate treatments. Patients with class I, IIa, and IIb required immediate revascularization to remove obstructing clots and treat underlying pathology.

ALI is a limb- and life-threatening condition and requires urgent revascularization. The selection of revascularization modalities depends on the severity of limb ischemia, occlusion level, and ALI's etiology. Revascularization approaches include surgical approach (thromboembolectomy, surgical bypass), endovascular intervention (thrombolysis, trans-arterial angioplasty), and combined surgical and endovascular technique (hybrid therapy).[5]

This study aimed to assess the outcomes of surgical revascularization in ALI patients. The primary outcome was defined as the limb salvage rate within 30 days after surgery.

Materials and Methods

Patients

This is a retrospective analysis of 70 patients (77 affected legs) with ALI who were treated in Prapokklao Hospital, Chanthaburi. The target population was recruited from the hospital database between January 2019 - December 2023. Patients who were diagnosed according to the International Classification of Disease 10th Revision (ICD-10) code I74.0 (occlusion of the aorta and iliac arteries), I74.3 (occlusion of the femoral and popliteal artery) and I74.5 (occlusion below the knee) were identified. The study protocol was approved by the ethics committee. All patients presented with acute lower limb ischemia within 2 weeks. Rutherford class I, IIa, and IIb were treated with surgical revascularization (Thrombo-embolectomy with Fogarty catheter, trans-arterial angioplasty with balloon/stent, and surgical bypass). Rutherford category III (irreversible limb ischemia) was excluded. All medical record data included demography, etiology (thrombosis or embolism), the severity of ALI, level of arterial occlusion, revascularized procedures underwent, 30-day outcomes (major amputation, mortality), follow-up data (major amputation, mortality, recurrent ALI, and walking status (return to normal, walking with a prosthesis, bedridden).

Preoperative protocol

Once the clinical diagnosis of ALI was confirmed, our protocol included immediate infusion of intravenous unfractionated heparin (UFH) to limit clot formation and prevent thrombus propagation and worsening ischemia. We start UFH at a loading dose of 80 units/kg, followed by infusion at 18 units/kg/hr, and adjusted to achieve therapeutic activated partial thromboplastin time (aPTT) every 6 hours (keep aPTT ratio of 2-3 times the control value). UHF infusion continued throughout the operation and postoperative period. Ancillary support measures included intravenous fluid infusion, oxygenation, and pain management. Preoperative imaging with duplex ultrasound and computed tomography angiography (CTA) is performed for treatment planning in complex cases, such as ALI in peripheral arterial disease, AAA, and previous vascular intervention (bypass surgery, trans-arterial angioplasty). All imaging performed without delay a definitive revascularized procedure. Revascularized procedure is immediately planned and performed as soon as possible after adequate patient preparation.

Limb salvage procedure

All procedures were done under general anesthesia. Both the groin and the entire legs were prepared and draped. All of our patients were approached through common femoral artery (CFA) bifurcation. Occasionally, popliteal artery or below-the-knee artery exposure may be required. Proximal and distal control of the vessel was ensured before arteriotomy. Fogarty catheter is first used for clot removal for both emboli and thrombosis cases until good blood flow is present. Endarterectomy with closure at CFA was performed in some cases. After the arteriotomy site closed, a completion angiogram was performed. The thrombo-embolectomy procedure was repeated if a residual clot was detected. Intra-arterial angioplasty with balloon and stent was applied after removing the clot for treated concomitant atherosclerotic lesion or focal dissection that interferes with the distal blood flow. Bypass procedure may be performed as a primary option or as a second-line treatment when thrombo-embolectomy or intra-arterial angioplasty fails. Fasciotomy is considered in patients with compartment syndrome. Technical success was defined as restoring blood flow to the lower limb, as confirmed by an intraoperative angiogram, Doppler ultrasound, and pulsation of pedal arteries. All patients were transferred to the intensive care unit.

Postoperative outcomes

Early period, 30-day outcomes measurement, including morbidities, mortality, and major amputation. Follow-up evaluation, including mortality, major amputation, and walking status.

Statistical analysis

Categorical variables were presented as counts and percentages, and continuous variables were presented as mean ± standard deviation (SD). Categorical variables were compared using the Chi-square test. Continuous variables were compared using the unpaired *t*-test. A p-value less than 0.05 is considered statistically significant. All static analysis was performed using Microsoft Excel®.

Results

Patient characteristic

A total of 70 patients. There were 46 male (65.72%) and 77 affected limbs. The mean age was 65.67 years (SD 13.69 years). 42 patients (60%) were active smokers. Overall comorbidities including 60% hypertension, 40% peripheral arterial disease (PAD), 37.14% atrial fibrillation (AF), 28.6% dyslipidemia, 26% diabetes, 5.71% abdominal aortic aneurysm (AAA), 4.23% polycythemia vera, and 2.85% malignancy (Table 1).

Table 1 Patient demography, relevant risk factors, and comorbidities

	N (total 70)	Percent (%)
Gender		
Male	46	65.71
Female	24	34.29
Age (years)		
Range	19 - 94	
Mean	65.67 ± 13.69	
Median	65.0	
Comorbidity		
Hypertension	42	60
Peripheral arterial disease	28	40
Atrial fibrillation	26	37.14
Dyslipidemia	20	28.57
Diabetic mellitus	18	25.71
Coronary artery disease	9	12.86
Cerebrovascular disease	4	5.71
Abdominal aortic aneurysm	4	5.71
Polycythemia vera	3	4.22
Cancer	2	2.85

Etiologies

Thrombosis was 36/70 (51.43%), and embolism was 34/70 (48.57%). For thrombosis, 34.29% was developed in the native artery, 10.0% was bypass graft thrombosis, and 7.14% was in-stent thrombosis). Embolism was 34/70 (48.57%), and 51.43% of emboli had AF (Table 2).

Severity and level of occlusion

Rutherford classification; class I = 1.43%, IIa = 30% and IIb = 68.57%. The median duration of symptoms before presentation was 2 days.

Level of occlusion: Aorta and iliac levels were 8 patients (11.42%), 11.27% iliac, and 85.92% femoral and popliteal artery. 1.41% below the knee level (Table 2).

Table 2 Etiology, location of occlusion, and severity

	N (total 70)	Percent (%)
Etiology		
Thrombosis	36	51.43
Native artery	24	34.29
Bypass graft	7	10.0
Stent	5	7.14
Embolism	34	48.57
Location of occlusion		
Aorta and iliac	8	11.42
Femoral and popliteal	61	85.92
Below the knee	1	1.42
Rutherford classification		
Category I	1	1.42
Category IIa	21	30.0
Category IIb	48	68.58

Modalities of revascularization

70 (100%) embolectomy, adjunctive procedure with 42.86% intra-arterial balloon and 22.86% stent for correct intimal dissection and atherosclerotic lesion. 11.43% surgical bypass. Technical success was 69/70 (98.57%). The median operative time was 170 minutes. All of the patients were treated by thrombo-embolectomy for blood clot removal. Other adjunctive procedures performed included intra-arterial angioplasty included 42.86% balloon angioplasty, 22.86% stent, 8.57% bypass surgery (1 axillo-femoral, 2 femoral-femoral, 2 femoral-popliteal, and 1 popliteal-posterior tibial bypass), 10% endarterectomy, and 11.43% fasciotomy. The mean operative time was 195.07 ± 95.91 minutes; the median operative was 170 minutes. In the thrombosis group, balloon angioplasty 21/36(58.33%), stent 14(38.89%), Bypass 8 (24.22%), endarterectomy 4 (11.11%). Operative time 226.94 ± 97.97 minutes, median 227.5 minutes. In the embolic group, balloon 9/34 (26.47%), stent 2 (5.88%), bypass 0, endarterectomy 3(8.82). Operative time was 160.30 ± 81.62 minutes, and the median was 150 minutes (Table 3).

Table 3 Revascularization modalities of patients with acute thrombosis and embolism

	Thrombosis (N = 36)	Embolism (N = 34)	*P* value
Revascularization (%)			
Thrombo-embolectomy	36 (100)	34 (100)	-
Balloon	21 (58.33)	9 (26.47)	0.007
Stent	14 (38.89)	2 (5.88)	0.001
Bypass	8 (24.22)	0 (0)	0.010
Endarterectomy	4 (11.11)	3 (8.82)	0.749
Operative time (min)	226.94 ± 97.97	160.3 ± 81.62	0.003
Technical success (%)	35 (97.2)	34 (100)	-

Postoperative results

Outcome data included 30-day or in-hospital mortality, major amputation, postoperative complications, and other adverse events. The mortality rate was 5.71% (4 cases included 2 strokes, 1 pneumonia, and 1 superior mesenteric ischemia). Major amputation was performed in 7 patients (10.0%). Complications after revascularization included 11.43% bleeding at the surgical site and fasciotomy wound, 10% compartment syndrome, 7.14% reperfusion injury, and 7.14% acute kidney injury (Table 4).

Table 4 Postoperative outcomes and discharge status

	N (total 70)	Percent (%)
Complications		
Bleeding	8	11.43
Compartment syndrome	7	10.0
Reperfusion injury	5	7.14
Acute kidney injury	5	7.14
Acute myocardial infarction	1	1.43
Discharge status		
Minor amputation	5	7.14
Major amputation	7	10.0
Limb salvage	63	90.0
Mortality	4	5.71

Follow up period

The mean follow-up period was 13.5 months (range 1-52 months). Walking status at home within 30 days included, return to normal status was 46 patients (65.71%), prosthesis used was 7 patients (10.00%), bedridden was 9 patients (12.86%), and unknown status was 8 patients (11.43%). Recurrent ALI occurs in 12 patients (17.14%) (11 thrombosis and 1 embolism). Nine patients (75%) were men with a mean age of 60.25 ± 13.12 years; the median age was 59 years. Of them, the active smoker was 9 patients (75%), common comorbidities included, PAD was 10 patients (83.33%), hypertension was 8 patients (66.67%), AF was 4 patients (33.33%), diabetes was 3 patients (25%), and AAA was 2 patients (16.67%). The major amputation rate was 8.57%. Mortality occurs in 4 patients (5.57%) (Table 5).

Table 5 Data during the follow-up period

	N (total 66)	Percent (%)
Walking status (within 30 days)		
Return to normal	46	69.70
Walking with prosthesis	7	10.60
Bedridden	9	13.64
Unknown	4	6.06
Recurrence ALI	12	18.18
Native artery	6	50.0
Bypass graft	4	33.33
In-stent	2	16.67
Major amputation	6	9.10
Mortality	4	6.06

Discussion

In this study, ALI affected older patients and was more prevalent in men than in women. Medical comorbidities and atherosclerotic risk factors include hypertension, PAD, AF, hyperlipidemia, diabetes, and active smoking. Our data is similar to those of other Asian and Western countries. In Thailand, Mutirangura P et al. report that ALI in the Thai population's mean age was 62 years, equally prevalent among men and women.[6] In Japan, Umetsu et al. report the demography of ALI patients; the median patient age was 72 years, with no sex differentiation.[7] Swedish study reported that the median patient age was 74, and 49% were women.[8] In the United States, Baril et al. report 20 years of experience in ALI treatment; the mean age was 80.6 years, and 60% were female.[9] Common comorbidities in all studies included hypertension, dyslipidemia, AF, PAD, and other atherosclerotic risk factors. Most patients are still actively smoking.

Thrombosis and embolism were the significant causes of ALI. The clinical presentation and outcomes of treatment between both groups were different. In our study, Thrombosis vs embolism was 51.43% vs 48.57%. In the thrombosis group, PAD is more common than embolism (61.11% vs 20.59%, $p < 0.001$, 95% CI 7.93 - 12.41). In the embolic group, AF is more related to thrombosis (52.94% vs 22.22%, $p < 0.001$, 95% CI 3.84-6.41). The severity of clinical presentation (Rutherford classification) was no different. Mutirangura P et al. concluded that peripheral pulse on the contralateral limb was more commonly found in patients with acute arterial embolism than in patients with acute arterial thrombosis (71.4% vs. 31.0%, $p < 0.001$). AF was detected more in patients with acute embolism than thrombosis (31.9% vs. 3.4%, $p = 0.004$).[10]

Currently, surgical treatment for ALI includes open surgery and endovascular and hybrid techniques. Thrombo-embolectomy using a Fogarty catheter is effective for removing blood clots; most surgeons are familiar with this technique.[11] However, open thrombo-embolectomy cannot wholly remove the thromboembolism. Up to 30% demonstrated residual thrombus on completion of angiogram after thrombo-embolectomy.[12] Residual thrombus associated with recurrent occlusion, re-intervention, and limb loss. The completion of angiography after thrombo-embolectomy is recommended. If residual thrombus was found, further thrombo-embolectomy or bypass may be considered.[5] Intra-arterial thrombolysis (catheter-directed thrombolysis) using recombinant tissue plasminogen activator (rtPA) or urokinase is considered an alternative to surgery.[13]

Modalities of revascularization in our institute included open surgery, endovascular, and hybrid techniques. All of our patients were treated by thrombo-embolectomy with a Fogarty catheter; no thrombolysis was used. In the thrombosis group need, more adjunct procedures were performed. Intra-arterial angioplasty with a balloon in thrombosis vs. embolism was 58.33% vs. 26.47%, $p = 0.007$. The stent used in thrombolysis vs. embolism

was 38.89% vs. 5.88%, $p = 0.001$. The operative time in the thrombosis group was significantly longer than in the embolic group ($p = 0.003$). In embolism, treatment may be resolved with embolectomy alone without other adjunct procedures because the arterial lumen is more normal than thrombosis. Some embolic cases needed trans-arterial intervention to treat atherosclerosis or focal intimal tear after embolectomy. Our data show that 26% of the embolic group was treated by intra-arterial angioplasty. Berczi V et al. treated seven acute thrombotic occlusions in iliac arteries by stent implantation to correct the atherosclerotic lesions. Technical success was 100%, no distal embolization.[14] Kim C et al. report the outcomes of stent-assisted recanalization in ALI. The common site of stent used was iliac arteries, which was 100% technical success. The mean follow-up period was 14.4 months, with no re-occlusion or restenosis.[15]

In this study, the bypass procedure was performed in 8 patients (11.42%). Bypass surgery in thrombosis vs embolism was 24.22% vs 0%, $p < 0.001$). Indications for bypass surgery include thrombosed iliac artery, thrombosed popliteal artery aneurysm, in-stent, or bypass graft occlusion. Bypass surgery may be the primary or secondary intervention after ALI. This procedure is indicated for patients with acute-on-chronic occlusion after endovascular or thrombo-embolectomy failure.[14] Patients who underwent bypass surgery were more likely to had previous endovascular intervention or bypass surgery for other conditions. Baril et al. reported the outcome of bypass surgery in ALI. Infrainguinal bypass was performed for 323 patients, and 40.6% of patients used a prosthetic conduit. Statistically significant factors for bypass with ALI included longer operative time ($p = 0.007$), greater blood loss ($p < 0.0001$), and increased rate of in-hospital major cardiovascular events ($p < 0.0005$).[9]

All of the major amputation in our study was performed in patients who developed progressive muscle gangrene or reperfusion injury after successful revascularization. Major amputation within 30 days occurred in 10% of patients, and the limb salvage rate was 90%. The mortality rate was 5.71%. Hemingway et al. reported that the major amputation rate in ALI Rutherford I and II was 9%, and mortality was 5%.[16] Overall outcomes after ALI treatment were a high rate of limb loss (12-50%) and mortality (20-40%).[17-19]

The mean follow-up time in our study was 13.5 months (range 1-52 months). Over 69% of patients return to normal walking status. Recurrent ALI occurred in 12 patients (18.18%), the limb salvage rate was 91.0%, and the mortality rate was 6.06%. In this present study, the most common cause of recurrence was thrombosis. The related factors of recurrent occlusion included active smoking, PAD, and hypertension. Vakhitov D et al. reported that the occluded bypass graft and impaired tibial runoff were significantly associated with the development of occlusion.[20]

Patients with ALI are prone to repeated major cardiovascular events, often leading to readmission, re-intervention, and mortality. In patients with symptomatic PAD, ALI is most often caused by thrombosis of the diseased native vessel, bypass graft, or stent. Following revascularization for ALI, regular follow-up may be beneficial, including clinical evaluation and assessment of functional status.[5,21]

The study's limitations include the retrospective, single-center design with a small sample size and the missing or inaccurate data obtained from chart review.

Conclusion

In our present study, ALI affected older patients and was more prevalent in men than in women. Over sixty percent of patients had medical comorbidities and atherosclerotic risk factors (hypertension, dyslipidemia, AF, PAD, and active smoking.). Etiology equally in thrombosis and embolism. In the thrombosis group, PAD is more common than embolism and requires more adjunctive procedures (intra-arterial angioplasty or bypass procedure). In the embolic group, AF is more related than thrombosis. Clinical outcome after revascularization for viable limb ALI revealed the 30-day limb salvage rate was 90.0%, and the mortality rate was 5.71%.

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